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Transcript of Cleveland BioLabs

Fourth Quarter 2012 Earnings Call
March 14, 2013/10:00 a.m. EDT

Participants

Rachel Levine – Vice President – Investor Relations
Yakov Kogan, Ph.D., MBA – Chief Executive Officer
Andrei Gudkov, Ph.D., D. Sci. – Chief Scientific Office
C. Neil Lyons, CPA – Chief Financial Officer
Ann Hards, Ph.D. – EVP - Regulatory Affairs and Quality Assurance
Ed Martin, Ph.D. – Retired Rear Admiral – Martin, Blanck & Associates

Analysts

Matthew Kaplan – Ladenburg Thalmann
Mara Goldstein – Cantor Fitzgerald
Elemer Piros – Burrill Securities
Christian Glennie – Edison Investments
Robert Brous – Wunderlich Securities
Ken Boyd – The Way Investment Advisors

Presentation

Operator

Greetings, and welcome to the Cleveland BioLabs' Year-End 2012 Earnings call. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Rachel Levine, Vice President of Investor Relations, Cleveland BioLabs. Thank you, Ms. Levine. You may begin.

Rachel Levine – Vice President - Investor Relations

Thank you, and good morning, everyone. Welcome to Cleveland BioLabs' Fiscal 2012 Investor Conference call. Joining us today are Dr. Yakov Kogan, Chief Executive Officer; Dr. Andrei Gudkov, Chief Scientific Officer; Neil Lyons, Chief Financial Officer; Dr. Ann Hards, Executive Vice President of Regulatory Affairs and Quality Assurance; and Retired Rear Admiral, Dr. Ed Martin of Martin, Blanck & Associates.

Before we begin, I would like to remind all listeners that throughout this call, we may make statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that any such forward-looking statements are not guarantees of future performance or the

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successful execution of the Company's strategic plan and involve risks and uncertainties.

Additionally, I want to emphasize that some of the information discussed on the call, particularly our financial and cash outlook and forward-looking development plans, are based on information as of today, March 14, 2013, and that actual results may differ materially from the expectations and assumptions discussed today as a result of various factors including the risks outlined in our Company's filings with the Securities and Exchange Commission, including our most recently filed Forms 10-Q and 10-K.

The information provided on this conference call should be considered in light of such risks. CBLI does not assume any obligation to update information contained in this conference call.

Dr. Kogan will open this morning's call with a review of the year's accomplishments and hand the call to Mr. Lyons to discuss our financial outlook. Dr. Gudkov will provide a few more details on some of our development programs, and hand the call back to Dr. Kogan for closing remarks and questions.

At this time, I'd like to turn the call over to Dr. Yakov Kogan, CEO. Please go ahead.

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Thank you, Rachel, and thank you to everyone for joining us for our 2012 Investor Conference Call. I would like to start by reviewing our success in 2012.

We have brought Entolimod into the pivotal stage of its development and moved several of our oncology programs forward in the clinic. One of our most significant achievements in 2012 was completion of a pivotal GLP non-human primate study. This study demonstrated with a high degree of statistical significance that a single dose of Entolimod given 25 hours after exposure to a 70% lethal dose of total body irradiation, improved animal survival by nearly three times compared to the control group.

Over the course of 2012, we also secured several agreements and further guidance regarding the remaining development steps required to file a BLA for Entolimod as a radiation countermeasure with the FDA. Much of this progress is the result of seven meetings we had with the Division of Medical Imaging Products since the transfer of our IND.

Some of the key agreements and further guidance we have achieved include: One - the scope and design of a proposed pivotal animal efficacy program including the pivotal non-human primate study I just mentioned. Second, acknowledgement that specific cytokines do play an important role in Entolimod's mechanism of radioprotection, and as such, can be used as biomarkers for dose conversion analysis. And three, advice on the structure of the remaining clinical studies in healthy subjects.

The achievement of these clarifications regarding the requirements and study designs for remaining development tasks have yielded $2.3 million in additional and redirected

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awards from the Defense Threat Reduction Agency (or DTRA) and Chemical Biological Medical Systems (CBMS) of the Department of Defense and enabled us to submit a development proposal to BARDA to fund remaining activities.

