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Transcript of
Cleveland BioLabs, Inc.
Fourth Quarter and Fiscal 2014 Investor Update Call
February 24, 2015

Participants

Rachel Levine - Vice President of Investor Relations
Dr. Yakov Kogan - Chief Executive Officer
Neil Lyons - Executive Vice President, Chief Financial Officer
Dr. Langdon Miller - Strategic Medical Advisor

Investors

Charles Hylkema - Private Investor

Presentation

Operator
Greetings, and welcome to the Cleveland BioLabs' Fourth Quarter and Fiscal 2014 Investor Update call. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. (Operator instructions.) As a reminder, this conference is being recorded.

I would now like to turn the conference over to Rachel Levine, Vice President of Investor Relations. Thank you. Please go ahead.

Rachel Levine - Vice President of Investor Relations
Thank you, and good morning, everyone. Welcome to our Fourth Quarter and Fiscal 2014 call. Joining us today are Dr. Yakov Kogan, Chief Executive Officer; Mr. Neil Lyons, EVP and Chief Financial Officer, and Dr. Langdon Miller, our Strategic Medical Advisor.

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 performer or the successful execution of the company's strategy plan, and involve risks and uncertainties. Additionally, I want to emphasize that some of the information discussed on this call, particularly our financial and cash outlook and our forward-looking development plans, are based on information as of today, February 24, 2015 and that actual results may differ materially from the expectations and assumptions discussed today as a result of various factors.

Such risks, uncertainties and factors include the risks outlined in our company's filings with the Securities and Exchange Commission, including our most recently filed 10-K and 10-Q. 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 by sharing highlights of the quarter and pass the call to Dr. Langdon Miller to review detailed progress with our clinical oncology programs. Mr. Lyons will then provide financial results for

the period, update the financial outlook, and hand the call back to Dr. Kogan for closing remarks. We will then host a Q&A session.

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

Dr. Yakov Kogan - Chief Executive Officer
Thank you, Rachel, and thank you to everyone for joining us this morning. Before we start reviewing the progress with our development pipeline, I want to say that we are 100% committed to making CBLI a success.

We have made it through some tough times over the past few years and have always emerged more focused and determined to thrive. More importantly, our science has continued to prove itself.

Regarding recent corporate developments, we executed a reverse stock split in late January to maintain our Nasdaq listing. We also recently announced a financing, which extends our cash runway and gives us the opportunity to hit a few important milestones, including filing of a pre-EUA submission for entolimod's biodefense indication and the formal release of clinical results for the completed entolimod oncology trial.

Neil will address the specifics of our financial outlook later in this call, but I want to emphasize our belief that 2015 will be a critical year for CBLI in terms of our ability to move entolimod's biodefense indication to potential commercialization and deliver clinical data supporting our novel oncology programs.

With that in mind, I will review the advances we have made in the last few months.

Our top priority is the preparation of a pre-Emergency Use Authorization or pre-EUA submission for entolimod's biodefense indication. As a reminder, EUA is the vehicle through which the US government is able to administer unlicensed rescue therapies in emergency situations. If the FDA grants pre-EUA status, we believe purchases of entolimod could be made for stockpiling in the event of a disaster, although actual use of the stockpiled drug would occur only in a declared emergency situation. The dossier is coming together nicely and we are on track to file within the first half of 2015.

Since receiving the FDA's agreement that we had sufficient data to file, we have been in discussions with several US government agencies to solicit their input to our pre-EUA package. We have also been looking for additional development funding to get to full licensure and laying the foundation for potential procurement. These discussions are ongoing, and we recently announced receipt of notice from the Department of Defense that our proposal to support ongoing development of entolimod was recommend for funding.

Our proposal is to conduct several pivotal animal efficacy studies required by the FDA for submission of a Biologics License Application, or BLA. The negotiations for funding of this proposal may last several months and funding is subject to these negotiations being successful and to availability of funds. Let me be clear that the activities covered by this proposal are not needed to file the pre-EUA for entolimod. Rather they are intended to support full licensure.

We believe that achievement of pre-EUA status in the United States would facilitate entolimod's commercialization in the United States, as well as partnerships and boost interest in this program from foreign governments.

