CEO CFO

Cleveland BioLabs, Inc.
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The Most Powerful Name In Corporate News and Information

Supported By Potential Customers The Department of Defense And The Department of Health and Human Services, Cleveland BioLabs Is Well Positioned To Develop And Bring To Market Its CBLB502 Drug To Protect The Body Against Radiation

Healthcare
Biotechnology
(CBLI-NASDAQ)

Dr. Michael Fonstein Ph.D.
Co-Founder, President and CEO

BIO:
Dr. Fonstein has served as the company's Chief Executive Officer and President since the company's inception in June 2003. He served as Director of the DNA Sequencing Center at the University of Chicago from its creation in 1994 to 1998, when he left to found Integrated Genomics, Inc. located in Chicago, Illinois. He served as CEO and President of Integrated Genomics from 1997 to 2003. Dr. Fonstein has won several business awards, including the Incubator of the Year Award from the Association of University Related Research Parks. He was also the winner of a coveted KPMG Illinois High Tech Award.

Company Profile:
Cleveland BioLabs, Inc. is a drug discovery and development company leveraging its proprietary discoveries around programmed cell death to develop treatments for cancer and protection of normal tissues from exposure to radiation and other stresses. The Company has strategic partnerships with the Cleveland Clinic, Roswell Park Cancer Institute, ChemBridge Corporation and the Armed Forces Radiobiology Research Institute.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Fonstein, the mission of Cleveland BioLabs is controlling cell death to protect human life; what is the plan, how do you accomplish this goal?
Dr. Fonstein: "Cell death is a program in our body which pushes certain cells into suicide when they detect levels of damage that they can not repair. In order for a cell to become cancerous, it needs to eliminate the suicidal death mechanism. If you restore the ability of cancer cells to commit suicide, you have a general approach to kill cancer. On the other hand, systemic stresses like radiation or stroke or heart attack may push certain tissues into premature suicide instead of sitting and repairing damage. When this occurs en masse, we see tissue death, and often the entire organism dies too. If you could temporarily block this suicide process, you could make certain tissues of our body more resistant to these stresses. This concept is the foundation behind our drug development. We are bringing the cell suicide function back to kill tumor cells, and then on the flipside we are selectively protecting normal cells from acute stresses like radiation or chemotherapy. This is the basic mechanism for our lead compound CBLB502, that protects normal cells from levels of radiation that would typically kill 70-80% of the cells."

CEOCFO: How does your drug do this?
Dr. Fonstein: "Our drug, CBLB502, protects normal cells in our body with lower suicidal thresholds from potentially lethal doses of radiation by temporarily blocking the suicide function and enabling them to repair, as well as promoting regenerating factors. For example, when a person is exposed to radiation, we suffer damage in key tissues including our bone marrow and guts. This can result in our inability to restore blood, or in perforation of our guts and sepsis – both of which are lethal. In our experiments, we can convert an 80% killing effect into 80% percent survival. Imagine if there was a radiation accident, such as with a power station or terrorist attack, with our drug you could cut the number of deaths by a factor of four.

Our drug is in advanced development. The pathway to approve this type of drug is through the FDA's animal efficacy rule, which applies to certain drugs where efficacy can't be ethically tested in humans. You show efficacy in animals and then establish safety and biomarkers of efficacy in healthy human volunteers. We just concluded our first human trial establishing safety and tolerability in humans and we have an enormous body of data demonstrating efficacy in animals. We are probably a year and a half away from being able to file our request for approval with the FDA."

CEOCFO: Who is paying attention to what you are doing?

Dr. Fonstein: "Our work is supported by two potential customers - The Department of Defense and The Department of Health and Human Services. We received development contracts from both agencies totaling roughly $22 million, and have scheduled updates where we present our results and get their feedback. We keep receiving additional funding from various federal agencies and people are excited about our progress."

CEOCFO: Are there many other companies doing research in a similar fashion?

Dr. Fonstein: "There is some competition out there, but we've published our results, and did not find a single publication with comparable results. It doesn't mean that there are no other products that may evolve, but we have found no such evidence. There are several companies with various claims of efficacy for radiation damage, but according to our information, they are much less advanced and less powerful in their effects."

CEOCFO: What else is in the pipeline?

Dr. Fonstein: "We have a deep pipeline including several applications for our lead radiation protector. I have been describing the effects of CBLB502's protection in a defense context of emergency exposure, however there is an even more significant market for medical use in radiation and chemotherapy treatment of cancer. Many are not aware that roughly 70% of cancer patients run into dose-limiting toxicities of radiation or chemotherapies, which prevent them from receiving optimal treatment. According to many physicians, if you can increase the dosage of radiation by 30%, then you can dramatically improve the cancer killing results of radiation treatments. We have impressive animal data showing that our product protects healthy tissues and not the tumor. We are planning to start our first medical trial for CBLB502 for reduction of side effects in head and neck cancer patients later this year.

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- Dr. Michael Fonstein Ph.D.

We also have a potential anticancer treatment that effectively wakes up cell death in tumor cells. The first generation of this product showed activity and safety in a Phase II trial and we will be moving forward with a new second generation compound that is potentially 100 times more efficacious."

CEOCFO: What is the financial picture like for the company today?

Dr. Fonstein: "We just finished a small round of financing, which allowed us to progress our lead program. We are very well funded from the government side between the DoD and HHS, which allows us to pay for close to 100% of CBLB502's development and should allow us to complete development all the way to potential approval and commercialization."

CEOCFO: Often the scientific people are not the right people to lead a product or a drug into commercialization; what sets Cleveland BioLabs apart in this area?

Dr. Fonstein: "Your statement is correct. We have the benefit of both highly qualified researchers and experienced drug developers with pharma backgrounds, who understand how to shift research into a commercially viable product."

CEOCFO: In closing, what should potential investors look for as you go along, and why should they be paying attention to Cleveland BioLabs?

Dr. Fonstein: "We are at an exciting point in our development, where revenues from defense applications for our lead drug are a year and a half or less away. With initial human safety now established for CBLB502, we are waiting for the publication of requests for proposals from various government purchasers, including those already financing our program's development. Several companies have been getting significant awards for similar products targeting anthrax or smallpox, so we see can easily potential revenues of several hundred of millions of dollars. Moreover, significant parts of medical applications for this program have already been funded by government dollars, which means less cost for our investors."

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