Operator: Greetings, and welcome to the Provectus Biopharmaceuticals, Inc., third quarter 2016 business update conference call. At this time, all participants are in a listen-only mode. If you have not already done so, please close all other programs on your computer. You may submit your questions through the Webcast at any time by typing them in the ask-a-question field on the left side of your screen. To ask a question by phone, press star-one on your telephone keypad. If anyone should require operator or technical assistance during the conference, press star-zero on your telephone keypad.

It is now my pleasure to introduce Lori Metrock, Outside Corporate Counsel for Provectus Biopharmaceuticals. Thank you. You may begin.
Ms. Lori Metrock: Thank you, operator. Good afternoon, everyone. At this time, I must advise all listeners that this call contains forward-looking statements as defined under the United States federal securities laws.

These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current view of future performance, results, and trends. Such forward-looking statements may be identified 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 the company's actual results to differ materially 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 they are made. And the company undertakes no obligation to update such statements after this date. Risks and uncertainties that could cause the company's actual results to materially differ from those described in forward-looking statements include those discussed in the company's filings with the Securities and Exchange Commission, including those in Item 1A of the company's Annual Report on Form 10-K for the
year ended December 31st, 2015, as supplemented by the risk factors set forth in the company's quarterly reports on Form 10-Q filed with the SEC.

It is now my pleasure to turn the call over to Peter Culpepper, Interim Chief Executive Officer, and Chief Operating Officer of Provectus. Good afternoon, Peter.

Mr. Peter Culpepper: Thank you, Lori. And welcome, everyone, to the Provectus Biopharmaceuticals third quarter 2016 business update conference call. I will be scrolling through Webcast online provectusbio.com. Should you wish to follow either now or later, go to provectusbio.com News, In the Media, top link to access the Webcast, or provectusbio.com just to investors, and you'll see at the top the access to the update conference call.

So, starting on the cover page, where patients win--when patients win, we all win, that's what we're focused on at Provectus, when patients win, we all win. Slide 2 online is--and thanks again to Lori for the forward-looking statements.

Slide 3, the presentation agenda, scrolling there, this is what I will cover in my comments, and then Eric will go through a much longer and more detailed scientific update with his presentation and numerous slides. So, again, I urge everyone who has access now to the Webcast feature to be able to access it. Particularly for Eric's comments and detailed
information, the Webcast feature to access the slides will be very helpful. Again, though, if you're not able to now, you can go back and refer to it later.

So, scrolling to page 4 online, actions while waiting, we're waiting for interim--the interim results of our Phase 3 clinical trial examining the use of PV-10 as a treatment for local melanoma.

Waiting can weary us. And we know your patience has been challenged, whether you've been with us since the beginning 14 years ago or just since last week. We know this because our patients have been challenged as well. But, this time we spend waiting is not permission to waste time. You don't have that luxury. We don't have that luxury. And our patients certainly don't.

We need to be ready for when those interim results arrive. And Provectus was been busily preparing in the last year, including a revision to the protocol to increase the pool of potential patients, which we will detail shortly.

We have continued with our other studies of PV-10 and our research into PH-10. We have taken the news of PV-10's promise to the scientific community through publications and presentations at international scientific conferences. We have the assurance of physicians the
world over that our drug is working and exciting. We have expanded our portfolio of intellectual property. We have worked to develop relationships with other entities involved in the fight against cancer. We could continue to develop our corporate structure and leadership so that, at any time, we can transition from a development-stage company to an enterprise with pharma relationships.

To put these events into context, I will briefly review the five clinical and business value proposition pillars of PV-10 and PH-10 that we have discussed over the last couple years.

Scrolling 5, the first pillar is our intellectual property. We hold a number of patents covering both PV-10 and PH-10 in the U.S. and overseas. These ensure that, if and when these investigational agents are approved for commercial use, we can expect to more adequately secure a significant revenue stream.

Scrolling 6, the second pillar is our control of the drug substance and drug product supply chain. Patents can only protect drugs to an extent. By controlling the supply chain and the intellectual property underlying that supply chain, we strive to minimize the risk of reverse engineering. We have already made and shipped PV-10 to a number of medical centers. In fact, quite recently, we supplied very high-profile institutions with commercial-grade PV-10 produced at
facilities accredited with the FDA. Numerous global medical organizations have received similar shipments.

Scrolling 7, our third pillar is the regulatory guidance we received from the FDA in the U.S. and its counterparts in other nations. Provectus works with our regulators to ensure the machinery of the bureaucracy keeps moving forward, despite enormous initial opposition from so large a machine. Here, I point to our activities in China, where Boehringer Ingelheim, our main Asian CRO, and others are all working in tandem with us to steer the applications for the availability of PV-10 through the Chinese FDA.

It is important to note that we have agreements with entities to collaborate on this, and the terms of the arrangements have not changed. In addition, we are strengthening ties with Australia's Therapeutic Goods Administration. We have even opened an office in Australia to be able to work more closely with our local collaborators and to function better with regulators and pharmaceutical companies in Asia. It always helps to be in a similar time zone and closer proximity.

Further, we are engaging regulators in other nations in Asia, Latin America, Europe in preparation to expand our activities there. Throughout Asia, we are seeking local partners that are in discussions for a memoranda of understanding to formalize these relationships.
Scrolling 8, the fourth pillar is the mechanism of action for both PV-10 and PH-10. We believe our drug works. But, now, we seek to know exactly how. And this work takes us to the foremost frontiers of cancer research.

At first, research into the complex ways PV-10 and PH-10 interact with the body's immune system and the body itself may seem a trivial academic exercise. Sometimes I catch myself thinking, "Okay. But, it works. How is that not enough?" However, unpacking the work into PV-10 and PH-10 will help us better understand how to optimize their use and guide advanced development in oncology and dermatology.

Scrolling 9, our fifth and final pillar is composed of the randomized and otherwise meaningful clinical study design that generates significant clinical data as well as key supportive data from various preclinical studies. Since we are waiting for data from these, Eric will spend some time talking about them.

Scrolling 10, in addition to the five pillars are our four focus areas of business and development. And I will remind all of you about them as they add further context and color to our actions. They are, number one, a higher public profile for Proventus, PV-10, and PH-10; number two, codevelopment discussions with big pharma about drug combinations; number three, other
strategic activities, which includes regional licenses, collaborations, investments, and so forth; and number four, grant programs that can help us fund research. With those in mind, let's turn to the research underway, scrolling 9--11.

In Phase--in the Phase 3 study, it's formally called PV-10 Versus Chemotherapy or Oncolytic Viral Therapy for Treatment of Locally Advanced Cutaneous Melanoma. And you can find it on the clinicaltrials.gov Website under the specific ID number.

As of right now, you will find nine sites listed, eight in the U.S. and one in Australia. Of the nine, eight are actively recruiting. And the other one is gearing up to do so. We believe more sites will come onboard in the near future. And to appreciate the challenges we've overcome, it is helpful to understand how a site joins a study, which Eric will discuss.

Before moving on from the Phase 3 study, we have also amended the protocol under which the study is being done. Amendments are not uncommon, and they allow researchers to fine-tune the research. In our particular case, major amendments to the protocol include the admission of T-Vec, trade name Imlygic, as an option for use as a competitor. This allows for more flexibility to the doctors.
The amended protocol also extends eligibility to include all Stage 4 M1a patients who have no active nodal or distant cutaneous or subcutaneous metastatic disease. These patients have disease characteristics and prognoses similar to that of the Stage 3b and 3c patients that initially defined the study patient population.

As we previewed earlier, this expands the potential patient pool and should help accelerate recruitment. In addition, the updated protocol clarifies 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 standard of care, as well as inclusion of patients who have failed targeted therapy.

In the latter case, patients who have failed targeted therapy but meet steady eligibility criteria has similar disease manifestations to the remaining study population, but have limited treatment options. This continues to expand the pool of potential patients.

In addition to the Phase 3 study, we have a Phase 1b/2 trial of PV-10 being used combination with pembrolizumab, Merck's Keytruda, to treat melanoma. There is an emerging school of thought that combination cancer therapies are the future, much the way HIV/AIDS has been attacked with a cocktail of drugs. This study will go a long way toward determining the role PV-10 might play as one of the ingredients in the cocktail.
Scrolling 12, beyond melanoma, we are looking seriously at using PV-10 in treating cancers of the liver. We have a Phase 1 study of PV-10 Chemoablation of Neuroendocrine Tumors, NET, Metastatic to the Liver, also clinicaltrials.gov identifier. We also have a separate Phase 1 called A Study to Assess PV-10 Chemoablation of Cancer of the Liver, another clinical trial identifier. We believe that the mechanism that makes PV-10 safe and effective for melanoma will also make it work against these cancers.

In addition, we have preclinical studies of PV-10 for breast, which also includes clinical, pancreatic, and colorectal cancers. Data regarding pancreatic cancer research is being presented at this year's annual meeting of the Society for Immunotherapy of Cancer by Dr. Shari Pilon-Thomas. She leads a team of researchers at the Moffitt Cancer Center. And she is one of several investigators looking into different indications.

There's another team at the University of Illinois Chicago doing research into colorectal cancer and PV-10. Dr. AV Maker presented data at the 11th Annual Academic Surgical Congress back in February. The abstract was titled PV-10 Induces Potent Immunogenic Apoptosis in Colon Cancer Cells.
In the presentation, Dr. Maker and his team stated, "Treatment of colon cancer cells with PV-10 induced cell cycle arrest, apoptosis, autophagy, and significant ER stress consistent with immunogenic apoptosis. In order for cytotoxic agents to act as potential immunotherapeutic strategies in the treatment of solid tumors, immunogenic cell death targeting the endoplasmic reticulum, ER, leading to ER stress may be critical. Therefore, based on these results, further evaluation of PV-10 as a potential agent to stimulate immunologic cell death in solid tumors is warranted." Succinctly, PV-10 killed the cancer cells.

These are all designed to fully use the time in which we are waiting for the interim data. For you computer pros, we are doing parallel processing instead of serial processing. If PV-10 works for several different indications during the Phase 1 and Phase 2 trials at the same time as the current Phase 3 melanoma study is underway means more patients will reap the benefits of it sooner.

Scrolling 13, to get word about PV-10 out, we continue to build awareness for Provectus and PV-10 through a number of initiatives, as we've done all year and expect to continue to do this quarter.

Scrolling 14, recently, we've had a radio news segment that ran on 400 radio stations across the United States. The segment included quotes from Eric Wachter, our Chief Technology Officer,
and Dr. Sanjiv Agarwala. In addition, Joya Dass of Small Cap Nation recently sat down with me to discuss the future of Provectus.

We've also attended notable conferences, where we were able to meet with attending journalists to build relationships and explore future new opportunities. As mentioned previously, these recent conferences include ESMO, the Australasian Melanoma Conference, Sidoti Emerging Growth Conference, International Society for Melanoma Research Congress, Bio-Europe, and International Society for Biological Therapy of Cancer, among others.

We're also pleased to be working with the Melanoma Research Foundation to cohost a Stage 3 patient Webinar led by Dr. Vern Sondak today, on November 14th. The recorded Webinar will be hosted on their Website and distributed through digital and social channels to patients.

Scrolling 15, in the last seven years, we have forged a solid relationship with the FDA. And we are hopeful that this will prove beneficial in the future if PV-10 performs in the trials as we believe it will.

We are working to determine the fastest and most effective way to bring it to market, whether it is through priority review, breakthrough therapy designation, accelerated approval, or fast track.
As the FDA's own Website acknowledged, quote, "Because each of these approaches implies speed, there can be confusion about the specific meaning of each and the distinctions among them."

We are making sure we have an intimate understanding of each. And we'll be able to choose the optimal path for PV-10 when the time comes. Also, our ties to big pharma increase in number and strength. The combination study of PV-10 with pembrolizumab has brought us close to the relevant people in Merck. And the patent that protects us in that study is one we hold jointly with Pfizer.

We have always said our exit strategy is to sell the company to one such firm if and when PV-10's value is proved clinically, if offered the right price for our company and your investment. Knowing the right people and proving to them our product's efficacy and safety are part of that process.

Scrolling 16, our cash position at the end of September 30th, 2016, is approximately 5.2 million. To ensure that there is adequate funding to see our ambitions through, we have filed--scrolling 17, we have filed with the SEC and mailed to our stockholders a proxy statement that has two
proposals that will be voted on at a special meeting of stockholders on November 28th, so two weeks from today.

The first proposal would amend our certificate of incorporation, as amended, to increase the number of shares of common stock that we are authorized to issue from 400 million to 1 billion shares.

The second proposal would authorize our board of directors to amend our certificate of incorporation, as amended, to affect a reverse stock split of our common stock at a ratio between one for 10 and one for 50, such ratio to be determined by our board of directors in its discretion.

The amount of common stock we have available for issuance under our certificate of incorporation is not sufficient to cover our existing obligations and our future financing needs because it is likely that the share--sale of shares of common stock or securities convertible into shares of common stock will be chief among the ways we will raise additional capital, until such time as we are able to generate earnings sufficient to finance our operations.

Shares of common stock may be used for various purposes without further stockholder approval. These purposes may include raising capital, which may be effectuated with the
contemporaneous listing of one or more of our securities or one or more of the Singapore or Hong Kong or Australia securities exchanges, although there can be no assurance that we will list any of our securities on any foreign securities exchange; providing equity incentives to employees, directors, and consultants; establishing strategic relationships with other companies; the acquisition of any business, assets, or technology; and other purposes.

Scrolling 18, we have filed a registration statement on Form S-1 with the SEC for a potential registered rights offering. We believe a rights offering is an attractive financing option, as it is nondilutive to our stockholders who participate in the rights offering and also enables us to raise the capital we need to complete our clinical trials.

We cannot complete the rights offering, however, unless our stockholders approve either the proposal to increase the number of shares of common stock we are authorized to issue or the reverse stock split.