Since then our team has been fully engaged in the execution of these funded studies, including a GLP compliant PK/PD study in non-irradiated non-human primates.

Simultaneously, the team is working on preparation for the next round of studies required for BLA submission. Our goal is to continue to work closely with the FDA on the remaining steps of our clinical protocols and position ourselves to file a BLA for Entolimod as a radiation countermeasure.

While this considerable effort proceeds, we have been moving several programs forward for oncology and other applications. Enrollment in the Entolimod advanced cancer trial at Roswell Park continues, and we are pleased to share that no serious adverse events have been reported to date.

Our next task is to move forward with additional efficacy clinical trials for Entolimod. These trials will be based on our growing body of knowledge regarding tumor types expressing the target for Entolimod. Andrei will share more details on this later in the call.

CBLB612 is progressing through formal pre-clinical and GMP manufacturing in order to file an IND later this year. Our plan is to conduct a trial in healthy subjects to evaluate safety and potential efficacy of CBLB612 as a stimulator of hematopoietic stem cell proliferation and mobilization. CBLB612's potency has been documented in multiple pre-clinical studies in mice and non-human primates, and our goal is to establish its potential as a complement to the current standard of care. In July, this program received a three year, approximately $4.6 million development contract from the Ministry of Industry and Trade of the Russian Federation.

Incuron has completed dosing of two cohorts in a Phase I study of the oral formulation of CBL0137. This study has been run with patients with advanced solid tumors which are resistant or refractory to standard of care treatment. An IND for the intravenous formulation of CBL0137 is on track for submission to the FDA this quarter.

We believe that CBL0137 is a primary target of interest for potential partners and are investigating ways to expedite generation of value driving clinical data. We have accumulated very promising pre-clinical data on various combination therapies and are optimizing a trial strategy in order to maximize its efficacy. This strategy will be driven in part by data provided by another diagnostic assay we have developed, which Andrei will describe shortly.

Dosing has been completed in the sixth cohort of the dose-escalation arm of Incuron's ongoing clinical trial of CBL0102. This trial is for refractory advanced cancer patients with liver metastases. Given the lack of dose limiting toxicity observed, progression into an additional higher dose cohort will take place before initiating the efficacy arm. This is, of course, positive news regarding the potential safety of the drug, but also means that the trial is not likely to report until early next year. In October, CBL0102

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was granted Orphan Drug status by the FDA for treatment of hepatocellular carcinoma, and a similar filing is being prepared for the European Union.

We are pleased to share that an investigator- initiated trial with CBL0102 is currently being prepared at the Case Comprehensive Cancer Center and the Cleveland Clinic. The protocol is for a Phase I/II study of Tarceva in combination with Quinacrine in patients with advanced non-small cell lung cancer. The prospects for this trial are quite exciting as CBL0102 is our precursor Curaxin compound and shares the same molecular target as CBL0137. Since this is an investigator-initiated trial, Incuron will be only supplying drug product, and will not bear other costs.

Panacela Labs continues pre-clinical work for its five pipeline candidates with a view towards potential IND filings. Xenomycins, a family of compounds in development as anti-infective agents, was awarded a three-year, approximately $4.8 million development contract from the Ministry of Industry and Trade of the Russian Federation.

Our achievements in 2012 clearly demonstrated our ability to work with the FDA and push multiple programs along the clinical path. Now our job is to complete Entolimod's development as a radiation countermeasure and bring our oncology assets to the next level.

At this time, I will turn the call over to Neil to review our financial outlook. I will return a bit later to share our goals for 2013.

C. Neil Lyons, CPA - Chief Financial Officer
Thank you, Yakov. Our audited financial statements for 2012 will be filed with the SEC on Monday, and I address your attention to our earnings release issued this morning.

First, let's start with our equity raise. In Q4 2012 we raised over $17 million gross, with net proceeds approximating $15.8 million to provide the financial resources to continue our clinical programs and keep our Entolimod defense team intact. As Yakov mentioned, the team is currently executing pivotal activities recently funded by DTRA and CBMS and is also working on critical ancillary activities for the next steps in Entolimod's development. This equity raise is one of the notable financial events easily discernible from our earnings release.

