



## **Investor Presentation**

*NASDAQ: **CBLI***

September 2015

# Safe Harbor & Risk Factors

This presentation includes forward-looking statements and predictions that are intended to be covered by the safe harbor for “forward-looking statements” provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements about potential revenue-bearing transactions of its products through governmental or pharmaceutical partnerships, the market potential of CBLI’s technologies and product candidates, and the potential value of pipeline products. All such statements represent CBLI’s judgment as of the date of this presentation and are subject to risks and uncertainties that could cause actual results 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.

The factors that could cause actual results to differ are discussed in more detail in CBLI’s filings with the Securities and Exchange Commission, including its registration statement on Form S1/A, its latest Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. These reports are available under the “Investors” tab on CBLI’s website at [www.cbiolabs.com](http://www.cbiolabs.com). Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not take undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

# CBLI Is Focused on Delivering Novel Immune Activation Approaches to Address Serious Medical Needs

## Radiation Countermeasure

**\$200M+  
US and Global Market<sup>1</sup>**

- Multi-mechanism rescue from lethal radiation exposure

## Oncology Immunotherapy

**~\$67.9B  
Global Market<sup>2</sup>**

- Combination therapy with checkpoint inhibitors
- Regional therapy for bladder cancer
- Hematorestoration following chemotherapy

## Vaccine Super-Adjuvant

**\$57.9B projected  
global market<sup>3</sup>**

Vaccination for multiple serious conditions:

- Anti-addiction
- Anti-infection
- Anti-cancer



**Toll-Like Receptor Activation Platform**

<sup>1</sup> US Strategic National Stockpile funding data

<sup>2</sup> BCC Research: Cancer Immunology and Oncolytic Virology: Technologies and Global Markets

<sup>3</sup> Markets and Markets: Vaccines Market by Technology (Live Attenuated, Toxoid, Conjugate, Subunit, Synthetic, Dendritic Cell, Inactivated), Type (Preventive, Therapeutic), End User (Pediatrics, Adults), Disease Indication (Infectious Disease, Cancer, Allergy) - Forecasts to 2019

# Our Leadership Team Has a Track Record of Success

## Chief Executive Officer

Yakov Kogan, PhD, MBA

Co-founder and Board Member

## Chief Medical Officer & President

Langdon Miller, MD

## Chief Scientific Officer

Andrei Gudkov, PhD, DSci

Co-founder and Board Member

## Chief Financial Officer

C Neil Lyons, CPA

## EVP, Regulatory Affairs

Ann Hards, PhD

## SVP, Government Affairs

Michelle Ross, DVM, PhD

# Cleveland BioLabs

## CEO

- 10+ years experience
- Former COO and EVP of BD at CBLI
- Secured \$41M in VC funding and \$59M in US & Russian Federation grants

## CMO

- 20+ years experience
- Medical oncologist with major roles in development of Neupogen®, Leukine®, Camptosar®, Elence®, Aromasin®, Sutent®, Zydelig™

## CSO

- 20+ years experience
- Internationally recognized TLR5 thought leader
- Inventor of entolimod
- SVP of Basic Science, Roswell Park Cancer Institute

## CFO

- 30+ years experience; 10+ years with Deloitte
- Led ~\$100M in biotech transactions, advised on \$1B in other industries
- Managed finance for \$300M defense contractor

## EVP

- 20+ years experience
- Regulatory expert with major roles in approvals of Lipitor®, Plavix®, Avapro®, Avalide®, Arixtra®, Fragmin®, Rezulin®, Multaq®

## SVP

- 20+ years of service in US Army
- Senior officer for national defense counterterrorism planning
- Policy expert on chemical, biological, and radiological countermeasures

# The Toll-Like-Receptor Platform Supports an Advancing Pipeline of Products and Projects

PRODUCT <i>Indication</i>	DISCOVERY				PRECLINICAL				PIVOTAL ANIMAL STUDIES				HUMAN SAFETY / DOSE CONVERSION							
ENTOLIMOD <i>Acute Radiation Syndrome (pre-EUA)</i>																				
PRODUCT <i>Indication</i>	DISCOVERY				PRECLINICAL				PHASE I				PHASE II				PHASE III			
ENTOLIMOD-Oncology <i>Novel Immunotherapy</i>																				
CBLB612 <i>Hematorestorative</i>																				
SA-702 - Vaccine adjuvant <i>Addiction, Infection, Cancer</i>																				
Next Generation Products																				