We have already started reaching out to select foreign countries in order to educate and update them on entolimod's advanced development status and our progress with the FDA. We will keep everyone apprised of any major developments in this area, as appropriate.

Now, let's turn to oncology where we have also made significant headway. I will ask Langdon Miller, our Strategic Medical advisor, to review the status of these programs and share his perspective on next steps. I will return in a bit for closing remarks.

Dr. Langdon Miller - Strategic Medical Advisor
Thank you, Yakov. Let's begin with entolimod.

In September, a Phase I study in patients with advanced cancer at Roswell Park Cancer Center was concluded. The formal results of this study were submitted for presentation at the annual meeting of the American Society of Clinical Oncology or ASCO, which will be held from May 29th to June 2nd in Chicago, Illinois. ASCO is the preeminent oncology conference for both clinicians and industry, and major new developments in the field are often showcased there.

The study was designed to evaluate the safety, pharmacokinetics and immune activation profiles of entolimod. Assessments for evidence of anti-cancer activity were also performed. Preliminary evaluations of the study indicate that the tolerability profile in patients with advance cancer was similar to that observed in two previously conducted studies in 150 healthy volunteers. This is significant for future clinical directions, but also adds to the safety database for our pre-EUA dossier.

Initial assessments of immunological response were consistent with activation of toll-like receptor 5, entolimod's target. Early analyses also indicate that stable disease was observed in several patients with heavily pre-treated cancers. These observations confirm our preclinical findings and strongly support the hypothesis that entolimod has potential as an immunotherapeutic agent.

In order to expand upon clinical observations made at the higher dose levels in the Roswell Park study and to gather further statistics on immune response to administrations of entolimod, we have initiated a follow-on study in Russia. We currently estimate that this second trial will conclude dosing sometime in late-spring and report later in the year. This study is supported through a matching funds development contract with the Ministry of Industry and Trade of the Russian Federation or MPT.

Our goal with these studies is to gather sufficient clinical data on specific innate immune response to administrations of entolimod to seek development partnerships with academic collaborators and other companies developing checkpoint inhibitors or vaccines that could potentially benefit from an entolimod-mediated enhancement of the immune response.

Now, let's turn to Curaxin CBL0137. Incuron's two ongoing clinical studies evaluating oral and intravenous administrations of Curaxin CBL0137 in patients with advanced solid tumors are recruiting patients to the ninth and seventh dose-escalation cohorts, respectively. To date, no dose-limiting toxicities have been observed with either oral or intravenous administration through the highest 137 dose levels tested. A formal interim analysis of the 19 patients enrolled in the first six cohorts of the ongoing oral administration study indicated that the drug was well-tolerated at all investigated dose levels. The observation of drug exposure in plasma documented high oral bioavailability, typically estimated to be greater than or equal to 50%.

Heavily pretreated patients from both studies with advanced cancers of the esophagus, colon, breast, cervix, and prostate have had stable disease for periods ranging from four to six months. This is an encouraging sign, considering the advanced disease in these patients, as well as the fact that we have yet to reach doses that had an effect on tumor response in preclinical studies. Peripheral blood mononuclear cells or PBMCs from evaluable

blood samples have also shown pharmacodynamic effects consistent with the expected mechanism of action of CBL0137.

Dose escalation in both studies will continue. In addition, based on preclinical results in hematological cancer models, Incuron is planning to initiate a multicenter study of CBL0137 in patients with hematological malignancies in 2015. We had a successful meeting with the FDA in December, during which we presented a staged-study design in patients with relapse cancers that will enable simultaneous evaluation of drug effects in several hematologic indications.

For my final oncology update, the Phase 1 study of CBLB612 in healthy subjects is ongoing. The endpoints of this study include establishing a maximum tolerated dose and characterizing CBLB612's ability to mobilize bone marrow stem cells into the blood circulation. Preclinical studies have shown that the efficacy of CBLB612 exceeds that of G-CSF, the market-leading drug used stimulating bone marrow to produce white blood cells. This study is also supported by a matching fund grant from MPT.

At this point, I will hand the call over to Neil to review the financials.