Another notable item is our position in cash and short term investment, which was $28.3 million consolidated and $18 million for CBLI standalone at December 31, 2012. You may recall that we had published a CBLI standalone pro forma cash balance at September 30th of $20 million, including the net proceeds from our equity raise in Q4.

On our Q3 call we confirmed net monthly cash burn guidance for CBLI standalone of $1.1 million to $1.2 million per month. Consequently, you might have expected the December 31, 2012 cash balance to be $17 million or less. The stronger cash position relates in part to receipt of some R&D tax credit refunds from the State of New York that were originally planned for Q1 2013 and other miscellaneous items.

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Since tax credit refunds were recognized earlier than planned, in Q4, the resulting favorable variance as compared to our guidance will be offset by an unfavorable variance as compared to our guidance in Q1. On balance, the March 31 cash position should align with our prior guidance.

These items and a deferred revenue item I'll discuss later cover the more interesting aspects of our Q4 financial results. The other financial results are more or less as expected, so I'll spare you the standard rundown of the numbers. If you have specific questions I'll be pleased to answer those in Q&A.

Now for the 2013 guidance. We continue our prior guidance, namely that our net monthly burn is in the $1.1 million to $1.2 million range, until we have an active contract with BARDA, if that is forthcoming. It is our expectation that either the award or the failure to award the BARDA contract will significantly change our financial forecast for the year. Since we cannot predict exactly when or if a BARDA contract will be awarded and since the BARDA contract is highly material to our financial projections, we will be providing only limited guidance for 2013 at this time. Once we have clarity on the BARDA contract we will refresh our financial guidance accordingly.

We can, however, provide some more details regarding our active contracts. First, I'd like to draw your attention to a new table we have included in the MD&A section of our 10-K. This table addresses all active contracts. It does not address contracts that have been completed. It identifies award amounts, funded values, revenue recognized to date, and most importantly funded revenue yet to recognize.

As Yakov mentioned earlier, we have been spending the DoD development funding we got from CBMS and DTRA in the Fall. Minor revenue was recognized in the fourth quarter, and we expect the remaining $2 million to be spent fairly consistently over the first three quarters of 2013.

Moving on to our Russian grants, note they're denominated in rubles and given exchange rate fluctuations the contract values in U.S. dollars are subject to change. As such, award amounts announced in our press releases are based on exchange rates at the time of the press release, award amounts evidenced in the table in our 10-K are based on award amounts in effect at year-end. Total award values differ. Accordingly, revenue is recorded in U.S. dollars based on average exchange rates in effect during the period. If you're not familiar with accounting for subsidiaries of foreign functional currencies you might find this a bit confusing.

Nevertheless, we received a grant for CBLB612 last July. We recognized approximately $0.9 million in the fourth quarter and expect $2 million of funded value to come in fairly evenly over 2013 and '14. Panacela received a grant for Xenomycins in November. We recognized approximately $0.9 million in the fourth quarter on that contract also, and expect $2.6 million to come in fairly evenly over 2013 and '14.

Incuron received a grant for Curaxin development in 2011. This contract has been fully paid at the end of last year. To date we have recognized $1.6 million as revenue and expect the remaining $3.3 million to come in fairly evenly during 2013; however, given that this contract has been fully paid, the $3.3 million of revenue still to be

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recognized is shown as deferred revenue on the Company's balance sheet. That is revenue next year will be recognized, but no more cash to come next year on this contract.

Incuron has received $11 million of funding out of a $17 million commitment from Bioprocess Capital Partners and expects to receive the remaining $6 million in its final investment traunch from Bioprocess in 2013. Panacela has received $9 million funding out of an approximately $26 million commitment from Rusnano over a four year period.

We have submitted other proposals pending with the Russian Federation similar to the two grants awarded this year and the Skolkovo grant awarded in 2011 for Curaxins. Our pending grants approximate $10 million. Of course, there can be no assurance that these proceeds and grants will be awarded.

