Provectus Biopharmaceutical

First Quarter 2015 Quarterly Business Update

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Operator: Greetings and welcome to the Provectus Biopharmaceutical's First Quarter 2015 Quarterly Business Update Conference Call.

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

I would now like to turn the conference over to your host, Mr. Michael J. Porter. Please go ahead.

Mr. Michael Porter: Thank you, Brock [sp].

Good afternoon, ladies and gentlemen, and welcome to the Provectus Biopharmaceutical's first quarter earnings call. To get the legal business out of the way, let me read that this call contains forward-looking statements as defined under the U.S. Federal Securities Laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates and expectations and express management's current view of future performance, results and trends and may be identified by the use the terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, and other similar terms.

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

Risk and uncertainty that could cause our actual results to materially differ from the described in forward-looking statements including those discussed in our filings with the Securities and Exchange Commission including those in Item 1A of the Annual Report on the Form 10-K for the year ending or any quarters thereafter.

At this time, I would like to turn the meeting over to Peter Culpepper, COO. Good afternoon Peter, the floor is yours.

Mr. Peter Culpepper: Welcome, everyone, and thank you, Mike, for that introduction. This conference call is the latest in a series designed to establish and enhance clear and comprehensive communication with our stockholders and to maximize transparency. We have committed to hold regular conference calls, such as this, timed to coincide with the filing of our 10-Qs and 10-Ks to allow for greater interaction between the company and stockholders as well as conference calls when especially notable news is at hand such as the potential partner transaction.

Today, we're conducting a conference call from the venue of the 2015 Accelerating Anticancer Agent Development and Validation Workshop in Metropolitan Washington D.C. Later in the quarter, on June 19th, we plan to conduct our 2015 Annual Meeting of Stockholders in Orlando,

Florida, where we will be guests later that evening at the 33rd Annual American Association of Physicians of Indian Origin AAPI Convention and Scientific Assembly.

Since our last call on March 12th, just eight weeks ago today, we have begun recruiting participants in our Phase 3 clinical trial of intralesional PV-10 as a treatment for melanoma. We will keep the market updated regarding a number of sites currently in the study, including updating study details on U.S. National Institutes of Health website clinicaltrials.gov. We have visited potential sites throughout the world and are committed to facilitating enrollment in the study as quickly as possible.

As per the protocol, which we announced and has been available online in a press release on March 16th, we are seeking 225 patients. The primary outcome measure is progression-free survival, PFS, to be assessed every 12 weeks up 18 months. The secondary outcome measures include complete response rate, CRR, and its duration to be assessed every 12 weeks up to 18 months and overall survival to be assessed every 12 weeks up to 18 months.

We have an estimated primary completion date of September 2017 and an estimated steady completion date of October 2017. An interim assessment of efficacy and safety will be performed by the independent review committee when 50 percent of the events required for

the primary endpoint have occurred. Therefore, meaningful data is potentially available via an interim analysis on a shorter timeline.

We continue to build our intellectual property portfolio to ensure that we maximize stockholder benefits from this research. Since we last spoke, Provectus has received a patent allowance in partnership Pfizer that covers PV-10 used in combination with systemic inhibitors of immune system down-regulation such as anti-CTLA-4, PD-1 and PDL-1 antibodies along with enhancers of immune system up-regulation such as IL-2 and interferon-gamma.

The indications covered under the patent are melanoma and cancers of the liver, although we are pursuing additional protection in other areas through one or more divisional applications. We hope that the patent protection afforded by the Notice of Allowance will enable Provectus to realize financial rewards if clinical research demonstrates the PV-10 used in combination with one or more of these other drugs improves patient outcomes.

In addition, we received notification of allowance from the European Patent Office for our patent application protecting the synthetic process used to produce the small molecule Rose Bengal, the active pharmaceutical ingredient API in PV-10. At the same time, the Japanese Patent Office has issued a patent for the same intellectual property. These follow on the heels of allowance in China, which we reported during the first quarter.

