Controlling cell death to protect human life

Rodman & Renshaw 13th Annual Healthcare Conference
September 12, 2011
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 develops drugs against major unmet biodefense and medical needs

- Countermeasure against lethal radiation exposure
  CBLB502

- Supportive care drugs against side effects of radiotherapy and chemotherapy
  CBLB502, CBLB612

- Novel anticancer therapeutics
  CBLB502, CBLC102, CBLC137
Investment Highlights

• Broad pipeline of drug candidates with multiple applications

• Accelerated commercialization through biodefense

• Strategic partnerships with Cleveland Clinic and Roswell Park Cancer Institute

• Track record of non-dilutive grants and contracts (~$100M, including $30M conditional purchase for CBLB502)

• Patents issued in US, Europe and Asia

• $30M cash and ~ $25M additional committed government and JV funding
CBLB502
Radiation Countermeasure
Supportive Care against cancer therapy side effects
Immunotherapy against cancer
Radiation Countermeasure Opportunity

- Nuclear attack identified by US and global leaders as number one security threat
- Reauthorization of Pandemic All hazards Preparedness Act includes radiation as top priority
- Terrorist attack with a 10 KT device will kill 400,000 people in NYC most of them via ARS (Institute of Medicine Report, June 2009)
- Fukushima disaster highlights risk of nuclear industry
- There are no FDA licensed countermeasures for ARS

CBLB502 uniquely positioned as therapeutic against ARS
CBLB502 as Medical Radiation Countermeasure

Origin & Mechanism of Action

- Protein of bacterial origin (flagellin) modified to reduce immunogenicity and toxicity and improve production
- Acts through multiple mechanisms mediated by activation of pro-survival NF-κB signaling pathway
- Selectively protects normal tissues (but not malignant tumors) from radiation
- Increases survival of stem cells and early progenitors of hematopoietic system and stimulated regeneration of different HP lineages
- Reduces radiation damage to and stimulate regeneration of crypts, villi and lamina propria of GI tract
Drug candidates, efficacy of which cannot be directly tested in humans due to ethical reasons, are developed according to Animal Rule:

- Efficacy in animal models that mimic human disease
- Human safety
- Well understood mechanism of action to justify selection of objective indicators (biomarkers) in humans
CBLB502 is efficacious in mice and monkeys in protecting and mitigating regimens

27 studies with non-human primates; >180 studies (with multiple strains of mice, types of irradiation, survival, HP, GI and other endpoints)
Summary of CBLB502 Efficacy Features in NHPs

27 studies with total of 905 non-human primates

- **Species:** rhesus monkey, *Macaca mulatta* (best-studied primate model in ARS); both sexes, young adults

- **Doses of radiation tested:** from LD$_{10/40}$ to LD$_{75/40}$ TBI in survival studies and LD$_{90-100}$ TBI in GI morphology studies

- **Efficacious times of treatment:** at least from -45’ to >48 hours (*treatment at 120 hours is not efficacious*)

- **Efficacious doses of CBLB502:** >=10 ug/kg efficacious at all time points and radiation doses tested, as single intramuscular injection

CBLB502 increases survival (up to 3 times); reduces severity and duration of thrombocytopenia; reduces severity of neutropenia; reduces morphological damage in BM, GI tract, spleen, thymus and lymph nodes
Completed Steps in Production of CBLB502

- Full industrial-scale production process based on recombinant DNA technology
- Single fermentation generating hundreds of thousands of doses
- Reproducibility demonstrated in multiple GMP runs
- Stable as a frozen liquid and in lyophilized form
- Release assays validated
• Total of 150 human volunteers received range of doses of CBLB502 in 2 studies

• Dose limiting toxicity (DLT) defined (manifested as flu-like syndrome)

• **Calculated efficacious dose in humans below DLT**

• Adverse event profile predictable and directly related to mechanism of action of CBLB502

• Methodology established to determine projected human efficacious dose (based on biomarkers)

• **All biomarkers project similar human dose**

• Collected information enables start of definitive safety/dose validation trial in healthy volunteers for CBLB502 defense
# CBLB502-Biodefense Path to Licensure

