Provectus Biopharmaceuticals Inc.
Second Quarter 2016 Business Update Conference Call
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Operator: Greetings, and welcome to the Provectus Biopharmaceuticals Inc. Second Quarter 2016 Business Update Conference Call. At this time, all participants are in a listen only mode. A question--a question and answer session will follow the formal presentation. And 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, Mr. Michael J. Porter. Thank you, Mr. Porter. You may begin.

Mr. Michael J. Porter: Thank you, Operator. Good afternoon, everyone, and welcome to the Provectus Biopharmaceuticals Second Quarter 2016 Business Update Conference Call. At this time, I must advise all listeners that this call contains forward looking statements as defined

under the U.S. Federal Security laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates, expectation, and express management's current view of further performance, future performance results, and trends. And such forward looking statements may be identified by the use of the terms such as anticipate, believe, should, 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 our 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 of such statements. We undertake no obligation to update such statements after this date. Risks and uncertainties that could cause our actual results to material different from the described, from the described in forward looking statements including those discussed in our filings with the Securities and Exchange Commission including those in item 1A of our annual report on form, on the form 10K, the year ended December 31st filed with the SEC.

It is now my pleasure to turn the call over to Peter Culpepper, Interim CEO and COO of Provectus. Good Afternoon, Peter.

Mr. Peter Culpepper: Thank you, Mike, and welcome everyone to the Provectus Biopharmaceuticals Second Quarter 2016 Business Update Conference Call. If you have been

watching the program “Game of Thrones”, you’ll be familiar with the phrase, “Winter is coming.” On TV, that is supposed to be ominous, but for us at Provectus, we expect the approach of winter to bring with it the interim data from our phase three study of PV-10 as a treatment for locally advanced cutaneous melanoma. I said in our last call quote, “This coming November, we will be in an excellent position to discuss the status and timing of data, and the effects on our business becomes with ever more advanced clinical data,” end quote.

As the second half of the year progresses, we will develop more clarity on our research timelines as well as on our corporate evolution to adapt to the results that are on the way. Eric will provide further guidance regarding the company’s activity during the interim period. During the second quarter of 2016, we took steps to increase the number of sites engaged in our phase three setting. There are now six sites actively recruiting, according to clinicaltrials.gov. five in the U.S. and one in Australia. Another site in America is listed on the site as “not yet recruiting”. As I have repeatedly said, even though there may be other sites in the process of opening, until they list on clinicaltrials.gov site, we are not able to publicly comment on them with any specificity.

In addition to increasing the number of sites, we have expanded the pool of potential patients in the trial by amending the protocol twice, in major forum in February and in a much more targeting manner in June of this year. Specifically, in February, we added the newly approved

melanoma drug Imlygic as a competitor, and in February and June, we added an extended eligibility to include stage four M1a patients having no active nodal disease. These patients had disease characteristics and prognosis similar to that of the stage 3b and 3c patients that initially defined the study patient population. The amended protocol also clarified eligibility for patients not having access to immune checkpoint inhibitors due to standard of care and those not having access to targeted therapy due to, due to standard of care as well as inclusion of patients who have failed targeted therapy.

So, there are more potential participants based on their medical condition, their geography, and their demographics. As Eric noted in our last conference--quarterly call, these changes are necessary in an area of rapidly evolving treatment options in oncology, and while they have resulted in some delays from our initial study timelines, we continue to push to have interim data available as soon as possible, possibly before the end of the year.

Meanwhile, we are actively moving ahead in clinical development for other indications. We are on schedule with our phase one b two study in more advanced melanoma that uses PV-10 in combination with Pembrolizumab, an anti-pd-1 drug approved by the FDA and marketed by Merck as Keytruda. The final data collection for the primary outcome measure continues to be projected as November 2018. There are currently three sites engaged in this study, two in the U.S. and one in Australia. We are making final preparations to open an additional U.S. site this

quarter with possible addition of one or two more sites in the second half of the year to keep the initial phase 1b portion of the study moving along to [unintelligible] out and commencement of the phase two portion of the study. In both portions of the study, Pembrolizumab will be administered at 21 day, 3 week intervals per prescribing information label commencing on day one for up to 24 months or until disease progression, toxicity requiring discontinuation of study treatment, or study termination. With treatment lasting up to 24 months, late 2018 is built into the study as a final data collection date.

In the last couple of days, we all learned the news that Bristol-Myers Squibb's Opdivo, as the Wall Street Journal put it, "Bristol-Myers said its drug Opdivo wasn't significantly better than chemotherapy in a study of patients with newly diagnosed lung cancer." The Journal went on to say Merck's immunotherapy, Keytruda, prolonged survival in a separate study of patients with newly diagnosed lung cancer compared with chemotherapy. Merck hasn't yet released the full results of that study. The Journal also said Keytruda also is currently approved to treat skin cancer in lung cancer patients who have already tried chemotherapy. On Friday, the U.S. Food and Drug Administration approved expanding Keytruda's use to include treating patients with head and neck cancer.

Now, Eric will get deeper into the difference in the drugs and the studies, but I want to say a couple things here. Both drugs are immune checkpoint inhibitors. They are closely related

compounds. Keytruda is a stand alone, but after Friday's new, Friday's news, Opdivo probably will not be, at least not for lung cancer.

However, this could be an opportunity for Provectus in that we are doing a study of PV-10 in combination with Keytruda. We believe patient outcomes may be better if both drugs are used. The same logic applies to Opdivo. Right now, the recent study results show that it is not better than chemo when used alone as first line therapy in lung cancer, but perhaps, it might be when used in combination with PV-10.

A successful study of the two together could change Opdivo's future, and it would be consistent with the widespread belief in the industry that drugs used in combination are likely to get better immune system results. PV-10 appears to be a significant opportunity in combination therapy because its mechanism is so different to other agents, is [unintelligible] to the other agents, and in multiple pre-clinical tumor models, it has been shown to create a very strong activation of immune system against injected tumors. These laboratory results have also been repeated in melanoma patients and are the basis for our combination work with Keytruda and possibly with Opdivo. It is for reasons like Friday's developments that we keep in close contact with other researchers and with big pharma.

Next, I want to touch on our work related to cancers of the liver. We have a study officially called a phase one study to assess the safety, tolerability and pharmacokinetics of PV-10 chemo

ablation of cancer metastatic to the liver or hepatocellular carcinoma not amenable to resection or transplant. This study has been expanded several times since the first patient was treated in 2010 and has grown from a single center to three centers in the U.S. We will open a fourth U.S. center later this month, and this study has provided us a way to test PV-10 in primary liver cancer, hepatocellular carcinoma, and in a number of other types of cancers that have metastasized to the liver. In this way, we're assessing whether there are attractive opportunities for more advanced development of PV-10 in liver cancers.

An example of a lead we're developed based on this exploratory work is a phase one study we recently opened in south Australia designed to assess the safety, tolerability, and effectiveness of PV-10 for chemo ablation of symptomatic, neuro, endocrine tumors or NET tumors metastatic to the liver. In this study, we are assessing not only the objective response of injected tumors, that is whether they are destroyed, but also the potential impact on biochemical markers and symptoms caused by these tumors. This continues our work building a foundation for future development of PV-10 as a treatment for cancers of the liver, much as we have done for melanoma. In addition, we have been developing a phase one b2 protocol to pursue development of PV-10 to treat hepatocellular carcinoma, HCC. Eric will comment further on this during his remarks.

Turning briefly to our work with PH-10, our investigational, dermatologic drug, I noted in our last conference call that we anticipate reporting results this year on our phase two mechanism of action study in psoriasis patients. The clinical portion of this work was completed at the end of December. Biomarker samples have subsequently been analyzed and we've recently reviewed these data with the team that did these analyses. Eric will comment on this during his remarks and the implications for projected end of phase two meeting with the FDA and toxicology work necessary support PH-10 approval.

I want to turn now to our conference participation this quarter and subsequently. These conferences are important for at least two reason. From a scientific standpoint, sharing data about PV-10 with researchers involved in cancer studies is part of the professional responsibilities that come with being a research scientist. Medical research is a team effort, and the more everyone knows about what everyone else is doing, the better treatment patients will get in the long run.

From a corporate point of view, these conferences are an important platform for us to market PV-10 and Provectus to potential partners. They help establish our credibility, and they allow us to meet face to face with decision makers who may be useful to us in the future. For instance, in April 2015, we were awarded a joint patent with Pfizer to protect the use of PV-10 in combination with certain other types of drugs in the treatment of melanoma and cancers of

the liver. Without the participation at these kinds of conferences, Pfizer most likely would never have worked with us, perhaps never even have heard of us. So, while our investigators are discharging their professional duties at these conferences, they're also helping us build corporate partnerships that will eventually translate into a greater shareholder value.

In April, Sheri Pilon-Thomas, PhD who leads a research team at Moffitt, presented data on PV-10 in combination therapy and T cell mediated immunity at the American Association for Cancer Research's annual meeting. She told the attendees quote, "Our results show that combining interlesional with anti-pd-1 co-inhibitory blockade, not only suppresses tumor growth versus either agent alone, but also yields marketed increases in tumor specific T cell activation against injection, injected tumor," unquote. This non-clinical study reaffirms the crucial role T cells play in response to tumor ablation with interlesional PV-10 and further demonstrates the potential value of combining PV-10 with T cell directed checkpoint inhibition such as the anti-pd-1 agent Pembrolizumab. Intriguingly, these data also highlight possible strategies for augmenting this paradigm by harnessing additional targets in T cell signaling.