We have a Memorandum of Understanding in place in China with Sinopharm-China State Institute of Pharmaceutical Industry, CSIPI, the leader among all pharmaceutical research institutes in China, and Sinopharm A-THINK Pharmaceutical Co., Ltd., Sinopharm A-THINK, the only injectable anti-tumor drug research and development manufacturer and distribution integrated platform within Sinopharm Group.

We met with Sinopharm executives last month in Shanghai and expect further discussions this month, which we expect to announce prior to the current MoU expiration, May 16th. We continue to work with potential partners in China and elsewhere to enter the optimal transaction possible for stockholder, patients and PV-10 development.

We continue to have the data on PV-10 presented at conferences of scientific researchers. Since we last spoke, Dr. Sanjiv Agarwala presented data on PV-10 at the HemOnc Today Melanoma and Cutaneous Malignancies Annual Meeting in New York City. We also held a panel discussion with Doctors Agarwala and Merrick Ross at the Harvard Club. Detailed information is on our site, pvct.com.

At the same time, we are gaining traction among research scientists with our work on cancers of the liver. At the end of April, for instance, we announced that the European Society for

Medical Oncology, ESMO, has accepted the company's abstract Phase 1 study of PV-10 for chemo oblation of hepatocellular cancer and cancer metastatic to the liver for poster presentation at the ESMO 17th World Congress on Gastrointestinal Cancer in Barcelona, Spain. As with many conferences of this type, our abstract and presentation are currently under an embargo, and we will therefore provide greater information when ESMO lifts the embargo.

In addition to meeting with researchers, we also attend conferences of biotech investors. We attended the 12th Annual BIO Asia International Conference, co-hosted by the Biotechnology Industry Organization, BIO, BioCentury and the Japanese Bioindustry Association, which brings together the global biotechnology and pharmaceutical industry to explore licensing and research collaborations in the current Asia-Pacific business and policy environments.

Shortly thereafter, we were at the Growth Capital Expo in Las Vegas, which featured 500 of the top growth company executives, investors and finance specialists focused on the pre-IPO and public microcap market. In addition, we attended the ChinaBio Partnering Forum. It is a life science partnering event that was held in Shanghai. The event attracted biotech and pharma leaders from around the world along with hundreds of China-based developers of novel technologies for two days of productive partnering discussions.

In two weeks, we expect to be At Asia Biotech Invest 2015 Conference in Hong Kong, organized in partnership with AusBiotech. It is a biotech investment conference in Asia, gathering over 150 of the world's leading biotech investors seeking new investment opportunities.

The reason for all of these investor conferences is straightforward and simple. The primary financial objective of the company is to strategically monetize the core value of PV-10 and PH-10 through licensing and other transactions. These conferences are important in making contact with potential partners who can help us do this. In addition, we have been in contact with potential partner entities in India and Brazil, and they also prove useful in aiding us to quicken development of PV-10 for their local markets.

While we have a lot going on, we have more than sufficient financial resources and various financial and clinical development advisors to assist in the execution of our plans. Looking at our balance sheet, our cash and cash equivalents were approximately 14.2 million at March 31st compared with 17.4 million at December 31st. The decrease of approximately 3.2 million was due primarily to reduced cash received from warrant and stock option exercises and reduced net proceeds from the sale of our common stock in the quarter ended March 31st since we are seeking to minimize dilution to our existing stockholders where practicable by limiting the issuance of our equity securities.

By managing variable cash expenses due to minimal fixed costs, we believe our cash and cash equivalents on-hand at March 31st, in addition to the cash we expect to receive subsequent to the quarter ended March 31st from private placements of our securities and repayment of bonuses pursuant to the settlement of the Shareholder Derivative Lawsuit we entered into in 2014, it will be sufficient to meet our current and planned operating needs well into 2016 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities.

Given our current rate of expenditures and our ability to curtail or defer certain controllable expenditures, I reiterate what I said during our last call, we do not anticipate needing to raise additional capital to further develop PV-10 on our own to treat locally advanced cutaneous melanoma, cancers of the liver, recurrent breast cancer, bladder cancer, lung cancer, pancreatic cancer, and other indications because we plan to strategically monetize PV-10 through appropriate regional license transactions, license PH-10 for psoriasis and other related indications described as inflammatory dermatoses and also complete the spin-out of Pure-ific Corporation and the other non-core subsidiaries.