# CBLI Is Primed to Achieve Near-Term, Value-Driving Objectives

## Radiation Countermeasure

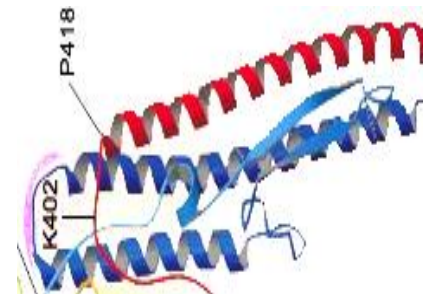
- Secure Department of Defense contracts (\$15M) to support entolimod BLA studies – 3Q2015
- Achieve FDA pre-EUA status for entolimod – 1H2016
- Launch commercialization activities for entolimod in US and foreign territories – 2H2016

## Oncology Immunotherapy

- Demonstrate preclinical proof of concept for entolimod combination therapy with checkpoint inhibitors – 2H2015
- File IND to support entolimod immunotherapy of bladder cancer – 1H2016
- Complete Phase 2 clinical study of CBLB612 hematorestoration in breast cancer – 1H2017

## Vaccine Super-Adjuvant

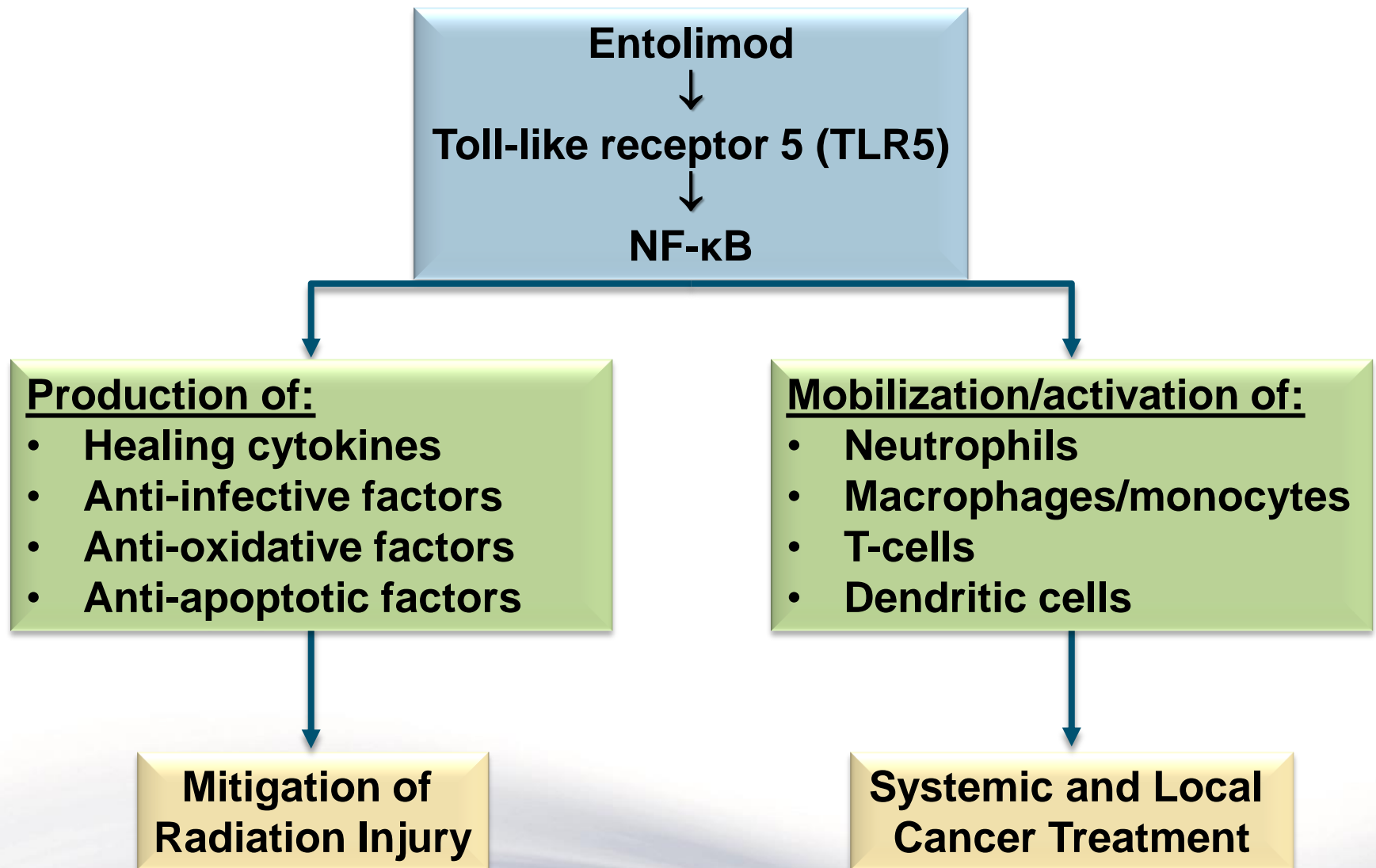
- Leverage academic collaborations to establish clinical proof of concept for SA-702 as immune super-adjuvant – 2H2016
- Generate clinical proof of concept for anti-addiction vaccines thru NIH/NIDA-funded program – 2H2016/1H2017



# Entolimod

Medical Radiation Countermeasure (MRC) for  
Rescue Therapy Following Radiation Disasters  
&  
Cancer Immunotherapy

# Entolimod Immune Activation Offer Opportunities for Dual Indications





# Nuclear Attack Is a Major Global Security Threat

THE WALL STREET JOURNAL.

