Provectus Biopharmaceuticals, Inc.
Fourth Quarter and 2015 Year-End Business Update
March-16-2016
Confirmation #13639346

Operator: Greetings, and welcome to the Provectus Biopharmaceuticals previously scheduled Fourth Quarter and Year--and 2015 Year-End Business Update Conference Call.

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

I would now like to turn the conference over to your host, Ms. Lori B. Metrock, General Counsel for Provectus Biopharmaceuticals.

Thank you, Ms. Metrock. You may begin.

Ms. Lori B. Metrock: Thank you, operator.

Good afternoon, and welcome to Provectus Biopharmaceuticals previously scheduled fourth quarter and 2015 year-end business update call.

At this time, I must advise 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, beliefs, estimates, and expectations 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 "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to materially 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.

We can now move onto the main portion of the call. And to get us started, I want to introduce Peter Culpepper, Interim CEO, COO, and CFO of Provectus.

Good afternoon, Peter.

Mr. Peter Culpepper: Thank you, Lori, for that introduction and thank you to everyone listening in today.

Almost two years ago, we began these investor calls as part of an effort to increase the transparency under which we, Provectus Biopharmaceuticals, operate.

On March 1st, we had a call brought about by a transformative event, the resignation of Dr. Craig Dees as Chairman of the Board, as well as CEO of the company. This morning, we announced the results of an internal investigation of Dr. Dees travel expenses undertaken by the Audit Committee of our Board of Directors. We dealt with this head on. We all feel a constant unsurpassable need to do what is right, but we also know that sometimes inevitably despite all our best efforts something gets by us. I'm sad to say that this is one of those times.

As many of you know, I came to Provectus because my elder daughter, oldest child of four, was stricken with rare brain cancer at age five and a half. For those who don't, the New York Times ran a story on this November 3rd, 2005 and another in CFO [sp] on May 19th, 2014. We had just arrived to the tri-state area from [unintelligible] in Europe, still in temporary corporate housing.

When cancer is diagnosed in a child it comes as a blunt, brutal shock, however, it is in fact the definitive manifestation of a long undetected growth. Immediate action was taken to remove the tumor, treat her with chemo and radiation, and through an arduous year save her. Sixteen years later still cancer free. My daughter's a thriving young adult, cancer free, and truly living. I'm telling you this to illustrate a point, but most of all to let you understand that our cancer research, Provectus, and everything that happens in our company is personal. I believe this goes for my colleagues as well.

As you can sense where I'm going with this, we've had our own cancer within us growing unnoticed for far too long. This realization was painful. As soon as we detected it, we dealt with it swiftly. Now, the body [sp] of Provectus is going through the remedial steps necessary to ensure we are cancer free going forward. This is as it should be, and I applaud the efforts of our Audit Committee and key company advisors.

Now, we turn our focus to the challenges at hand. For those you who were unable to listen in on March 1st, I'd like to reiterate the main points we discussed. First of all, Craig's contribution to PV-10 research has been on the immunology side of things. We had external validation of this part of our research. So, his work is complete.

Our CTO, Dr. Eric Wachter is the person who has handled the FDA process for PV-10 research rather than Craig. So, appointing him to our Board to take Craig's old seat only makes sense. The Board is strengthened in that particular area. We now have a member of the Board who is directly in charge of regulatory matters. Taking over as Chairman is Alfred E. Smith, IV. Having served as Chairman of the Board of Saint Vincent's Catholic Medical Center, he knows how research and hospitals work, not just as medical entities but also as business operations. He has an impressive financial pedigree that will be of emissive benefit to Provectus. In December 2006 after 35-years on Wall Street, he retired from his position as Managing Director of Bear Wagner Specialists, LLC, a specialist and member firm of the New York Stock Exchange. He is a Senior Advisor for the Marwood Group and sits on the Boards of the Tony Blair Faith Foundation and Mutual of America.

With respect to Provectus, Al Smith has been a member of our Board since July 2011. He is completely up to date on our operations. When you take into account that he's already the Chairman of our Audit, Compensation, and Nominating Committees, it is hard to imagine a better suited candidate for the position of Board Chairman. We are fortunate to have him and grateful for his willingness to take on these added duties.

As for Craig's CEO responsibilities, I will take on that role on an interim basis. It is a logical extension of my roles as both CFO and COO, and until we can find a full-time CEO, I believe the additional duties are manageable.

As stated in our call on March 1st, a Search Committee has been formed under the auspices of the Board to identify a permanent CEO. We don't have a specific timeframe, but we want this result sooner rather than later.

I want to clarify a final point about Craig's resignation regarding the patents in our portfolio. These patents belong to Provectus Biopharmaceuticals not Dr. Dees personally. There are upcoming patents, and they, too, will be corporate property, not part of Craig's personal holdings.

In our last couple of calls and our most recent shareholder letter, we have talked about our five clinical and business value propositioned pillars of PV-10 and PH-10, as well as our key--four key focus areas. You can get deeper into the details of these on our website, pvct.com. But, for those of you new to the Provectus story let me recap them very briefly.

The first pillar is our intellectual property portfolio. The second pillar is our expertise with and control of drug substance and drug supply, drug product supply chain. Third is the regulatory guidance we receive from the FDA in the U.S. and its counterparts in other nations. The fourth pillar is the mechanisms of action for both PV-10 and PH-10, which we continue to research. And fifth is the clinical study designs that generate randomized clinical data to support potential approval of PV-10 and PH-10 for the respective indications.

Our four focus areas in business and corporate development are a higher profile for both Provectus and PV-10 from a media awareness and visibility perspective, co-development relationships with big pharma based on rational PV-10 and immunotherapy combinations, other strategic activity such as regional licenses, collaborations, investments, etc., and grant programs in various global jurisdictions. Although this is our previously scheduled year-end call, I would like to focus on the fourth quarter of 2015 and look forward to 2016 more when we file our Form 10-K later this month.

Our clinical trials are the foundation of our company. They include our Phase 3 trial for PV-10 as the treatment for 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, our study on PV-10's potential use in treating cancers of the liver and other solid tumor indications. In addition, there's our Phase 2 study of the cellular and immunologic changes in the skin of patients receiving PH-10, our investigational topical treatment for atopic dermatitis and psoriasis. Other research is going on with PV-10 and other cancers, but these are the most advanced studies and, therefore, the most likely to result in marketable treatments in the near future.

Beginning with our Phase 3 study, we have a protocol that calls for 225 patients at our first site with St. Luke's University Hospital and Health Network, Bethlehem, Pennsylvania. We have announced that our first patient was dosed last year. As stated in our previous call, our estimated primary completion date remains 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 Impendent Data Monitoring Committee will issue an interim assessment of efficacy and safety. So, meaningful clinical data could come this year. I stress

the word “could.” And as we get closer to the 50 percent level, we will refine that target date. Eric Wachter will discuss this further in his remarks in a few minutes.