We believe that our financial position and corporate governance are such that we will continue to meet the relevant listing requirements of New York Stock Exchange MKT, although there can be no assurance that we will continue to be listed on New York Stock Exchange MKT.

We are more confident and bullish on our future potential than ever before. We're very excited to be able to further develop, both PV-10 and PH-10 and very much look forward to each week and month this quarter and next and continuing onwards until we realize our objectives as a company for benefit of patients and stockholders.

As a quick recap, we are now generating meaningful clinical data and randomized trials, have enhanced intellectual property protection globally as global supply chain manufacturer capability are generating robust clinical mechanism of action data for PV-10 and PH-10 and are working effectively and efficiently with our FDA and regulatory bodies worldwide.

I'm honored to now ask Eric to continue with the conference call and his prepared comments before we take questions from those on the call. Eric, please update us further.

Mr. Eric Wachter: Thanks, Pete. And as you noted in your remark, these are indeed exciting times for Provectus. But, before I discuss the status of our technical programs, I'd like review some very recent relevant developments on the regulatory front.

Last Wednesday, a 23-person advisory committee met all day here in Washington to weigh the pros and cons for approval of T-VEC another intralesional therapy under development for

melanoma. Such committees advise the FDA when there are technical questions about a license application such as flaws in study design or where the risk to benefit ratio is in doubt. While the agency is not bound to follow advice of the committee, it's rare that they do not.

After hearing the case for and against approval, including review of a very detailed analysis of the study design and data by agency statisticians, the committee voted 22 to 1 in favor of the following question. “Does T-VEC have an overall favorable benefit risk profile for the treatment of injectable regionally or distantly metastatic melanoma. In voting, please consider only whether the available evidence which support traditional approval and not accelerated approval.”

Despite the fact that our--that the pivotal Phase 3 study of T-VEC did not show a statistically significant survival benefit in its secondary endpoint of overall survival, the committee vote was resoundingly in favor of full approval. This means the committee believed that an agent with minimal side effects and that acts locally to reduce tumor burden is potentially a clinical benefit. And this is exactly the case we've been making for PV-10. Committee member Leisha Emens, M.D. of Johns Hopkins was quoted after vote, saying "The bulk of the data suggests there is clearly a favorable benefit risk ratio for this particular therapy. It represents an important new tool for patients."

And committee member, Brian Rini, M.D. of the Cleveland Clinic was quoted saying, "I thought the totality of evidence was there if there was a clinical benefit. And it seems to be beneficial even giving the evolving current landscape in melanoma."

We are grateful for the insight of the committee members and believe this vote is very good news for all intralesionally administered oncology drugs in development, including PV-10.

In advance of the meeting, the agency prepared an extremely comprehensive 79-page briefing document describing and analyzing all available clinical data on T-VEC. This included analysis of a number of shortcomings in study design, study execution, end-points and outcomes. Many of these shortcomings were familiar to us. And I was pleased to note that our Phase 3 study of single agent PV-10 is designed to avoid these shortcomings.

For instance, enrollment of a carefully defined patient population and use of a standard primary end-point should minimize questions about clinical meaningfulness of study results while adjudication of outcomes - that is disease progression - by an independent review committee serves to minimize potential discordance between sponsor reported results and those of the agency following their audit of the study.

A decision on approval is currently scheduled for the end of October. Since it is unknown whether T-VEC will be approved this year, and if approved, when it will become available, this does not directly impact our Phase 3 study. In fact, the decision of the committee supports the fundamental hypothesis underlying our study that local therapy can afford direct clinical benefit to melanoma patients in terms of eliminating lesions. If T-VEC ultimately comes available during our study, it is likely that we would amend the protocol to allow its use as a competitor.

Turning to status of the Phase 3 study of PV-10, we've opened our first site for enrollment of patients and are in the final steps of opening a number of others. As noted previously, these initial sites will be both in the U.S. and Australia. And as Pete noted, we're actively engaged in bringing additional sites, both in these countries and in a number of other strategically selected countries such as Brazil and China, into the program.