The SEC has not yet declared our registration statement effective. And we may not consummate the rights offering until such time as the SEC declares our registration statement effective and our stockholders have approved at least one of the two proposals.
Scrolling 19, as per the reverse stock split authorization, this is the hard, ugly truth. We have been notified by the New York Stock Exchange that it has commenced proceedings to delist our shares of common stock and class of listed warrants from the NYSE MKT due to the low trading price of our common stock.

An effectuated reverse split should, by definition, result in a high enough stock price to allow our common stock to remain viable and trade on the NYSE MKT, although there can be no assurance that the NYSE will grant our appeal or that our common stock and warrants will remain listed on the NYSE MKT.

Moreover, a higher price would enable institutional investor participation that is not present currently owing to issues of proceed liquidity and marketability.

Scrolling 10--20, excuse me. Before I close, let me pause to address what I as a seasoned businessman and corporate officer understand, which is that reverse stock splits can be controversial. But, do not forget we as a company are built not only shifting the paradigm, but breaking it.

Out of all cancer therapies approved or in development, PV-10 is the only drug of its kind that we know of. We are a company of three employees based in a small office in Tennessee. And
we can and have approached the industry's greats without delusion and have returned with partnerships and international recognition.

It's never been easy fighting the tide. But, it's what we have always done with both our company and investigational drugs. So, why should it be any different now? All I have left to say on this point is let's fight the good fight.

We urge our stockholders to read our proxy statement for the special meeting carefully and vote your shares or common stock for both proposals. Our board has unanimously approved both proposals and believes it to be in the best interest of PBCT and our stockholders that you vote to approve those proposals.

At this point, our Chief Technology Officer Eric Wachter will update us on the scientific side of the business. Eric?

Mr. Eric Wachter: All right, Pete, thanks. I'll take the baton from there. I will focus my comments on clinical development and other technology aspects of the company. I'll start by repeating the slide on forward-looking statements. I will invariable engage in some forward-looking statements in this portion of my presentation.
And I would also like to point to safe harbor statements and make it clear that PV-10 as an investigational drug undergoing clinical study as an ablative immunotherapy for solid tumor cancers. PH-10 is an investigational drug undergoing clinical study as a topical therapy for inflammatory dermatoses. Neither PV-10 nor PH-10 have received approval for marketing in any country.

Okay. So much for the formalities. The outline of my talk is shown on this slide. I'll discuss oncology in general, then walk you through the technology with PV-10, where we've taken it clinically, how we expect to develop it commercially, provide some overview of the clinical trial process so you can get a little bit of a peek under the hood in terms of what we perform here out of this office, briefly touch on PH-10, then offer some personal opinions, finally, my conclusions.

I'd like to start by looking at technology curve. And breakthroughs in any technology, be they microprocessors or oncology drugs, generally follow a common path. There's a period of discovery, if that's successful, followed by development, launch, set point saturation of market, and then rational understanding of the position of the mature product in the market.

Look at it another way, there is typically a period of hope followed by a period of enthusiasm, followed often, as one of our illustrious Chairman of the Federal Reserve referred a period
potentially of irrational exuberance. That often can lead to retrenchment as experienced with that technology growth. Sometimes, frustration follows that, retrenchment. There is ultimately realization of the natural place of that technology in society, and then finally rational assessment and use of that technology.

It's clear that progress in virtually any technology occurs in a nonlinear manner. And what we hope is that, as we move from left to right, we do accomplish progress moving forward technologically and moving forward as society.

This pattern is evident in many what I'll refer to as megatrends in oncology. This pattern was clear 10 to 15 years ago when there was a tremendous amount of interest in developing therapeutic vaccines for cancer; that is, vaccines that could be used to treat or cure cancer that existed in patient. That was followed five to 10 years ago by a period where a targeted therapy was very popular in oncology. And there were tremendous advances made in the treatment of many cancers using targeted therapy.

Lately, this has been fixated by the era of checkpoint inhibition or immuno-oncology, or so-called I-O. Interestingly, each of these have been hailed at their peak as the solution to melanoma. I heard this personally stated to me about these technologies.
In our view, each has been a major step forward, but equally, inarguably, each has failed to solve melanoma.

James P. Allison, who's given credit as the inventor of anti-CTLA-4, which is the first commercialized immune checkpoint inhibitor--it's commercialized as ipilimumab or Yervoy as it's first name--really is the father of modern immuno-oncology. And I would argue that he is likely to receive the Nobel Prize in this decade. He's recently stated that "we're in an era where we can occasionally discuss curing cancer." He followed that up by saying that "we need to find ways to routinely cure cancer."

In a more recent interview, he was quoted as noting that "combination therapies presumably may be the key to success in getting closer to that routine cure," period, said, "There's enough progress being made across the board that I think we can start thinking about some of the colder tumors if we just keep studying and making rational combination decisions.

He's saying is that we need to make rational designs of therapies to allow us to treat tumors that are not responsive to the standard [unintelligible] that we have available to us.

Went on to say, "As we understand this better, we can rationally put two things together that won't just duplicate or cancel each other out, but will do different things that can at least
additive, if not synergistic." I think that statement really does summarize where we're heading with PV-10 or at least where we hope that we're headed with PV-10.

An important pattern in immuno-oncology is the rational assessment and use phase, where there's a notable push in this case for a combination of core immuno-oncology drugs with other classes of agent or other classes of therapy.

One of our lead investigators Sanjiv Agarwala has been at the forefront of this push, recommending that oncologists "make the patient's tumor his or her friend." It would seem, between the statements of Allison and the statements of Agarwala, that intralesional therapies may have arrived at an opportune time. And I would argue that we are positioning PV-10 to capitalize on this new phase in oncology.

Like to talk about PV-10 at this point in some detail. It is a sterile nonpyrogenic solution of Rose Bengal disodium. It's a small molecule fluorescent dye that's been around for over 130 years. It has a lengthy prior use in humans as a diagnostic intravenously, in neonates for hepatobiliary diagnosis intravenously, as a topical ophthalmic diagnostic, and more recently, as a food dye in certain parts of Asia.
This has established a very good safety profile for the molecule. And we know that it is not metabolized, has a short lifetime in the blood stream, and that it is excreted via the bile. It's stable at room temperature. It's radiopaque. We'll talk about the reason why that's important later. And in many cases, we found that intralesional injection can yield ablative immunotherapy.

That ablative immunotherapy can produce a rapid destruction in tumor burden, can produce a high rate of objective response. It can produce tumor-specific immunologic activation. It can produce prolongation of progress-free survival. And it provides potential synergy with other classes of therapy.

We believe the locoregional intervention with a small molecule agent, such as PV-10, aligns with current care standards for many solid tumors, which has led us to a development pipeline, where locoregional melanoma is the leading indication in Phase 3. And we have orphan drug status since 2007. We opened recruitment for our Phase 3 study in April 2015.

We've followed that in the second half of last year with initiation of combination studies looking at PV-10 in Phase 1b/2 study in combination with pembrolizumab. Also looking at the mechanism of action and completed a mechanism of action clinical study with comprehensive data published in May of this year.
We have an ongoing Phase 1 study looking at metastases of liver. This includes metastatic hepatocellular carcinoma and other tumors that have metastasized liver. We have an orphan drug indication designation for that since April 2011 for hepatocellular carcinoma.

We've also completed Phase 1 testing in breast carcinoma, and we are in nonclinical development leading potentially to clinical development in basal cell carcinoma, bladder cancer, colorectal cancer, non-small cell lung cancer, pancreatic, and prostate cancers.

One of the interesting features of PV-10 is that we found that it has the selective insistent ability to ablate injected tumors. We found this to occur in multiple murine models of both mouse tumors and human tumors, covering a very wide range of tumor types, liver tumors, kidney tumors, melanoma, breast, colon, lung, in this case multidrug resistant lung cancer, even human PC-3 prostate tumor line.

And a couple years ago, one of our associates Vernon Sondak at the Moffitt Cancer Center stated at a meeting that "PV-10 appears to be agnostic to tumor type." That is, it appears to show this ablative response in a wide range of tumors.
This ablative response begins with accumulation of drug inside tumor cells. And the first step is crossing the cell membrane. We found in murine tests is that PV-10 will show distinctive accumulation within the tumor cells, shown on the right-hand side of the screen, while it can still be present in surrounding tissue, not inside the cells, but in the interstitial volume.

This accumulation in the cancer cells leads to accumulation in the lysosomes of the cancer cells, shown here looking at hepatocellular carcinoma cells on a microscope slide and, within a matter of 30 minutes or less, complete destruction of the exposed cancer cells, in this case looking at the same hepatocellular carcinoma cell lines.

This appears to be due to release of the contents of those lysosomes, which lead to degradation and digestion of the tumor cell from the inside. We call that autolysis. That autolytic process has been confirmed in hepatocellular carcinoma cell lines, breast--human breast carcinoma cell lines, and human multidrug resistant cell lines. So, this process at the subcellular level is also agnostic to tumor type as far as we can tell.

And that destruction of tumors, tumor cells, is selective. If we compare the toxicity of Rose Bengal to melanoma cell lines, indicated by the first set of red arrows, we see that that occurs at a much lower concentration than happens when we expose Rose Bengal in vitro to normal
skin cells. The same differential has been shown comparing murine colorectal cell lines to human cell lines to show that there is, again, a selective toxicity across cell lines.

These results are consistent with the ablative process that we saw in those murine models. That destruction of tumor cells is primarily necrotic in nature, which accounts for the very rapid process pharmacodynamically, where we see this destruction within a matter of minutes to hours or less.

And in fact, we can see that this destruction can lead to a bystander effect if we ablate a tumor in an immune-competent animal and leave an untreated tumor to be addressed by the immunologic stimulation.

This process, as I indicated, is referred to as ablative immunotherapy, where the primary ablative process for the tumor, precipitated directly by interaction with Rose Bengal, leads to autolytic cell death. That autolytic cell death then triggers systemic immune stimulation via a T-cell mediated process.

There's a figure that's used very commonly in oncology today to model immuno-oncology. It's called the cancer-immunity cycle. It was published by Chen and Mellman in 2013. And it describes a seven-step process where, step one, killing of tumor cells and release of cancer cell
antigen leads to uptake of those antigens by antigen-presenting cells, step two; priming and activation of those APCs in lymph nodes, step three; trafficking of T cells to tumors in step four; infiltration of T cells into tumors, step five; recognition of those activating tumor cells by T cells in step six; and finally, killing of cancer cells in step seven.

What we found is that the ablative process that is precipitated with PV-10 leads to release of cancer cell antigens and subsequent downstream signaling of all of the remaining processes in this cancer-immunity cycle.

We've worked for a number of years with outside collaborators to show at each of these steps that this process is occurring. So, for example, we've seen this in murine and human melanoma cells, murine breast cells, murine colorectal cells, and now in murine pancreatic adenocarcinoma cells. So, the immunologic process also appears to be conserved just as the fundamental ablative process is conserved.

Step one is the release of cancer cell antigens. And that is epitomized in the case of melanoma with the release of damaged associated molecular pattern called high-mobility group box 1, or HMGB1. And we've been able to find that that first sign that the cancer cell has been killed and is releasing antigenic material is present in vitro in murine melanoma cells that have been
treated with PV-10. And it's detectible in the blood of patients who had melanoma tumors treated with PV-10.

Step two, the antigen present--cell--cancer antigen presentation process, has been documented through the migration infiltration of dendritic cells into draining lymph nodes. These are lymph nodes that drain the ablative site from a tumor that's been treated with PV-10. And that dendritic cell activation is evident in terms of increased activation markers of dendritic cells in those draining lymph nodes.

Step three, priming in activation T cells, the ablative process with PV-10 clearly elicits at tumor-specific T-cell response in multiple models that we've looked at, in this case, murine breast carcinoma, melanoma, and colorectal all showing the same thing, which is T cells isolated from mice that have tumor treated are responsive selective against that autologous tumor, against that tumor tissue that has been treated.

Trafficking of T cells to tumors has been detected in patients. We see upticks in cytotoxic CD8 T cells, CD4, and NKT cells in patients within one to two weeks after ablation of tumors, in this case, melanoma tumors with PV-10.
That would be expected to lead to infiltration of T cells in tumors. And in fact, we do see that as well, in this case, in a melanoma model, CD3 T cells in untreated bystander tumors 96 hours after injection of a companion melanoma tumor in the opposite side of the mouse.

Those T cells do have functional response. And they are capable of killing cancer cells. In this case, we see that as complete pathologic response in untreated bystander tumors in melanoma patients.

The implications of these immunology data are several. Tumor ablation can elicit a functional tumor-specific T-cell response. That's shown in the data that I just presented. This T-cell response may be implicated in regression of untreated tumors, call this the bystander effect, potential prolongation of progression-free survival--this is the primary endpoint for our Phase 3 study--and rational design of combinatorial strategies. This is the science that underlies our combination study with pembrolizumab.

So, how do we put that T-cell response most effectively to work? Well, we can combine the ablative immunotherapy of PV-10 with the immune activation of the immuno-oncology drugs, the checkpoint inhibitors. And we've done just that work to show that this is a sound concept.
You can see that PV-10 works in concert with anti-CTLA-4. That is ipilimumab. We see that it works together with anti-PD-1--that is pembrolizumab and nivolumab, or Keytruda and Opdivo, by their commercial names--and that it works with anti-PD-L1 antibodies. These drugs are still undergoing clinical development and may be the next big thing in melanoma.

Combinations we know are potentially valuable so far, where we've seen additive or better response in multiple models, hepatocellular carcinoma when combined with 5-fluoruracil, which is an antimetabolite, it's an unexpected combination; melanoma when combined with anti-CTLA-4, anti-PD-1, and anti-PD-L1, data that I just showed you; and in data that we've just shown at SITC over the weekend, the team at Moffitt has shown that pancreatic adenocarcinoma responds favorably to the combination of PV-10 with gemcitabine. This case gemcitabine serves as a suppressor of myeloid-derived suppressor cells. It decreases immune suppression. In each case, the combination appears to be T-cell mediated.