As we announced recently, there have been some amendments to this protocol. The kinds of amendments are commonplace and they take into consideration addressing the approval last October of an Imlygic by the FDA as the first and only oncolytic viral therapy. Also, certain Stage 4 M1a patients are now eligible. It is important to note that the amendments to the protocol do not effect the completion date, although, we will assess timing as we continue to add new studies [sp].

As the trial progresses over the course of 2016, we will assess the paths for expedited development, fast track accelerated approval, market approval with the FDA in the U.S. and the Therapeutic Good Administration in Australia. I want to stress here that the disappointment we all shared when the FDA declined to give us breakthrough therapy designation 2014 has no relevance to these accelerated options. The fact is that we will have much more data to bolster [indiscernible] and there is no regulatory penalty incurred because our BT [sp] application was not approved then.

Next, we have our Phase 1b/2 testing the PV-10 in combination with Merck's Keytruda in patients with Stage 4 melanoma. In September, we announced completion of the protocol for Phase 1b/2 testing of PV-10 in combination with pembrolizumab, which sells as Keytruda, in patients with Stage 4 melanoma. This study will approximately 144 patients with 24 of these in the initial Phase 1b portion of the study and the remainder in the Phase 2 portion. We expect completion in of enrollment in the Phase 1b portion this year, and if all goes as expected to commence enrollment in Phase 2 about four months after the last patient enters Phase 1b. We announced early--earlier the Phase 1b portion is expected to be completed this year. The first patients have been treated in this important study.

Scientifically and from a regulatory perspective, it is important for us to develop data that addresses the mechanism of action of PV-10. In March last year, we completed enrollment in a Phase 1b--Phase 1 study at the Moffitt Cancer Center, and in November topline data were presented at the Society of Immunotherapy of Cancer 30th Annual Meeting. In a poster presentation entitled: Intralesional Rose Benga in Melanoma Elicits Tumor Immunity via High Mobility Group Box 1, the authors showed that tumor specific T cells were increased in the blood after tumor ablation with PV-10. This information was vital in designing the combination study with Keytruda and will be useful in guiding future research.

We will be building on our research into hepatocellular carcinoma, HCC, in cancers metastatic to the liver. In July, our data were presented to two different conferences: [unintelligible] Barcelona and the Asia-Pacific Primary Liver Cancer Expert meeting in Osaka, detailing data from our Phase 1 study of PV-10. The main conclusion was that preliminary efficacy, evidence of efficacy in treatments of cancer of the liver with PV-10 was observed. Eric will provide details shortly on how this is being translated into a clinical program tailored to address HCC in Asia.

The Moffitt Cancer Center researchers will be presenting data on intralesional PV-10 and co-inhibitory blockade in a melanoma model at the American Association for Cancer Research's Annual Meeting 2016 in April. The data are taken from the research of a team of researchers led by Dr. Shari Pilon-Thomas and is the latest in a series of presentations that serve to keep the scientific community up to date on developments in PV-10 research. Complementary mechanism data on PV-10 was also presented during the year for colon cancer. In vitro testing of PV-10 on colon cancer murine CT-26 cells done by a research team at the University of Illinois of Chicago showed cytotoxicity consistent with immunogenic apoptosis. Researchers observed cell arrest, apoptosis, autophagy, and endoplasmic reticulum ER stress. These results are consistent with immunologic cell death caused by PV-10. These results fit well with clinical data from our liver metastases trial, I just mentioned, which has included several patients with colon

cancer metastatic to the liver. Protocols for [indiscernible] trials for colon cancer are now on our radar. We intend to move forward with PV-10 as a treatment for [sp] other indications as the data suggests. Also, we are determined to continue our efforts on what we have learned from our longstanding Compassionate Use Program to the greatest extent possible.

Touching briefly on PH-10, as Eric will provide much more information, I want to make three points about 2016. First, we expect to report on our Phase 2C mechanism results--and mechanism results. Second, we expect to have an end of Phase 2 meeting with the FDA regarding toxicology and further clinical development. And third, we will be seeking a licensing agreement based on the strength of the mechanism in other PH-10 Phase 2 studies.

I would like now to discuss corporate developments, in particular our efforts to commercialize PV-10 and PH-10 as rapidly as regulators allow. We remain committed to the Chinese market and our relationships with Sinopharm and especially Boehringer Ingelheim remain in place. We are navigating the Chinese FDA's rules and regulations with expert guidance from our partners there, and we are making headway. We continue to explore similar partnership arrangements in other markets, India and Brazil in particular, and we will announce any formal arrangements we make in due course.

Owing [sp] in part to Craig's resignation, we have modified the terms of our warrant exchange offer. Originally, we had offered holders of outstanding warrants issued between January 6, 2011 and November 01, 2015, a simple deal. If they would exercise their options at $0.75 they would receive new warrants expiring June 20--June 19, 2020 to purchase an equal number of shares of the company's common stock at an exercise price of $0.85 per share. In addition to extending exchange offers expiration date to Monday, March 21, 2016, at 4 p.m. Eastern, we also lowered the exercise price of existing warrants on a temporary basis from $0.75 to $0.50 per share. This discount to $0.50 is also a partial recognition of our common stock's price on the New York Stock Exchange to make the exercise of the existing warrants more attractive.

If we presume the exercise of all 59,861,601 existing warrants at an exercise price of $0.50, the company would net $26,927,029 after estimated offering expenses of $3,300,772. If all the warrants are exercised in an exchange offer, our cash position would go up significantly, which we expect to announce and address further when we file the Form 10-K later this month. However, there can be no assurance as to how many outstanding warrants subject to the exchange offer will be exercised for common stock and exchanged for new warrants in the exchange offer.

To build public wareness [sp]--public awareness for Provectus and PV-10, we have been actively conducting regular outreach and desk side [sp] meetings with key journalists. More specifically, we have been working closely with Thomson Reuters, a global newswire, to develop an extensive story that was ultimately published on Friday, February 26th last month, reaching an expansive audience. The feature story, which was hosted on the Reuters website with an accompanied video, showcased the history of Rosman Gal [sp] and the promising results that Provectus is seeing with PV-10. The global impact of this story is already being felt with more than 22 resulting stories in influential media outlets, such as Fortune, SteetInsider.com, FoxNews.com, and Yahoo News, as well as a significant surge in social media discussions linking to the online story. Our media relations program continues to be a priority, and we remain committed to securing more stories like Reuters that will increase awareness of Provectus and the implications of PV-10.