I don’t anticipate that company will provide site by site or patient by patient announcements of study milestones since this would be highly unusual for our industry, but we do anticipate providing periodic summaries of study status. And also as noted by Pete, when we open new centers, these will be shown on the NCI clinical trials registry website.

Our international efforts have indentified important prospective regional investigators, and we’re optimistic about the role these investigators can play in their respective regions to lead

further investigator engagement and patient approval. As I've noted previously, we expect enrollment to be approximately one-third from the U.S., one-third from Australia, and one-third from the rest of the world. If this balance ends up shifted more to non-U.S. and non-Australian patients, our efforts to access key investigators and their patients from different parts of the world should help assure that we have a diverse patient population similar to patients in the U.S.

And in addition to the progress on the combination therapy patent front that Pete mentioned, we've also made substantial progress towards commencement of our proposed clinical study of PV-10 in combination with immune checkpoint inhibition. We have identified the investigators who will lead this work, the agent to be used in conjunction with PV-10, the patient population and the dosing schedule for both agents along with the study end-points. To assess potential benefit of PV-10 for patients with advanced melanoma, this phase 1b/2 study will incorporate a modest sized single arm Phase 1b component with expedited safety and efficacy endpoints supporting expansion to a larger randomized Phase 2 component.

Endpoints for phase 1b are expected to comprise assessment of acute safety of the combination regimen and objective response rate at three to four months. For the Phase 2 portion, end points will be progression-free survival and overall survival.

Once the protocol addressing each of these areas is complete, we believe the pieces are in place to commence clinical work on this important second development path for PV-10 in melanoma. Since the checkpoint inhibitor we expect to use is licensed in the U.S., we can commence this study with or without the assistance of a partner.

Turning briefly to work on the PV-10 mechanism of action, as I noted on our March call, with enrollment now complete in the study of PV-10 at Moffitt Cancer Center, we continue to expect further data to be reported on this topic later this year or early in 2016. Since the preliminary findings reported last year from this study showed that the immunologic effects of tumor ablation with PV-10 are complementary to immune checkpoint inhibition, this study has been instrumental in devising our combination strategy for melanoma.

Enrollment is also continuing under our expanded access protocol for PV-10 with well over 100 melanoma patients having received PV-10 in the U.S. and Australia. Since this protocol excludes patients who are candidates for other PV-10 trials, we continue to expect to keep this protocol open, at least through the near-term.

Additionally, our Phase 1 study of PV-10 for liver tumors has continued to recruit patients at our clinical sites in the U.S., especially those with tumors metastatic to liver, and is providing

valuable insight into potential additional areas for development, since a range of cancers metastasized to liver.

We also expect this study to be instrumental in achieving our Pivot Asia for hepatocellular carcinoma, or HCC, and it is playing an important role in our partnering activities in China and elsewhere. As Pete noted, we will report initial data from the study at the ESMO Congress on Gastrointestinal Cancer in early July with additional data presentations possible during the second half of the year.

We've also begun the preparatory process for regulatory filing necessary to begin clinical work for this indication in China in support of an anticipated corporate partnership as well as to begin enrollment for the Phase 3 melanoma study.

With regard to HCC, planning and design of our proposed Phase 1b/2 study of PV-10 plus standard of care for HCC remains unchanged. Moving forward on the regulatory side now will allow us to move forward in Asia with or without the assistance of a corporate partner.

Switching briefly to PH-10, at the beginning of the year, we began enrollment in our Phase 2 mechanism of action trial of PH-10 for the treatment of mild to moderate psoriasis, and enrollment is continuing at our three study centers in the U.S. This work builds on prior testing

in Phase 1 and 2 studies in a total 226 patients. The mechanism study is probing possible changes in the immunologic, structural and hyperproliferative state of the skin in target plaques and evidence of cellular atypia following PH-10 application. Data from the study should avoid and should aid in further development of PH-10 with our objective to co-develop or license PH-10 with a dermatologic partner. We expect the study to enroll up to 30 patients with enrollment and data collection to be completed in December.