Also in April, we attended the third international conference on the, on the Progress of Regenerative Medicine and its Cultural Impact at The Vatican which was hosted by The Vatican's Pontifical Council for Culture, the Stand for Life Foundation, and the STOQ, Science, Theology, and the Ontological Quest Foundation. One of our key investigators, Grant

McArthur, was with us, and he leads investigations into new cancer treatments that control cell growth division and differentiation. Our research, our research into the mechanisms of action for PV-10 suggested there are treatments to harness the body's own disease fighting powers that could bring new tools to the medical profession in treating many kinds of disease.

Another of our investigators, Dr. Sanjeet Igawawa [sp] presented a poster at the annual meeting of the American Society of Clinical Oncology in June. Dr. Igawawa's presentation reviewed both the phase three clinical trial PV-10 as a, as a single agent therapy for locally advanced cutaneous melanoma and the phase one b two study of interlesional PV-10 in combination with immune checkpoint inhibition.

The meeting, this meeting was particularly useful because we have had numerous discussions with key investigators over the several months since our phase three protocol underwent significant updating earlier this year to address changing in standard of care for patients with locally advanced cutaneous melanoma. These discussions identified several small but important changes to patient eligibility to align protocol requirements more closely with typical patient characteristics, and we intend to implement these in the near future, particularly in light of the positive feedback we received to these at the meeting. These changes in the phase three study were premiered at the meeting and implemented later that month.

On the last day of the quarter, Dr. Igawawa was a participant in a symposium at the sixth European Post-Chicago Melanoma Skin Cancer Meeting in Munich, Germany. His presentation covered the status of clinical trials of leading oncolytic agents for the treatment of soft tissue and skin metastases including the ongoing phase three study of PV-10 and the phase one b study of PV-10 in combination with Keytruda. Subsequent to the quarter's end, we learned that the European Society for Medical Oncology Scientific Committee has accepted an abstract for a poster presentation detailing the use of PV-10 as a treatment for stage three and four melanoma as part of ESMOS 2016 Congress in October. We will tell you more about that as the conference approaches.

Conferences, of course, are just one method of getting the word out in the scientific community. Publications are important as well. In April, two abstracts related to research into intralesional PV-10 for treatment for melanoma were published in a special issue of the ANZ Journal of Surgery detailing The Royal Australasian College of Surgeons 85th Annual Scientific Congress in May in Queensland, Australia. A full article on one of these quote, "intralesional PV-10 for in transit melanoma, a single center experience," unquote, was published in a special issue of the ANZ Journal of Surgery.

In May, we had an abstract called quote, "A phase two study of intralesional PV-10 followed by radio therapy for localized in transit or recurrent metastatic melanoma," unquote, published in

conjunction with the ASCO meeting. Also, in May, a watershed article was published detailing the immunoablative mechanism of action of PV-10. The article, titled quote "Intralesional Rose Bengal in Melanoma Elicits Tumor Immunity Via Activation at Dendritic Cells by the Release of High Mobility Group Box One" unquote, appears in Oncotarget, a high impact, open access journal, and the title notwithstanding, comprehensively documents the interaction of PV-10 with cancer cells and the downstream signaling in the immune system that occurs in the wake of the primary ablative process.

As we continue to expand awareness for, for both Provectus and PV-10, we have been featured in a number of media outlets including Oncology News, Oncotarget, Annuls, Annuls of Surgical Oncology, Small Cap Nation, and Stock News Now. Additionally, our participation in notable conferences has allowed us to meet with attending journalists to build relationships and explore future news opportunities. These recent conferences include American Society of Clinical Oncology, BIO International Convention, Tumor and Cancer Immunology and Immunotherapy 2016 Conference, among others. In addition, we are pleased to be working with the Melanoma Research Foundation to cohost a stage three patient webinar this fall and look forward to sharing progress on this initiative.

Lastly, on the public relations side of things, we're underway in creating a company video that tells the incredible story of Provectus and PV-10 and expect it to, to debut this fall. We remain

committed to building top tier media relationships that will ultimately secure more news coverage as well as creating content that drives awareness and connection. Subsequent to the end of, end of the quarter, we enhanced our intellectual property portfolio when we received a notice of allowance from the U.S. Patent and Trademark Office covering additional aspects of our process for synthesizing halogenated xanthenes, the family of compounds to which rose bengal belongs. The allowed claims cover use of certain halogenated xanthenes and pharmaceutical compositions and as medicaments.

Without getting too technical, we got a patent in September 2013 that covers our novel process for synthesizing rose bengal and related analogs. This daughter case confers protection to a wide range of analogs both as composition of better and in or as therapeutic products. Since the daughter case also covers pharmaceutical use of novel rose bengal analogs that can be made using our patented synthesis process, it provides a significant potential commercial lifetime for these analogs. Such patent strategy is common in our industry, building on original innovation by allowing value to be derived from one generation pharmaceutical products, thereby driving further innovation.

Another point on the corporate side which occurred in July was the establishment of an Australian subsidiary Provectus Biopharmaceuticals Australia PTY Limited and the announcement that we are opening a Sydney office in New South Wales. With a subsidiary in

Australia, we are bringing our corporate structure in line with our scientific work. Our research and development program has been international from the very beginning, and now Provectus is an international company. The new unit should make it easier to work with the Australian regulatory authorities and having an office in the region may facilitate our work in Asian markets such as Sydney, two hours ahead of Beijing, Hong King, and Singapore. If and when PV-10 receives approval in Australia and other nations in the region, we will have prepositioned ourselves to develop a sales and marketing force.

Added to our cash position, we note that we are considering the optimal manner to finance the company this quarter as we continue our efforts to enter a co-development partnership that provides non-dilutive cash inflows. We believe the data we are now generating will enable one or more co-development partnerships. However, we believe we will continue to finance the company otherwise until such data is available. At this time, with over $6 million in stockholder equity, we exceed our listing requirements with the nearest stock exchange MKT. We suspended the cancer ATM facility in order to focus on more traditional financing structures. We offered the second Warren Exchange transaction to capture any positive stock movement and will consider another Warren Exchange transaction if the market allows it.

We continue our efforts, search efforts to identify a permanent CEO and CFO. In each, in each of our recent calls, I've outlined the Provectus' business strategy which rests on five clinical and

business valued proposition pillars of PV-10 and PH-10 as well as our company's four key focus areas. For the first time listeners, let me review these quickly. The first pillar is our intellectual property portfolio. The second comes from our management and control of the drug substance and drug product supply chain. Third is the regulatory guidance and support we receive from the FDA in the U.S. and its counterparts in other nations. Our fourth pillar is the knowledge of the mechanisms of action for both PV-10 and PH-10 which we continue to better understand and more comprehensively discuss publicly. And, fifth is the clinical study designs that generate randomized, pivotal, and otherwise significant clinical data to support potential approval of PV-10 and PH-10 for their respective indications.

The four focus areas in business and corporate development are a higher public profile for both Provectus and PV-10, co-development discussions, other strategic activities such as regional licenses, collaborations, investments, etc., and grant programs including those in the EU, Singapore, and Australia via R&D expense of tax offsets. Although there can be no assurance that such events will occur, we do pursue them.

At the corporate level, we are making preparations for the commercialization and marketing of PV-10 and PH-10. Data from the phase three and the phase one b two clinical studies in melanoma should give us the ammunition needed to secure regulatory approval. We don't want to wait to figure out the best path to approval and start forming relationships to market

these drugs. We want to be ready to hit the ground running, so we continue to review our options with the FDA here and the TGA in Australia to find the quickest route to the market and be prepared before the data are complete.

Furthermore, we need to be ready to, to move forward in places like China, India, and Brazil where we, where we had been building relationships and learning the local terrain. Those three, three nations are home to more than 1/3 of the entire human race. To maximize the value of our drugs, we need to be in those markets as soon as possible. We are working with Boehringer Ingelheim in China to be prepared for action there. It is a slow process, but we cannot afford and cancer patients certainly cannot afford a delayed due to inattention to regulatory options and requirements. We have established similar but less developed and formalized relationships in India and Brazil, and as those advance, we will keep you informed.

In order to, in order to keep you better informed, and in order to, for you to be able to access information about our activities more easily, we have worked on updating our social media efforts. Since we aren't a software firm, and since most of us are closer to 60 than 20, we didn't take to this as quickly as others. But we do see the value in it and we're working to do social media better than we have. Our newly redesigned website, provectusbio.com, has been showcasing our mission for several weeks now, and the feedback has been positive. We have also received good reports, good, about our new Facebook page which serves as another

communications platform for us. We invite you to connect with us through these new platforms, and all feedback on them is welcome.

At this point, our Chief Technology Officer, Eric Wachter, wants to share a few things about this quarter directives from his unique perspective. Eric?