Given the growing awareness of the company, we are also actively undertaking a more formalized multi-phase patient advocacy program, which is focused on developing valuable relationships that can serve to advance knowledge of PV-10 clinical trials among patients. Specifically, Provectus is reaching out to melanoma organizations, given the phase three trials presently underway.

Before I turn the call over to Eric, let me recap what we have done and allow me to explain its significance. The Phase III study of PV-10 for melanoma has begun, and we are awaiting interim data. If those data confirm PV-10's value, we expect negotiations with international partners to accelerate. The Phase 1B, II, study of PV-10, in combination with Keytruda, establishes a strong position in an area of very active scientific and commercial interests in our patent that protects PV-10 when used in combination--is held jointly with Pfizer. We are making progress in our relationships with Big Pharma, including our collaboration with Boehringer Ingelheim. Finally, we are working on other research to broaden the application of both PV-10 and PH-10.

I'd like to now turn the call over to Eric Wachter, our Chief Technology Officer, for further details on what I mentioned previously. Eric?

Mr. Eric Wachter: Actually, a very informative overview, Pete. I'll start my remarks with a brief synopsis of major technical aspects of our business before going into detail on key elements. As Pete noted earlier, in the fourth quarter Provectus started a combination therapy trial in late-stage cancer patients where the safety and preliminary efficacy of PV-10 in combination with pembrolizumab, also known as Keytruda, is being assessed.

We're also in the midst of a Phase III clinical trial for locally advanced cutaneous melanoma. Promise and interest in locally advanced melanoma and local treatments for melanoma were buoyed at the end of October of last year when talimogene laherparepvec, or Imlygic, was approved by FDA as the first intralesional agent for melanoma. We announced earlier today that Imlygic has been added as a comparator in the Phase III study.

Tumors of the liver--we have continued to add patients to the Phase I study of hepatocellular carcinoma and metastases of the liver and have been actively engaged with the investigator community in Asia to expand this program to that important region. We've also initiated a companion study, assessing potential PV-10 in symptomatic neuroendocrine tumors, or NETs, metastatic to the liver.

Additional mechanism data on PV-10 was presented in November, further advancing our understanding of the immunologic signaling that can occur after ablation of tumors with PV-10. And the topical program--I'm sorry. And the topical PH-10 program has been moving ahead with completion of clinical work in our recent mechanism of action study in December. Analysis of tissue collected from study participants is underway, and we are awaiting review of the results of skin biopsies collected pre- and post-PH-10.

We had two productive meetings with FDA in recent months, one in November and the other in January, to address topics in support of a possible, eventual NDA filing for PV-10. And on the intellectual property front Provectus recently reported the issuance of additional patent coverage for the manufacturing process for rose bengal, an important aspect for eventual commercialization of PV-10 and PH-10.

So much for the synopses. Now for some details. In our Phase IB combination study, we began enrollment in the fourth quarter, and we expect enrollment in this portion of the study to be completed this year. We've been working with the sites listed on the clinictrials.gov listing for the study to get each one open for enrollment to patients and working to add several additional sites in the U.S. and Australia with the goal of having five to seven sites participate in Phase IB. We are also working with our global CRO to prepare for transition of the study to Phase II and to expand the study to include sites in Europe when that work commences.

The study was designed to demonstrate the potential additive benefits of combining the ablative and immunological aspects of PV-10 with an immune checkpoint inhibitor. And a success could pave the way for potential combination with many other agents. The mechanism data on PV-10, both nonclinical and clinical, suggests that this should be the case. But, of course, we can't be sure until we begin to see initial data, expected later this year.

Turning to our Phase III clinical trial of PV-10 for locally advanced cutaneous melanoma, as Pete and I noted earlier, we announced today that the protocol for the randomized control Phase III trial has been amended to reflect current and evolving standards of care in applicable patient population for global study in melanoma.

Major changes to the protocol include the addition of inLogic [sp] as an option for use as comparator. We've also extended eligibility to include Stage IV M1a patients having no active nodal or distant metastatic disease. These patients have disease confined to their skin, and their clinical characteristics and prognosis are similar to the Stage IIIB and IIIC patients that initially defined the study patient population.

In addition, we've clarified eligibility requirements for patients not having access to immune checkpoint inhibitors due to differences in standard of care. And we've clarified eligibility requirements for those patients not having access to targeted therapy due to standard of care as well as extending eligibility to patients who have failed targeted therapy.

In the latter patient--in the latter case, patients who have failed targeted therapy but meet the eligibility criteria have similar disease manifestations to the remaining study population but

very limited treatment options. And we've relaxed the eligibility criteria for patients who may be candidates for crossover upon documented progression in the compared [unintelligible]. This is possible since these patients have completed the primary endpoint and no longer need to make resist [sp] requirements for disease burden.

These kind of amendments are commonplace in Phase III studies and serve to fine tune the patient population and study procedures to match changing care standards for a large global study. For example, the protocol for the pivotal Phase III study of Itlomad [sp], also known as urgway [sp], versus chemotherapy incorporated nine amendments, with the first six occurring prior to enrollment of the first patient. In our case this amendment is the direct result of evolving options for patients and has been developed with extensive input from leading melanoma investigators in the United States, Australia, Europe, Mexico, Brazil, and China.

As a particular example for the Phase III study, the most obvious change addresses approval in late October of Imlygic by the FDA as the first and only oncolytic viral therapy. This gives investigators the option of using chemotherapy or Imlygic in those regions where Imlygic is available. As I noted in my remarks during the November investor call, approval of Imlygic not only validates our approach for seeking approval of PV-10 in patients with locally advanced

cutaneous melanoma, but it also allows us to offer a comparator that is more attractive to patients and investigators.

Interestingly, the body that decides standard of care in the U.S. for cancer patients, the National Comprehensive Cancer Network, updated the guidelines for treatment of patients, like those eligible for the Phase III study, shortly after Imlygic was approved. But note, while they added Imlygic as a treatment option, clinical trial remains the recommended option, as it has for many years, indicating there is still room for new therapies such as PV-10.

While the amendment was just disclosed to the public today, we began implementing the amendment--the amended protocol several weeks ago and are assessing and will continue to assess potential impact these changes may have on study time lines. None of these changes are expected to have a negative impact on execution of study, and all were carefully considered to assure that they would not compromise integrity of the study design.

I expect we will be able to refine study time lines by the time we have the next quarterly investor call. Importantly, all of the amendments are expected to enhance patient eligibility and enrollment in this global study. It's also important to note that many of these changes will facilitate opening the study efficiently on a truly global scale, incorporating advice from regional

leading investigators and institutions to assuredly address differences within and between regions.