So, this has led to development of a clinical program predicated on two fundamentally different patient populations. The patients with locally advanced disease--these are patients with disease that has not progressed to the internal organs--we believe that those are potential candidates for single-agent therapy.
For patients with more advanced disease—that is, disease that has spread to the internal organs—we think those are best served in combination of the local ablative immuno-ablative process with systemic immunotherapy. I'll note that this general approach appears to be applicable to both melanoma and other solid tumors.

So, starting along the single-agent development concept, we began in 2005 with a Phase 1 study looking at 20 patients with melanoma treated once followed for up to 24 weeks. We followed that up in 2007 with a Phase 2 study, 80 subjects, treating patients up to four times following for 52 weeks.

And we have followed that up with an expanded access program that was open from 2009 to 2016, where a total of 177 melanoma patients were treated, 10 other patients with nonmelanoma cancers were treated under that expanded access protocol.

Treatment looks something like this. And I'll apologize for the graphic nature of the next several slides. This is three tumors in a patient with locally advanced disease immediately prior to treatment. In the middle tumor, you can see recurrence at the margin of a very large excision scar.
The next series of images show the injection process during injection, immediately after, and several minutes after injection. You can see accumulation of drug in the injected tumor tissue. You can also see the drug spreads to surrounding tissue, this very pink coloration in surrounding tissue. The next day, we see that the injected tumor is necrotic. We see that there's little effect in surrounding tissue despite the presence of the extravasate in the surrounding tissue.

Another clinical example, in this case, a patient with multiple in-transit lesions of the lower extremity, again, a large lesion--actually, two large lesions inside of an excision scar. In this case, 10 lesions were injected with PV-10. One lesion, B1, was left intentionally untreated.

At week four, you can see the formation of eschar confined to the lesion areas. By week 24, complete resolution of that eschar on this patient, who was deemed to be a complete response at week 24, both at the injected lesions and their untreated bystander lesion.

Similar case, in this case, a 73-year-old male, multiple lesions injected, in this case, with three cycles of PV-10 to achieve complete response at week 36.

Subjects in the Phase 2 study were generally of advanced age. The median age was 70. They had a considerable disease burden. And they were refractory to multiple previous
interventions. So, this was—they were bona fide patients that would be challenges clinical for most therapeutic approaches.

In that study, we found that 26 percent of patients achieved a complete response, 25 percent overall a partial response. When we looked at patients where we injected all lesions, we found that 50 percent of those patients achieved a complete response with another 21 percent partial response.

This is another designing data point that was used in preparation of the Phase 3 study. We also found that over half of lesions achieved a complete response after one or two injections. And in fact, when all of the patients' lesions were injected, 74 percent of them achieved a complete response.

Objective response in untreated bystander lesions correlated strongly with response of injected disease. When a patient had a response in their injected lesions, they had a very high rate of complete response in their uninjected lesions. Conversely, if they did not respond to injection of their disease, they failed to respond in their uninjected lesions. This is, again, consistent with an immunologically remediated response.
Those bystander responses were not confined to locations close to the injection site. A number of patients with lung NETs, we found that injection of their skin disease led to regression of uninjected, untreated metastases in the lung. In this case, patient age 57 with multiple lung metastases had general improvement with no focal parenchymal pathology, so no lung disease at week 52.

Another gentleman, age 40, Stage 4c disease, had 10 lesions in the lung. After injection of his skin disease, nine of those 10 lesions showed a complete response. The 10th lesion showed a partial response after 12 weeks.

The adverse event profile for the drug appears to be principally confined to the injection site and general area around the injection site. Injection site pain and various manifestations of inflammation are the most common adverse events. Photosensitivity is a rare but important systemic adverse event. And we have precautions that we take in all of our studies to minimize the occurrence of that.

So, for clinical development, we are moving forward in patients with locally advanced disease in our Phase 3 study, patients with more advanced disease in our combination study.
This strategy for locally advanced disease continues to jive with guidance from the National Comprehensive Cancer Network. This is the organization that delineates treatment decisions in the U.S., gives recommendations to investigators, physicians. And despite major advances in the treatment of melanoma in the last 10 years, clinical trial remains a primary treatment recommendation for patients with locoregional disease.

For patients with recurrent, locally recurrent--locoregionally recurrent disease, clinical trial also remains a recommendation for patients. This is very interesting because it suggests that there's still a lot of opportunity to develop a definitive treatment for these patients.

That is becoming a relatively crowded marketplace. Today, there are at least 13 intralesional drugs in melanoma clinical trials. This is a list from clinicaltrials.gov by searching melanoma plus intratumoral or intralesional. And notably, in 2014, there were only four drugs in similar clinical trials.

And there are at least seven drugs, intralesional drugs, in combination clinical trials with various checkpoint inhibitors. In 2014, there was only one drug in combination clinical trials. So, this whole field has grown very rapidly and unfortunately represents a dual-edged sword. There's little doubt that our intralesional approach with PV-10 is sound. But, there is growing competition for investigators and patients.
This is reflected in our development activities and timelines, where we have had to adjust activities, timelines, schedules, locations for studies, traces of investigators, patient populations to maximize patient eligibility and pursue opportunities in regions with less competition.

This is borne out in the history of the Phase 3 study design. The version 1.1, which is the first version that was released to the investigator public, was completed in March of 2015. In February of 2016, based on experience with that protocol and, in particular, also the addition of Imlygic as a comparator following approval of that in the United States and other parts of the world, that protocol was amended. We expanded eligibility with regard to checkpoint inhibitors, targeted therapy, and disease stage, adding Stage 4 M1a patients.

In June of this year, we modified the size requirements for target lesions to conform more closely to the guidelines that we used for approval of Imlygic. And we increased the total number of lesions that were allowable.

This fall, we've been discussing with key opinion leaders around the world a likely further amendment to the protocol to, again, address the changing environment in the development sector.
Specific changes would include allowing subcutaneous target lesions--these are allowed within resist [sp], and so this is not a major impact on endpoints for the study--increasing the maximum lesion size, and other additional eligibility optimization steps. We anticipate that it is very likely that a fourth version, a 1.4 version protocol, will be issued before the end of the calendar year.

Protocol was rolled out in 2015 with the anticipation about a third of sites would be in the U.S., third in Australia, and about a third in the E.U. As we gained experience and understood how the playing field was changing, we modified plans and extended plans to include Latin America, Russia, and Asia, with 60 centers now expected to participate in the study; 16 plus in the core of Europe, Germany, Italy, France, and Poland, with half in Germany where Imlygic is available. A regulatory review underway--is underway in Germany, Italy as we speak. And we expect to have initial approval of our first sites in Germany next month.

We expect uptake to be high in Germany. Note that the version 1.2 amendments of the protocol earlier this year focused specifically on meeting requirements for Germany and German investigators. And we also expect to open four centers in Russia, seven in Argentina, five in Mexico, five or more in Brazil, and one or more in China to allow us to access sufficient number of patients and sufficient number of investigators to enroll with patients necessary for the study.
At the present time and going into the New Year, we are expanding outreach to new investigators in the USA and Australia. We expect expanded eligibility criteria to attract a number of the initial declines. In fact our experience has been that that has been successful.

I must say, however, that the slow uptake in the U.S. and Australia has set back timelines by an additional six to nine months. We have been working diligently all year to move as fast as possible, to open centers as fast as possible. But, we are playing in a very active clinical development environment right now and have done as best as we could.

We expect that the simultaneous launch of sites in Germany and Italy--immediately followed by those in Italy will help to stabilize our timelines going forward. Adding more sites in U.S. and Australia will also help to stabilize timelines. And the second quarter 2017 opening of sites in Latin America, France, and Russia should accelerate progress, particularly Latin America and Russia, where there's little competition for patients in clinical trials. We are continuing to review selected other regions for a possible study expansion.

I must note that I see no fundamentally competitive threat on the horizon. This patient population remains underserved, and the 13 intralesional drugs that are undergoing clinical trials do not in my mind represent a significant competitive threat.
Overall, the playing field has improved substantially in the second half of 2016, particularly with a reduction of headwinds going into 2017, partially as the understanding of the role of immuno-oncology has matured in the community, and we've been able to attract investigators that might have been hesitant to look beyond the current rage.

For the 1201 study, this is our combination study, PV-10 plus pembrolizumab. In 2015, we anticipated four to six centers in the U.S. and Australia. And we currently have four centers open. We are in the process of opening two additional centers. I expect those to open in the first quarter of 2017. And we are assessing whether we should open one further center in Phase 1b to round out that investigator team.

In 2017, we still expect initial Phase 1b data to be available for prospective partners. And so, I foresee at this time no significant impact on timeline for the initial safety results, which are the primary endpoint for the study.

Preliminary efficacy data is also not expected to be significant impact. And I would expect that we will have data to present at ASCO and ESMO as initial public readout of data from that study, so in June and October of next year.
We are in the process of preparing for expansion of the study the Phase 2 with the expectation that the primary endpoint will be met in Phase 1b.

I'll just point out that, unfortunately, melanoma continues to grow in incidence in the U.S. at a monotonic rate since we began tracking it in 2004, increasing from about 55,000 new cases to about 75,000 new cases expected in 2016. And unfortunately, deaths have followed that pattern and increased monotonically. So, there is certainly opportunity for improvement in melanoma. As I said at the beginning, melanoma has not been solved.

Moving onto hepatic tumors, we have a Phase 1 study that has been underway for several years, performing a single injection into the center of a single hepatic lesion. Patients are followed up for 23 hours initial safety observation and then followed up periodically for the first 15 months and then quarterly thereafter for survival.

This is--would be called a basket study using current terminology, where we bring together multiple tumor types to be able to study them in a single design and develop sufficient numbers for particular tumor types to be able to draw conclusions about the favorability or unfavorability of those tumors in terms of response to therapy.
An example subject looks like this. This is our first subject who had a 3.5-centimeter hepatocellular carcinoma injected once with PV-10. The top row of images are under CT. And I mentioned at the beginning of my comments that Rose Bengal is radiopaque. It has iodides. And so, we can readily visualize the distribution of PV-10 in the injected tumor.

Twenty-eight days after, we see that that injected dose is still present in the injected tumor, even 15 months still present at the injection site. Perhaps more interestingly, looking at the second row of images in MRI, we can see that, by the first day 28 follow-up visit, the tumor is completely killed, with gradual involution over the succeeding 15 months.

We've now treated 18 lesions under this study in 16 patients. We have the ability to reenroll patient to treat a second tumor. And two patients have been reenrolled, one with HCC, actually the first person--first patient, the one that I just showed you, and one with melanoma metastases of the liver.

And I think we can conclude, based on initial trends in these data, that the HCC indication is looking favorable. These patients have a relatively dire prognosis. And we are seeing evidence of potential therapeutic activity in HCC. And we are, as I said, in a basket study beginning to accumulate sufficient patients, in this case, with metastatic colorectal carcinoma, to begin to conclude that that may also be an indication that we want to focus on going forward.
At the heart of that study, from the beginning, has been evaluating PV-10 as a potential treatment for HCC. And this is an example of the treatment paradigm that’s used for defining how to treat patients with various severities of HCC. And we've been working for several years now meeting with key opinion leaders throughout Asia, where HCC is at epidemic levels, to determine where PV-10 fits in this treatment algorithm. And we've concluded that there are two options. One is neoadjuvant PV-10 plus local standard of care, in this case, treating patients that would go on sorafenib, treating them with PV-10 prior to their start of sorafenib. In Phase 1b, that would be a single-arm study. In Phase 2, that would be neoadjuvant treatment versus standard of care. So, that would be neoadjuvant PV-10 plus sorafenib versus sorafenib in a randomized study.

Perhaps more interestingly, using modern drugs, is the potential for a combination of PV-10 with checkpoint inhibition, either PD-1 or PD-L1. And it certainly makes sense to contemplate a similar study design looking at Phase 1b PV-10 plus checkpoint inhibition segueing to a Phase 2 randomized looking at PV-10 plus checkpoint inhibition versus checkpoint inhibition.

The sorafenib study is ready to be advanced pending resource availability. The checkpoint combination work is ready to advance pending nonclinical validation. We have been in discussion with translational medicine experts in Singapore to design studies to characterize the
immunologic signaling of PV-10 injected into HCC. And we would like to start that this quarter. This would be a direct analogy to the work that we conducted with Moffitt delineating the immunology of PV-10 in melanoma.

This would support collaboration with our corporate partner Boehringer Ingelheim and also potentially attract interest from Merck, Bristol-Myer, and other players that have PD-1 or PD-L1 drugs that unfortunately that class of drug did not work particularly well in HCC and could potentially find that to be a way to make those cold tumors hot, as Jim Allison alluded to in his comments.

When we started working in HCC in the States, the incidence was relatively small. We started in 2010, 25,000 cases. And at the present time, that's pressing 40,000 cases as a disease that's growing very rapidly. So, while we've talked a lot about the Asia opportunities in HCC, this is a very rapidly growing opportunity also in the West, particularly in combination checkpoint inhibition, if we can show that's a valid concept.

So, we plan to continue our basket study, opening additional centers in the U.S. and Australia to allow all comers, expanding numbers for important tumor types, but we also expect to focus enrollment on certain high-priority tumor types, such as uveal melanoma. And we expect to report the next round of data in February of next year in China.
We're also looking at the possibility of leveraging that study with our work, combination work in melanoma to look at combinations in hepatic disease. One that we discussed in a press release today is the potential combination of PV-10 plus gemcitabine in metastatic pancreatic adenocarcinoma. This would also potentially leverage our quality-of-life experience that we've gained in our Phase 3 study. So, it's a triple play. PV-10 plus PD-1 for hepatic metastases in melanoma is also a very interesting possible area for us.