Mr. Eric Wachter: Thanks, as always, Pete, for that overview. I'll start with a brief synopsis of major topics before going into detail on key elements. As Pete noted, in the first quarter, we announced a major update of our phase three clinical trial for locally advanced cutaneous melanoma, and this was followed by a minor update in the second quarter. Together, these expanded patient eligibility and added Imlygic, the first intralesional agent for melanoma approved by the FDA, there's an option for comparator.

Since we started our combination trial in late stage melanoma patients in the second half of 2015, assessing safety and preliminary efficacy of PV-10 in combination with Pembrolizumab, also known as Keytruda, we've opened three of a protected four to six sites with a fourth one about to open. Tumors of the liver, we've had a, we have continued to add patients to our phase one study of metastatic carcinoma in metastases liver and have continued working with investigator community throughout Asia to expand this program to this important region. And, we open enrollment in a companion study to assess potential PV-10 in symptomatic neuro endocrine tumors, or NETS, metastatic to liver.

Additional mechanism data of PV-10 was presented in April, further advancing our understanding of the immunologic signaling that can occur after ablation tumors of PV-10 and possible strategies for combining PV-10 with other classes of immuno oncology agents beyond that, anti-pd-1 antibodies like Keytruda. And, a watershed journal article was published that walks through the entire immunoablative mechanism of PV-10. Talk about these later.

As PV-10, as Pete noted, we've completed analysis of biomarker samples collected during the clinical portion of our recent mechanisms of action study, wrapped in December and are working with the team who conducted these analyses to determine the significance of the study data.

And, on the intellectual property front, we continue to expand our most recent patent families covering the manufacturing process for rose bengal, an important aspect for eventual commercialization of PV-10 and PH-10. Now, to some details. Starting with our phase three clinical trial of PV-10 for local advanced cutaneous melanoma, we announced in March the protocol for the randomized control phase three trial was amended to reflect current and evolving standards of care and applicable patient population for a global study in melanoma. This included addition of talimogene laherparepvec, aka Imlygic, as an option for use as comparator and extension and clarification of criteria for patient eligibility. After additional

meeting with global key opinion leaders, we followed this with a much smaller amendment that further clarified eligibility criteria appropriate for such a global study.

As I noted in May, these kinds of amendments are commonplace in phase three studies, and serve to fine tune the patient population and study procedures to match changing care standards for a large, global study. In our case, these two amendments address evolving options and care standards for patients in the United States, Australia, Europe, Latin America, and China. Also, as I noted in May, evolving options and care standards for melanoma patients necessitated the major changes implemented through the first of these amendments. And that led to some delay in execution of the study. With that behind us, and the incremental changes we've instituted in June, the study remains solidly placed to support licensure of PV-10.

Part of this evolution in options and care standards has required us to look carefully at our options for enrolling patients, and despite the recent discouraging news about Opdivo that Pete mentioned earlier, this evolution [unintelligible] is rapid and far reaching, particularly with regard to melanoma in the U.S. and Australia. We've made changes to the study to address the realities in the clinic, and since late last year, have been working on options with our lead contract research organization, CRO, that's charged with implementing the study outside the U.S. and Australia to implement additional measures to minimize the impact of this constantly shifting playing field. This includes expansion of our plans for Europe with additional sites in

the startup process in key countries, particularly Germany, and expansion of reach of the study to other countries with an appropriate patient population such as Argentina.

We held our final advisory board meeting for Europe in June and have a motivated team of melanoma investigators at top centers ready for the study. After months of preparation, we expect to begin filing applications for, with local regulatory authorities in Europe later this month. We're also continuing to work with the investigator community in our traditional territories of the U.S. and Australia to build on a very solid base of sites that have been rolling throughout all, all of this.

Pete noted in his May conference call remarks that we will be in a good position at the November call to be more precise on timelines, and I'll state that we currently have no updates regarding timelines that we, timelines while we are in the midst of opening these global sites.

But, before I move on to our other studies, I'd like to comment on the Opdivo news Pete brought up earlier, both regard to the phase three study and as a segue to our combination work. Opdivo is Bristol-Myers anti-pd-1. That is anti-programmed death-1 antibody that serves to enhance the tumor fighting ability of T cells. It's often described as taking the breaks off of the immune system. Opdivo and Merck's closely related Keytruda, or Pembrolizumab, another anti-pd-1 antibody that targets the same immunologic mechanism, are leading the way in many of the evolutions I eluded to earlier in oncology, including in melanoma.

Like PV-10, Opdivo and Keytruda have potential use against a number of tumor types, and both are now routinely used to treat melanoma in the U.S. And, despite the size and importance of this melanoma market, Bristol-Myers and Merck have been developing Opdivo and Keytruda for a much larger market in lung cancer. Opdivo's recent failure to meet study endpoints in pivotal phase three testing as a first line single agent therapy for lung cancer highlights the critical nature of study design in drug approval and serves as a precautionary tale of the risks inherent in all steps of drug development.

With the exception of the exploratory studies aimed at initial assessment of safety and efficacy in new indications, we strive to implement strategies that minimize such risks while highlighting the competitive features of our investigational products. For example, we designed our phase three melanoma study based on enrollment to patients with stage three b to four M1a disease, a patient population for which we have considerable experience. Our phase one b two combination study, we're focused on patients with more advanced disease who require a more aggressive approach. I think this is a unique aspect of our clinical development plan. That is, very careful design of our trials at the fundamental level to maximize likelihood of success through very careful patient selection.

Despite the changes we've made this year to the phase three study, we've not deviated substantially from the patient population or treatment strategy we delineated at the outset of

the study. And, this is also the case with our combination study. I mention this because it is fundamental to our clinical development strategy and allows us to remain focused on execution of our studies despite the potential distractions of this changing playing field.

I also mention this since it clearly demonstrates that despite tremendous progress in oncology, it is not time to declare quote “mission accomplished” unquote. Pete mentioned that the Opdivo situation highlights the need for combination strategies, and we certainly believe that this is the case for patients with advanced cancers. This is the fundamental implication of our immunologic work on PV-10 and is the basis for our combination study of PV-10 with Keytruda in advanced melanoma.

As I noted, we’re opening our fourth center in the phase one b portion of the study, and I'm pushing our clinical operations team to expand this to six centers, both to assure timely completion of the phase one b portion of the study and have those centers ready to commence phase two, presumably early in the new year. [unintelligible] clinical data strongly support this strategy and have a high degree of confidence this study will be successful.

Before I move on from melanoma, I’ll note briefly that as I stated in May, we closed our expanded access program for PV-10 to new enrollment effective the end of June. Over the course of this program, over 150 melanoma patients, primarily just like those ones eligible for our current phase three study, received PV-10. Pete mentioned the data on some patients

reported earlier this year in Australia, and I note that a few, and as I noted a few minutes ago, this experience shaped our phase three and phase one b programs.

Turning to tumors liver, we continued to add patients to our phase one study of the hepatostatic carcinoma and metastases to the liver. And, as I noted in May, we expect to add one or two additional centers in the U.S. this year to facilitate completion of enrollment. One of these centers is slated for, to open for enrollment later this month, and the second is expected in September or October. The primary focus of both these new centers will be non-HCC metastases, allowing us to continue exploring potential new indications for PV-10. We also expect to present updated data on this study later this year at a major oncology conference in Asia and to get a companion journal article into the literature.

As I've noted in previous quarterly calls, we're working to move the emphasis for HCC development to Asia where it is a major health issue. Following up on meetings in the first quarter with investigators in Singapore and India, we felt critical follow up meetings at ASCO in Chicago and back in Singapore and in Hong Kong. A message from these and preceding meeting in late 2015, for example in Shanghai, are clear. It is time to move PV-10 development for HCC to Asia. As a result of this effort, we've identified investigators and institutions to move this forward and expect to be in a position to detail this at our next call in November. As I noted last time, these meetings point the way to one or more phase one b slash two studies of

PV-10 alone or PV-10 plus standard of care. I'm grateful to our colleagues at Boehringer Ingelheim in China, in Singapore, and in the U.S. who continue to facilitate this effort via crucial advice and contacts throughout the regions.

As noted earlier, we've opened a companion study assessing potential PV-10 in symptomatic neuro endocrine tumors, or NETs, metastatic to liver. This study builds on what we've learned so far from our initial phase one liver study and has been opened, now, to patient enrollment.

We'll follow progress with the study and, if initial results appear encouraging, we may elect to expand the study to additional sites to accelerate completion.

Between Pete's comments and my introductory remarks, we've stated most of what needs to be mentioned regarding documentation of the amino ablative properties of PV-10, and years of work conducted by Moffett Cancer Center both in animals and man was detailed in a pivotal paper published by this team in May. After a long haul, it is now clearly accepted that tumor ablation with PV-10 can lead to stimulation of a useful anti-tumor immune response.

We're continuing research activities along this line of reasoning. But, at the fundamental level, this is probably the most important paper published to-date on the drug.

Turning to PH-10, we're sorting through the immunologic and histopathologic data from our mechanism of action study of topical PH-10. I, unfortunately, can't go into detail yet about what we're learning, but in general, my assessment is that these results will be as important to PH-10 as the Moffett work has been to PV-10.