As a final note on melanoma, I mentioned in the November call that approximately 140 patients had received PV-10 at that time under our expanded access protocol. And as of the end of the fourth quarter this number has risen to 160, with the vast majority having melanoma. As Pete noted, we currently plan to keep this protocol open to patients who are not eligible for other PV-10 studies.

Moving onto tumorous liver, we continue to add patients to our Phase I study of hepatocellular carcinoma and metastases of liver and are working to add one or more additional centers in the U.S. to facilitate completion of enrollment. We expect to report additional data this year as a followup to our initial reporting in mid-2015.

Because HCC is a major health issue in Asia, we've been actively engaged with an investigator community there to expand this program into this important region. Following up on a productive meeting with key investigators from Greater China in October, we're meeting with a similar group in Singapore this month to review our strategy and assure that our plans meet the needs for development of PV-10 for HCC in Asia.

As noted previously this work is expected to lead to commencement of one or more Phase I/II studies of PV-10 or PV-10 plus standard of care. This effort has been facilitated in large measure by our relationship with Boehringer Ingelheim, who have provided crucial advice and contacts throughout Asia.

We also announced recently that we have initiated a companion study assessing the potential of PV-10 in symptomatic neuroendocrine tumors, or NETs, metastatic liver. This study builds on what we've learned so far in our initial study, PV-10 [unintelligible] I, looking at HCC and other metastatic tumors. In addition to standard objective response assessments, since they are well established quality of life instruments specific to these patients, this study will allow us to assess topics concerning symptomatic benefit that are increasingly important to regulators.

And they are excellent biomarkers to allow us to test concordance of objective response and biological response. The single center study is designed to have two successive cohorts of patients. And if initial results appear encouraging, we may elect to expand to additional sites to accelerate study completion.

The PV-10 mechanism of action clinical trial conducted by Moffitt Cancer Center completed followup of the last study participant in the fourth quarter and additional mechanism data on PV-10 from the study. And from--a companion nonclinical research study was presented in November at the SITC annual meeting.

These data further advanced our understanding of the immunologic signaling that can occur after ablation of tumors with PV-10. As is common in our field, we expect further detail on the material presented at SITC to be published sometime this year. Related data on combination of PV-10 with immune checkpoint inhibition or so-called co-inhibitory blockade will be presented next month at the AACR meeting by the same research team from Moffitt.

As I noted earlier, we've been busy on the mechanisms of action for topical PH-10 as well and reported completion of clinical work in our mechanism of action study in psoriasis patients in December. We are finalizing compilation of clinical data from the study, and analysis of tissue collected from study participants is nearly complete. We expect to review results of skin biopsies collected pre- and post-PH-10 in the very near future.

The study was designed to allow us to probe possible immunologic, structural, and hyperproliferative changes in psoriatic plaque and detect any evidence of cellular atypia upon

application of PH-10--will also allow us to assess concordance of any such changes with clinical observations in those plaques. We expect these data to inform decisions on an anticipated request to meet with FDA to address strategies for advancing the program from Phase II into Phase III.

With regard to such meetings we've had two productive meetings with FDA in recent months, one in November and the other in January, to address topics in support of a possible eventual NDA filing for PV-10. The first meeting addressed topics related to standard safety and pharmacology testing, while the second focused on manufacturing and specifications. Both Type C meetings were a written response-only format, which allowed us to obtain comprehensive written guidance on a range of material in these topical areas.

The second of these meetings dovetails with our recently-reported issuance of additional patent coverage for the manufacturing process for rose bengal, an important aspect for eventual commercialization of PV-10 and PH-10. This process is at the center of the manufacturing and specifications discussions held with the agency in January.

To summarize, we continue to actively pursue existing clinical programs while moving towards implementation of companion programs in related areas, such as our Asia HCC initiative. We're

continuing to expand our knowledge of the mechanism of both PV-10 and PH-10, which allows us to plan appropriate strategy for future work. And we remain active in both regulatory and intellectual property matters.

We appreciate our stakeholders' patience while all these pieces are brought together to move Provectus forward. However, the most important stakeholders in all of this are the patients. All our clinical programs have always been mindful of unmet patients in need. And if current studies are successful, patients may gain more options. We encourage those in the patient community and their caregivers to consider clinical trials and discuss that option with their physicians. And we encourage everyone to remember that when patients win, we all win. With that, I believe we're ready for questions.

Operator: At this time we will 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. And 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 pull for questions.

Our first question comes from the line of Greg Cantic [sp], a private investor. Please proceed with your question.

Mr. Greg Cantic: Thanks. Good afternoon, gentlemen. I want to address the unfortunate circumstances surrounding Dr. Dies [sp]. I was wondering if the audit committee reviewed all employees or if it was--they just concentrated only on Dr. Dies--if you can comment on that.

Mr. Eric Wachter: In the press release this morning--the press release is titled, of course, The Results of the Internal Investigation. And so, the findings and conclusions of the committee did specify Dr. Dies. And it also should be noted in that same press release that there is a focus of the committee and the necessity that the company put in place more clearly defined, tighter controls, including a clear process for limiting, approving, and documenting advances, etc. So, there's definitely a focus on the internal control structure. We mentioned that also in the AK [sp] filing as well. But, the investigation that was concluded did focus on Dr. Dies.

Mr. Greg Cantic: Okay. Thank you very much.

Operator: Our next question comes from the line of Joseph Baffle of ATIS. Please proceed with your question.

Mr. Joseph Baffle: Hi, Peter and Eric. Sorry for the delay there. I had to come off the speaker. There was a lot to digest there, and I'm sure there's going to be a lot of questions. But, I want to specifically make sure, Eric, that I understand. There's been guidance given. And I think the guidance today was later this year, Peter, where you said that the interim data on the Phase III melanoma would be released.

When that data comes out, Eric, the two questions I have--will there be a statistical analysis, showing a statistical difference between PV-10 and the DTIZ [sp] and maybe even now the Teva [sp], where, when you release the data, you say, "Okay, we treated 110 patients, and here's the difference between the patients," and they get to see statistically the difference on the different endpoints, which are, I believe, complete response, overall survival, and progression-free survival. That way--that anybody looking at that--those data sets will be able to say, "This was directly the cause of PV-10," if there is a significant statistical difference.

And then, my--the follow on to that question, Eric. Does the FDA have any responsibility or anything in their bylaws that says that if the data is statistically greater--I know you guys are preparing an NDA--is there any requirement of the FDA to say, "Okay, it's a life-saving drug?"

Do they have any policies in place that say that they will let you market the drug while you do post-studies?