So, our development plan attempts to balance primary focus on our lead indication with high potential opportunities. Our lead indication is our Phase 3 melanoma study. That consumes the majority of our clinical development resources. Following along on the side is the Phase 1b/2 melanoma combination study and our work in hepatic tumors.

We also pursue special indications. An example would be an assessment of whether it makes sense to proceed in metastatic pancreatic adenocarcinoma. And we continue to work on development of preclinical leads. So, we have work that is being done by various third parties that we interact with.

Moving onto the supply chain, we have a very nice bit of work that resulted in patenting of a new process for manufacturing Rose Bengal, dramatically improving on the 1880s process from
Ghanem with a priority date of September 2010. So, this establishes a lengthy runway for potential commercialization of Rose Bengal and related xanthine pharmaceuticals. That has been allowed or issued in Canada, Mexico, E.U., China, Hong Kong, Japan, and Korea, in addition to United States.

That new process has been integrated into our supply chain. And it tightly controls the impurities characteristic of pretty much historic process from the 19th century to meet ICH standards. This includes related substances, solvents, organics, inorganics. We manufacture our drug substance and our drug product in the United States by established drug manufacturers. Specifications that we set meet FDA and European requirements for an injectable drug. And the first of three NDA stability lots was manufactured this half, 8,000 vial a lot to support potential NDA.

So, I mentioned ICH on the last slide. And all work we've conducted is guided by ICH principles. This is the International Council for Harmonization. And it's a group that harmonizes the regulations and the standards that are used in scientific and technical aspects of drug registration.

Since its inception in 1990, it's gradually evolved to address global focus of drug development. It provides a common framework for our clinical development. So, mission is to achieve
harmonization worldwide to ensure safe, effective, and highly-quality medicines developed and registered in the most resource-efficient manner. And I'll note that Proventus conforms to ICH principles to assure safe and efficient execution of each clinical study.

Take a few minutes to walk through the clinical trial process, which starts with a protocol. And that protocol is submitted to a competent authority--in the United States, that would be the FDA--along with some sort of an application. In the United States, it's an investigation new drug application. It might be a clinical trial notification or clinical trial application. The details are different. The general features are similar.

That typically goes with a suite of supporting documents that support the toxicology, pharmacology, pharmacokinetics, manufacturing, and clinical advice in terms of investigator brochure that is provided to investigators.

Once that authorization is effective, we work with clinical trial sites. Oftentimes, large sites will have a scientific review committee that will review our protocol. We develop a site contract to define how work is conducted at the site, an informed consent form specific to the site, and we work with the site or, in some cases, a national independent review board or ethics committee to make sure that that informed consent form and other patient-related documents are compliant with ethical requirements.
And we also have a contract with the pharmacy in some cases, with the radiology department in some cases, and with local lab in some cases. So, there's a lot of business activity that's involved in opening the site.

If this is a multicenter site, we multiply that by the number of centers. And if this is a multinational site, we multiply that process by the number of countries.

At the clinical site, the site contract and the protocol define how the investigational team interacts with the patient population on our behalf.

Under the auspices of the study, the investigational team will review their patient population and identify potential subjects. Those subjects will be consented. And then once consented, they'll undergo screening processes. And eligible patients are finally identified from that population.

Investigational team will then enroll the study subject. They will undergo the study procedures, receive study medication, and undertake any other requirements involved in performance of that study. We typically will have a logistics partner that delivers investigational product to the
site and also, in some parts of the world, other study supplies that might be necessary for conducting the study.

Each study subject then is a source of raw study data. This is captured in the form of case report forms or electronic case report forms; lab reports, either local or central; in many studies, photo documentation; in most studies, radiologic imaging that goes to a core laboratory; and in some studies, patient-reported outcome or electronic patient-reported outcome devices.

As that data is being collected and compiled, a monitor hired by the sponsor will work frequently with the site to review all of that raw data to assure that it properly represents what has happened with the study subject.

Those data streams then feed into a central study database. In case of efficacy data, study data from a subject will go in many cases to an independent review committee. In the Phase 3 study, we have a dermatology independent review committee that looks at skin lesions. And we have a radiology independent review committee that looks at visceral disease.

That and any other relevant clinical data that's captured in the study documentation will then be fed to the endpoint assessment committee, who defines the official endpoint for the study.
That analysis then is multiplied by the number of subjects in the study. And those final datasets are fed into a statistical analysis per a statistical analysis plan, so a predefined plan for how study data is going to be analyzed. The outcome of that statistical analysis is the final study efficacy endpoints.

For safety analyses, again, that process is multiplied by the number of subjects. Safety data from case report forms, laboratory sources, other relevant sources is fed into the same type of statistical analysis to produce a steady safety endpoint for that subject.

Those safety endpoints, efficacy endpoints, and complete tables and listings of all study data are then combined at the end of the study into a clinical study report. This is the final report for the study.

And we conducted a very small pharmacokinetic study recently just in support of the toxicology understanding of PV-10. This was an eight-subject pharmacokinetic study. It took three days of clinical work, resulted in a clinical study report shown here, 884 pages. So, you can get a sense of the amount of detail that's involved in this process.

In terms of managing that work for sites in the U.S. and Australia, we manage in-house the core regulatory dossier, protocols, and the investigator brochure. We work directly with the study
sites to implement contracting local approval, interfacing with scientific review committees and/or IRBs, conduct study monitoring, coordinate delivery of supplies by study vendors, and coordinate any other study supplies that need to go to the site.

In parts of the world where we don’t have physical operations, such as Europe, Latin America, and Asia, we start with the same core package, and we work with a CRO, contract research organization, who transforms those core documents into a local format, typically different format for the regulatory dossier and then translated protocol and investigator brochure. And then they work directly with the study sites for all of the things that we would do in the U.S. and Australia.

It's important to note, however, that we retain ultimate responsibility for the safe and efficient execution of the study. We own the study and everything ultimately that goes on in that study.

There's two levels of monitoring under--that are undertaken during the conduct of a study. We send out monitors. Typically, they're clinical research associates that go to the site and regularly visit, verify protocol compliance, review all data reported versus source records, and follow up to share that any errors identified are corrected in the reporting of those data.
So, we have a clinical trial data monitoring committee for large studies, which is an independent committee managed by the lead CRO, in this case, for the Phase 3 study. This is the lead project manager for the CRO, study medical monitor, and study biostatistician, plus three independent oncologists identified by the CRO. So, they're independent from us that have independence from the sponsor, independence from the sites, independence from the IRCs, complete independence from the study. And they conduct a periodic review of safety and efficacy data.

So, for large pivotal trials, which the Phase 3 study, that will contain all of these elements. In earlier phase studies, such as the 1b combination study, contains many of these elements. Using the full model early allows the study to expand quickly. But, selecting only those components necessary can control costs during initial testing.

For exploratory studies, such as the hepatic work, they'll containing many of these elements, but we can oftentimes address these using less expensive traditional methods, such as paper CRFs, in-house data aggregation, and so on. However, in each case, the necessary elements are there to assure compliance with ICH.

This is necessary to ensure regulatory compliance and also to provide data portability for regulatory submission globally.
Very briefly, on PH-10, we are conducting advanced immunologic analyses and biopsy specimens underway. We conducted initial analyses in the first half of this year, which pointed to potential interesting leads. And we have given the go ahead for our investigator to conduct more advanced analyses. We expect those to report next month.

Okay. So, to conclude this long and winding road, I wanted to give a few personal opinions. And I'll offer a warning that anyone that's interacted with me knows that I avoid giving personal opinions about Provectus and about the company's prospects. But, in light of recent trends, I will take a pause from this policy and offer my personal opinion on the following slides. It's important note that I'm a major shareholder and that I'm heavily vested in the success of the company.

So, I'd like to start with why you should consider exiting the company. And first and most obvious reason is that the time to read-out of the melanoma Phase 2 study cannot be quantified with certainty. If you listened carefully to my remarks about the Phase 3 study, there are manufacturers that are impacting timelines. It's a very rapidly changing area, and very large players are aggressively staking claims.
There's a changing standard of care. And there's also a de facto standard of care that poses difficult challenges. For example, Imlygic, our comparator drug, is approved in Australia, but it is not commercially available in Australia. So, it is possible for investigators to believe that the standard of care has changed to make Imlygic a appropriate standard, but it isn't available. It's a de factor standard of care.

This has impact on investigator interest and center opening, competition for patients, study timelines, and total study cost.

Secondly, we may fail to achieve crucial clinical milestones completely. Many drugs fail in Phase 3. We may not receive adequate capital to reach key milestones. And our secondary and tertiary indications may not be successful. Our work in combination therapy may not be successful. Our work in tumors of the liver may not be successful.

And inarguably, we've made missteps. And we're likely to make more in the future. We may not recognize new landmines before it's too late. As a small organization, we're also susceptible to what's referred to as death by 1,000 cuts. We are also susceptible to disruptive change in management or housecleaning that could alter the course of our technology and/or our capital structure. And we might even fail to manage transition to a larger organization. I
refer to this as growth precipitating collapse. Okay. Those are the reasons why you should consider exiting.

To counter that with reasons why you shouldn't head for the exit, most importantly, the news about our technology gets consistently better. Working with high-quality third parties continues to build credibility for our core indications and truly is supporting potential multi-indication promise of PV-10.

We've shown that at the ablative level. We've shown that at the immunologic level. The immunology that we're observing in melanoma has been replicated in colorectal carcinoma. We're seeing it replicated in pancreatic adenocarcinoma. I personally expect it to be replicated in hepatocellular carcinoma.

Basket study data from our hepatic trials is closely paralleling work in the labs. What we're seeing in the clinic is matching what we're seeing in the laboratory. And our Asia path forward is clear. And the advanced path using immuno-oncology could be a game changer there and particularly in the West.
The Phase 3 interim assessment and Phase 1b preliminary assessment will occur if we stay the course. PV-10 has a novel mechanism of action in a crowded field hungry for novelty. And the same could apply to PH-10.

We have technology that leverages megatrends in oncology. The latest period of irrational exuberance in oncology seems to be coming to an end. PV-10 addresses an opportunity to build on challenges that are causing difficulty with the expansion of the current immunoncology backbone.

PV-10 appears to make the patient's tumor his or her friend. And PV-10 could be a breakthrough for immunologically cold tumors, tumors that don't respond to other immunoncology approaches.

It could be a compelling value proposition for big pharma, particularly if we find some important cold tumors that are high target value.

It can be a global play. Sanjiv Agarwala has said that one of the interesting features of PV-10 is it--because of its stability, it could be hauled in a backpack to the farthest reaches of the world. It does not require cryogenic supply chain. It is potentially something that can play in the First World, in the developing world, anywhere in the world.
And again, PH-10 may fit many of these parameters as well. The ongoing work in the dermato-immunology will show us the direction there.

We've addressed key structural challenges in clinical development. Our supply chain is robust. The first NDA stability lot of PV-10 has been successfully manufactured. We've implemented quality systems necessary for Phase 3 testing. We've built a global clinical development team. And we've fostered corporate collaborations to smooth globalization programs. Boehringer Ingelheim in China is an example of that.

Drug development is slow, and drug development is expensive. A recent report in Scientific American suggested that the typical drug takes over 10 years and $2.5 billion to develop, both preclinical and nonclinical costs. Despite our many missteps, we've spent a tiny fraction of what is typically required to bring a new drug to market.

We've also consistently advanced clinical development of PV-10 from initial IND filing in 2004 to Phase 1 to Phase 2 and now to Phase 3. While we were charting a course for melanoma between Phase 2 and Phase 3, which coincided with the end of the targeted therapy era and the start of the immuno-oncology era, we continue to advance clinical understanding via
expanded access, via our mechanism of action work, via work with radiation therapy, and via our hepatic programs.

This experience provided the necessary foundation for a dual path forward in melanoma, both single agent and combination that we're advancing today. Our primary endpoint in Phase 3—that is, progression-free survival—is now being advanced by industry as the preferred endpoint for oncology studies. And we remain at the forefront of noncutaneous clinical development for intralesional agents. Our work in liver is nonpareil.

So, to conclude, PV-10 is a unique small molecule investigational oncolytic immunotherapy, stable at room temperature, can pose no biosafety restrictions. The toxicity is predominantly local to the administration site. It can provide a high response rate, often with minimal intervention required, can reduce tumor burden rapidly, can produce a systemic immune effect, and it can be a viable candidate for single-agent or combination use.

PH-10 is under investigation as a potential topical immunomodulatory agent in many of the same ways, in this case, for inflammatory dermatoses. Emerging data from ongoing work may be crucial in demonstrating a market niche and will guide future clinical development.
And with that, I would like to thank you for your attention and pass the baton back to Pete before we take questions.

Mr. Peter Culpepper: Thank you so much, Eric. So, that is definitely a record at 113 slides, a fantastic amount of information. We definitely encourage everyone to look at the Webcast.

There's lots of questions. There's 55 on the Webcast itself. And I've been trying to address some of them, the quicker ones. We'll take all the really substantive ones on the Webcast. And then we'll also handle the questions, and we'll ask the operator to poll for questions in the audio piece here in just a minute. But, first, we'll take a look at some of the key questions. And Eric and myself will address these.

So, a classic type question, and I'm not going to mention the people's names, but if PV-10 is so very promising, why has it proven impossible to enlist a financing partner? I think that's a great question. It touches on a lot of different topics.

It's very clear to the industry that PV-10 is so different. And whenever something is so different, it takes potential partners time to get their arms around it. So, we have a patent with Pfizer jointly owned. We're doing a study with Merck's Keytruda. We've been working at
world-class institutions, like Moffitt, University of Illinois Chicago. We have a collaboration with Boehringer Ingelheim.