When new kinds of therapy come along, everyone likes to understand the biologic story underlying clinical observations, and it appears that this may be a very interesting story that explains observations we've made throughout clinical development of the drug. I look forward to sharing details on this with our stakeholders in the next few months. I will note that the observations from this study should play an important role in anticipated discussions with FDA to assess strategies for advancing the program from Phase I--I'm sorry--from Phase II to Phase III.

So, to summarize, we continue to make strides pursuing existing clinical programs in support of our core development mission in melanoma, while moving towards implementation of companion programs in related areas, such as our AHCC initiative.

Our acknowledgement--I'm sorry--our knowledge of the mechanism of both PV-10 and PH-10 continues to expand, and, as illustrated by our Phase IB-II combination study in melanoma, allows us to plan appropriate strategy for future work.

And although I didn't focus on it, we remain very active in both US and global intellectual property matters. We appreciate your continued patience while we endeavor to move Provectus forward, but I'd like to remind everyone that the most important stakeholders in all of this is our patients. I've always been mindful of unmet patient need and, if current studies are successful, patients may gain more options. We encourage patients and their caregivers to consider clinical trials, whether with our products or others, and we encourage everyone to remember that, as Pete has noted, when patients win, we all win.

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

Mr. Peter Culpepper: Operator, please poll 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 poll for questions.

Our first question comes from the line of Carl Byrnes of Lake Street Capital Markets. Please proceed with your question, Carl.

Mr. Carl Byrnes: Good afternoon, thanks. It's Carl Byrnes. Just a real quick question for the [unintelligible] of doubt with respect to PV-10 in Catrudo [sp], the Phase IB-II trial, you were not giving any guidance with respect to when completion of enrollment is anticipated. That's my first question. And that's a 24-month progression-free survival primary endpoint? I just want to clarify. Thanks.

Mr. Eric Wachter: That is the--that is correct. That's the primary endpoint for the Phase II portion of the study. For Phase I, it is safety and tolerability. So, we have a much earlier readout in that case after 15 weeks of treatment. So, we generally never provide ongoing patient accrual data, and we don't expect that we'll change that. We have provided, as we've done in the past, periodic guidance on status timelines. And as I noted in my prepared comments, we have not modified those as of today, and we expect to be able to update this guidance by the time of the next shareholder call in November.

Mr. Carl Byrnes: Great. Thank you.

Operator: Our next question comes from the line of Steve Jensen of Jensen Capital Management. Mr. Jensen, please proceed with your question.

Mr. Steve Jensen: Hello. Mr. Culpepper, I would like to know how you personally feel about the current status of the company.

Mr. Peter Culpepper: For my part, and I think this is something that I can say I have felt really since the beginning of the journey of Provectus. I joined the company, as many of the stockholders know, over 12 years ago, and I'm passionate. And I think Eric concluded nicely. I'm very passionate about what we're doing for patients. We know we have--everyone on the call can appreciate this. We know we have a such a fundamentally profound opportunity to change the course of how we're treating cancers, and excitedly, dermatological indications as well. We have a unique set of compounds, investigational agents, and to my knowledge, there's nothing like them.

The--so, I'm--I came to the company because I wanted to find a solution to how we were treating disease, and I'm thrilled that there are innovators. It's a long path, but the innovators here were the ones who saw something that nobody else has seen. And I think through the years of the struggle and the challenges, we are now coming through to the very end of this journey.

We're in the position right now with interacting ourselves on a regular basis with top medical professionals literally globally. And it's very gratifying to see this play out. I very much, as a stockholder, are [sic] very focused on the value of the valuation. But, I do know that we will persevere, and we will see this through, and I firmly believe that, as [unintelligible] the problem of PV-10 and PH-10, and in the analogs, the platform. I firmly believe we're going to be very successful in our efforts.

Mr. Eric Wachter: I'd like to add to that, Pete, from the technology side. I think it's very interesting that we have maintained a consistent pattern throughout the company, starting with hypotheses in the laboratory that we test on simple model systems and then move as quickly as possible into the clinic. We differ from conventional companies in that we haven't

invested the time and effort into understanding the mechanism of those processes at the minute level until we've seen that there's a clinical signal to justify that additional work.

And what's remarkable to me is the way in which the immunologic mechanism data that we've amassed on PV-10 has guided our understanding on how to move the drug from early stage clinical development to late stage clinical development, and we're seeing exactly that same pattern being repeated with PH-10. So, I think from a technology perspective, there's never been a better time for the company.

Mr. Steve Jensen: Thank you, both. I was wondering if you could comment about the current cash position and what your plans are to raise money.

Mr. Peter Culpepper: Yes. The cash, obviously, for everybody on the call, is a concern. As a biopharma company, until we can get a partnership, we do need to raise money. That's the way the reality is in the industry. We're very, very encouraged by the progress. But, we have to keep going, generating data. We have something extremely unique with PV-10 and PH-10. And

that--and we need to generate enough data in context to get the non-dilutive financing. We're confident we can get there. We believe we're much, much closer than the market suggests.

But, we have to keep going. And until we're there, we're going to have to raise money. And in the 10-Q we filed yesterday, we did make clear we will need to raise money this quarter. I don't have any doubt about that. I'm very appreciative, and I'm gratified. We have many dedicated stockholders. We know them personally. We've known many of them for years. We have some of the--in my opinion, some of the best people possible that are invested and involved and committed to our success.

And that's really priceless. So, I'm confident we can get the financing that we need. We obviously--and I want to emphasize this. We really are focused on doing the kind of financing that is the least dilutive possible. As we can appreciate, that's a challenge. But, it's obviously--you know, today's a tough day. And we've been through tough days. We've been through tough times in the company. But, I have no doubt we're going to get through it.

But, I want everybody on the call to know that we are as committed to being successful as any human beings--group of human beings could possibly be. And we're going to have people that we know very well that will finance us. And those people know the value. They know us well. We've known them for years. And we're dedicated. We're dedicated. We're in it ourselves, and we're going to be committed to getting the cash that we need to get to the data we need so that this drug see the promise that we all know is there.

Mr. Steve Jensen: Thank you.

Operator: Our next question comes from the line of Peter Eckerhoff [sp], a private investor. Phosphoglycerate, Peter.

Mr. Peter Eckerhoff: Hi, guys. Thanks for your time on today's call. I think you--Peter, you pretty much answered the question about fundraising. But, you know, to be clear, we're about halfway through the third quarter, and you are saying unequivocally that by 9/30, there will be additional, you know, cash funds in your coffers to continue the progress that you're on?

Mr. Peter Culpepper: Well, I can certainly--thank you. I can certainly say that, you know, I cannot tell you or anybody with 100 percent guarantee anything. Life doesn't work that way. I can say that I know investment bankers who have funded us for years. I know them very well. I know the stockholders who have sent and wired money to our bank account. I know them very well. I can tell you that as here as I'm talking to you and everyone now, we feel very good about that. But, our effort at Provectus has been a--every single day for me for over 12 years, for Eric, and its cofounders for much longer than that, we have been able to keep moving forward.

And I--and I'm telling you that we say in the filings we are going to seek financing. I'm very confident on that, absolutely. As you know, Eric and I and many others have personally funded the company. I can also say that it's clear that we have gone through even tougher times than this, if we go back to the beginning of the company. So, I have no doubt that we're going to get there.

My focus is on minimizing the time for the drug to see the benefit for many, many more patients than we already have. So, in other words, getting the funds that we need to get the data that we need to get PV-10 and PH-10 in the position for appropriate approvals for the regulatory process. So, funding, I can tell you this is clear. We're going to do that this quarter. But, until it happens, I cannot commit to you any more than we can commit to you that our Phase III is going to be a success. We're very, very confident that it is. We have every reason to expect it. I believe the data of the way PV-10 works has been in all the publications and the [unintelligible], has got us to this point.

That's why we have the Pfizer patent and the Boehringer Ingelheim collaboration, and that's why we are able to show all the mechanism data that we do in the two different areas. And we're going to keep going. You have that commitment from us.

Mr. Peter Eckerhoff: Thanks. Can I follow up, Peter? Can you--I just want to switch gears a little bit. I believe, you know, your relationship with BI is under a LOI, is my understanding. Can you just tell, you know, mostly investors which are retail investors, exactly what is the role of BI? And is it possible that BI can change from, you know, an advisory role to something in

which, you know, could be more of a partnership role? You know, do they have the inside look at that because I'd believe that they'd want to build their oncology portfolio and have the access into the markets you want to be in?

Mr. Eric Wachter: Peter, this is Eric. Before Pete dives into the response to that question, I would just like to point out that I work very closely with our colleagues at BI. And we have a very open relationship with them. They have the opportunity to see the data that is not publicly available as a consequence of that LOI. But, they also have provided us with assistance on multiple fronts.

An example that I gave I think in the last conference call was organizing a meeting of key opinion leaders in Shanghai in October where they identified the individuals. They identified the individuals. They invited the individuals and managed the logistics for that meeting so that we could present PV-10 to the hepatocellular carcinoma community in China and hear their input into our program. That's had an incredible input into our design of subsequent work for the study.

We had a meeting in April of this year in India similarly organized with the assistance of BI. We had meetings with HCC KOLs at ASCO and subsequent to that, in Asia, again, also organized by BI.