Mr. Eric: Okay. Those are great questions. So, yes, of course, we would conduct a statistical analysis of the data that's reported on an interim basis. The agency reviews such data routinely, looking at both statistical significance and clinical benefit. And so, I can't speculate what the outcome of any such hypothetical review would be, but I will indicate that if they reviewed those data, they would look at both the statistical importance of the numbers and the implications for potential benefit for patients.

Mr. Joseph Baffle: But, the market itself--the market will get the data when you make the release, the day of the release, whatever that date is.

I've been involved in other companies and other clinical trials where they say, okay, today we were measuring this and we were nine decimal points to the right for the drug that's going against the comparator, which means it was absolutely the drug. And all the people that were involved in the call were saying congratulations.

Mr. Eric Wachter: Yes, we would report the statistical characteristics of those data. So, we would analyze that in the way you expect.

Mr. Joseph Baffle: Okay.

And the--in terms of a--what the FDA's own responsibility is, there is nothing stated or in print saying that they--if the statistical data is overwhelming, that they have to do anything. They're just going to--you then apply for and submit an NDA.

Mr. Eric Wachter: We could apply for an NDA. It's more likely at that point it would trigger some very intense discussions.

If we look at, for example, the approval process for vemurafenib, which is the drug that [unintelligible] in 2012, as the data become more mature there was a series of meetings between the agency and the sponsor that led to an ultimate decision on how to get that drug approved as quickly as possible. If the data was particularly encouraging, I would expect that similar meetings might be likely.

Mr. Joseph Baffle: Okay.

And then, I'm sorry to add to it, but, I mean, I think what you--listening to you specifically about adding the new protocol that'd be in addition to the protocol today, that with the increase in the stage four patients, now that they're getting additional standard of care with T-VEC, that it will broaden the amount of people and patients that could come into the trial. And you don't right now foresee that delaying us getting enrollment.

Mr. Eric Wachter: No, absolutely not. So, we have been continuing to open the study with the original protocol. As that currently amended protocol has been developed, as I mentioned in my remarks, we began the process of distributing that to investigators and their sites about a month ago. And so, there's no expected interruption in the process of moving the study forward.

Mr. Joseph Baffle: Thank you.

Operator: Our next question comes from the line of Grant Johnson [sp], a private investor. Mr. Johnson, please proceed with your question.

Mr. Grant Johnson: Thank you. I've got two questions. One, maybe I missed it, but how many people do we actually have enrolled in our PV-3--you know, the phase three study of PV-10?

Mr. Eric Wachter: We have not commented on that. We did not comment on that in November. And as I indicated in my remarks, we expect to update the market on timelines and presumably enrollment by the time of the next quarterly call, which I believe is in May.

Mr. Grant Johnson: Well, okay. Then I'm going to ask three questions. I got one other one. Why is it so difficult for you to come up with a specific answer to a question like that?

Mr. Eric Wachter: It's--I think it's standard practice in the industry not to comment on an ongoing basis in these types of matters.

Mr. Grant Johnson: Well, I find that hard to believe.

Anyway, my next question has to [inaudible] Dr. Dees. Do we have an exact amount of money that was misappropriated on his behalf? And if we do, are we taking criminal action toward him?

Mr. Peter Culpepper: We are. And we did say in the 8-K filing, the first one this morning, the company intends to pursue collection efforts on all of Dr. Dees' unsubstantiated travel expenses.

So, there is clearly a recommendation that a demand be made to Dr. Dees for reimbursement of any monies advanced to him if unsubstantiated, and that these monies voluntarily be reimbursed by him or recovered by legal action if necessary. So, that's absolutely the case.

Mr. Grant Johnson: Okay. Do we have a guesstimate as to what the amount might be that we're seeking?

Mr. Peter Culpepper: That will be disclosed more fully in the 10-K filing, which is expected by the end of the month.

Mr. Grant Johnson: Okay. All right. Thank you.

Operator: Our next question comes from the line of Howard Boyles [sp], a private investor. Please proceed with your question.

Mr. Howard Boyles: Yeah. Pete, a couple of questions. Dr. Dees, when we announced it last month that he was going to resign based on personal and health issues, was that at his request or the company's request?

Mr. Peter Culpepper: That was his resignation. That is exactly what said--what was stated on his resignation letter so that's how we reported it. So, that's accurate at that--when we announced it, of course, February 29th, and then had the call on March 1st.

Mr. Howard Boyles: Right, right. Okay.

And the other question, on the amendments that came out this morning to the PV-10 trials, is that going to incur any additional cost? And if so, do you feel like we have the funds to see us through the end of the trial?

Mr. Eric Wachter: I'll answer that. That's a great question.

It could incur marginal additional costs in certain parts of the world where Imlygic is available but regulatory authorities or local regulations require reimbursement for its use in clinical trials. And that would particularly be the case in Germany, for instance.

Mr. Howard Boyles: Right.

Mr. Eric Wachter: And we suspect a number of instances where that would occur, even if we had to pay full cost for Imlygic, would not increase the cost of the study by a significant amount.

Mr. Howard Boyles: I understand, and I appreciate that.

Now, do we have the funds available that will take us through the end of the phase on PV-10?

Mr. Peter Culpepper: We have stated that we have the adequate funds to get us through the interim data. We do have, as we said on this call, the ongoing warrant exchange--.

Mr. Howard Boyles: --Yes--.

Mr. Peter Culpepper: --Transaction for the purposes of ensuring there is additional capital to maintain our ongoing listing on the New York Stock Exchange.

Mr. Howard Boyles: All right. Will you be able to update us on that on the next conference call?

Mr. Peter Culpepper: Yes, exactly. That's our purpose for having the next conference call when we file the 10-K and when we expect to complete and close that warrant exchange transaction, yes.

Mr. Howard Boyles: Very good. Thank you, sir.

Operator: Our next question comes from the line of Max Isenheimer [sp], a private investor. Please proceed with your question.

Mr. Max Isenheimer: Hey, good afternoon, gentlemen. Can you hear me?

Mr. Eric Wachter: Yes, go.

Mr. Peter Culpepper: Good afternoon. Please go.

Mr. Max Isenheimer: Okay. I have a couple questions. My main question is, I mean, I really--I'm excited about what you're doing with the drug and--you know, and how well this is progressing. My only--my main question is, though, why are we--why is the company constantly cutting the legs out from underneath the share price of the stock?

We can raise money easier and greater than trying to raise with the most shares at the least amount of price. I mean, this is not standard operating procedures on how you're raising money. I don't understand why we're hurting the share price continually.

Mr. Peter Culpepper: I can address that first and then Eric can add.

We agree with you. Eric and I are large stockholders. We have others of the Board of Directors that are large stockholders. So, certainly absolutely--and there's a--the number of our fellow--our colleagues who are--we know and appreciate, the large stockholders, would also completely agree with this.