## Remaining Tasks

<table>
<thead>
<tr>
<th>✓ Completed</th>
<th>Remaining steps</th>
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<tbody>
<tr>
<td><strong>CMC</strong></td>
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<tr>
<td>GMP process developed and tested, drug suitable for clinical trials released</td>
<td>Additional consistency runs</td>
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<td><strong>Efficacy</strong></td>
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<tr>
<td>Data from ~1,000 primates demonstrates dramatic survival benefits and accelerated recovery</td>
<td>Pivotal animal studies</td>
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<tr>
<td><strong>Human safety</strong></td>
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<tr>
<td>Two trials: 50-subject dose-escalation and 100-subject study completed</td>
<td>Definitive safety study</td>
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<tr>
<td><strong>FDA process</strong></td>
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<tr>
<td>Open IND, Fast Track Status, Orphan Drug Status</td>
<td>Coordinating study protocols, BLA submission</td>
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## CBLB502 Federal Contract Funding

<table>
<thead>
<tr>
<th>GRANT/CONTRACT</th>
<th>TITLE</th>
<th>AMOUNT</th>
<th>DATES</th>
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| **DoD/CBMS-JPEO**  
Chemical Biological Medical Systems Joint Project Mgt. | BAA-07-01- Advanced Development of a Medical Radiation Countermeasure | $10,340,000 | 3/08-10/09 |
| **NIAID (NIH)**  
BioShield Program | CBLB502 mitigation of radiation induced thrombocytopenia | $1,230,000 | 9/08-3/10 |
| **BARDA (HHS)**  
BioShield Program | BAA-08-08 -Development of CBLB502 of mitigation of HP syndrome | $15,800,000 | 9/08-10/10 |
| **NIH/NIAID**  
Grand Opportunities (GO) Grant | Protectan CBLB502 | $5,300,000 | 9/09-9/11 |
| **DoD/CBMS-JPEO**  
Chemical Biological Medical Systems Joint Project Mgt. | RFP W9113M-09-R-0010  
Advanced Development of a Medical Radiation Countermeasure | $45,000,000  
($15,000,000 + 30,000,000) | 9/10-9/13 |
| **DoD/CBMS-JPEO**  
Chemical Biological Medical Systems Joint Project Mgt. | RFP W9113M-09-R-0010  
Advanced Development of a Medical Radiation Countermeasure | $1,343,759 | 6/11-9/13 |
CBLB502
Medical Applications
CBLB502 in Preclinical Model of Local Irradiation

Result:
• CBLB502 efficacious against radiation-induced mucositis and dermatitis

Significance:
• Strong preclinical support of CBLB502 as radiotherapy adjuvant
• Justification of new application (protection from radiation-induced dermatitis)

Approval of “CBLB502 as supportive care” trial protocol in head and neck cancer patients by Scientific Review Committee of Roswell Park
Extending Indications of CBLB502
Mitigation of chemotherapy side effects and direct antitumor action

Irinotecan and CBLB502 against Wart colon tumors in Fisher rats

CBLB502 displays both supportive care and direct antitumor activities in rat model of colon cancer
Prospective Clinical Trials of CBLB502 in Cancer Patients

- Reducing severity of mucositis and enhancing efficacy of radiotherapy of H&N cancer
- Reducing severity of bowel toxicity and enhancing efficacy of radiotherapy of pancreatic cancer
- Reducing severity of diarrhea in colon cancer patients treated with Irinotecan
- Treating primary hepatocellular carcinoma (liver cancer)
- Treating liver metastasis of colon cancer
- Treating liver metastasis of breast cancer
- Pre-operative treatment of prostate cancer

Many of these trials enable assessment of both supportive care and direct anti-tumor activity of CBLB502
CBLB612
Stem Cell Inducing Agent
CBLB612 is 6x more efficacious than G-CSF and induces both early and late progenitor cells. Effects of CBLB612 and G-CSF are synergistic.
Dramatic improvement of blood recovery during Cyclophosphamide treatment in mice
CBLB612 Product Development Strategy

- 6-month Phase I safety study in healthy volunteers enables accurate estimate of induction and mobilization of stem cells in peripheral blood, a direct predictor of efficacy of the drug