There are very serious people that go beyond those names that are very focused on PV-10. It is very promising. But, until we get enough--and I--this is tough for us as investors--we have to get enough data in context. Data in context means relevant data in a fashion that makes sense to the industry so they can see where PV-10 fits.

It's completely different for them based on the way it works, the way it's delivered, everything about it. And so, we're going to have to just say that we're literally in touch with the most sophisticated people that there are on the planet. And we're just going to have to stay tuned. It's a--but, it's a very legitimate question.

Another key question is, why haven't we sold the licensing arrangement with the big pharma in a specific area or geographical location to get the necessary financing instead of diluting? That's rather similar to the last one. It's very important for big pharma. And we're specifically talking about upfront cash that's nondilutive.

We have the relationship with Boehringer Ingelheim. We're obviously working with Pfizer to the extent that we have a patent that's jointly owned. We're obviously working with other key
It's a small industry at the top. There are people that are well aware of what is happening. And we're in direct touch with these individuals on a regular basis. So, we're going to have to point out, again, the importance of the data that's now being generating so we have data in context.

There's some other key questions that we want to point out. One multipart question relates to the importance that we have, the management. The board, myself, the management in general are--the importance we have on the stockholders. We care about the stockholders.

And the way I can illustrate is these are family and friends, a lot of us. We live relatively small town in the Knoxville area just on a NOBO list, the nonobjective beneficial owners list alone, we have over 2,000 named investors. We know these people. We spend time with these people on a regular basis. On literally a seven-day-a-week basis, we mingle with people that we know own our stock.

They are very concerned about the survival and success of the company. We know that. We get that. Now, I'm very much like a lot of cancer sufferers. My daughter's a cancer survivor. I'm here because we are passionate about dealing with cancer in a way that is so visceral. This is my oldest child of four. She still lives at home, going to college. But, I see the effects of the
cancer on her daily as in every single day ever since this happened in 1999. So, we get this at a very, very visceral level. We just happen to have something that’s so different.

Now, the reverse split--this is another part of this multipronged question. The reverse split is very tough for the long-term stockholders. No one wants a type of financing that is so challenging to the stock. No one wants that. And no one wants a reverse split.

We have to deal with the state of affairs as they are. And that’s why the board has put out the proxy, the two proposals and recommends a proposal--both proposals to be voted upon in the approved--with a yes.

So, funding ideas, you know, something that Eric and I and others, we work very closely with Tim, with Tim Scott, with the very core people, so three of us, Tim, Eric, and myself as management, other core people that we work with. And there's many of these who are very focused on co-development transaction, a co-development transaction.

Say, for instance, you can think about U.S. Merck with pembrolizumab in combination with PV-10 and say melanoma and GI malignancies, GI malignancies of which there are eight. That would include liver cancer and pancreatic cancer and colorectal cancer, stomach cancer, a number of very, very tough GI malignancies, where we know PV-10 has activity in HCC, in
Third Quarter 2016 Business Update Conference Call
November-14-2016
Confirmation #13648197
Page 61

colorectal, in pancreatic now. So, that would make a lot of sense, and yeah, combining PV-10 with Merck's Keytruda in, say, multiple indications.

Same thing on the dermatology side. We haven't been able to talk as much about that, but very important information on PH-10 supports what we've been saying on, again, nondilutive type structure. And that case would be, we believe, a PH-10 global license.

So, that deals with certain of the questions--well, a three-part question from one of the retail shareholders. We also have commentary related to liver cancer work specifically. And I would like to toss this over to Eric to go into perhaps a little bit more specific roles, the expanded Phase 1 cancer study. Does the FDA approve of metastatic liver cancer as an indication? Perhaps be specific, like breast cancer, metastatic to the liver. So, this is a particularly precise question, if we could focus on liver cancer and the rationale for the expanded Phase 1, which is on a lot of [unintelligible].

Mr. Eric Wachter: Sure, the rationale for expanding the Phase 1 is to allow us to have sufficient numbers of patients to draw statistically valid conclusions from the study data. We are finding that the patients are falling into three baskets, HCC, colorectal, and others. And as we expand the study, we expect that that will continue.
Third Quarter 2016 Business Update Conference Call
November-14-2016
Confirmation #13648197
Page 62

I mentioned that we may look at some other targeted and focused areas of tumor type, such as uveal melanoma metastases to the liver. And the expectation there is that that is potentially a new initiative for us in melanoma to provide a faster way to approval in that it is a disease that there is no apparent standard of care. There is no significant response with current classes of agents. And it's an area where the patient population is in desperate need of new solutions, so scenario where we would not be competing with so many other companies if we are able to show relevance there.

Mr. Peter Culpepper: So, there's a lot of other questions on the Webcast. Why don't we, operator, poll for questions to take some verbal questions, some Q&A. And then we'll come back to the additional questions on the Webcast. So, we'll mix it up by taking some verbal audio questions. So, if you could poll for questions, please, operator.

Operator: Yes, sir. And again, to ask a question on the phone, press star-one on your telephone keypad. Our first question on the phone comes from Max Assenheimer [sp]. Please state your question.

Mr. Max Assenheimer: Hi, gentlemen. How are you tonight? My question concerns credibility of management. At the Rodman & Crenshaw Conference, you guys mentioned that we'd be looking at end October, early November for Merck results, mid-November to late December
for--mid-December for interim Stage 3. We've been told that, you know, we had enough money to run through interim results multiple times, no dilution.

Everything is opposite of that. We're expanding trials everywhere over the world. But, we're not accomplishing the main focus, which would be to get this drug to interim results so it can be brought to the FDA for immediate approval. There is nothing hard about that. There is nothing hard about raising money at 90 cents compared to a nickel. There's no reason to walk the share price down to do a rollback at a nickel and hurt the shareholders that have been supporting this company for 10, 15 years.

There's--I just don't understand why you have an Interim CEO that is walking share prices down and is still the CEO. Put somebody in there that has the credibility because the share price represents the credibility of the management.

Mr. Peter Culpepper: Well, I'll take that first that there is no question that we are going to be up to the task to get this done. The reason we took the time today to deal with all this information is to point out how very complex what we're doing is.

There's a lot more that's involved than the three employees. We have many different consultants, many different relationships. And what Eric has laid out on the scientific side
highlights the significant amount of detail and the--when we meet with potential partners, they know that management is up to the task. They know that. The public markets, where we deal with potential funders, they don't have a question on the management either.

What the question is, and it's a very legitimate question, is the data. And that's where the importance of generating the data is so front and center. And to keep ourselves focused, the importance of the rights offering is to raise the necessary capital to ensure we get the data. And that gets to the importance of the proxy filings, one or two--either--at least one of those two proposals--we recommend both--either one or two of those proposals has to pass in order for the rights offering to be conducted, in order for cash to come in sufficiently, in order for us to generate the data that is necessary.

Please take the next one, operator.

Operator: Our next question comes from George Klo [sp]. Please state your question.

Mr. George Klo: Yes, did any of you at Provectus--and I'm talking about management and the board of directors--make any effort to raise funds from any other company than Maxim?
Mr. Peter Culpepper: Yes, that's an easy answer. Absolutely. We've met with and have spoken to all the--literally all the tier two banks over the years. So, Maxim would be viewed in tier two. There's a number of relatively comparable entities, such as Maxim, we have spoken to, met with over the years. Tim and I have met with a lot of these different groups. Even others have been involved, been meeting with these, with--usually with myself. We've done this throughout.

And invariably--and we've been forestalling--invariably, they have required a financial advisory agreement and a reverse split when--and there was no support from the stockholders to do so at that time.

We are now at a point where, in order to remain listed on the New York Stock Exchange, we have to put out the possibility of the reverse split as necessary to raise the stock price sufficiently.

Next question, please, operator?

Operator: Our next question comes from Joseph Bafolk [sp]. Please state your question.

Mr. Joseph Bafolk: Hey, guys, how are you? Peter, can you hear me?
Mr. Peter Culpepper: There you go. Yeah, thanks, Joe, for calling in.

Mr. Joseph Bafolk: Peter, I know it's outside the focus of what you want. Is there any comment--two things I'd like to know. We know that we have to have a nondilutive cash, that we need to get data out, to secure financing, that it's the data read-out.

Are we--is the PH-10, the method of action that's about to be released in December, are we going to have to do additional trial work, or is there enough sufficient data on PH-10 that it could make a partner move?

And then my other question, if you could just touch on pediatric oncology for PV-10, that would be my two questions.

Mr. Eric Wachter: Joe, I'll touch on the PH-10. So, I'm just answering a few of the online questions on this topic. And what we do as the precise steps from here will be dependent upon what we are learning from this work in immunology.

As I've indicated, we expect to have the next and presumably final set of data from those patients available to us for review next month. If that looks good, we will certainly push that
towards publication. If it looks good, we'll certainly push that towards meeting with FDA to discuss the consummation of the final steps in this development. If that looks good, we will certainly show that to potential corporate partners.

We've already discussed this with one of our potential corporate partners, placing them on notice that that data will be coming. So--.

Mr. Joseph Bafolk: --Okay. Good--.

Mr. Eric Wachter: --As I said, that is a lot of interesting things that are possible with this ongoing work. I wish that it was available right now so I could talk about it. But, we don't always have full control over the timelines of third parties that we work with, particularly very busy third parties.

Mr. Joseph Bafolk: Okay.

Mr. Eric Wachter: With regard to pediatric indications, that's certainly an area that could be potentially of interest to us. Based on the comment that Vern Sondak was quoted in one of my early slides about PV-10 being agnostic to tumor type, while we haven't tested PV-10 in significant extent in, for example, sarcomas, which are common pediatric tumor types, or
blastomas, I would not be surprised if it showed some activities in those types of tumor lines. But, until we have some data to show that that is the case, it's all hypothetical.

So, I will say that one of the things that we're very encouraged about is the evidence of significant pediatric diagnostic use of Rose Bengal in the '50s and '60s. And that suggests that we will presumably have to do appropriate safety testing by modern standards that suggests that there is unlikely to be unexpected safety signals that arise from those testings.

Mr. Peter Culpepper: Next question, operator?

Operator: Our next question comes from Mark Follett [sp]. Please state your question.

Mr. Mark Follett: Yes, I would like to know, under the current financial circumstances, how the --all of the directors can justify an $810,000-a-year annual salary.

Mr. Peter Culpepper: Well, the--so, the stock and the salaries for management is, of course, authorized by the Provectus Compensation Committee. So, there's--part of, I believe, your question relates to management. And the management has taken a $200,000-per-person reduction in their employment agreement salary as part of the settlement compensation.
So, management is already reduced its actual cash that is being taken. Furthermore, management has stated in the S-1 filing that--this is Tim Scott, Eric, and myself--we all intend to participate in the rights offering. So, we'll be actually putting cash into the company as part of that.

Now, as for the independent board of directors, they are the Compensation Committee. And so, they have determined what their salaries should be in accordance with our independent compensation consultants and their deliberation relative to peer companies.

There's no question, though, that for management--and I would--I believe strongly the entire company is very focused on getting through the rights offering successfully so we have enough cash in order to ensure we get enough data for the partnerships that Eric was just touching on as our goal in the last question.

Mr. Mark Follett: I understood that the--there was a possibility that you had insurance to cover the settlement claims. Is that correct, or not?

Mr. Peter Culpepper: Oh, I'm sorry. Yes, the--for the settlement claim, the insurance does cover the class action suit and the related derivative. So, that's been disclosed in the filings. So, there is no more out of pocket from Provectus related to the preliminarily settled class action.
And there's no more out of--there's no out of pocket for the already definitively settled definitive for those derivative.

So, for those suits, yes, there's no additional cash for the settlement. For the compensation, management has agreed already and is repaying back prior bonuses. So, all that's already been established as well.

Mr. Mark Follett: Thank you.

Mr. Peter Culpepper: Thank you. Next question, operator?

Operator: Our next question comes from James Onimbo [sp]. Please state your question.

Mr. James Onimbo: Yeah, am I to understand the reason we're going to do this reverse split, primarily for the New York Stock Exchange?

Mr. Peter Culpepper: That is definitely a key reason, yes, because we indicated that the intent of the New York Stock Exchange is to delist Provectus unless we're successful in our appeal, which would be based on increasing the price of our stock sufficiently so we're at least at the 20 cent level.
So, that is why we believe it's important. The New York Stock Exchange we believe is important for the overall visibility of Provectus here in the States and globally. It enables better access, more flexibility for institutional investors. And it also enables even retail stockholders and certain--with certain broker dealers.

It is a passionate--again, as we indicated in the statement, it's a passionate controversial topic for all of us. And so, that's why we say that both--there's two proposals. There's two proposals for stockholders. The board recommends both. But, as we said, at least one of the proposals has to pass in order for us to effectuate a rights offering. I hope that helps somewhat.

Mr. James Onimbo: It appears to me that you have a large hurdle to get over dealing with the FDA. It appears to be it's a distraction with the New York Stock Exchange. The drug is what it is. If it's as good as what we're being led to believe, you have plenty of visibility. You've been out there now for years at all the conferences. It's well known in the industry what this drug is. The more important thing to me is focusing on getting it through the regulatory process rather than staying with the New York Stock Exchange, which is just another bureaucracy you have to fight.
Mr. Peter Culpepper: Well, I think that's a very legitimate question. The way I would address that, and then I would like to toss it over to Eric, is there's no doubt that we have dealt with the FDA for years. We believe now we're in a much, much stronger position with our programs.

It's well regarded, the Phase 3 protocol and what we're undertaking. That's well regarded by the industry. It's very important with the right endpoints, with the right sort of nuts and bolts requirements that the industry expects for a successful Phase 3. We have to run it. We have to prove it, but it beats what the regulators expect and need, sufficient to approve PV-10, assuming we get what we expect.

Same thing with the 1b/2 combination study with Merck's Keytruda. That's very appropriate for the industry. So, we're dealing with the industry in both ways. So, really both studies together are critical in our management and working with the FDA.