One final comment on guidance, until we have better clarity on BARDA we anticipate that both our consolidated R&D costs and G&A costs will trend in line with 2012 in total amounts, with the main variance being a switch from R&D spending on Entolimod as a radiation countermeasure given that the 179 animal GLP/NHP study concluded mid-year 2012. That spending will be replaced by an increase in expenditures for Curaxin research through our Incuron subsidiary, which Andrei will highlight next.

Andrei Gudkov, Ph.D., D. Sci. - Chief Scientific Office
Thank you, Neil. As Yakov mentioned, we have made substantial progress with our oncology programs. Not only are Entolimod and two Curaxin drugs currently in clinical trials, but we have compiled a significant body of data regarding the expression of the molecular targets for these drugs.

Our companion diagnostic for Entolimod has enabled us to measure Toll-like Receptor 5 activity in 135 tumor samples we received from Roswell Park surgeons. Among the tumor samples we have tested, several have demonstrated a fairly high proportion of TLR5 expression such as bladder, breast, lung, melanoma, prostate, and colorectal. This information, combined with our knowledge regarding particular tissue types expressing TLR5, is guiding our Phase II trial strategy.

Our intention is to proceed in to a Phase II trial without waiting for the current trial to finish, and we are working with clinicians at Roswell Park to design one or two multi-center protocols, which could be submitted to the FDA in the coming months.

We are performing similar tests for the molecular target of Curaxin CBL0137, which is a chromatin remodeling protein complex named FACT. To date, we have analyzed levels of FACT expression in more than 850 tumor samples from patients at Roswell Park. Our research has concluded that FACT is not expressed in the majority of normal tissues, but is overexpressed in several types of cancers; and that this FACT expression is an indicator of poor prognosis similar to HER-2/neu in breast cancer. Pancreatic, colorectal, and lung are a few examples of the tumor types with high proportion of FACT positive ones, potentially making them good targets for trial.

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We're also using a FACT monitoring assay in Incuron's ongoing clinical trial with an oral formulation of CBL0137 to measure reduction of FACT levels in patients. Our hope is that we might provide our potential partners with a pharmacodynamic indicator of CBL0137's activity as this trial progresses and a new trial is opened with an i.v. formulation here in the U.S.

All in all, we are very excited by the insights these diagnostic assays are providing and believe they will add significant value as we move forward.

With that, I'll pass the call back to Yakov for concluding remarks.

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Thank you, Andrei. We are incredibly focused on increasing shareholder value through two primary objectives: One, securing the BARDA development contract for Entolimod as a radiation countermeasure and performing all final program requirements for a BLA filing; and second, achieving value driving efficacy data for our oncology pipeline.

In our view, the Entolimod radiation countermeasure program represents our nearest term opportunity to achieve revenues. We have made enormous headway with the FDA and are doing our best to translate this success into the government funding and support we need to get to a BLA and ultimately, procurement. We see last night's signature of the Pandemic and All Hazards Preparedness Reauthorization Act into law by President Obama as a strong signal that the government continues to believe in the importance of these countermeasures for our Nation's security.

I would like to reiterate that we are not just sitting around and waiting for BARDA's response to our most recent proposal so we can execute on the bulk of the remaining activities for the BLA. The team has been actively executing the work plan under our DTRA and CBMS contracts and doing whatever background preparation they can to move forward with our studies as soon as we have the funding to do so.

At the same time, we are strategically advancing our oncology pipeline, which we think contains compelling first-in-class assets and are evaluating every business development and alternative funding opportunity along the way.

As always, we thank you for your ongoing support. We will now open the call for questions. Operator, please begin the Q&A.

Operator
Our first question is from Mr. Matthew Kaplan of Ladenburg Thalmann.

<Q>
Hi; good morning, guys. Thank you for the additional detail. Could you give us a sense a little bit in terms of—I know it's hard to predict; it's out of your control—in terms of the BARDA contract when do you expect in terms of timing to hear back and be able to say that you're able to start recognizing—I guess you're requesting $50 million. I guess we were expecting perhaps in April—when do you think you'll be able to have visibility of that?

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Yakov Kogan, Ph.D., MBA - Chief Executive Officer
I will ask Neil Lyons and Ed Martin to answer this question.