And so, the objective here is exactly what we're trying to accomplish right now with these clinical studies. So, for instance, the phase three interim data, that's what is of particular interest to our ongoing discussions with potential partners; our work with Boehringer

Ingelheim, principally in Asia, but also focused very much on how unique PV-10 is in treating hepatocellular carcinoma and other solid tumors.

Same thing with our efforts combining PV-10 with the checkpoint inhibitor class. And that's Merck's Keytruda, but we can also combine PV-10 with other very high profile pharma companies, their systemic immunotherapies.

So, the idea here with data that we now have ourselves that will be coming public literally in the coming weeks--we know AACR next month. We know other conferences where data will be presented, publications that are in process of the data. All that helps the industry and enable the non-dilutive cash inflow.

So, this is why our focus area on co-development transactions is so high profile. Our focus area on media awareness, the Reuters article we believe is just the first, the Reuters piece. Additional visibility will raise the awareness and focus, as well as the data that's coming.

So, right now we believe we're on the crest or on the forefront of a significant amount of additional information that we strongly believe will result in the credibility of Provectus and PV-10 in particular in the market.

Mr. Eric Wachter: And I would like to--.

Mr. Max Isenheimer: Well--yes, I'm sorry.

Mr. Eric Wachter: Oh, I'm sorry. I would say that I can certainly, as Pete has suggested, understand the frustration of shareholders.

It appears to me that we are rapidly approaching a tipping point in terms of clinical trial data, in terms of mechanisms of action data, in terms of regulatory path forward certainly for PV-10. And as I said, I can understand frustration in the efforts to capitalize the company, but we're not at that tipping point yet.

We're approaching that tipping point. We can anticipate when and where that will happen with some degree of understanding. But, until we reach that tipping point we haven't reached that tipping point, if you understand. Once we've passed that, I think that things get to be very easy for us.

So, my job is to continue to push forward on those three areas that I enumerated, clinical trials, understanding the fundamental science of our products, and making sure that the regulatory

house is in order. We've made enormous progress in all of those areas in the last two years, and I can say that's why I'm of the belief that we are very close to that tipping point.

Mr. Max Isenheimer: Well, one suggestion--or a couple suggestions going forward just so it's out there.

Mr. Eric Wachter: Right.

Mr. Max Isenheimer: Number one, there are biotech specific hedge funds that would love to take a stake in this company without having to offer additional warrants in addition to exercising the warrants at cheaper prices.

Also, there are multiple countries out there that would love exclusives in their country where if you had a--where if you worked with--in conjunction with a biotech company or another partner, that they would love to, you know, partner up with you for a--you know, for a--for an actual--an exclusive in their country. And they'd be willing to pay for that also. So, you can also pull a CEO potentially out of that deal, you know, a combined CEO choice.

But, I mean, these are things that I hope you're exploring. I would if I was part of the company. And I think it can be done a hell of a lot easier than you're making it on the financial side, that is, not the drug side.

Mr. Peter Culpepper: Those are exactly what we have been pursuing on the financial side. But, we agree that a--the potential new CEO would be such a person who would be very familiar with those sorts of topics you just addressed.

Mr. Max Isenheimer: Well, thank you, gentlemen. I appreciate the time.

Mr. Eric Wachter: Thank you.

Operator: Our next question comes from the line of Brett Benson [sp], a private investor. Please proceed with your question.

Mr. Brett Benson: Good afternoon, gentlemen. My question is for--I have two questions and they're--pertain to Eric, please. Are we still expecting PH-10 data by the end of the month is my first question.

And my second question is with regard to the TGA. Do we still think that once 300 patients have been treated that they will seek approval?

Mr. Eric Wachter: Okay. Those are great questions.

As I mentioned in my remarks, we have completed all of the data collection from the patients. We are in the process of compiling the clinical data. So, this is the numerical data that's collected when a patient visits the clinic.

We are working with a major research university on analyzing skin biopsies that were collected three times during the course of the study for each patient; at the beginning of the study pretreatment, after four weeks of application of vehicle, and then four weeks after application of PH-10.

That work is essentially complete. We are in the process of receiving that this week. And I think that it's possible that we will have a preliminary analysis of that completed this month. Certainly if not this month, early into the next month, the month of April.

Mr. Brett Benson: Great. Look forward to seeing that. I don't know much about PH-10.

Mr. Eric Wachter: It's--I think it'll be very interesting. When we started the mechanism work for PV-10, we discovered some things that we predicted and we discovered some things that were a pleasant surprise. And hopefully we'll have the same case for PH-10.

In regard to the TGA, yes, definitely moving forward with approval in Australia is something that we have been considering, we are currently considering, and we will continue to consider, especially given that roughly half of the melanoma patients that received PV-10 throughout the history of our development have been from Australia. So--and we have a significant base of data now on patients in Australia.

Mr. Brett Benson: Thanks for your time.

Operator: Our next question comes from the line of Bruce Benzel [sp], a private investor. Please proceed with your question.

Mr. Bruce Benzel: Yes. I want to pose a question about intellectual property in a practical question. Last fall there was a New Zealand hospital that published a poster about producing their own rose Bengal 10 percent formulation and using it on a patient.

Given that that would be covered by the CUP, compassionate use program, if they were participants and they're--and there's no fee or whatever, prelims involved in that, what--did you have any contact with them? What can you tell us about the company's reaction to hospitals reproducing 10 percent rose Bengal solutions and using it for cancer patients?

Mr. Eric Wachter: Okay, sure. That's--that is a very interesting situation, and I liken it to producing penicillin starting with moldy bread. Of course, that's how penicillin was discovered, but that's not how modern grade pharmaceuticals are manufactured in the modern era.

We are continuing to investigate that situation. And we expect to provide very strong advice to the individuals that we believe to have been involved with that activity, advising them of the risks associated with making bootleg investigational drugs.

That's also part and parcel with one of the reasons why we developed the intellectual property that's wrapped around the manufacturing--modern manufacturing process for rose Bengal, because we discovered that the kind of material that someplace like that hospital would be able to access is very unpredictable in its purity, and would be impossible to justify as a commercial product really anywhere in the world.

So, it's an example of a--potentially an overzealous investigator conducting some unauthorized work based on a reading of the literature. So, as I said, we expect to follow up with that in the near future with a very strong warning to the individuals involved.

Mr. Bruce Benzel: Well, it certainly seems like some word about rose Bengal and its therapeutic use is getting out through the back channel, so that's good news. But, it sounds like you're not discussing any legal actions with them.