Now, the liver study is so important because we're dealing with a large unmet need. Melanoma is a crowded space. Eric went through all the different studies that are currently actually now being pursued in melanoma. We're the only agent that's in a Phase 3 intralesional agent, but there's a lot of activity in melanoma. There's, relatively speaking, much less in liver. So, all three are critically important, and that's why we're doing all three on--from a FDA standpoint.
The point about the New York Stock Exchange relates to how do we optimize the value when we see the pharma partnerships that we're working to actually enter into. How do we optimize that from a financial standpoint? And I'll touch back on that when we go back to some of the webcast questions, because there's more webcast questions that relate to our actual financing strategy and how we balance the financing objectives with our scientific.

Next question, please, operator, on the audio piece?

Operator: Our next question comes from David Lewis [sp]. Please state your question.

Mr. David Lewis: Hello, gentlemen. I'm a little confused here on the--how dilutive if we give you the right to issue us to a billion shares and do a 50-to-1 reverse split. Say I had a hundred shares of your stock. What would I wind up with? And I'd also like you to touch a little more in depth on the rights offering. What's going to be included in that?

Mr. Peter Culpepper: Okay. So, number one on the rights offering, we have to just make sure everyone understands we have to be a stockholder when the record date is set for the rights offering. So, we'll set the record date. We'll know about the rights offering after we get past the proposals on November 28th.
So, soon after November 28th when we have the special meeting, we'll announce the results of the two proposals and then we'll be able to discuss more particulars of the rights offering. But roughly speaking, it's going to be very much, from a marketing standpoint, desirable for current stockholders to enter into the rights offering. All stockholders who own stock will be able to participate voluntarily. It's--the rights offering is designed to be anti-dilutive. So, stockholders who participate will not be further diluted.

But if there's a--to your point, if there's a reverse stock split, that proposal passes and the Board decides to do 50-to-1 and you have a hundred shares, your hundred shares, say at 5 cents, would end up being, in that case, two shares. You know, divide the hundred by 50, two shares. And then you'd multiply, so 250. So, that's what would actually happen. You'd--the same value exists on that calculation, but you have less shares at a higher stock price.

But the reason there's two proposals that are out before stockholders is to determine--to ensure that at least one passes. So, the stockholders will choose how to--again, the Board recommends for the stockholders to vote in favor of both proposals. But the stockholders make that determination.

And then, depending on how many shares are available based on those proposals, we will enter into a rights offering for all stockholders to take advantage of that opportunity to essentially
fund the company necessarily in order for us to ensure that we're successful given what we're communicating in our, of course, forward-looking statements.

We're very confident. We believe we'll be successful, but we need to keep going to ensure that that's the outcome that we expect. I hope that--.

Mr. David Lewis: --And now, please--.

Mr. Peter Culpepper: --Helps somewhat. I'm sorry?

Mr. David Lewis: One more question on that, please. Right now--.

Mr. Peter Culpepper: --Sure--.

Mr. David Lewis: --If you're at a hundred shares, there's four--approximately 400 million outstanding. When you're through with the reverse split, what will be the outstanding shares that my two shares would represent a portion of?

Mr. Peter Culpepper: Okay. So, in that case, it would still be the 400 million. Say the first proposal does not pass, the authorized shares still stays the same.
Mr. David Lewis: So, then I would go from having a hundred shares out of 400 million to two shares out of 400 million.

Mr. Peter Culpepper: That is correct, if the reverse split proposal does pass and if the Board determines that they elect to do the 50-to-1, say, versus the 10-to-1. You know, a lot of that's going to depend on where the stock's at, what--the proposals, of course, are voted on by the stockholders, and then what the Board determines.

The objective here--.

Mr. David Lewis: --So then--.

Mr. Peter Culpepper: --In all of this is for the Board to operate--.

Mr. David Lewis: --And in order for me to recover my money that I had invested, you would have to sell rights or sell the company for 50 times more than what you would right now--.

Mr. Peter Culpepper: --Well, the--.
Mr. David Lewis: --For me to recoup my money.

Mr. Peter Culpepper: Well, the--yeah, from our standpoint, we're--again, we're trying to address other questions that we've already stated, just to reemphasize. We're large stockholders. We want to be successful ourselves financially.

When patients win, we all win. We're firmly fixed on the patients winning, the scientific data hitting enough data and context for the potential partners, and what we believe the--will be the approval of both PV-10 and PH-10. But it's critical we keep going. We're, with the Board, going to do what is most shareholder value friendly as possible.

We're--I think we're going to have to move on to another question. Let's take one more question on the audio and then we'll move back to the webcast and take a few of those, and then come back to the audio. Operator, one more for the audio?

Operator: Our next phone question comes from Ed Galen [sp]. Please state your question.

Dr. Ed Galen: Evening, gentlemen. Two quick areas, Peter, Eric. The warrant exchange program failed because we didn't have really newsworthy development. For the rights offering that is under--that's being discussed, the shareholders' rights offering, for that to be successful,
will we need news development to raise the share price, because we're at 5 cents, or are we looking at the shareholders participating in this rights offering as a defensive measure just to preserve their percentage of ownership? Does that make sense?

Mr. Peter Culpepper: Yeah, I follow you, Dr. Galen. So--but the--I think the point here is that the rights offering, for it to be successful, first we have to vote on the proposals. So, all stockholders will vote on the proposals.

Dr. Ed Galen: Correct.

Mr. Peter Culpepper: We announce that after the special meeting on November 28th. We believe the rights offering will be designed by definition from a marketing standpoint to be successful.

And we, of course, will be working diligently to get additional news out and continue to communicate as best we can. There's no doubt about that. The rights offering, though, is designed for stockholders who are committed to success for their investment. And like I've tried to emphasize, Eric, Tim, and myself, we all intend to participate ourselves in the rights offering. We want the capital to go into the company to ensure we'll be successful.
So, for the rights offering to be successful, we'll design it from a marketing standpoint to be successful. But we don't know what we can work on share-wise until we get through the proposals. So, first step is the proposals--.

Dr. Ed Galen: --Right--.

Mr. Peter Culpepper: --To be passed.

Dr. Ed Galen: Yeah, I understand that, Peter.

Mr. Peter Culpepper: But then we get to the stock--then we get to the rights offering.

But I will point out, though, since you mentioned the warrant exchange, the warrant exchange was a--partly a--it was partly successful. We were able to secure 3.9 million.

Dr. Ed Galen: Correct.

Mr. Peter Culpepper: But the fee--the key on that, Dr. Galen, is the--if all remember, that was priced at a premium to the fair market value of the stock.
Dr. Ed Galen: Correct.

Mr. Peter Culpepper: That's not as marketing friendly as we will design the rights offering, we believe. Now, we have to be a stockholder--.

Dr. Ed Galen: --Um-hmm--.

Mr. Peter Culpepper: --Of--in order for participation in the rights offering. But the rights offering will be priced and designed to be priced, I believe, more favorably than the warrant exchange. Again, it's designed to be successful. The rights offerings, for instance, that Maxim has led this year have, in fact, been successful, a very high percentage of subscription--.

Dr. Ed Galen: --Um-hmm--.

Mr. Peter Culpepper: --Based on the rights offering. So, we're going to do an extensive road show once the rights offering kicks off. We're going to be very active with our large stockholder groups. So, we're--our intent is to--for that to be very, very successful. I hope that--.
Dr. Ed Galen: --And I’m looking forward to that too, Peter, but I see a necessity of a higher share price to generate enthusiasm in participation. That’s what I’m looking at from my end here.

Mr. Peter Culpepper: Oh, okay. Well, thank you. And I know your situation, so I’m glad you were able to dial in. Thank you so much. And--.

Dr. Ed Galen: --I got one other quick question, please. As far as Australia, I know that the TGA accepts compassionate use data. Do we have all the necessary data to submit our application for approval with--on PV-10 or in PH-10 for approval in Australia?

Dr. Eric Wachter: We are collecting data from that expanded access program. We closed enrollment of new patients effective the end of June of this year. We expect the last treatment of patients to occur prior to the end of December of this year. So, we’re collecting those data, but we haven’t got a complete dataset from that work yet.

Dr. Ed Galen: [Inaudible} submitted an application or anything like that just yet, because we’re still working on the data for it.
Dr. Eric Wachter: That's correct. And whether that will be adequate to support approval in Australia is a question that we will assess as we have a better, more complete dataset. I will point out this is one area where having a subsidiary in Australia may inure to our benefit now.

Dr. Ed Galen: Okay, fine. Thanks, guys.

Dr. Eric Wachter: It focuses us more with Australia. It aligns our efforts more closely with TGA in Australia.

Mr. Peter Culpepper: So, we're going to come back to--operator, we'll go from audio back to webcast and then we'll come back to audio, because I recognize there's still people in the queue on the audio. But we'll try mix it up again.

So, going to the--there's many questions. We're up to 106. We're trying to answer some of them online, but some I think we'll just handle on--verbal ourselves.

So, here's a question. Is your--in your opinion, from a business standpoint and management, why do you feel with the stock price--why do you feel that the stock went up with good Phase 2 data? And with interim Phase 3 data in the process of being released, it has continually went down to now a consideration of reverse splits and issuance of more stock? I think it should be
worth a lot more than the current value. In retrospect, what is the management's opinion of
the reason for the loss and to show accountability for the loss?

Okay, that's--you know, that's an excellent question. A lot of these questions that are asked are
very--of course very legitimate. The anticipation--as we go back in time to the first part of
2014, the anticipation very much, and even if we go back to 2007--you know, this has been a
long haul, absolutely--we can see, within rise of stock price, a lot of times related to the
anticipation of a shortened regulatory process.

We have been trying at every turn, every interaction, to shorten the regulatory process as best
we could. And so, stock--the stock goes up, we're largely a retail stock base, when the retail
stockholders see the potential--the potential, I underscore, potential for a shorter timeframe.
What we have determined through--as we said in our prepared remarks, what we have
determined is we have to continue to go through the very rigorous Phase 3 in order for us to
get to enough data for a potential partner.

And let's keep in mind, say as an example on this point, in the comparator for the Phase 3, we
have now Imlygic. Imlygic is the--is actually the drug that Amgen acquired through their
acquisition of BioVex, a private company. Amgen acquired BioVex on the basis of interim Phase
3 data.
So, BioVex was acquired when they had gone through interim Phase 3. Amgen took that acquisition, finished the Phase 3, put together all that was necessary to get that drug approved, and it was just approved literally October last year. That's why it's been added as a comparator in our Phase 3. That took a process for BioVex to get to interim Phase 3.

We have a much clearer trial design than VioVex did--BioVex did, but it's not been easy, for the reasons Eric articulated, to enroll in the Phase 3 without very important additional modifications and considerations. So that's, again, why the importance is. We are reacting properly. We are being proactive.

And we should underscore we're the only one in the industry that's ever done this in the Phase--with an intralesional agent that's a small molecule chemical. We're the only ones that are now in Phase 3. We're the only agent of its kind to actually get into Phase 3, and we're the only type of trial design that's ever existed in Phase 3.

This is a unique--completely unique. There is no comparator here of the trial design. So, this is--the crown jewels, really, of the company's clinical development progress is our Phase 3 trial design. So, that's just the way it is and that's something we have to just accept. Another--not
that we want to accept it, but we have to. And we have to keep moving forward to--on--and that's why we want the rights offering.

So, the next question, which is number 69, is that a Phase 3 pivotal and registration study? No, it was a Phase 2b.

This was an investor who was asking why can't we release more information about where we are in the Phase 3. And so, my comment was, well, we're in a Phase 3 pivotal and registration study. We don't have the capability that's appropriate in the industry to release data prior to interim Phase 3.

There are statistical penalties for releasing data prematurely. And Eric can comment further if he'd like at any point, of course.

So, the next question is, will this be the last financing needed? Excellent question.

We believe the rights offering--and again, this is the importance of what we've said in the S-1 filing, the amended S-1 on November 1st. We believe, with the capital that we are seeking to raise, the up to 21 million, that will be sufficient so that this would be the last financing. That's the whole point.
We do not want--that's what--we would have wanted to have gone to the stockholders in a rights offering earlier. We could not get this done and get this set up. We've tried. We wanted to get this set up and out to stockholders earlier. We have to do the Maxim financing August 24th/25th, close on August 30th. We had to do that in order for the capital to be sufficient in order to get to this point of the rights offering.

Now question number 73. Why would we not sell off PV-10--sorry, excuse me. Why would we not sell off PH-10 to survive? Even getting 25 million is better than that last financing; another very key question on PH-10.

We had the same challenge with PH-10 than we do with PV-10. We're in touch with the industry experts in both areas. We have met with the top pharma entities in dermatology about PH-10 just like we have with PV-10. In PH-10, the uniqueness of what PH-10 is doing dermatologically required the mechanism study that we completed.

We are now going through what we need to do in conjunction with Eric's comments, with the regulators, with the FDA, with potential partners, with the mechanism study-based entity. We're working through in order for PH-10 to be ready to license. If we could sell it for 25
million we would is the short answer to that. But we have to further characterize PH-10 in order to get there.

Question 74; how do you keep the preferred shareholders from selling the shares they acquire from the ratchet to sabotage the next capital raise and generate additional shares from the sales on the second and subsequent ratchets?

So, this is a type of question that--if someone looks carefully at the 10-Q that was filed for Q3, if someone looked very carefully into that--so that filing, of course, occurred on November 9th, so just last week. Look at the way we describe the convertible preferred and what actually we put in the subsequent event footnote.

You would see, if you put together all that, the vast percentage of the convertible preferred has in fact already been converted. So, we'll just have to leave that on that point.