C. Neil Lyons, CPA - Chief Financial Officer
Our policy on discussing further about the BARDA contract is pretty much no comment. The rules out there are fairly clear; 180 days is what BARDA publishes to review all proposals submitted, and we're in that process. We will comment if we get an unfavorable review as soon as we get an unfavorable review, but if the discussions continue and contract negotiations ensue, we will not comment until we have a signed contract to announce.

<Q>
Okay. Fair enough, but is it reasonable to assume kind of first half of this year that you could have some resolution?

C. Neil Lyons, CPA - Chief Financial Officer
We're just not commenting.

<Q>
Okay. Fair enough. In terms of the Russian subsidiaries (Incuron and Panacela) can you give us a sense in terms of just full year 2013 gross revenues and expenses for those on a fully consolidated basis? How is that going to impact CBLI and Cleveland on a fully consolidated basis?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Neil, could you please answer this question?

C. Neil Lyons, CPA - Chief Financial Officer
Yes. Like I said in the opening remarks the amount of G&A and R&D spending is in line with what we reported for 2012. The revenue rundown of the existing contracts I went through on how much revenue we can expect in 2013 and '14 from the existing contracts. The net consolidated burn is in the range of $2.3 million a month for the consolidated group, and then there's the potential that we may get a $6 million capital infusion from Bioprocess Capital Partners, as I mentioned, for Incuron.

<Q>
Okay. So kind of the way to think about it is net $2.3 million per month burn in total?

C. Neil Lyons, CPA - Chief Financial Officer
Yes.

<Q>
Okay. Great. Thank you very much and congrats on the progress.

Operator
Our next question is from Ms. Mara Goldstein with Cantor Fitzgerald.

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<Q>
Hello. Thanks very much for taking the question. I just wanted to make sure I understood you correctly. I thought I heard you say that Entolimod in oncology will proceed into Phase II while the Phase I is still ongoing. So I'm wondering if you then have achieved the maximum tolerated dose and what that would be, and if you could just discuss that a little further? Thanks.

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Thank you for your question. So, as of today, the maximum tolerable dose in oncology patients wasn't established. We are continuing dose escalation in the ongoing trial. At the same time, we are designing the efficacy study which would hopefully prove efficacy of Entolimod in cancers and tissues which we believe express TLR5, the target. We are discussing multiple clinical designs with clinical thought leaders, which would answer the efficacy question. So, we do not want to focus on a Phase II study only, but we are still working on the exact design.

<Q>
Okay. Thanks for the clarification.

Operator
The next question comes from Elemer Piros of Burrill Securities.

<Q>
Hi. Yakov, I may have not heard this correctly, but did you say that CBLB612 or that you might file an IND for CBLB612 this quarter, or was I confusing it with some other program?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Thank you, Elemer. To clarify my statement, it was this year.

<Q>
This year, okay. What is the remaining work that you need to undertake with CBLB612 before filing the IND?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
We have to complete toxicology studies and put an IND together.

<Q>
Okay. And Neil, how would you define an unfavorable review? What would that look like? They reject the whole thing, or they have some problems or issues that they would like you to readdress? What is unfavorable?

C. Neil Lyons, CPA - Chief Financial Officer
Well, being the finance guy, unfavorable is no money. Now there can be a variety of negotiations and questions and follow ups and we can't predict that. We can't predict the timing that it will take to go through, but in the end we, of course, want the funding to continue the development of Entolimod.

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<Q>
So, in response to your development plan that you submitted some five months ago, you expect them to say how much money would be awarded for finishing development of Entolimod?

C. Neil Lyons, CPA - Chief Financial Officer
Yes. We expect them to respond to the proposal, and we have said the proposal is in the range of $50 million. There is a variety of options in that total package that they can select. They can select when they want to fund discrete work efforts versus other work efforts, so it all depends on how BARDA concludes their development decisions and negotiations with the company. Of course, BARDA can always say they're not interested, but it's just impossible to make any predictions at this point.

<Q>
Sure. And have you buttoned down all the issues, all the remaining questions with the FDA with regards to the remaining work for Entolimod?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
I will ask Dr. Ann Hards of Regulatory Affairs to answer your question.