So, they provided us with advice, with contacts, with support. And so, I think that that's probably not just out of their magnificence. They're not a charitable organization. So, I'll hand it over to point.

Mr. Peter Eckerhoff: Right.

Mr. Peter Culpepper: Yeah. I appreciate that. BI's a great forward-looking indicator in the way Big Pharma looks at Provectus, in my view. So, what--I'm glad you raised it because BI is one of the top pharmaceutical companies in the world. They're very well-respected in the industry. They're certainly the largest private pharmaceutical company in the world. They are well-respected in the industry. They did a tremendous amount of due diligence in the data room before we entered into the formal LOI.

They're well-known and well-respected, and they're forward-looking from our standpoint because they're the first company that's actually shown the ability to provide soft dollar costs that we don't see on the balance sheet, but it's invaluable to help us advance PV-10 in a meaningful way. So, in my view, they're like many other potential partners, Merck and Bristol and Pfizer with German Merck and Hoffmann-La Roche and Novartis that are very closely monitoring everything we do.

We know that ourselves because we interact with them. We're very close with a number of potential partner executives. And so, BI just happened to be the first one that's more public. But, I believe that we are so closely monitored that data that comes out more and more will continue. We--Eric and I were both in New York City last--just yesterday meeting with very credible individuals that are very networked into the global oncology and dermatology markets.

So, it's just a question of that we hit enough data to trigger these relationships to something financially meaningful to stock in the company.

Mr. Peter Eckerhoff: Thanks for the answer, and best of luck.

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

Mr. Bruce Benzell: Hello. This question's for Eric. Eric, you made it clear that you will not release information on the enrollment of the Phase III. I don't believe that you've made it clear--you have made it clear that interim analysis will be triggered after one-half of the required events. If I heard right, the November date, is that the interim analysis trigger date? So, you expect one-half of the required events on that date?

And then working back from that, I'm assuming a required event is either reaching 18 months depth or progression, and the progression's measured every three months. And so, anybody that you're expecting to progress by November would have effectively needed to be enrolled by now. So, I read the--that November progression as saying that you've already enrolled one-half

of the required number as of this date. Can you either agree with me or tell me where I went wrong on my logic?

Mr. Eric Wachter: Okay. Yeah, I'd like to walk you through that, Bruce. So, when we began designing the study several years ago, we looked at the issue of how to schedule an interim assessment. And while that was a rather uncommon idea, we looked at that very carefully. We even had discussions with FDA on that topic. And they were adamant that they were strongly opposed to any sort of effort to schedule an interim assessment. Our hypothesis at the time was that, for example, because the interim assessment and the final assessment are based on a number of progressions, they're modeled using standard statistical models. If there was a longer progression-free survival in the PV-10 arm than expected, there would not be the required number of progressions in that arm to add up to the required number of events.

But, interim assessment is triggered by the number of progression events that occur in all of the patients. The final assessment is triggered by a number of progression events that are occurring in all of the patients. The statistician assumes that they will be equally divided between the two arms. That's the null hypothesis. That is that there's no difference between

the two. And the study--these studies are designed to disprove that null hypothesis. That is to show that there is, in fact, a difference in progression between the two arms.

So, we worked with FDA on that topic, and we were unable to get them to move substantively on that position. What we ended up working through was some language that allows us to end the study if after enrollment of all of our patients, so looking at the final endpoint, the study continues along for a rather lengthy period of time, that the study is ended. The outcome is looked at by the review committee, and the outcome of the study is determined based on what has happened to patients at that time--that point in time.

So, it's not a correct hypothesis to say that every patient that is going to contribute to interim analysis would have to be enrolled at this time because there isn't a specific time that elapses before that interim assessment occurs. That's one of the reasons why we can't project with a high degree of certainty at this point when that's going happen. While we make periodic predictions about when we expect that to happen, but you'll continue to hear us use sorts of statements that Mike Porter alluded to in the beginning, that we expect, we anticipate, we project, rather than we can say with certainty that the interim assessment will happen at a

certain point because we don't control. It has--it's controlled by the patient's biology, how they respond to treatment.

So, we're continuing to--as I said in my comments, we're continuing to enroll patients in our existing centers, at centers in the US and Australia, and expand the study throughout other regions of the world that we've identified to bring us to that interim time point and eventually to the final outcome of the study.

Mr. Peter Culpepper: One comment, I just have a quick comment to add onto Eric. And that's to say that, to be precise, we said we would have more of a refined understanding we believe to communicate on the November call. I--the actual--I believe it's fair to say from the comments the interim assessment would be by the end of the year at the earliest, but we'll have a more refined assessment for you and for stockholders on the November call. A lot will depend on a lot of the in-play activity that Eric has alluded to that we should have a better handle on communicating more precisely on the November call.

That's--so, you keep that in mind. This dialogue and this communication is something we care about ourselves because we know how important it is for potential partners, for the FDA, for patients, and for the market.

Mr. Eric Wachter: Bruce, I'll add to that. We're like every other pharmaceutical company, and I've said previously to certain parties, maybe on one of these quarterly calls, that one of our crown jewels is our study protocols because they represent everything that we've invested in the company up to the point that that protocol is issued.

So, we--I mentioned that we amended our protocol twice this year for the Phase III study, once in February, once on the 25th of June of this year. And sponsors never share those publicly until they're forced to do so, because, as I said, they're the crown jewels. They explain how you build a clinical trial.

Now when studies--pivotal studies lead to drug approval published in major journals, one of the requirements most of those journals in modern times is that the sponsor has to allow the

journal to publish the protocols. So, at some point, hopefully, if everything goes well, we will publish our clinical trial protocol. But, I just wanted to highlight from Section 4.9 of the Phase III protocol. This is the section on interim analysis, and I hope that this will clarify for you and for other interested parties on this topic.

An interim assessment of efficacy and safety will be performed when the IRC--that's Independent Root [sp] Committee--will be performed by the IRC when 50 percent of the events required for the primary endpoint, that is 81 disease progressions as defined in the study protocol, have occurred. And so, that explains to you that there's a set number. It's designed at the beginning of the study, and that's the point when that number of progressions have occurred.

It doesn't matter if they're all in the PV-10 arm, if they're all in the comparator arm, which isn't possibly because there aren't enough patients in the comparator arm. We have to have enough progressions to hit that metric. Now, we had hoped, as I said, to have some sort of a mechanism in the study that would allow that to be triggered early if, for example, we're going along and we're not seeing progressions as we expected.

And so, while we worked on that with the agency, as I said, they're adamant that that was not appropriate for a pivotal study. So, what we managed to compromise on was that in Section 4.10, which is captioned "Study Duration", that subjects will be monitored until survival--for survival until death, loss to follow up, withdrawal of consent, or study termination by the sponsor.

And so, we are able to monitor at the terminal end of the study, and if the clinical trial data monitoring committee determines that it's in the best interest to end the study, it could end before we had all of the progression events occurring. I doubt that'll happen. It will be a very unusual circumstance, but it would probably be positive for the drug because it would suggest that a large number of patients weren't progressing because of the majority of the patients in a two-to-one randomized study are from the PV-10 arm, and that probably would imply that the PV-10 patients weren't progressing.

But, this is all speculation. But, I think it helps you to understand that a randomized trial is based on a number of events that statisticians set when the study is initially designed and the study continues until that number of events occurs.

Mr. Peter Eckerhoff: Yeah. I am a statistician, so I do understand that. I certainly understand the lack of progressions. If they occur in the active arm, that's great news. But, I think I heard from Pete that there is--that I misunderstood that there's no projection that the interim analysis will be triggered in November. And then your comment, my question on the three months or the November 15th, it's my understanding nobody--that you--nobody triggers a progression in less than three months. You're only using that--or what's that? The 12-week scan to determine whether somebody progressed, is that right? Every 12 months--or, excuse me--every 12 weeks, you do a scan and determine whether there's progression or not?

Mr. Eric Wachter: So, the--we've talked about this in the past, but I think it makes sense to outline a couple of the unique features of the study. So, when we were originally designing this study, we looked at a number of modern clinical trials in melanoma. We looked at a pivotal study designed for Imlygic that was used to approve that drug recently. And we looked at the

study designs that were used for Yervoy and for vemurafenib, which I forget the trade name of that. But, it's a kinase inhibitor.

And in those studies, there was a standard pattern that's very common in oncology because this is typical in almost all oncology practice, which is the patients are scanned. They receive CT, MRI, or both on a 12-week timeline as they're being followed for status of their disease. And so, understanding the salient features of PV-10, we felt that that was potentially detrimental to patients. And so, we used that standard paradigm, scanning every 12 weeks for full resist assessment. But, we included periodic clinical assessment in the original study design every four weeks because PV-10 and the chemo arms, both patients were treated on a four-week schedule, to allow the investigator to identify unambiguous progression in the patient.

We're talking about disease of the skin. And so, it is patently obvious if the patient is developing new lesions, for example. We don't have to run a CT scan on the patient to detect those in the skin. Those are photo documented every four weeks. And so, we have a way to conduct a--basically an interim progression assessment between that 12-week milepost. When we added Imlygic, things got a little bit more complicated because there's an initial five-week

treatment cycle. But, basically everything lines up the same with Imlygic or with PV-10 or chemo patients with that clinical assessment every four or five weeks during that 12 or 13 weeks in the case of Imlygic initial treatment cycle.