- 2.5 years from today to critical human data

- Hisun licensing deal of 2009 provides additional data and possibility of synergistic development

Principle efficacy assessment in Phase I = potential partnering
Curaxins
Anticancer drugs
Curaxins

• Synthetic small molecules with proprietary structure

• Unique mechanism of action: simultaneously affect multiple molecular targets in cancer cell

• Efficacious in a broad spectrum of preclinical tumor models

• Mechanism of action enables additional clinical indications beyond cancer treatment (anti-inflammatory, anti-infective)

• Recent peer review publications:
  • *Science Translational Medicine* (2011)
  • *Journal of Virology* (2010)
  • *Cell Cycle* (2009)
  • *Oncogene* (2009)
Incuron – JV for Curaxin Development

- 50/50 joint venture with Bioprocess Ventures, Moscow
- ~$18M to reach inflection points for primary molecules
- CBLI oversees mechanistic studies and formal development
- Phase Ib trial for prototype CBLC102 in liver metastases started October 2010 in Russia
- Phase I trial with oral formulation of next generation CBLC137 in solid tumors planned for 1Q12 in Russia
- Optimization of IV formulation of next generation CBLC137 for future trial in US ongoing
Milestones

- Start of pivotal animal efficacy studies for CBLB502 defense
- Start of definitive safety/dose validation trial in healthy volunteers for CBLB502 defense
- CBLB502 trial as single agent in advanced cancer patients
- CBLB502 trial as supportive care in head and neck cancer patients
- Completion of CBLC102 trial in liver metastases patients in Russia
- Phase I trial next generation Curaxin CBLC137
- High profile peer reviewed publications
Financial Summary

- **Shares Outstanding**: 35M common, 52M fully diluted

- **Government Grants & Contracts** support CBLB502 for defense and limited medical applications: **$14.8M unspent** as of 6/30/11 (excl. $30M option for first purchase)

- **CBLI subsidiary Incuron** funds Curaxin development for next 2-3 years: **$12.1M left**

- **CBLI Cash & Receivables** (at 6/30/11): **$29.5M** (CBLI only), **$2.3M** (Incuron – first tranche)

- **Avg. Monthly Burn Rate** (on CBLI cash): ~ **$1-1.4M** (CBLI only)
Senior Management Team

Chief Executive Officer & President
Michael Fonstein, PhD
- Scientist and entrepreneur
- Founder of Dia-M and The Fellowship for Interpretation of Genomes (FIG)
- Founder and Former CEO of Integrated Genomics, Inc. (‘97-03)

Chief Financial Officer
Neil Lyons, CPA
- 30 years of financial and operations management and accounting experience
- 6 years as CFO of a public biotech company
- 15 years experience in federal contracting

Chief Operating Officer
Yakov Kogan, PhD, MBA
- Former Director of Business Development at Integrated Genomics, Inc.
- Expert in technical sales and contract negotiations

Chief Scientific Officer
Andrei Gudkov, PhD, D.Sci
- SVP of Basic Science, Roswell Park Cancer Institute
- Former Chair, Dept. Molecular Biology at Cleveland Clinic
- 30+ issued patents
- 150+ research publications

Chief Medical Officer
Michael Kurman, MD
- 25 years global oncology drug development experience
- Senior positions in clinical operations at CROs
- Led clinical development in several publicly traded biotech companies

Executive Vice President, Regulatory Affairs and Quality Assurance
Ann Hards, PhD
- Over 20 years of regulatory experience at large and small pharma
- Multiple successful NDAs, MAAs, sNDAs, advisory committees
Scientific Advisory Board

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Chairman of SAB, Member of NAS, Former director of LRI, Scientific Advisor to Amersham and Genentech, pioneered numerous major research technologies

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Professor, Chair in Transplantation Immunology of University of Minnesota. Member of the FDA Advisory Committee, SAB member of BioMarin Pharmaceutical, Seattle Genetics, etc.

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CSO, Cleveland BioLabs, Inc

Yakov Kogan, PhD, MBA
COO, Cleveland BioLabs, Inc