Ann Hards, Ph.D. – EVP - Regulatory Affairs and Quality Assurance
We have tied down the pre-clinical programs; the non-human primate pre-clinical program is completely agreed. The FDA did agree with us on a proposal that we had for the mouse program last year; although, we have decided that we would like to tweak one of those studies, the design of it slightly, so we will be going back to them to make sure that they're in agreement with the tweak.

The main point that still needs to be negotiated - FDA did agree last year or they provided us a review last year of a proposed clinical program design, and among other things in their review was comments that they would like to see the study that we had proposed broken into two parts. One being a PK/PD part and one being a safety part. I think we discussed that on the last call, and we are close, but have not yet gone down to discuss the design of the revisions that they requested in the clinical program.

Essentially, there are three parts that remain for agreement. One is the tweak on the mouse study design, and then we need to discuss the clinical program that has been split into two.

<Q>
So you mean two and three is the PK/PD portion, and the then the third piece is the safety component.

Ann Hards, Ph.D. – EVP - Regulatory Affairs and Quality Assurance
Correct.

<Q>
When do you hope to meet with the FDA or how long would you need to actually be able to set a meeting from your end?

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Ann Hards, Ph.D. – EVP - Regulatory Affairs and Quality Assurance
Well, I can easily tell you that a meeting requires 75 days to set it up, but we are still doing some additional data analyses before we finalize what we're proposing, and I cannot comment yet on when we're actually going to request a meeting.

<Q>
And do you think that BARDA would like to look at a full agreement with the FDA before committing funding?

Ann Hards, Ph.D. – EVP - Regulatory Affairs and Quality Assurance
I can't comment on that.

<Q>
Okay.

Ed Martin, Ph.D. – Retired Rear Admiral – Martin Blanck & Associates
This is Dr. Martin. Essentially, in the BARDA review process they have had and continue to have access to all the discussion and formal communications between Cleveland BioLabs and the FDA. They clearly understand, because they've got many other drugs in development across a spectrum of different biodefense hazards that the FDA process is iterative and continues on. I don't think they necessarily anticipate finality. Indeed, the proposals we've submitted to BARDA are to help develop and carry the process even further through with the FDA.

<Q>
Thank you, Dr. Martin, for that. That was all for me. Thanks.

Operator
Our next question is from Christian Glennie with Edison Investments.

<Q>
Just quickly on just following up on the potential BLA filing you previously guided to Q4 of 2014. Is that still your current estimate?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Our guidance is dependent on the timing of the BARDA award.

<Q>
Okay. But essentially there is nothing changed. I mean it will still be Q4 '14 or are you sort of slightly changing?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
If the BARDA funding will take place in the second quarter this year, our guidance will stand.

<Q>
Okay. Thanks. And then just following up on the proposed Phase II oncology for Entolimod, can you give any more sort of insight in to the potential targets? Is it likely

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to be one target or maybe multiple and sort of rough timing of when that might get underway?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
I would like to ask our chief scientific officer, Andrei Gudkov to answer, this question.

Andrei Gudkov, Ph.D., D. Sci. - Chief Scientific Office
Well, as I mentioned in my presentation, we are working closely with lead physicians at Roswell Park and several leading oncologists in the country to find the optimal way how to translate the current knowledge about CBLB502 (Entolimod) and the information we generated during the trial into the most optimally designed Phase II trials. Although I cannot promise it 100% right now, but most likely we'll start one or two trials in the near future; each of which will be focused on a specific indication. The consideration of the choice of cancer will take into account several things; one of which is the expression of the target in the cancer itself and in the target organ; second, the availability of patients and our ability to reach quick endpoints so that we can have some conclusive data within a short rather than long period of time; and three, how quickly we can do the trial provided the availability of patients with those particular diseases in the centers which we are planning to include.

What are these cancers going to be? I gave a list of those candidates we are considering, among which are for example, bladder cancer; however, as I said, final determination will be done shortly, but we are not ready to say that for sure now.