Neil Lyons - Executive Vice President, Chief Financial Officer
Thank you, Langdon. For the quarter ended December 31, 2014, our total revenues decreased by $2.5 million to $1.4 million compared to the fourth quarter of 2013. For the year, they decreased by $4.8 million to $3.7 million compared to 2013. These decreases related to the completion of development contracts with DoD for entolimod's biodefense indication, and variances in the levels of development activity under our contracts with the Russian Federation.

Research and development expenses for Q4 of 2014 decreased by $1.8 million to $2.8 million compared to Q4 of 2013, and for the year, they decreased by $9.9 million to $9.7 million compared to 2013. These decreases were primarily due to the completion of third party contracts for several compounds in line with and largely in support of the contracted development work discussed previously, as well as reduced compensation costs in line with our reduced workforce between the periods.

For Q4 2014, general and administrative expenses decreased by $230,000 to $2 million compared to Q4 of 2013, and for the year, they decreased by $3.6 million to $8.5 million compared to 2013. For the year, $2.2 million of these decreases were due to reductions in personnel and consultants.

I'd like to take a moment to highlight a few special items in our financial statements that pertain to our deconsolidation of Incuron and recording of our investment in Incuron through the equity method. We have recorded a non-cash gain of $14.2 million due to Incuron's deconsolidation. That gain is comprised of two parts - the recognition of the fair value of our ownership interest in Incuron and the elimination of Incuron's accumulated deficit from our consolidation. $4.6 million was recorded as the fair value of our ownership interest in Incuron, as determined by an independent valuation expert and adjusted for uncertainties of the Russian capital market.

Starting then with the $4.6 million asset as of the date of deconsolidation, which was November 25, 2014, we reduced the value of that asset by approximately $300,000 through the recognition of our equity in Incuron's loss for the post-deconsolidation period of November 25, through December 31, 2014. The deconsolidation gain of $14.2 million resulted in a significant increase in net income for both the fourth quarter and fiscal 2014. Income for each period increased to $11.3 million, or $3.95 per share and $1.6 million, or $0.60 per share, respectively.

Excluding the gain on the deconsolidation of Incuron and on a non-GAAP basis, net loss per share for the fourth quarter was $1.02 and net loss per share for fiscal 2014 was $4.66. Please reference the non-GAAP

reconciliation of loss per share to the comparable GAAP measure as set forth on the bottom of our Statement of Operations included in our earnings release this morning.

Let us now review our existing liquidity and capital resources. At December 31, 2014, CBLI had cash, cash equivalents and short-term investments of $3.1 million, $500,000 of which was restricted for the use of Panacela. In addition, on February 6, 2015, we closed an equity transaction with two institutional investors, pursuant to which we received net proceeds of approximately $3.7 million, bringing our pro forma December cash balance to $6.8 million.

At December 31, 2014, we had $3.1 million in funded contract backlog and $2.1 million in unfunded contract backlog, all with contracts from the Russian Federation.

Now, moving onto historical cash burn and cash guidance. Please reference the table of non-GAAP cash burn measures included in our earnings release this morning for a reconciliation of these non-GAAP measures to the comparable GAAP measures.

CBLI's stand-alone monthly cash burn for the fourth quarter, that is without Incuron and Panacela, was $770,000 compared to our guidance of $1.1 to $1.2 million on average per month and down from $957,000 for Q4 2013 and down from $923,000 for all of 2014.

We expect Q1 2015 average monthly cash burn to be higher than Q4 2014 due to the additional expenses of our equity raise, the professional services that support the annual audit, proxy and shareholders' meeting, and our outsourced pre-EUA activities. After Q1, we expect our monthly cash burn to decline with the falloff in these related activities. With that, we anticipate monthly cash burn to be approximately $1.1 million on average through June, and we believe CBLI's stand-alone cash resources will last into June 2015.

CBLI's consolidated monthly cash burn was $1.3 million for both Q4 and all of 2014, which is in line with our guidance of $1.2 to $1.4 million. Going forward, we will no longer include Incuron's activities and will therefore reduce our guidance to an average monthly consolidated burn of approximately $1.2 million.