Number 77, and I--and some of these you're going to start skipping because we've been trying to address different questions as we go along. The main problem with a reverse split is that it multiplies the approved shares not an old share basis by 10X to 50X. Do you consider decreasing the approved shares post reverse split?
Well, we're going to have to get--quite frankly, get to the point where--we're not saying that--the stockholders determine if there is even a reverse split authorization for the Board in the first place, and then the Board has to determine what they're going to do. But the authorized shares is a determination, at that point, on--after the proposal, so we'll have to come back to that.

Number 78; what specifically has been the obstacles to signing a partnership or a license agreement for either PV-10 or PH-10. This is, as you can tell, a very repetitive but very well worded still question. It's repetitive because this is on the minds of a lot of people.

We have something--we all, who are on the call still after pushing two and a half hours, for the longstanding stockholders, for all of those who are committed to our success, we want this done. We want this done for patients. We want this done for ourselves. There's no question about that.

So, what are the problems or the obstacles? The biggest obstacle that we see for PV-10 and PH-10 is there's nothing like either one. They're unique. They're singularly unique in the mechanism. This is an old dye. We have synthesized it in a way that meets the ICH specifications so we have intellectual property that protects it. So, we've improved the old dye so that it's actually a therapeutic grade.
But still, it's been around for decades, routinely used in humans for decades, yet nobody else in the entire world, thousands of publications as you can see on Pubmed.gov., no one has figured out how to work this compound successfully but the founders of Provectus. And this should really strike a chord here.

The true innovators in any aspect of life come from people like the founders of Provectus. And big pharma, for partnerships and licensing, they want us to get there. We're the experts. This is very radical for stockholders to understand, that we understand.

Eric's a physical chemist. Tim is a chemical engineer. These are both very brilliant, competent, well published with patents and publications. They are very experienced with this type of compound. It operates on physical chemistry. It's different than the other compounds. The way it's delivered is also local. It's the first local agent that we believe could be surgery plus. It can actually be a neoadjuvant to surgery. Why? Because it kills the tumor completely and primes the immune system.

Now, we have to prove that, but we have seen that its power to kill tumors is very well documented. We know the safety profile. We believe that we have something so landmark, that it's so unique, potential partners got to get enough data and context, meaning to say they
have to have enough data in a fashion—and this is exactly the settings that we're doing to provide that data.

Now, 79 is you stated that participating in the rights offering would avoid dilution for shareholders. So, would shareholders who did not participate experience the crippling dilution that is possible through a reverse split followed by more dilution?

Well, the reverse split discussion, of course, is based on the proposals on November 28th. So, that's when the reverse split topic comes. Then for the stockholders, after the reverse split discussion occurs from November 28th, everyone's going to be on the same playing field there for the rights offering.

So, whatever we have after November 28th, we're all going to be the same. We could all buy stock. We could do whatever—excuse me—we could all do whatever we prefer to increase our ownership. The record date will be set and we'll all be able to participate. It's voluntary, but it's key for all of us. We want this to be successful for all stockholders.

Now, the—you know, some questions like this question, why the maximum with a ratchet makes no sense, no one wants to a financing like that. There's no question you only do things like that when you have no other options. And so, that's the hard, ugly truth on that topic.
On 83, Maxim is--again, we meet with all the New York City based and then--investment banks, and others ex New York City, so we know the drill here. Pro vectus is unique not just with our drugs, but we're the only company that I know of in phase--with a compound in Phase 3 that had even formed with a reverse split to start with.

We formed with a reverse split. We became a public company not through an IPO. We've bootstrapped this from day one with retail stockholders. And I believe we're going to see it through largely because of the success of the rights offering because of our retail stockholders.

Now, here's question 84, the status of suing the former CEO and his wife, there is--certainly that's being taken to the fullest extent possible. There is a collection effort underway. Anything that we can get from the former CEO and his wife will, of course, be to the benefit of the company.

Now, here--you know, certain of the financing suggestions like raising $10 million in debt and announcing a stock buyback, well, some--we're going to have to take questions or topics like that after we get through what's already front and center. So, already front and center is the November 28th proposals. We recommend--the Board recommends in favor of both, and then the determination of what then exists in order to go through the rights offering successfully.
Okay, I'd like to take a pause there since we'll come back to the webcast questions. And operator, can you poll for a couple questions that exist on the queue?

Operator: Certainly. Our next question on the phone comes from Nicholas Chapano [sp]. Please state your question.

Mr. Nicholas Chapano: Yes. I understand what you're doing, but I got one question. People have paid $2.00 for the stock or $3.00 for the stock. You're going to make a reverse split. On a hundred shares, we'd wind up with two shares worth how much, 20 cents, compared to what it cost us for a hundred shares? It doesn't make sense. It's just impossible to recognize that we're going to get our money back. So, can you do it without doing a reverse split?

Mr. Peter Culpepper: Well, the way I would address that is the only way for us to ensure that we're successful, in our belief, in our strongly held belief, which is why we're still here, which is why we're still operating, is because we know if we keep going, we're very confident, extremely passionate, that as long as we keep going and do not give up, we will succeed and get the drugs approved and the pharma partnerships, and whoever is holding stock will be of benefit.
That's the only thing we can do at this point. We're--we have to deal with reality. We have to face reality. We're facing reality on all fronts. We're going to ensure that we're successful by not giving up. It's the--.

Mr. Nicholas Chapano: --But it'd be good to know--if you get the okay for the third paragraph to expand the amount of shares, can you eliminate the reverse split?

Mr. Peter Culpepper: Oh, well, if the first proposal passes, so the increase in authorized shares, and the second proposal does not pass, there--the authorization for the Board, then there could--there will not be a reverse split, correct. If--so, that's why we say at least one of the two proposals has to pass in order to effectuate the rights offering.

So, stockholders can vote for just the first proposal. Yes, the Board recommends for both proposals. But even if the second proposal passes and also the first proposal, the Board still has to make a determination of what to do. The Board still determines, if the second proposal passes, if a reverse split is even effectuated. And they also have to discuss is it going one share for 10 up to one share for 50.
So, there's--a determination has to be made by the Board after even the second proposal is presumably passed and stockholders also vote in favor of that; more than 50 percent of outstanding, that is.

Mr. Nicholas Chapano: Any a reverse split--.

Mr. Peter Culpepper: --If there are enough--.

Mr. Nicholas Chapano: --On a stock--I've been in the stock market a long time and I've been through reverse splits. Anytime there's a reverse split, the stock goes under, plain English.

Mr. Peter Culpepper: Yes. Well--.

Mr. Nicholas Chapano: --Okay--?

Mr. Peter Culpepper: --That is--yeah, again, that's why I said in my prepared comments it is controversial. That's no question about it.

But for--again, Provectus is completely unique, I believe, on so many different levels. Like I said, we started the company a reverse split into a--what thankfully was a clean shell. So, we started
the company, ironically, a reverse split into a clean shell. And we have shown every step of the way that we believe there's more and more evidence for us to be successful with PV-10 and PH-10.

Mr. Nicholas Chapano: Well, it was--.

Mr. Peter Culpepper: --The point of the--.

Mr. Nicholas Chapano: --Successful 30 years ago when I got melanoma twice, once on my back and once under the arm. They took all my nodes out. But from 30 years ago when I went through it then, it was something that was more simpler and I was cured. I was cured. All right?

I was cured by my tumors going into bottles and rotating until they got enough serum to shoot it back into me. And that serum killed all the other bad cells in my body. So, 30 years ago, I was put through that and--30 years ago. I'm still here. So, that goes to show that--.

Mr. Peter Culpepper: --Well, that's--that is fantastic. That's why we're fighting. We know lots of people that want us to succeed because they have cancer. Now, that's great to hear from your standpoint.
But there's lots of suffering people. I know that personally with my daughter. Ken knows that personally. Eric knows that personally. All the people we work with from our Chairman of the Board, throughout our entire Board, we all know absolutely that cancer suffering is real and we have to improve what we are doing in order to improve patient outcomes. There's no question about it.

Mr. Nicholas Chapano: Okay. The only thing I'm going to say before I sign off, do not reverse split the stock because you'll crucify all the investors that's been with you for the past eight years, nine years. You'll crucify them.

They will have no money to buy the rights offering. That's the problem that's going to be. Everybody's invested in this stock hoping that eventually they were going to make money. So, you do a reverse split, there's no money to buy the rights offering. That's the problem.

Mr. Peter Culpepper: Well, that--again, that's exactly why the two proposals are out there for stockholders. That's exactly why the Board determined both proposals should be put out there for stockholders to make that determination.

Mr. Nicholas Chapano: Okay.
Mr. Peter Culpepper: Operator, could you take the--another question on the audio and then I'll go back to the webcast?

Operator: Our next question comes from George Klo. Please state your question.

Mr. George Klo: Yes. What happens if the first proposal doesn't pass, the one that says that you want to expand the authorized shares to--I believe it's one billion?

Mr. Peter Culpepper: That--yeah, that's correct. From 400 million to one billion, correct. So--.

Mr. George Klo: --If you don't--if that doesn't pass, then what happens to the agreement with Maxim about the ratchet?

Mr. Peter Culpepper: Well, that's going to be determined when November 23rd occurs. And that'd be determined also in the other proposal. Like we said, we have to meet one or two of the--we have to get one or two of the proposals passed.
So, we need one or two to pass in order for us to be successful going forward bottom line anyway, because we've already said we're going to do the rights offering. We've already said that--that's already stated with the amended S-1. So, we're very clear on that.

But we really have to get to November 28th. What I'm trying to communicate is that we want--the Board wants and recommends both proposals to pass, but we have to have at least one to pass in order for us to move forward. And as long as one of the two passes, we'll be able to move forward, we believe, to effectuate the rights offering and we--and move forward.

But I will tell you that there is absolutely--where there is a will there's a way. We are--we know that there's so many people--a lot of people are asking questions and I still want to go through more webcast questions. There's a lot of interest in ensuring that we're successful. I regularly get people contacting me saying, Pete, we have money that we want to invest in your success; regularly, on a very regular basis.

So, I--but we're all stockholders here and we're all wanting to ensure that we're successful. There's no question about that. That's--.

Mr. George Klo: --But my question is--.
Mr. Peter Culpepper: --But I would like to--.

Mr. George Klo: --If you don't get the first proposal passed, how can you get the second proposal passed?

Mr. Peter Culpepper: Oh, they're--.

Mr. George Klo: --I don't--.

Mr. Peter Culpepper: --Both independent--.

Mr. George Klo: --Understand that. How--?

Mr. Peter Culpepper: --No, the stockholders--.

Mr. George Klo: --You do a 50-to-100--.

Mr. Peter Culpepper: --They're both independent--.

Mr. George Klo: --To-1 reverse split without sufficient shares.
Mr. Peter Culpepper: Well, again, the--both proposals are independent. So, stockholders vote for the--proposal one is increasing authorized shares from 400 million to one billion. That's proposal one.

Proposal two is to authorize the Board to be able to effectuate--again, it's not saying that they will effectuate a reverse split, but it authorizes them to have a deliberation from a range of 1-to-10 to 1-to-50. So, the--proposal two gives the Board the authorization.

So, if proposal one does not pass and proposal two does pass, then the Board would ensure the success of the company by determining what needs to be done in order for enough shares to be used for the rights offering. So, again, one of the two of the proposals has to pass. The Board recommends both.

I would like to go back to some of the webcast questions. And they're--there's a lot of good questions on--here's--and, you know, some we're trying to answer. We'll continue to, operator, answer these even if we don't get to all of them and people continue to add up. We'll do the best we can to answer all questions.
The question number--and this is question number 91. There are two important branches to
the achievement of the financial success of the company, success of the science and success of
the financial part of the house. Eric spent 90--or 80 minutes detailing the science. Can you
spend 20 minutes detailing your strategy going forward to protect and enhance stock value for
your current shareholders?

There's no question that the financial effort that we are undertaking is very much integrated
and it's symbiotic. The relationship is very much part and parcel with the scientific. This is
tough for retail stockholders. If the scientific progress was sufficient that we could enter into a
co-development transaction right now with upfront non-dilutive cash, we would absolutely do
that immediately.

If we could right now enter into a licensing transaction with upfront cash for PH-10 or for PV-10
in various geographies, we would absolutely do so right now. I'm here to point out that that is
not--that has not been done because the science needs to continue to move forward to
generate enough data in context. That's the reality.

We know we have--we--all of us know we have something very important that we're doing. But
we have to continue to focus on the fact that the data that has been generated, it's very
promising, but it's not yet done. Again, Amgen acquired BioVex on the basis of interim Phase 3,
interim Phase 3 data. We're not yet to interim Phase 3. We're still in the process of getting to interim Phase 3. So, that's a very important preceding transaction.

A lot of deals go down on the basis of interim randomized studies. So, when we talk about pillar number five, we're talking about clinical data that's meaningful in randomized studies. Now, that's not black and white necessarily. Deals also occur when there's sufficient mechanism data or sufficient understanding of a compound in the context of the--in our case the immuno-oncology environment so we understand PV-10 immunologically.

How can we understand it sufficiently to enable, say, a Merck or a Bristol or a Roche or a Novartis or a Pfizer to enter into co-development? Those are the discussions we're having. Those are--that's the focus. That's the importance of the 1b/2 combination work. That's the importance of what Eric was saying on H--or on hepatocellular carcinoma.

So, there's absolutely--the strategy for the financials' side is to get more cash to Eric. The best way we can get cash to Eric right now and the success of the science is the rights offering. The rights offering is when all stockholders have the ability to fund the company at their choice after they vote on the proposals. We can only be successful if we are funding the company at this point.
Now, if between now and November 28th we get a call from any of the companies that we talk to and we want to announce something, absolutely, of course. But these--we've been in those discussions. We've been trying to do that. We will continue to, and we will ensure that those continue.

So, number 92; have we attempted to get funding from NCI for trials? Other oncology companies have trials sponsored and paid for by NCI. That's an interesting question.

