Cleveland BioLabs, Inc

Controlling cell death to protect human life

Annual Meeting
June 25, 2009
This presentation includes forward-looking statements and predictions, including statements about potential revenue-bearing transactions, the market potential of CBLI’s technologies and product candidates, and the potential value of pipeline products. These statements represent the Company’s judgment as of the date of this presentation and are subject to risks and uncertainties that could cause actual results of events to differ materially from those expressed in such forward-looking statements. In particular, CBLI faces risks and uncertainties that it may not be able to sustain its business model, that revenues may be lower or expenses higher than projected, that product sales may not increase, that development of product candidates in the Company’s pipeline may not succeed or that commercial transactions may not go forward as planned.
CBLI Target Product Market Opportunities

- **CBLB502 - Defense**: Protection from Acute Radiation Syndrome (ARS) (accelerated NDA pathway)
  - $500 million or more annually

- **CBLB502 - Medical**: Reduction of cancer treatment toxicities
  - ~$20 billion market (70% of patients experience regimen-limiting toxicity)

- **CBLB612**: Stem cell induction, mitigation of cancer treatment toxicities
  - Potential to compete with G-CSF ($4+ billion drug from Amgen) or other hematopoietic growth factors

- **Curaxins**: Anti-cancer drugs with potential activity in broad range of cancer types
  - $50 billion + growing market
Recent Achievements – CBLB502 Defense

• Phase I ascending-dose safety trial successfully concluded June 2009 = critical data point for potential customers

• Submitted response to Department of Defense Sources Sought Notice for Radiological and Nuclear Medical Countermeasures

• Received more than $22 million in development contracts from Department of Defense and BARDA/HHS in 2008
Recent Achievements - Curaxins

• Proof of concept Phase II trial demonstrated activity and safety; “next generation” lead shows dramatic increase in efficacy and is ready for formal development

• Published new insights into mechanism of action of first generation in leading cancer journal, 

• Pending Joint Venture with Russian fund to support development through Phase II
CBLB502 - Defense Market Potential “Back of the Envelope”

**Initial sales targets:** Need understood, concepts of use developed, high degree of financial commitment, relations with CBLI in place

- 1-2 million doses for US army
- 5-20 million doses for protection of US civilians
- ~5 million doses for protection of Israeli army and civilians

**Secondary sales targets:** Serious public concern, policies being developed

- UK, Canada, China, Japan, S. Korea, India

Projected addressable market ~$500 M/year

No competing products today

Possibility of sale or “conditional” sale before approval
CBLB502 – Defense:
Received $25M in grants for radioprotection

<table>
<thead>
<tr>
<th>Funding Agency / Type of Funding</th>
<th>Title</th>
<th>Amount</th>
<th>Dates</th>
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<td>NASA / Phase I SBIR Grant</td>
<td>New Class of Biological Radioprotectors</td>
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<td>DoD / DARPA Grant</td>
<td>Tissue Protecting Antidotes from Anti-apoptotic factors of Mycoplasma</td>
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<td>BARDA-HHS / BioShield Contract</td>
<td>Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation</td>
<td>$13,271,283</td>
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Human safety is the last remaining development milestone: Phase I study was completed in June 2009

We expect to complete all other remaining requirements needed for FDA approval within 2 years
# CBLB502: Summary of Primate Studies

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<th>TBI Dose</th>
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<td>LD&lt;sub&gt;60-70&lt;/sub&gt;</td>
<td>Survival benefit</td>
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<td>Thrombocytopenia reduction</td>
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<td>Neutropenia reduction</td>
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<td>Improved BM, spleen, thymus</td>
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<td>Improved GI mucosa</td>
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<td>Cytokine release (G-CSF, IL-6, etc.)</td>
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<td>Data on dose dependence of efficacy</td>
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<td>LD&lt;sub&gt;10-20&lt;/sub&gt;</td>
<td>Thrombocytopenia reduction</td>
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<td>Data on dose dependence of efficacy</td>
<td>Ongoing</td>
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<tr>
<td>No TBI</td>
<td>Increased platelet levels</td>
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<td>Increased neutrophil levels</td>
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<td>Cytokine release (G-CSF, IL-6, etc.)</td>
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<td>Data on dose dependence of efficacy</td>
<td>Ongoing</td>
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+++: strong effect; ++: moderate effect; +: minor effect; √: data collected