As Yakov noted, we are nearing potential commercialization of entolimod, and our oncology products are starting to produce clinical results. We are evaluating a variety of options to continue to fund our operations, including the sale or licensure of any or all compounds, the sale of interest in our subsidiaries or joint ventures, various partnership structures, foreign sales of entolimod, as well as the sale of additional equity. Our goal between now and the end of June is to submit the pre-EUA filing and formally report the entolimod oncology study results at or around the ASCO meeting.

Before I hand the call back to Yakov, I want to review some of the special items to be covered in the upcoming proxy for our annual shareholders' meeting, which is scheduled to take place on April 14 at our headquarters in Buffalo. One of the main topics for this proxy is shareholder approval of our recent financing, in accordance with the NASDAQ 20% rule (Listing Rule 5635(d)), which requires shareholder approval of a transaction other than a public offering involving the sale of securities equal to 20% or more of the common stock outstanding at a discount to market price. Approval of this item is very important to the company's ability to continue operations.

Other special items include changes to our employee incentive and employee stock purchase plans, which are designed to attract and retain talent. These are important votes, particularly with regard to the approval of our recent financing, and we encourage all of our shareholders to vote.

In addition, one of our largest shareholders, Dr. Mogutov, has notified us that he proposes to nominate eight directors for election to our board, including himself, all of whom are Russian citizens, and that he intends to bring

two proposals at the annual meeting relating to the ability of shareholders to call special meetings and director compensation. Our board does not recommend voting for his nominations or his proposals other than Elena Kasimova, who was also nominated by our board, as our board does not believe his proposals to be in the best long-term interest of the company. His nominations and proposals may be withdrawn before the annual meeting. If not, you may receive a separate proxy card from Dr. Mogutov on these items. If you do, we advise that you not sign or return any such proxy card.

That concludes my comments. Yakov, please continue.

Dr. Yakov Kogan - Chief Executive Officer
Thank you, Neil. Before we open the call for questions, I want to reiterate our commitment to realizing the value of our pipeline of first in class therapeutics. I hope recent developments have demonstrated that there is more to CBLI than biodefense. While commercializing entolimod's biodefense indication is both a high priority and a major value driver, we believe that our oncology drugs present an equally exciting opportunity and hope that future clinical data releases will continue to validate our approaches and drive value creation.

We will now open the call to questions. Operator, please begin the Q&A.

Operator
Certainly. (Operator instructions.) One moment while we poll for questions. Our first question comes from the line Charles Hylkema, a private investor. Please proceed with your question.

<Q>: Yes. My question, I think, is for Neil. I'm looking at the press release with the financial summary and the announcement of this meeting. One thing that's included in the press release is the fact that there is 2.3 million shares of common stock reserved for issuance pursuant to outstanding warrants. I'm trying to cross reference that to the recent 8-K filing regarding the stock issuance. Does that 2.3 million shares include about 1.4 million shares discussed in the 8-K at $3.64?

Neil Lyons - Executive Vice President, Chief Financial Officer
You're exactly right. It does include that 1.4 million shares at $3.64.

<Q>: Okay. So, under the 8-K filing, and if my interpretation is correct, the total potential issuance of shares is about 2.8 million between now and the end of the six-year period that these warrants are available for issuance or exercise. Would that be correct?

Neil Lyons - Executive Vice President, Chief Financial Officer
Just to clarify, the deal we just did was for a total of 2.8 million shares. We issued some common shares directly at the time, we have two other securities, a prefunded warrant and a convertible preferred stock, when fully converted—when both are fully converted, along the common shares we issued, we would have issued 1.4 million shares in regards to that transaction and there was 100% warrant coverage for another 1.4 million shares, which would be 2.8 million in total.

<Q>: Okay, 2.8 million, okay. Prior to that, there was 2.9 million outstanding.

Neil Lyons - Executive Vice President, Chief Financial Officer
Yes.

<Q>: Prior to any of those transactions there was 2.9, but it has the potential to go up to, if my arithmetic is correct, about 5.7 million. Okay. Thank you.

Operator

Okay. Thank you. Ladies and gentlemen to access a replay of this call, please dial 877-660-6853 and enter access ID 13601010. As a reminder, this call will be archived on the company's website. This concludes today's teleconference. You may disconnect your lines at this time and thank you for your participation.