So, we have the opportunity with patients that have locally advanced cutaneous melanoma to identify what's going on with those documented in an objective fashion because we're taking photographic data on every patient at each of those interim time points. And so, we can then assess progression on a fair basis applied across patients, irrespective of what drug they're receiving on the study.

So, we've taken, as I said, a conventional study design, and we've added our own little wrinkle, and that's based in large measure on experience that we gained from work in Phase II and from that 150-plus melanoma patients that received PV-10 under expanded access.

Mr. Peter Eckerhoff: Okay. I think I understand you, and thanks for the clarification. If I understand you right, progression can occur either at the 12-week scan or every four weeks on the clinical scan?

Mr. Eric Wachter: That's correct. So, we require patients to be assessed after the first four weeks, and it would be theoretically possible for them to be deemed to have progressed at that point.

Mr. Peter Eckerhoff: Okay. Thank you, Eric.

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

Mr. Ted Kidd: Hey, Pete. Hello, Eric. I wanted to just ask you what the projected cash need is to get to Eric's projected data read goals. Then I'll have a follow up on that.

Mr. Peter Culpepper: Yeah. So, we haven't communicated with any guidance. We will want to make sure at a minimum to $6 million stockholder equity requirement that we have referred to on the New Stock Exchange NKT [sp]. We are at slightly more than $9 million at the end of Q2. So, we certainly want to continue to be above the $6 million in stockholder equity. So, that's a sixth floor that we look at from a cash standpoint.

We certainly, as we know from a burn rate perspective, have a certain burn that different people have done a good job in this course. It's clear from the 10Q that we filed yesterday what the burn rate is. I think we want at a minimum get enough cash this quarter to cover a quarter burn. I think it's probably fair to say this is going to be--we're going to be very transparent with stockholders how we are effective at moving forward.

We all know that we're focused in our filings and us talking to you on the phone in this conference call. We're very focused on non-dilutive cash through a potential partnership. We know that our co-development type transactions on the basis of the Phase IB-II PV-10 and Merck-Acruda [sp] study is the near-term on the IB piece, which we said last call would be the

IB would be the end of this year, early next year, from the standpoint of when the IB data would be available.

That's very important for potential partners, which we discussed in the September press release last year when we commenced that study. We also know that the same sort of immune signaling, understanding, and work on the liver--in the liver PV-10 programs. That's also very helpful in those discussions. So, I think initially it's going to be the quarter of burn, and then we'll--that's where I would project. And then we'll continue to assess this and be transparent to stockholders how we want to make sure we can get to, again, enough data to have meaningful, non-dilutive financing through one or more corporate co-development partnerships.

Mr. Ted Kidd: Okay. So, when you're saying non-dilutive, of course, you're not going to issue additional shares. But, at what cost is it going to be through borrowings? You know, my concern is that share price now is getting close to the point where--which could have a potential white knight come in and try to, you know, save the company, and leave the shareholders out in the cold.

Mr. Peter Culpepper: Yeah, we're--we are very aware of that. We do have a certain, let's just say, provisions, that we can--that we believe to be effective at employing to thwart any sort of company takeover at an unacceptable level. And I don't think that the potential partners that we're working with or talking to and interacting with, they're focused on the data. They know that there's a tremendous upside opportunity in this sort of space.

So, I don't think we're going to see that. I think it's just a question of getting enough data out of these studies. We've had active dialogue with potential partners, in particular over the last 15 to 18 months, so since really we got into Phase III in April of last year.

We have had very active dialog that continues. It continues build momentum. And the potential partners--they are really just interested in making sure they understand how PV-10 works. It is unique. The same discussion applies to PH-10, although we can see a lot more data now with PV-10. So, potential partners are interested in what we're all interested in--is optimizing the use of PV-10. And from that standpoint, we want to just get enough data to trigger that.

Mr. Ted Kidd: Right. So, in the event that something like that were not to come to fruition, has the company entertained the idea of presenting to existing stockholders, you know, additional shares with [unintelligible] attached? I don't know how many, you know, would be appropriate at this point. But, you know, say you needed a couple more quarters of cash burn, maybe $10 million, you know, you would have to issue between, I think, 55 and 60 million shares at today's closing price in order to continue that. That should--something like that, or along those lines, would get the company through that mid [unintelligible] data, wouldn't you think?

Mr. Peter Culpepper: Well, I think--I appreciate that. And I can say that the Board and myself were very active--were very much focused together as a unit. The company is right now in very close contact--the entire company board and officers--on ensuring that we have a unified, united front, in dealing with this. We're very focused on stockholders. We know these people. And I can say that we have every stockholder in mind in trying to go forward and get this done right. So, I can't be too precise, other than to say we know we're going to focus on raising some cash this quarter, but I also can say that we are very cognizant of the importance of involving stockholders to the extent that we can.

Questioner: Okay. All right. Thank you very much.

Mr. Peter Culpepper: Okay.

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

Mr. John Skushanhan: Yes, thank you. My question is for Eric. Eric, can you unpack the statement--or the reference you made to the--about the research that was recently done, where they compared the ablative properties to the--a useful immune response? And that's what I'm more interested in, this useful immune response, because it's not clear to me if PV-10 is stimulating the adaptive immune system to produce antibodies after, you know, the tumors are removed. If you could, you know, shed some light on that--and color, I would appreciate it.

Dr. Eric Wachter: All right. I'd love to do that. In fact, Pete suggested yesterday that rather than giving a prepared set of talking points that we go through a very detailed presentation as a webinar. I resisted that because I don't know that it would be of interest to most investors. But, in the case of the immune response to PV-10, there is an immuno-oncology cycle that has become extremely popular in the industry and in the medical community that describes the--it sounds like a joke, but it's a seven-step process from destruction of tumor to triggering the immune system to come around and destroy tumor.

So, you're using--in the case of the classic example, you might be using a chemotherapy agent to kill tumor cells, leading to recruitment of the immune system through antigen presenting cell collection of tumor debris, educating of T-cells, generation of functional T cells against that tumor antigenic material, and then trafficking of T cells to other tumor tissue, ultimately leading to destruction of that tumor tissue by those cytotoxic T cells.

And when we began the modern era of immunology of PV-10, we started working with the group at Moffitt Cancer Center. And their particular expertise was one of the steps in that process, which is considered to be very important as an indicator of functional immune

response against tumors, which is the detection of tumor-infiltrating lymphocytes, the T cells penetrating into tumor and interacting with tumor cells.

And ironically we ran into problems immediately when we started that work because the ablative process, that first step, the destruction of tumor, occurred in such a robust nature that in samples that were being looked at there basically was no remaining tumor, so there was nothing to look at for infiltration of lymphocytes. So, we took a step back and we looked at the entire cycle. It's called the Chen Mellman immuno-oncology cycle [sp]--and began working our way through that cycle.

And I believe there is a representation of this on the company website, which shows that over the last several years we have worked with colleagues at Moffitt Cancer Center, we have done some work internally, and we have done some work at the University of Illinois-Chicago to show that PV-10 unambiguously triggers that first step, the destruction of tumor. And that event performs all of the expected downstream signaling of the immune system, leading eventually to a functional immune response against an untreated tumor.

So, when we started this work in Australia in the clinic in 2005, we described that as a an bystander response, which was the common terminology at the time. Immuno-oncology was not particularly well regarded at that period. It got to be even less of an important area of investigation as we approached the end of the first decade of the 21st century. And then, it became a very hot area with the approval of anti-CTLA drug Urvay [sp] and subsequent approvals of a number of anti-PD-1s and presumably eventually anti-PD-L1s, all drugs that harness T cells to have a functional--or improve their functional response against tumor tissue.

So, I think that the story is now very well documented in the literature. We have shown that this occurs in [unintelligible] models of melanoma. We have shown this occurs in [unintelligible] models of colorectal carcinoma. We have evidence to show that this happens in [unintelligible] breast carcinoma. And, most importantly, we have shown that key elements of this signaling are occurring in melanoma patients. That was one of the key aspects of that work with Moffitt. I have touted them many times.

They are experts at so-called translational medicine, which is taking bench-top results into the clinic and then taking what is learned in the clinic back to the bench top, and back and forth.

And our work with them over the last several years has been a perfect example of that, where we have gone back and forth between us and them multiple times, trying to understand all the steps in this process. I can say that we now have unequivocally demonstrated that for melanoma. Our next tumor on the radar will be hepatocellular carcinoma because there are challenges in HCC that are comparable to those in melanoma.

We already know that we can destroy HCC with this ablative process and the hypothesis that that should lead to similar signaling, which can have implications for--well, single-agent therapy [unintelligible] HCC, but more importantly for combination with things like anti-PD-1 [unintelligible] . We have already shown that the basic immunology occurs in HCC models, so I would say that--one of the things I'm highly confident in, I'm highly confident that we will show that this same functional immune signaling functions in HCC.

And I use that as an opportunity to comment on something that I didn't mention in my prepared remarks, which is we have talked about our HCC strategy for Asia, and I made some comments about that during the prepared remarks and looking at it as both a single agent and in combination. I firmly expect that that will play out as a combination strategy at two levels.