Mr. Eric Wachter: Well, assuming that they're not involved in commercial trade with that bootleg product, then there's not a tremendous amount of enforcement capability on the patent front. We could certainly elevate that if there was evidence that there was continued malfeasance, taking it to higher authorities within the country of New Zealand in this case.

Mr. Bruce Benzel: Thank you.

Operator: I would like to remind all participants, if you would like to ask a question during the Q&A session, please press star-one on your telephone keypad.

We have a follow up question from the line of Joseph Baffle of ATIS. Please proceed with your question.

Mr. Joseph Baffle: Yeah, thanks again. You know, Peter, when I asked that question, Eric did a good job regarding the interim data, but I've been involved in the company for 13 years, and I've been with biotech for a long time.

I've told my clients, my customers that this data that is coming out, the interim data on the Phase 3, is the most significant clinical data in the company's history because it's that data that will be the basis on this company of the drug eventually getting to the market.

And I don't want to set expectations for my clients. I don't want them--the thing is, when a customer gets a news release and it's not even what they were expecting and they don't get the--not only the results, but they don't get the information that they were looking for.

And we've been told that, you know, our customer is the FDA. Our customer is big pharma. The customer is also the market, right, the guys that are the call right now. They would figure that the market is also one of our customers.

And so, when that data's released, I just want to be specific. Not only will the shareholders in the market be able to get to see that data, but--and we all know that no one can talk for the FDA. They're opaque. And they make their own decisions. And nobody ever knows where they're going to go.

But, the partners, the potential partners that see the data, the people that are experts in the field, they'll be able to see that data as well when the release comes. So, not only will the market be able to see it, so will potential partners, correct?

Dr. Eric Wachter: That's absolutely correct. And it's often the case that those are the points in time where a decision is made on a transaction between the sponsor of that study and some larger partner.

Whether that triggers some early approval of the drug or not at that point, if the data is good, very often that leads to a very favorable interaction in that partnering area of activity. I can draw your attention to, for example, the aforementioned Phase 3 trial of ipilimumab, which was amended three times after they enrolled their first patient. That had provision for interim assessment very similar to interim assessment that we have in our protocol.

That interim assessment data was reported, I recollect. And it certainly appears to have led to a consummation of a transaction with a larger partner once that data were available. It did not lead to approval until the full study was complete.

Mr. Joseph Baffle: Right, right, of course. So, but, the data that's going to come out, correct--am I wrong, Eric, in thinking it's complete response of the lesions that are injected, progression-free survival, and overall survival? Are those the three endpoints that will be measured?

Dr. Eric Wachter: In addition to complete response, progression-free survival and overall survival, we would have duration of complete response.

Mr. Joseph Baffle: Duration of complete response. And all those bases, they'll be compared against--statistically against DTIC.

Dr. Eric Wachter: That's correct.

Mr. Joseph Baffle: And do you know the historical performance of DTIC when it's injected in? They don't inject that. DTIC I believe is given--is it given systemically?

Dr. Eric Wachter: So, DTIC is given as an intravenous route of administration. Temozolomide, which is the other chemotherapy comparator, is given--temozolomide is given as a pill. And T-VEC, or Imlygic, is given as an intralesional injection.

In amending the protocol, we did a very careful assessment of the data that's publicly available on all three of those drugs to understand what to expect in terms of progression-free survival, complete response rate, duration of complete response rate, and overall survival among patients receiving those comparator drugs.

Mr. Joseph Baffle: What was the best of the three? What was the best complete response rate of the three that was publicly available?

Dr. Eric Wachter: I don't have those numbers in front of me at this moment. But, in each case, the complete response rate is quite low.

Mr. Joseph Baffle: Even for T-VEC.

Dr. Eric Wachter: Even for T-VEC.

Mr. Joseph Baffle: And I think, in the Phase 2 for the 28 patients that had all their lesions treated, was our complete response rate 51 percent, or was it even higher for the ones that had all their lesions treated?

Dr. Eric Wachter: It was 50 percent.

Mr. Joseph Baffle: Was 50 percent. Okay. Thank you. And so, Peter, it's correct assuming that partners will be able to see the data as well as the market.

Mr. Peter Culpepper: Yes, and two specific examples that we could cite, Eric refers to ipilimumab. That was Bristol acquiring Medarex for 2.4 billion on the basis of that particular steady--so, that was the beginning of Phase 3 when Bristol acquired Medarex.

And then the other study that's of note is Amgen acquired Biovex in the middle of Phase 3, interim Phase 3 data, for 1 billion. And Amgen acquired Biovex and received in that acquisition the drug that was just approved, T-VEC or Imlygic.

So, there's two great examples right there of large transactions on the basis of data that we right now are generating this year. So, we would expect to see our most promising year yet.

Mr. Joseph Baffle: And then for--and then so, clients understand--the CEO conference, you said--I think you said four times midpoint, which we don't know, you know, May, July, August--June, July, August. Now, are you changing that a little bit with the change in the protocol and saying it's a little bit later than midpoint?

Mr. Peter Culpepper: As I come at it, we're reviewing those timelines in real time right now. And we will update that by the time of the next quarterly conference call, which is soon, May.

Mr. Joseph Baffle: Thanks, Eric. Thanks, Peter.

Operator: Our next question comes from the line of Scott Amintranel [sp], a private investor. Please proceed with your question.

Mr. Scott Amintranel: Good afternoon, gentlemen. I just have a brief question about one of today's multiple filings. One of them said that the Audit Committee is considering appointing an Interim CFO, which, Pete, is your job or one of your jobs. Are you being replaced?

Mr. Peter Culpepper: Well, I think this is clear from the 8-K filing that the Audit Committee is serious about implementing recommendations made by the council of the Audit Committee to remediate the issues.

So, we, like I said at the beginning of my remarks, applaud the efforts of the Audit Committee. And there's no question that we want to ensure that what occurred with Dr. Dees's travel expenses never occurs again.

Mr. Scott Amintranel: Okay. Thank you.

Operator: Our next question comes from the line of a George Clout [sp], a private investor. Please proceed with your question.

Mr. George Clout: Thank you. A question for Pete. Pete, are you a candidate for permanent CEO?

Mr. Peter Culpepper: I have been asked to apply by the Board and plan to do so. However, as I've said on this call, I fully support a CEO that's a--is a recognized leader, a medical professional that has the kind of experience to lead the company forward.

That being said, what my role is and has always been in the company is to ensure that we are successful. And as Eric commented in his remarks, the patients win, and then we will all win. So, that's--I'm going to do whatever is necessary myself so the company's successful.

Mr. George Clout: Thank you. I've got another question. And that is, to clear up in my mind, the interim data that you're going to come out with, is that referred to just your--you know, the results against the chemotherapy, or is it against both the chemotherapy and T-VEC?