Finally, as Pete noted earlier, we've made considerable progress on the patent front, both this quarter and for the first half of the year. Starting in January, we received allowance of our novel synthesis patent application covering Rose Bengal and related analogs by the Chinese patent office following on the issuance of the parent case in the U.S. in September 2013. And this has been followed more recently by issuance of the patent for this invention by the Japanese patent office and a Notice of Allowance from the European patent office.

We've also recently announced progress on our joint patent application with Pfizer in combination of PV-10 with certain systemic immunotherapies, fundamental concepts underlying our planned combination studies for melanoma. We're receiving allowance in the U.S. for an initial set of claims for this invention. And in March, we received a U.S. patent covering PH-10.

So, as Pete and I noted earlier, these are indeed exciting times for Provectus. And with that, I'll turn the call back to Pete, who would like to make a few additional remarks.

Mr. Peter Culpepper: Thank you very much, Eric.

I would like to underscore primarily the point that we are now in the final phase of development as we have embarked and are recruiting in our Phase 3. It's very gratifying with all the people that working with, I--and particularly recognizing Eric and his cofounders Craig Dees and Tim Scott. The innovation that has been landmark in the industry, quite frankly, with this type of compound [unintelligible], and to be able do this work now in the final phase with so many opportunities before us and coming together is quite profound. So, these by far are the most exciting times of the company, and we are very much looking forward to literally these coming weeks and months this quarter, next quarter, literally this year.

So, let's please turn it over for questions to those who are on the call.

Operator: Thank you. At this time, we'll be conducting a question-and-answer session. If you would like to ask a question, please press star and one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, then two if you would like to remove your question from the queue. For participants using speaker

equipment, it may be necessary to pick up your handset before pressing the star keys. One moment please while we poll for questions.

Once again, to ask a question, please press star, then one at this time.

The first question today comes from Joseph Befo [sp] of ADUS. Please go ahead.

Mr. Joseph Befo: Hi, guys. I have two questions, one for Eric and one for Peter. Eric, with the 22 to 1 approval for T-VEC and the way the panel--specifically, I think I read that they said that the destruction of the tumor was clinically relevant. When we applied for breakthrough last year, was--correct me if I am wrong. Did the FDA agree with that statement then, or do you think that this decision by the panel would have affected our breakthrough application differently? And then, the second question is for Peter, which would be, Peter, can shareholders expect anything--any type of formal presentation out of ASCO this year?

Mr. Eric Wachter: Okay, Joe, I'll address your questions to me first. So, we really can't speculate on the direct implications of the T-VEC decision other than to say that, clearly, the regulatory environment is continuing to change what the agency identified as deficiencies in the T-VEC package, things that may come up as significant review questions when the agency

finalizes the review and potential decision to approve or not approve the BLA, the application for approval for that biologic may have relevance for us going forward.

That being said, the endpoints that were used for the T-VEC pivotal study were different than the ones that we used in the Phase 2 study. And more importantly, the T-VEC Phase 3 study, pivotal study was larger, so it had more patients than we had in the Phase 2 study. I would speculate that we can see that what was clearly very strong headwinds a year ago are maybe abating here in Washington, and that presumably bodes well for future success with PV-10.

Mr. Joseph Befo: Okay, thank you, Eric.

Mr. Peter Culpepper: And my comment, Joe, is that our corporate policy is to always communicate information once we have it for any scientific conference, publications. When anything is public or it comes to our attention it's public, we're going to communicate it in conjunction with our efforts to work with our stockholders and the market to make it very clear that we're moving forward, and we're very keen on showing the progress we have [unintelligible]. So that's the only thing I can comment on your question to me.

Mr. Joseph Befo: Okay, thanks, Peter.

Operator: As a reminder, if you would like to ask a question, please press star, then one on your touchtone phone.

We have another question from Ed Gallam [sp] of Provectus. Please go ahead.

Mr. Ed Gallam: Peter, Eric, good afternoon. I have two questions. One, if a Chinese--if we don't have a firm signed agreement with the Chinese either by May 16th or the very near future, would you consider pulling any future test sites out of China? That's one question. And then the second question is can you comment on the share price, exactly what you feel is necessary to elevate it at this point? As industrialists, we're being patient as possible.