The first is a successor to our current study, where we're using PV-10 with sirafative [sp], and there is--from our interactions with KOLs [sp] around Asia there is no reason not to proceed with that to a larger study in Asia. And that's what we expect to do with the work in Hong Kong, Taiwan, and Singapore that I alluded to.

But, we are also looking at conducting the non-clinical studies to show that Chen and Mellman signaling--the seven steps occur in HCC in mice to justify, then, a second-pronged approach, which is particularly relevant for the West, which would be a combination of PV-10 with a checkpoint inhibitor, be that anti-CTLA-4, anti-PD-1, or anti-PD-L1. And so, that work we are starting, and I expect that that would presumably lead to similar development in HCC that we have seen in melanoma, which is a 1b/2 combination, or PV-10 plus a checkpoint inhibitor for HCC.

Questioner: Well, thank you. That was a very detailed explanation, and I appreciate you taking the time to do that.

Dr. Eric Wachter: Yeah, I probably should have listened to Pete and used this last 'cause I can usually talk much more efficiently from slides than I can extemporaneously, but we have talked about this very Chen and Mellman cycle very extensively to lots of audiences, so it's a really important part of our story at this point.

Questioner: Thank you, again.

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

Dr. Ed Gallum: Hello, Peter. Hello, Eric. Can you hear me okay?

Mr. Peter Culpepper: Yes--can hear you, Dr. Gallum.

Dr. Ed Gallum: Okay. You know, there is two questions or two areas that I need to address. We saw the Warren [sp] exchange program number 1, with an extension, nothing really done. And then, we saw the Warren exchange program 2 with another extension and nothing really done. To an investor we're anticipating some news breaking event to make this happen, and we didn't see it. And that span of time encompassed months. Was there something that didn't materialize? Is it still in the works, or can you elaborate on that a little bit more? And then, I have one more question.

Mr. Peter Culpepper: I can say that certainly when we put up those, the Warren exchange 1, which resulted in the 3.9 million, as you know, in Q1, that Eric Jankow [sp], one of our Board members and myself all participated in, as well as other Warren holders. And then, the Warren exchange 2. We did expect and had hoped for a better response in the stock, based on current activities. These structures were designed to capitalize on potential stock.

There are very active--we have alluded to--very active efforts with co-development through the time period of Q2, AACR, the Conference that had fundamental data of PV-10 combination with co-inhibitor blockade [sp]. We also had Asgo [sp], we had BIO International, we had the

Chicago, so multiple conferences and interaction with potential partners. We did want and expected more stock-moving news out of those events, to be sure. I think it's fair to say those efforts are very much continuing and building on all of the data we have discussed.

What we are trying to do is be sensitive to minimizing dilution until we can get enough of data in context for potential partners. So, those structures were, in our view and the company's view, the least offensive to the stock that we could come up with, which is why we tried them. And at this point we will work very hard to continue to minimize dilution, like we have discussed with other questions, until we can get the kind of data that we need to get non-dilutive financing.

So, I think there is no question that we want--all of us want the stock to perform better [unintelligible] partners activity that speaks to our media relations efforts or investor relations efforts, that speaks to all the conferences, pretty much a recap of our prepared remarks. And we're going to keep at that, Dr. Gallum, until we can get the type of visibility and activity in the stock that we're all pleased with.

Dr. Ed Gallum: You know what, Peter? As we are focusing on minimizing the dilution, we need to address the share price because as the share price decreases it just augments or makes dilution that more susceptible, based on a current market share price. The other--but, that's--the other question I have is you are in constant communication with the New York Stock Exchange officials regarding our listing status. Do these officials have more information than shareholders regarding whatever, other than just what is your cash balance, what is the share price, da-da-da-da-da, you know, certain perameters that they are interested in only? Or are there--other information that keeps them perhaps at bay from acting? I don't know how else to put it.

Mr. Peter Culpepper: Sure. We have communicated with them--we're real time in our communication with regards to press releases, with regard to our interaction to--and our openness to comply with all the NYC [unintelligible] regulations, our visit with--on the floor with our specialists, with the exchange officials. So, we are active in that relationship building and maintenance in the regulatory framework with the Exchange.

But, they don't get any initial or special information that stockholders are not aware of. They give them a real time, in terms of when [unintelligible] comes, so that happens. I can say after we lost the [inaudible] therapy designation attempt, going back May of 2014, we are very active in communicating with them our way forward. So, we are very--in that case went over our business plan with them, made sure they understood what we were doing, moving forward, in Phase 3, so they [unintelligible] work closely with them.

So, they knew we have a real viable opportunity here in advancing PV-10 and, of course, PH-10 is with it. We went over that in detail. So, that is very important. So, we have a very effective relationship because we are transparent, and we are open. We know we have an opportunity to move forward. We absolutely agree that the stock price is critical for minimizing dilution, and that is where the effort on [unintelligible] partners and really our openness here and addressing the questions and having these kind of calls. We want stockholders to feel good about what we're doing, and we really believe that this is the most compelling story that there is, the most compelling opportunity there is in bio-pharmaceutical drug development. And I think that's going to win the day.

It's--we're a very unusual example of a company against all of our parent companies that we track--to my knowledge, we have the most unusual set of circumstances--on the type of compound, the way it has been used, the way it has been developed. And even going to the fact that we did not the traditional way of financing the company from the very beginning. So, there is many unusual aspects. But, what we do have is a very promising set of compounds and analogs that we're developing, and that's what is going to win the day.

We see this firsthand, and that's what we're trying to convey to you, we as a--Eric and myself and others in the company. We see this firsthand and who we are interacting with at the institutions, not just the regulatory bodies but the oncology and dermatology-focused research and development institutions, institutions that are very well known. Eric alluded to Moffitt Cancer Center as one. There is the University of Illinois-Chicago. There is other high profile, well-respected institutions that have been very active in their involvement with PV-10.

And I'm confident that more will become public. And we're thrilled with the reception. And this speaks to how we are more bullish than ever in seeing this through. What we're trying to

convey to stockholders is we should feel good about what we're doing, and we're going to power right through to as successful a conclusion as we can.

Dr. Ed Gallum: Well, I appreciate that, and I can see both you and Eric hard at work. You are set on a strategy, you are implementing that strategy, and that's the way it should be. I only wish that we had 50 million in the bank to make sure that we get there. I think the reason why the stock went down today drastically--and the market investors are hungry for data, hungry for results, hungry for something that will move the share price.

And I am concerned as an investor--I think I heard you earlier comment on April 30th, and you have investors on the sidelines waiting to help us along with a cash position. I--if they are listening, please act soon rather than later. And that's it, gentlemen. Thank you so much for all you do. I appreciate it, and I really want a win on this thing.

Mr. Peter Culpepper: Yes, and that's what we're going to do. When patients win, we're all going to win, and we're very focused on that.

Dr. Ed Gallum: All right. Thanks, gentlemen.

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

Mr. George Kafakarker: Hi, guys. Thank you for taking the call. I know it's a long call, so I have a few questions here, but I'll try to be very quick. What is the status of the Sinopharm relationship? I am assuming it is not going to proceed.

Mr. Peter Culpepper: Sino--?

Mr. George Kafakarker: Sinopharm, yes.

Mr. Peter Culpepper: Sure. So, yes, George. So, Sinopharm is very focused--just like Boehringer Ingelheim, except it's not a formal relationship. They are very focused, like a lot of global potential partners in exactly what we're doing--and in Sinopharm's case in Asia. So, we're working through--and we alluded to it in the prepared comments--we're working through the regulatory bodies in Asia, including China. And as a matter of fact we met with Sinopharm twice in Q2, so the Sinopharm executives know the potential for PV-10 as an injectible for multiple cell tumors in China.

Of course, liver cancer is very high profile in China. Sinopharm and the particular anti-tumor subsidiaries that we are directly working with [unintelligible] subsidiary that Sinopharm is focused on PV-10. They understand injectibles, they appreciate injectibles, they understand our relationship with Boehringer Ingelheim. Sinopharm has a relationship with Boehringer, as they do with Pfizer. So, those--that interaction and those discussions with Sinopharm continue. We will continue to meet with them. We know them well.

And quite frankly we're going to continue to work with Boehringer Ingelheim, as Eric alluded, because they are providing invaluable support. Whatever we would do with Sinopharm we will

very much include Boehringer Ingelheim in the discussions. We don't want to cut off our nose to spite our face, so to speak, with regard to Boehringer Ingelheim. But, we also are cognizant of the inter-relationships of different companies.

Mr. George Kafakarker: Yeah.

Mr. Peter Culpepper: Like I say, Pfizer has a relationship with Sinopharm. Boehringer Ingelheim has a relationship. So, there is a lot of room for growth in this industry in a good way because people are suffering in China. We know that. People are suffering in most parts of the world with inadequate cancer treatments. And it's a growing problem. In China the incidence of liver cancer continues to increase, the incidence of numerous cancer types, and we think we have a real opportunity here. And this goes for most geographies in the world. There is a real unique opportunity for PV-10. It's a chemical, stable molecule. We have a very significant manufacturing logistic set of--ability to operate globally the biologics and the more complicated other cancer therapies just do not have.