<Q>
Okay. Thank you. One quick follow-up on that if I may, is this proposing that Cleveland undertakes these studies, or are there potential partners coming in to help?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
These studies would be done by Cleveland BioLabs.

<Q>
Okay. Thank you.

Operator
The next question comes from Robert Brous of Wunderlich Securities.

<Q>
Thanks for taking my question. Yakov, in follow up to your prepared remarks, what formal plans does management and the Board have in place to protect shareholder value in the event you receive an unfavorable answer from BARDA?

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
We have a contingency plan in place, but at this time I do not want to comment on this.

<Q>
And that plan can be enacted rather quickly or?

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Yakov Kogan, Ph.D., MBA - Chief Executive Officer
Yes.

<Q>
Okay. And then just a follow-up on Andrei, how many more samples are you guys going to need to take to build up that body of knowledge or to assay for TLR5? You mentioned bladder, are there going to be a lot more samples that you're going to want to assay before you start to decide which avenue to go down or which studies?

Andrei Gudkov, Ph.D., D. Sci. - Chief Scientific Office
Actually, at this point we are not depending on the number of samples because we have already substantial amount of evidence which allows us to get all the necessary arguments based on the expression of the target. We are also waiting for the results or analyzing the data from already finished experiments with some pre-clinical efficacy modeling of specific cancer types, and the type of delivery of CBLB502 (Entolimod) for those particular cases. There will be no delay based on the number of additional samples analyzed. Actually, there will be no delay at all. I would say that we are working so actively on designing this new trial that we have all the necessary information in place to make the decision. We just need to compare expert opinions and prioritize the protocols we have in mind.

<Q>
Thank you for taking my questions; I appreciate it.

Operator
The next question comes from Ken Boyd with The Way Investment Advisors.

<Q>
Thank you all for taking my call and congratulations on the progress so far. My question I guess relates to Dr. Martin if you could elaborate with the signing of PAHPA and the enactment yesterday. What would the anticipation of an EUA and progress going toward the EUA look like going forward? What solicitations under BAAs for procurement might look like going forward, and procurements from not only BARDA's predisposed need of 2.7 million doses what it may look like going forward optimistically? How is that?

Ed Martin, Ph.D. – Retired Rear Admiral – Martin Blanck & Associates
I'm never optimistic about the government, but essentially the critical importance of PAHPA being signed is it's a very significant reauthorization of the entire piece of legislation that runs this entire research effort across a number of fields. It was bipartisan, the House and the Senate came to agreement through negotiations, and the President signed it. In Washington today, that's huge.

Now what it did, is allow very effectively not only a continuation of all the processes and procedures that are currently underway and have been underway, but it is significant because Congress felt it was important enough to get this Act passed while they're obviously busy with a lot of other things. Now in regard to projecting, I think the whole point of it is now we know the process is going to be the one that we

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anticipated, EUAs are going to be continued to develop the same way they have been.

Just as a note and I'll close with this, the EUAs are developed by the government, either the Center for Disease Control or BARDA, and then worked through an intergovernmental system ending up with the FDA and ultimately the Secretary of Health and Human Services. The good news is neither the issue around the continuing resolution or the sequester is affecting us at all because the special reserve fund is a key part of PAHPA and that's where the largest or an overwhelming amount of the money comes for all these kinds of developmental programs.

<Q>
Thank you. What do you anticipate—usually the government in March and April is putting out the solicitations to get under the fiscal budget year, obviously ending in September. Is it possible to reflect on when we anticipate possible solicitations may be put out for procurement?

Ed Martin, Ph.D. – Retired Rear Admiral – Martin Blanck & Associates
The way the—it's true, actually it's more like April through about June, and this year that may even be delayed for what they call RFQs or they call RFPs. Those are very specific requirements. Essentially BARDA operates under a BAA, which they publish every couple years and it is a very wide, often broad ranging mechanism by which interested parties can apply. We don't need to have RFPs come out for our activities with BARDA.

<Q>
Okay. Thank you.

Operator
Mr. Kogan, there are no further questions at this time. I would like to turn the floor back over to you for closing comments.

Yakov Kogan, Ph.D., MBA - Chief Executive Officer
I just want to thank everyone for joining us today.

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