Mr. Eric Wachter: Okay, Ed, I'll start--this is Eric. I will start by commenting on China. It is, of course, in our interest to have a relationship with a partner or partners in China sooner than later. However, that does not fundamentally affect our plans to move forward with clinical work in China, both on melanoma and in hepatocellular carcinoma. Particularly given the lengthy regulatory runway that's ahead for approval of clinical work in China, roughly 12 months, we're beginning that process, as was suggested to us by one of our Chinese investigators. We're getting in line, and that will provide some opportunity to consummate a deal, should there be a delay at this point in May.

Mr. Peter Culpepper: And then, on my part--Peter here, Ed. The--with regard to our efforts with partnerships, the partnership interest in China, India, Brazil and every part of the world that we are operating in is very strong and actually goes quite hand-in-hand with the generation of data and the commencing of study.

So, if anything, we're gonna see the partnership interest continue to increase as we continue to work in prospective--the various geographic areas. So, that's a general comment.

Mr. Ed Gallam: [Unintelligible.] Go ahead, Peter. I'm sorry.

Mr. Peter Culpepper: Just quick on the stock price, on the stock price, I think it's clear that the market wants validation in the stock, and that's where the potential partnerships are critical. Any sort of validation through big pharma or large scale biotech relationship is very helpful. Certainly, peer-reviewed literature is helpful, generating data as we move through the Phase 3, starting these other clinical studies, the liver data being communicated, there's a number of very strong positive catalysts that we would expect here even in this quarter and next quarter that are going to be very helpful for the stock price. Ultimately, we want to, as we said in my prepared comments, we want to monetize value in the stock through these different interim transactions, which is very typical in the industry. J&J with Pharmacyclics, before Pharmacyclics

take out, Medarex with Bristol, before Medarex was taken out by Bristol - it's very clear in the industry, a relationship, free--a larger transaction is very appropriate.

Mr. Eric Wachter: So, I'd like to make an additional comment on the topic of China. Of course, as I mentioned, it's a valuable corporate endeavor from the partnering and financial side, but from the clinical development side, it's a compelling story, both for our melanoma indication and for hepatocellular carcinoma. So, we're doing the appropriate thing right now, which is moving forward in a position that will allows us to get into China with or without a partner in China.

Mr. Ed Gallam: Okay, thank you, guys.

Operator: The next question comes from Philip Smith, [ph] a private inventor. Please go ahead.

Mr. Philip Smith: Hey, Peter, I missed part of the call. I apologize. But, two things stand out. At the end of year, we talked about having liver protocols into the FDA or Phase 2, and that didn't happen. And here we are well into Q2, and I know that last call you guys spent some time on that. And then, secondly, you've got the agreement of Sinopharm, which I think the date next was May 15th. Did I miss something on the call? What's happened to the liver

protocols? And the fact that you're now going on your own path in China, is--something must have changed there to make you guys go out on your own.

Mr. Eric Wachter: Let me jump in on this, Pete. So, the liver protocol, we have continued to mature through discussions with perspective investigators. And as we've developed a closer relationship with investigators throughout Asia, the concept for that study has been further developed. The consummation of that, since it is an Asia specific study, hinging principally on China, is somewhat longer horizon than we might have anticipated a year ago or even six months ago before we developed a full appreciation of the regulatory climate in China, which [unintelligible] the U.S. is a moving target.

That being said, again, I will reiterate my comments earlier that the--from the clinical development perspective, work in China is compelling. There are wonderful investigators in China with access to appropriate patients to allow clinical development to move swiftly and potentially to make an important difference in China. That being said, we think that that will help to provide a compelling argument in Pete's side of the process.

Mr. Peter Culpepper: Yeah, let me emphasize on this point Philip, and add if you're still listening, and for everybody on phone call, there is no doubt we'll enter into a partnership in China in my mind. It's very clear with our active meetings in China, let this be crystal clear, that

there's significant interest in a partnership. There' s no question about that at all. We meet with numerous entities. We have the Sinopharm MoU. And I want this to be very clear because there seems to be a little confusion on the phone call - there is no doubt that partners want to access and have relationship, a commercial relationship with PV-10. There's no doubt at all. The only question, like I said in my prepared remarks, is how to optimize the transaction for the benefit of stockholders, patients and PV-10 developments.