17 studies with total of 525 non-human primates
CBLB502 Efficacy: Survival (Mitigation) after LD$_{70}$ IR

Effective when injected up to 48 hours after radiation
Radiomitigation by CBLB502: organ and tissue recovery in lethally irradiated primates

Pathology data demonstrates protection of GI tract, blood, immune system and skin

50% subjects have no observed abnormalities by day 40

Gross pathology (post-mortal) in various divisions of GI tract in experimental and control groups

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Cleveland BioLabs, Inc
cGMP Production of CBLB502: CMC Participants

- Laboratory Strain
- Production Strain, DSP
- Cell Bank
- QC protocols, stability
- Bioassay
- Test Residuals
- Preclinical Trials
- Formulation
- Fermentation Improvement
- Manufacturing

Cleveland BioLabs, Inc

SynCo Bio Partners

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Human Trial Design

**Escalating dose Phase IA:**
- Cohorts of 6 healthy volunteers
- Safety
- Pharmacokinetics
- Biomarkers
- Immunogenicity
- TLR5 genotyping
- Dose selection for Phase IB safety trial

**Phase IB (to be confirmed with FDA):**
- Safety in ≥ 500 healthy volunteers
- Confirm Pharmacokinetics
- Confirm Biomarkers
- Confirm Immunogenicity
- Incorporate limited repeat-dose arm

CNS Comprehensive Phase One
(Miramar, Florida, USA)

- Experience: 14 years
- Number of beds: 120
- State-of-the-art 46,000 sq. ft.
- No 483’s
Summary of Phase 1 Trial of CBLB502

• Dose limiting toxicity defined
• Adverse event profile described; predictable and related to the known pharmacology of CBLB502
• Safe dose in humans that mimics protective dose in NHPs based on biomarkers achieved
• All biomarkers project similar human dose below DLT
• Trial extended to precisely determine MTD
• NHP dose finding study is ongoing to accurately define projected human dose
CBLB502- Defense: Development Status

COMPLETED (2006-2009)
- Meetings with FDA laying out the development path
- Animal efficacy in multiple regimens, radiation doses and timepoints
- Phase IA trial to determine MTD in humans
- Establishing efficacy biomarkers in humans

PENDING (2009-2010)
- FDA meeting finalizing protocols for Phase IB and pivotal NHP studies (summer 2009)
- Phase IB (fall 2009 – summer 2010)
- Pivotal NHP study (2009 – early 2010)
- Manufacturing consistency runs and extended product stability (2009-2010)
- FDA submission (Late 2010)
Total Body Irradiation

- Acute leukemia - reduction of lethality and improved recovery of patients from allogenic bone marrow transplantation

Local Irradiation

- Head and neck cancer - reduced radiotherapy side effects (mucositis of mouth, throat and esophagus, larynx and dental caries)
- Prostate cancer - protection of GI (rectal bleeding, diarrhea, bladder damage)
- Lung cancer - protection of healthy lung tissue from inflammation

Chemotherapy

- Multiple drugs and cancers - reduction of dose limiting adverse effects of chemotherapeutic drugs (myelosuppression, GI toxicity, nephrotoxicity, etc.)
Strong mitigation of radiological damage of healthy tissues shown in mouse model of head-and-neck damage directly supports first medical trial.
CBLB612: Medical Applications

- Recovery from myelosuppression associated with chemotherapy (breast cancer, leukemia, lymphomas, etc.)
- Donor treatment in bone marrow transplantation (improvement or replacement of aphaeresis)
- All other clinical applications of G-CSF (e.g., myelodysplastic syndrome)

Opportunity for combination with or substitute for G-CSF (Neupogen®)
Next Generation Curaxins

- Completely proprietary compounds
- Similar mechanism to CBLC102
- Potentially 100x more efficacious than CBLC102
- Manufacturing process and formal pre-clinical safety to be completed pending partnership
CBLI Competitive Advantages

• Deep understanding of mechanisms behind regulated cell death (apoptosis)

• Unique approach to protecting healthy tissues by temporarily suppressing regulated cell death

• Broad IP on use of human microflora for tissue protecting compounds

• Strategic partnerships with world class leaders in research areas:
  – Cleveland Clinic (co-founder): one of top 3 clinics in US
  – Roswell Park Cancer Institute: first cancer center in US
  – Armed Forces Radiobiology Research Institute: federal center for radiation biology research
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