We have--interestingly enough, a number of the studies we've been conducting, the Moffitt Cancer Center, University of Illinois Chicago, a number of other studies that are not public actually are--and Eric, please comment--are actually in effect--excuse me--under the auspices of NCI funding in a lot of cases. Would you like to comment on that, Eric?

Dr. Eric Wachter: Well, certainly we benefit from the infrastructure that the NCI supports at third party centers that we work with, if that's what you're alluding to.

Mr. Peter Culpepper: Yes, absolutely.

So, when we say on our focus areas, we are definitely active in trying to get funding that's not dilutive from other sources. So, that's part of what we're doing. And a lot of the work we do
with these centers is very much, let's just say, under the auspices of NCI and with a lot of the people we work with.

Number 93; could a PH-10 deal possibly provide an upfront cash? I think that's, again, a good topic.

If we have a PH-10 licensing deal with upfront cash, that would obviously be very welcome, and we would immediately announce that. So, that's certainly, with the co-developments, top priority from the standpoint of non-dilutive efforts.

Number 94; what is an appropriate offer that can make management sell the company with or without a CVR? Now, a CVR is the contingency value right. Secondly, are there offers on the table that may or may not be currently considered?

I'm not aware of any offer on the table. The Board would make any determination, but I'm certainly not aware of any offer on the table. I'm not aware of any offer that--you know, we would announce it.

We do not engage in communicating, of course, material nonpublic information. We do not do that. We only communicate what is public. Anything material nonpublic would be
communicated in an appropriate news--a press release publicly or--and if we conduct another conference call for the purpose of announcing such an arrangement.

But an appropriate offer that management would sell the company is going to be my--the way I think best to answer that is when the science has been validated sufficiently so the market recognizes it with a pharma partnership. That's when the market recognizes the value of a drug. And this is why biopharma companies like Provectus are very much the hockey stick or the J curve type.

And that's--you know, that's a discussion in and of itself, but you have a very, very challenged stock price over a long period of time, and then you have a very rapid increase in the stock price. Why does that occur? Because the industry is trying to get their arms around the data of the biopharma development company, the data from their investigational agents. That’s where we are.

Once pharma in the industry, including the FDA, recognizes the validation, like interim Phase 3 data, PV-10 is superior to Imlygic, superior to systemic [unintelligible] chemotherapy--once that occurs, that’s public. Boom, that’s when you see the good part of the hockey stick where the validation is very quick, same thing on the 1b/2 combination study with Merck's Keytruda, same thing with relevance in hepatocellular carcinoma.
So, number 95, does management apply in cost-cutting activities like reduction in salaries as well as work compensation? Well, we have addressed that to a certain extent by management has reduced through our settlement on the compensation. We are intending to invest, and literally, from my standpoint, I’m liquidating other assets to participate in the rights offerings. I already have a view I’m going to participate as much as possible. I don’t know what that’s going to be. We’ll know a lot more after November 28. But, I’m committed to the success. I know Eric is. Eric is the largest stockholder that I’m aware of, and I know Tim Scott is as well.

Number 97, we definitely understand the reverse split concern.

Number 98, this is something we can touch on, the six to the nine-month delay that Eric spoke about. I believe Eric’s referring to just the study itself, and we’re not making specific commentary on the interim data readout. The whole point of the rights offering, though, is to get through interim data at a minimum. That’s the whole point of the rights offering along with advancing 1b/2 combination study the 1b/2 liver study, and same thing with PH. PH is also going to be helpful in minimizing any dilution period.

Now, the next question, 99, why not sell the company for $3.00 or $4.00 a share with [unintelligible] CVR so that pharma can advance it. Well, again, if we have an offer or know an
offer, that’s going to come to the board for deliberation because there’s no question. We want this to be, as quickly as possible, proved out enough for big pharma to make this a very robust success. We expect and want a CVR, the contingent value rights to go along with it because we believe there’s a lot of upside potential. But, we’re going to have to get to that point.

Okay, question number 101 is very meaty. We’ve addressed some of that. I think the successful outcome is only going to be if we continue--and Eric, Tim, and I, we’re as committed to this, as far as I can tell, as humanly possible. And I’m going to say the same thing as the independent board directors. We’re in this to ensure we’re successful. There’s no doubt about that.

Now, 102, the rights offering will be delivered to the extent of their preferred right to shares and to the additional shares, correct? Well, if whatever occurs after November 23--and we’ll know about that topic after we get through the special meeting on November 28. The rights offering is going to ensure that whatever we have at that point, based on the proposals that are voted on, we’re going to deal with what we have to deal with in order to fund the company. So, we’re just going to have to face the fact that we have the situation as it is and we’re going to ensure, again, given the stockholders have the ability to vote on the proposals, we’ll be able to ensure, we believe, with the rights offering, our success.
Okay, number 103, I’m going to just address part of this question. Certain people that the stockholders do not hear from, they’re extremely involved in what we’re doing, same thing with our independent board. There are people that are riveted, literally, that we know of, personally, to everything that we’re doing that’s close to 24/7. I know Eric, and I, and Tim, we’re working as close to 24/7 as humanly possible. Obviously, we eat. We have to sleep. So, this is what we do all the time, and people that don’t hear from these, they’re not as public. That doesn’t mean that they’re busy. There’s a lot of key consultants that support what Eric is doing that are critically important to the success of the company. They’re vested. Even some of them I’m aware own shares of Pro vectus. They’re consultants. But, they want this successful. That’s why they’re slugging it out with us. They want PV-10 and PH-10 approved.

Now, level four [unintelligible] are lesser valuable long-term if PH-10 and PV-10 be sold for 50 million today. I don’t believe so. If there was a proposal on the table, it would go to the board. I don’t believe so. I believe both PV-10 and PH-10 need more data. So, that’s the answer to the first part of the question there, which I believe it’s not so. We would love to delude ourselves that, oh, if we had the ability to enter into a relationship for, say, PH-10--I believe, myself, PV-10 is going to be extremely valuable because it’s for all solid tumors. But, PH-10 is also extremely valuable because we believe it’s a topical agent for all inflammatory dermatoses. But, both have to be further advanced.
Number 105, the recent Maxim offering was done based on the authorized shares that are out there, the 400 million. That’s why this $6 million for this close on August 30 was the determination, the best determination at the time. But, that was the amount of money that could be weighed given the authorized shares.

Some of these I really can’t completely address. I’m going to do some of these further by, probably--okay, here’s one, 107. If the one for 50 split approved, and the first ratchet issues another 200 million shares and 250 million more, and we have a price of $2.50. Nine million shares, current hopeful ratchet, 1 divided by 50. If, after the rights offering issues 9 million shares at $2.00, then you have 18 million for the price of $0.50. The second ratchet issues another 20 million. Well, now, the ratchet stops on November 23. So, that’s when that period ends. So that’s a [unintelligible] key to keep in mind.

Number 110, if the rights offering is expected to generate about 20 million, the interim Phase 3 is delayed for six to nine months. Will we need at least one more fund after this one? Okay, I appreciate that question. I don’t believe that we’re trying to communicate guidance on the six to nine months on the interim. The key is, and Eric went through this in detail with all the different sites that are in process of turning up in the different geographies, we need cash through the rights offering to fund that work. The quicker we get up those sites, the quicker we get interim data on top of what we already have, of course, active. So, that’s something to
keep in mind that the interim data speed is very much related to the rights offering generating
and opening those additional sites.

So, this takes us down to question 114. And then, I’m going to keep going until Eric kicks us off,
because obviously, we’re going to want to continue to push the company’s activities. So, in
question 114, if the authorized shares increase is approved and the reverse is also approved,
will the reverse be applied before or after the additional shares are added? In other words, will
there still be 1 billion shares authorized at the reverse split? Yes, if those proposals pass, there
would be 1 billion authorized shares. Correct. And then, again, the reverse topic is separate.
The board has to make a determination, if the second proposal passes or not, whether to do
the reverse and for what range. So, again, we have to get through November 28.

On 115, if management says patients randomly all win, then why not take a reasonable offer
from the potential partner now, and then drag the trials out and let big pharma, with
[unintelligible], finish the remaining trials so Provectus won’t dilute current shareholders. So,
there’s a lot of investors asking these sorts of questions, and so I think it’s clear that we want a
pharma partner. Pharma partners actually come to us as well saying, we want to do a
partnership. We want to figure this out, though. So, it goes both ways. Retail stockholders and
all stockholders should really understand this particular point.
We have to appreciate that pharma entities do not just put down money without a justification.

They do deals. Every single deal they do is because they have a justification for this. All the deals, all the fundamental relationships they go are in, every specific one we can point to why that transaction occurred. It’s for specific reasons, and often times, it relates to very similar areas of research within immunotherapeutic, or targeted therapy, or vaccines, so very well-known areas of research, very well-known compounds, very well-known approaches. Again, what we have is physical chemistry, not biochemistry. It’s completely unique, and so we want to win, and the only way to win for patients and for all of us is to continue to generate data so that a potential partner can justify coming into a transaction.

So, I think we’ve hit 117 before--118, the rights offering usually provides stockholders with an option to buy shares at a discounted price relative to the marketplace at the time. How much a percentage point is the discounted to be, if any? We’re going to have to cover that. Good question. We’re going to have to cover that. That’s going to be, definitely, a marketing effort and definitely won’t be available for us to comment on until after November 28.

How many shareholders do you have to go in the rights offering? Again, that depends on what the stockholder’s ownership is. Each stockholder has a pro rata number of rights. So, if a stockholder owns a million shares or a thousand shares, it’s based on pro rata ownership. So, if it’s a 1% owner or a .1% or a .01%, that’s how many rights they get. So, it will depend, again, on
the marketing effort because that’s the number of shareholders, or in this case, how many people participate in the rights offering. Again, the marketing’s going to be such that we want the rights offering to be successful.

Number 120, Woo relates to a public available information about the large amount of cash.

Number 121, I think it’s very fair that we are trying to be, as best we can, like this very long call over three hours now, answering and dealing with all topics we can with all the very dedicated and committed stockholders. So, there’s nothing in our DNA, I believe, that is intending to mislead or try to deceive anybody. We are being upfront. We’re completely unique in everything that’s happening, and that’s why, I believe, we’re going to be successful because we have something that’s worth pursuing.

So, we have a number of other questions, and I think we’re starting to run out of questions that are unique. Here’s an interesting one, 126. Once the P3, the Phase 3 interim trigger is reached, how long is it expected to take to process the data under these results? Now, that’s something I think I can toss over to Eric.

Dr. Eric Wachter: Surprised you couldn’t see that I just answered it in my [unintelligible.]
Mr. Peter Culpepper: Okay, good. Eric has answered that one already. Thank you, Eric.

Dr. Eric Wachter: So, the answer to that is that data that’s outlined in my presentation is monitored on a regular basis. The database is relatively current at all times. The endpoint assessments are conducted in a batch-wise basis, so as an interim trigger is approached, all the data is relatively current. We would expect it might take a couple of weeks to finalize that assessment.

Mr. Peter Culpepper: Number 128, does management board benefit directly or directly by recent Maxim fundraising? No. We’re not benefiting. There’s no related party transactions. We’d have to disclose anything related party.

Number 129, if management’s committed--we are committed. We’re putting our cash into the rights offering. Eric’s exercised; I’ve exercised all my stock [unintelligible] on 1.7 million. The way the average stock price is $1.00. I remember buying stock at $1.25 and Q4 through stock option exercises. That doesn’t feel very good right now, but I’m committing everything. My wife, my four children and I are committed to our success.
130, are you saying that the rights offering will not generate a second ratchet preferred shares?

So, the rights offering is separate. The rights offering is only after we go through the November 28 stock proposals.

Then, the 131, what benefit has it been to withhold this PH-10 data, withholding the PH-10 researchers? I don’t believe that any data is being withheld. It’s being carefully documented, validated. That data’s been generated but is being corroborated. And there’s a process that, unfortunately, we just have to accept. And, as much as we want that out and communicated, we have to go through a rigorous, scientifically sound process to communicate that. And, until the data is available after it’s sufficiently validated, it’s inappropriate and inexcusable to communicate the data.

132, do you believe you have a successful rights offering without a reverse split? Again, you’ll have to wait until the November 28 proposals. But, if say, proposal one passes and proposal two does not pass, so therefore, a reverse split cannot happen, or if proposal also passes but the board decides not to effectuate the reverse split and decides just to go with proposal one, I believe a successful rights offering is going to occur myself. That’s a form of [unintelligible] by definition, and I believe we’re going to be successful. And that’s why I own 1.7+ million shares.
133, how will rewards be handled in regards to the rights offering? Well, that’s going to be disclosed as, again, we get past the November 28. So, some of these questions, very good questions, we’re going to have to deal with, again, and want to deal with and address sufficiently after we get past.

Now, that’s all I see going through on the webcast. I believe, Operator, if we could go to my closing comments or double check the audio, do you see anything further, Operator?

Operator: There’s no audio questions at this time.

Mr. Peter Culpepper: Thank you. Thank you, Operator. So, before I conclude, I do want to point out that there will be a full version of this transcript, the prepared remarks, and detailed presentation of myself and Eric Wachter as well as all our prepared remarks, and the question and answers in the replay audio for those who want to listen again or for the first time. And I very much want to thank everybody for listening in and for all the questions. And, as always, you can contact Marla Nurse [sp] and the Porter, LeVay & Rose team if you want additional information. He is available, Mike Porter, as is the Porter, LeVay & Rose team. I'm available to the extent that I can be.
Our next call will cover the fourth quarter, and we expect to hold that in March when we believe much of the waiting for results of our Phase 3 clinical trial of PV-10 will be over insofar as our understanding of all the activity to support the interim, and Phase 3, and other activity, and we’ll hope to have our best call yet. Truly, for patients and stockholders alike, the best is yet to come.

Operator?

Operator: Thank you. This concludes today’s call. All parties may disconnect. Have a good day.