What Eric is saying is very similar to the 1b/2 combination topic. There's no doubt we'll have a partner interest in the use of PV-10 with the CHEK 1 [sp] inhibitor. That's why Pfizer did their patent in the first place. They saw the value of PV-10 in combination with the CHEK 1 inhibitors. There is commercial benefit to these discussions. The question is when does transaction becomes optimized, when does it make sense, upon which data, and what time?

And that's what--and I can appreciate Philip and Ed and others--that's what you're trying to figure out. What I'm telling you is that the serious people in the industry recognize that PV-10 is a drug product candidate that they want access to. It's a candidate that can work numerous other tumors, and it's just a question of timing now on when the deal makes the most sense. So--.

Mr. Philip Smith: --Let me ask one, I guess one clarification. I had understood, probably incorrectly, that the Phase 2 submission to the FDA would kick off the Sinopharm agreement. Now I'm not hearing much about the Phase 2 protocols to the FDA. I'm hearing more talk about what's going on in China, which I totally believe everything you said - great market, lots of people, good investigators, plenty of test subjects there. So, my question is what happened to the FDA protocols we were working on? That was gonna kick off the Sinopharm. At least that's the impression I got in December and again in the March call. Do you have something?

Mr. Peter Culpepper: Oh, no, yeah. I think you've put your finger on a topic that we have discussed in recent conference calls, and that's to say that the most important indication in China for potential partners is liver cancer relative--it's more important than say melanoma, just because of the size of the market. So, it makes sense--we've said in prior comments, it makes sense for the protocol to be finalized so that it can be generating data, not completing data, but just file so that it can begin to generate data with the partner involved in that process. So, yes, once that protocol is filed--and we're just talking about the 1b/2 liver protocol--that's a good way to think about what a partner is interested in.

This is not a black--a completely black and white scenario. We need to be careful and realize there's a lot of gray here. And what I mean by gray is partners are interested in what we're doing. It's a question of when. And we'll let the public know when it's appropriate. We'll let

the market know when it's appropriate. It's a question of when a partnership makes sense. But, a good way to think about it is, when protocols are filed so that data can then start to be generated that's meaningful to those partners, because the partners just want the data to get the drug approved, so that they can, of course, provide the drug to the patients for commercialization of the product and start--and that's what important about getting the protocols done so that data can be generated.

Mr. Eric Wachter: Yeah, so let me--.

Mr. Philip Smith: --Any update on when the protocols--I'm sorry.

Mr. Eric Wachter: Well, let me follow up on Pete's comment. So, as I mentioned in my introductory remarks, we are working to prepare the regulatory filings to allow that process to commence in China. It's very akin to filing an IND in U.S., but with the Chinese format for that particular document. We're working with a couple of CROs to get our investigational new drug documentation from the U.S. into the appropriate format so that that IND can be conveyed to the Chinese FDA in the appropriate structure.

Mr. Philip Smith: One clarification - are we still submitting to the FDA, because I thought that was the original focus back in December, to submit the liver protocols to the U.S. FDA, not to

the Chinese government, but the U.S.? Are we still focused on that, or has it now changed to submitting to the Chinese?

Mr. Peter Culpepper: It's really part of the same process in the sense of you've got to have the Chinese authorities have in effect what the FDA has, but then they--the Chinese authorities get the liver protocols just like the U.S. FDA gets the liver protocols. So, what Eric is saying is he's setting it up for the Chinese to have--to catch up, in effect, with--to what the FDA has already, and then the Chinese get the new protocol for liver as does our FDA. So--.

Mr. Philip Smith: --Okay--.

Mr. Peter Culpepper: --We're catching China up, and then we advance both in tandem.

Mr. Eric Wachter: That's a good way to put it, Pete.

Mr. Philip Smith: Okay, thank you.

Operator: As a reminder, if you'd like to ask a question, please press star, then one on your touchtone telephone.

Mr. Michael Porter: Ladies and gentlemen, I want to thank you all for listening to the call. As you know, we will be doing this quarterly, and we'll be looking forward to seeing you on the next quarter. Have a good day. Bye bye.

Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect your lines.