Mr. George Kafakarker: Yeah.

Mr. Peter Culpepper: So, we know that that is a role, and organizations like Sinopharm understand that.

Mr. George Kafakarker: Yeah. Nobody disputes the opportunity piece, I don't think. So, I just want to know where we are with Sinopharm.

Mr. Peter Culpepper: Okay.

Mr. George Kafakarker: How long have we had a relationship with Boehringer? How long has that been?

Mr. Peter Culpepper: Well, we formally signed the LOI with them in Barcelona on July 2nd, 2015.

Mr. George Kafakarker: Right.

Mr. Peter Culpepper: But, we were talking to them before that. So, that is when the formal LOI for commercialization of PV-10 in mainline China, Hong Kong, and Taiwan--so, that was signed July 2nd, 2015.

Mr. George Kafakarker: Right. Okay. Switching gears, if I could, PH-10. My understanding is that all the raw data has been collected. There was a mention, and I just didn't follow it on the call. I apologize. So, if you have to repeat, please forgive me. Is there an expectation of a time frame where there will be PH-10 news?

Dr. Eric Wachter: George, this is Eric. I will address that. So, we have recently met with the investigational team that we have been using that [unintelligible] prominent immunology expert and dermatology in New York to review the immunologic data that we collected in that study. It was actually a fascinating experience because we had some hypotheses about how PH-10 might be working. And this certainly has confirmed some of those hypotheses, and it has opened up some new areas of investigation.

So, we are wrapping up the analysis of what--I think it was interesting he referred to it as the basic analysis data set. In the next weeks we will assess whether there is a way to fast track that information into the public domain. And we're also moving to conduct a secondary, more detailed analysis of those same samples that we are collecting from those patients. We enrolled between 20 and 30 patients in that study last year.

And we have biopsy specimens that they provided at various time points in the study. The initial analyses of those look very encouraging. We will report on those as soon as possible, and we're going to conduct, as we said, a more detailed analysis to get a finer point on that

mechanism. It does appear that we have potentially a very unique mechanism of action that would be possibly quite valuable.

Mr. Peter Culpepper: And, related to that, we have had numerous discussions with potential dermatology partners. We even discussed that at this recent interaction there I was referring to with this very connected dermatology immunologist. We [unintelligible] that we have set [unintelligible] board, so we are poised to take this sort of information in advanced dialog with potential partners in the industry. And this is exactly the kind of data, just like on PV-10, that is invaluable for potential partners, a real characterization of the uniqueness of PH-10, in this case.

Mr. George Kafakarker: No, no, I think it's very exciting. I mean, guys, you know, this is a very strange situation. There is more momentum in Provectus today than ever before. There is a lot of good stuff going on. You are alluding to many things. You guys are alluding to many more things. And yet we're kind of in the dumps with the valuation, right? And it seems to me the only thing that is driving the decline in the valuation is the knowledge of some that we need to

raise money. I do not think those two things are unrelated. I'm just hoping when you raise money it's from a brand-new source, if I could be very honest.

Mr. Peter Culpepper: Thank you.

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

Mr. Bill Watterson: Good afternoon, Dr. Wachter. Do you expect any Phase 1 b melanoma [unintelligible] to be released at major conferences here? And then, number two, could you explain how you got to 81 progression events for the melanoma Phase 3 trial with the trial population number of 225? And then, finally, how would you explain reaching that progression event when it is probably reasonable to believe that patients in the comparator arm of InLogic or chemotherapy, of which there are 75, are likely the generator progression event within some reasonable amount of time, but with the protocol of hitting all accessible disease in the PV-10 arm? How--there probably is a less likelihood of hitting progression events there. Thank you.

Dr. Eric Wachter: Okay, Bill. I will try to address those in the order that they were asked. It's possible that we would report some initial data from the Phase 1 b portion of the study this year. If that is the case, it would be some form of interim data. It is much more likely that will be in the first half of next year, picking up into the 2017 oncology cycle. If we submitted an abstract today to a major meeting, that wouldn't be recorded until sometime late in the fourth quarter, so we have to acknowledge that it's likely that a public readout of those data would not be until sometime in the first half of next year. That is not to say that in the context of confidential discussions with potential corporate partners, there may not be some opportunity to share those data with partners, but that is also, again, pure speculation at this point.

Turning to the 81 events, that is 81 events for the interim analysis--so, that is when half of the total events necessary for the primary endpoint occur, so the primary endpoint for the study would occur when 162 patients have progressed. This is why it may be important at the end of the study for the data monitoring committee to look at study data at some period after all the patients have been enrolled in the study, if those events have not occurred, implying that some patients in some arm of the study, or maybe in several arms of the study, or maybe all the arms

of the study, are not progressing at the rate that was projected when the study was designed, so--.

Mr. Bill Watterson: --So, are you suggesting that all 225 patients have to be enrolled in order to undertake the interim analysis, then?

Dr. Eric Wachter: I will give you a ludicrous example, and that is that if we enrolled 162 patients, so this is the number of events that occurred. And every one of those progressed on day one, the study stops. We have hit that milestone without having to enroll 225 patients. So, the statisticians will take a model of the study. We give them projections on the progression-free survival in the different arms of the study. And, based on calculations of the necessary power of the study, statistical power of the study, then they can run classic models to understand how large the study has to be.

This is power your study. You hear in oncology discussion about powering the study. And so, we use standard models for design of the study, expecting a certain rate of progression in the

comparator arms, based on literature data that was available and projected based on our experience in Phase 2--what the rate of progression would be for patients to receive PV-10. And I mentioned previously in one of these calls that in addition to that we then took those two rates of progression. We multiplied the time that we expected for the comparator arm to happen by a factor of two. And we divided the time that we expected the PV-10 arm to occur by a factor of two, fed those numbers into the model.

And then, we assumed that 20 percent of the patients would drop out of the study because they didn't see a result, for example, in the comparator arm, or they didn't like some aspect of PV-10, or what have you, which is consistent with rates of patient dropout that occurred in some earlier, recent Phase 2 melanoma studies. So, all of those considerations went into powering the study. That is how our [unintelligible] statistician that we worked with for design of the study came up with a requirement for 225 patients overall, 162 events, leading to the primary endpoint at half of that. That is 81 events necessary for the interim assessment.

Mr. Bill Watterson: Super. That last question, with regard to PH-10, previously you announced or mentioned or discussed or disclosed publicly that Moffitt was--or Moffitt Cancer Center was

working on or conducting work at least on your mechanism of action. Why haven't you done that with respect to the investigator you named, but not named, on this call? Why haven't you disclosed or been transparent about that?

Dr. Eric Wachter: Normally, we have become transparent in those matters once that information is publicly available, so we did not talk about [unintelligible] until they presented data at a meeting. At that point it was clear to the community who that was, and so at that point it was no longer necessary to protect their anonymity. While this process is playing out in terms of PH-10, we will protect the anonymity of the team that we're working with on the immunology there. If we are able to turn that into some sort of publishable form, that will become public knowledge as well.

I will use that as an opportunity to jump on a soapbox that I think--I hate to bring this up. But, one of the problems that plagues Provectus--[unintelligible] have got a lot of very interested stakeholders. And occasionally some of those stakeholders do inappropriate things like, for example, they might contact an investigator in a clinical program or a non-clinical program and under some pretense try to probe for inside information. And I consider that to be very

unethical. And it's one of the reasons that we try to protect these outside parties that we work with. And it's something that I feel very passionate about. We're not trying to be deceptive. We're simply trying to protect those individuals until it is no longer possible to do that.

We have responsibilities to report the names and locations of our clinical investigators when they go on clinicaltrials.gov. We have responsibility to report newsworthy items, publications, conference presentations, for example, when those become publicly available. And it's at that point where we are no longer able to protect those individuals. But, I would encourage all our stakeholders to respect the sanctity of those relationships with those third parties. We count on them not only to do legitimate, objective, independent work, but to remain motivated and not become irritated in their relationship with Provectus and its various stakeholders.

Mr. Bill Watterson: Thank you, although I will note that the company did press release Moffitt's engagement in the mechanism of action prior to the first presentation of the paper. Thank you, Dr. Wachter.

Operator: There are no further questions in the audio portion of the conference. I would now like to turn the conference back over to management for closing remarks.

Mr. Peter Culpepper: Thank you, operator. Before I conclude, I do want to point out that there will be a full version of this transcript, the prepared remarks and Eric Wachter, as well as all the Q&A. It has been an outstanding entire set of Q&A--most appreciated. I do apologize. I believe there was an incorrect version of this transcript also online prematurely. There was just part of the prepared remarks. So, the full prepared remarks and the full Q&A will be posted, as well as the replay audio, for those who want to listen. And I very much want to thank everyone for listening in, for all the questions.

And, as always, you can contact Marlan Nurse [sp] and Porter Levay & Rose if you want additional information. He is available, as is the Porter Levay & Rose team. I am available to the extent that I can. Our next call will cover the third quarter, and we expect to hold that in November, and we expect to have a handle, again, on the timing of our results at that time. And until then thank you very much, and goodbye for now.

Operator: This concludes today's teleconference. Thank you for your participation. You may disconnect your lines at this time. And have a wonderful rest of your day.