Dr. Eric Wachter: It would be in top-line numbers against the comparator on a whole. So, it would be a mix of chemotherapy and T-VEC patients. Depending upon the number of patients that receive the two different classes of therapy, it may be possible to report on subgroups of that.

Given that it's going to be at an interim number, there may be a small number of patients in one or the other groups that would make that statistical analysis complicated.

So, we'll determine that. But, certainly, in terms of reporting outcome for the primary analysis of the study, which is PV-10 versus comparator, we would report that on all of the primary and secondary endpoints.

So, as was discussed with the last caller, progression-free survival as the primary endpoint, complete response rate, duration of complete response rate, overall survival as secondary endpoints.

Mr. George Clout: Okay. So, it's really not necessary to include the most recent addition of T-VEC. I mean, you could release interim data if the data was good enough that would signify that you then switched the chemotherapy people to PV-10. Is that correct that--could you do that just with the chemotherapy, or do you have to include now the T-VEC data?

My point is I don't know half the weight to get the T-VEC data. And that will delay the interim report of the chemo data.

Dr. Eric Wachter: We don't think that adding T-VEC to the study will delay reporting of the data versus if we had left it out. It will certainly help to speed enrollment of patients as we endeavor to fill out the study.

We don't have any control over which comparator the investigator chooses. It's up to their discretion. And in some regions, one will be available over another. There might be parts of the world where temozolomide is used, but dacarbazine, DTIC, is not, for example, or regions where chemo is available and T-VEC is not, regions where T-VEC is the preferred therapy over chemotherapy for these patients, and so on.

So, we can model that based on understanding what standard of care is for our investigator base. But, we can't dictate the selection between the three different potential comparators for the patients. So, the interim data will be based on a mix of patients receiving dacarbazine, or DTIC, temozolomide, and Imlygic.

Mr. George Clout: Thank you, gentlemen.

Operator: Our next question comes from the line of Laura Intrinken [sp]. Please proceed with your question.

Ms. Laura Intrinken: I had a question for Eric. What is the status of the liver protocols?

Dr. Eric Wachter: So, the current study, we're continuing to enroll patients, as I mentioned in my remarks. We expect to add one or more additional centers in the U.S. this year to allow us to fill out that study.

We have reported as of middle of last year initial data that led us to conclude that it was a sound move to pursue further development in Asia, as I mentioned in my remarks.

We have been, with tremendous assistance from Boehringer Ingelheim, interacting with investigators throughout Greater Asia, both Greater China and ex-China, from the fall of last year through this month to finalize approaches for starting that program in Asia.

We would expect that that would be one or more studies, either PV-10 as a single agent or PV-10 in combination with standard care in a combination strategy.

Ms. Laura Intrinken: All right. Thank you.

Dr. Eric Wachter: And I might also reiterate that I mentioned that we expect to publish some data from the original study this year.

Ms. Laura Intrinken: All right. Thank you, Eric.

Operator: Our next question comes from the line of Doug Dillon [sp], a private investor. Please proceed with your question.

Mr. Doug Dillon: My question is, when are you going to publish some more CUP data?

Dr. Eric Wachter: I'm sorry, more what data?

Mr. Doug Dillon: The CUP data.

Dr. Eric Wachter: Oh, I did provide an update on that in my remarks. I noted that we have, as of the end of 2015, enrolled 160 patients, the majority of those being melanoma. We are working with investigators at several of our larger higher-enrolling centers to release data on their individual sets of patients, which looks to be very interesting. And I would anticipate that some of that will come out in the first half of this year.

Mr. Doug Dillon: Thank you very much, Eric. And I had one other question. What's the status of some of your grant requests?

Mr. Peter Culpepper: We are going through right now an extensive grant request in Europe. So, that's very active. And that's complementary to our efforts in expanding in Europe, principally Germany, Poland, Italy. So, that's active right now.

We'll also be doing the same thing in Asia through principally Singapore. And then we have an effort in Australia. So, there's three separate efforts. All are active. But, probably the most advanced is what's happening in Europe.

Mr. Doug Dillon: If you're successful, do you think that'll have a positive impact on your status of your cash?

Mr. Peter Culpepper: It wouldn't--I don't think it would be in time to reflect in the 10-K. But, there's high probability that we'll have more--much more to talk about in our 10-Q filing in May.

Mr. Doug Dillon: Thank you, Peter.

Operator: Our next question comes from the line of Shazed Birky [sp], a private investor. Please proceed with your question.

Mr. Shazed Birky: Good afternoon, Pete and Eric. I just wanted to make a quick comment, and then I had a quick question. I wanted to actually thank you and--Pete and Eric both, for your leadership role right now during this kind of momentous momentum that we're kind of gaining as we're ending the third quarter of the ballgame and entering the fourth.

So, I know there's been some distractions recently with Craig and other items. So, just wanted to wish you well, and I personally have a lot of faith in your leadership. And thank you for communicating with me from time to time.

And I'm sure, as shareholders, we're all anxious, and we feel like we don't get enough information. But, I'm trying to be as patient as I can. So, I look forward to your leadership.

And then I had a quick question. And that is that, if the warrant exchange program is not very successful by the time the deadline rolls around, will you guys consider extending it, or will this be the final extension that you all would've allowed it to have?

Mr. Peter Culpepper: Like I can say from our part right now, it certainly is a topic that we are-- as you can tell, we have extended it. It's a wonderful structure for current warrant holders. It's a flexible structure.

We have to close it, we believe, this month at a minimum. The only question would be, do we extend it one more time? We would rather not do that. We would rather not extend it. But, we also want to maximize the potential. We have other options.

So, the best way I could say is we're evaluating that. And we're doing that literally on a daily basis right now. So, it's possible to extend it. It's flexible to extend it. We'd rather not. But, even if we did, the expectation would be this month, maximum.

Mr. Shazed Birky: Thank you, both of you. Thank you.

Operator: There are no further questions in the audio portion of the conference. I would now like to turn the conference back over to our CFO Mr. Peter Culpepper.

Mr. Peter Culpepper: Thank you, operator. We had a fundamentally profound 2015. And thus far, 2016 shows great promise. We expect interim data from our PV-10 studies this year,

multiple key data publications, and medical conferences. And our research programs are moving forward.

On the corporate side, we are continuing our work in establishing partnerships around the world to commercialize our products as rapidly as possible. And we will not relent here until it is done.

Thank you for your time this afternoon. And we look forward to being with you again when we file the Form 10-K this month and in May when we file the Form 10-Q.

Operator: This concludes today's teleconference. Thank you for your participation. You may disconnect your lines at this time.