



## **COMPANY'S THIRD QUARTER 2017 - Frequently Asked Questions**

### ***1) HOW IMPORTANT ARE THE TRIALS/DATA TO THE COMPANY'S FUTURE?***

A) It is importance to generate the data which is 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.

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.

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 BioVex 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.

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.

B) 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.

## **2) DOES THE FDA APPROVE OF METASTATIC LIVER CANCER AS AN INDICATION?**

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.

I mentioned that we may look at some other targeted and focused areas of tumor type, such as 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.

## **3) WHAT IS YOUR RELATIONSHIP WITH THE TGA?**

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.

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. It focuses us more with Australia. It aligns our efforts more closely with TGA in Australia.

#### **4) WHY HASN'T THERE BEEN A LICENSING AGREEMENT?**

The data is 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 players in the industry. 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.

#### **5) WHAT HAS BEEN THE DIFFICULTY SECURITING A FINANCIAL PARTNER?**

A) 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.

B) We believe the rights offering 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.