**WSJ**

*“China Warns North  
Korean Nuclear  
Threat Is Rising”*

*“The World is  
Facing a  
Growing Threat  
of Nuclear War”*

**The  
Economist**

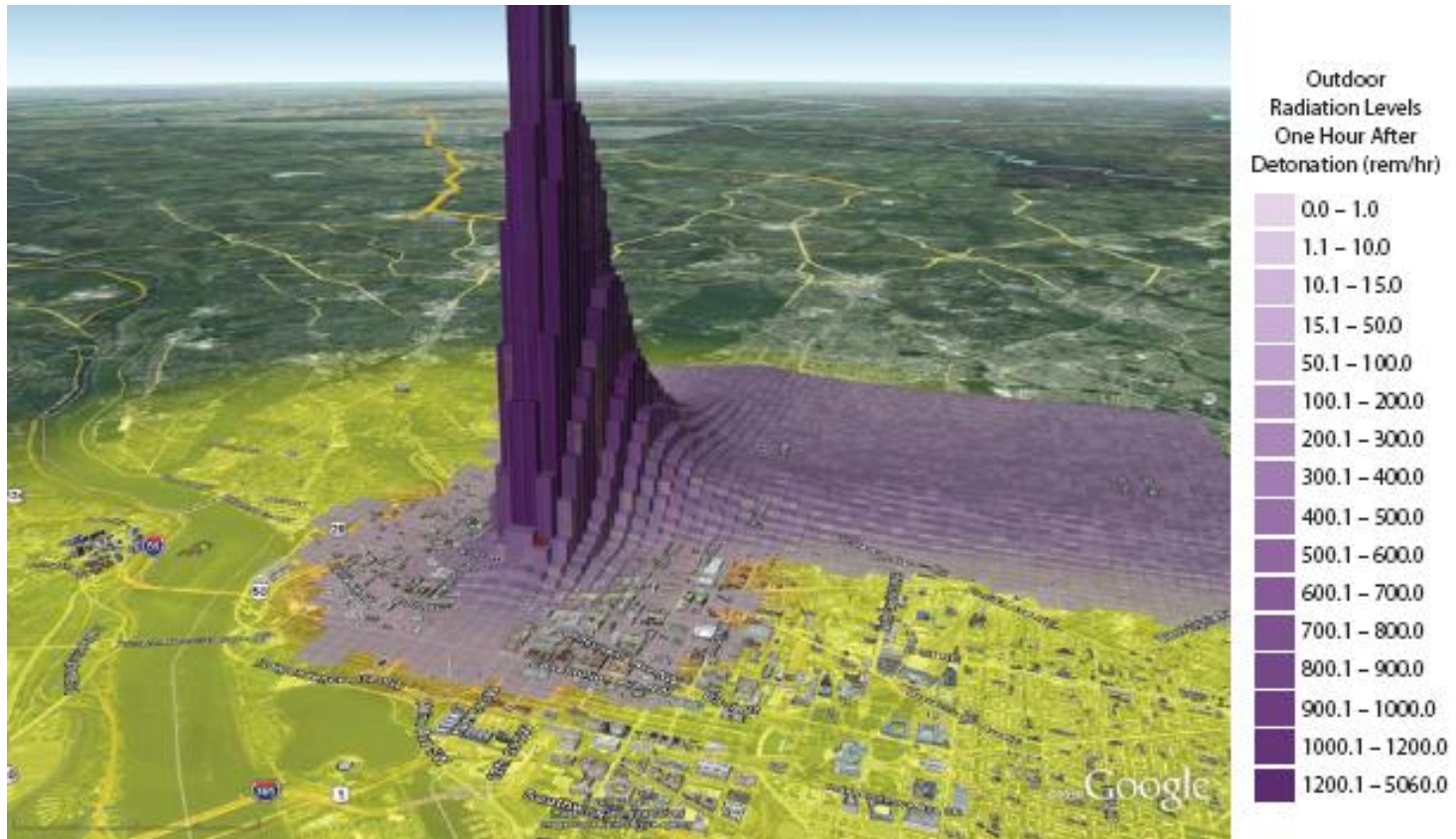
**FT**

**FINANCIAL  
TIMES**

*“The Nuclear Gun is  
Back on the Table”*



# In a Major City, Radiation Exposure after a Terrorist Attack Would Claim the Lives of Tens of Thousands

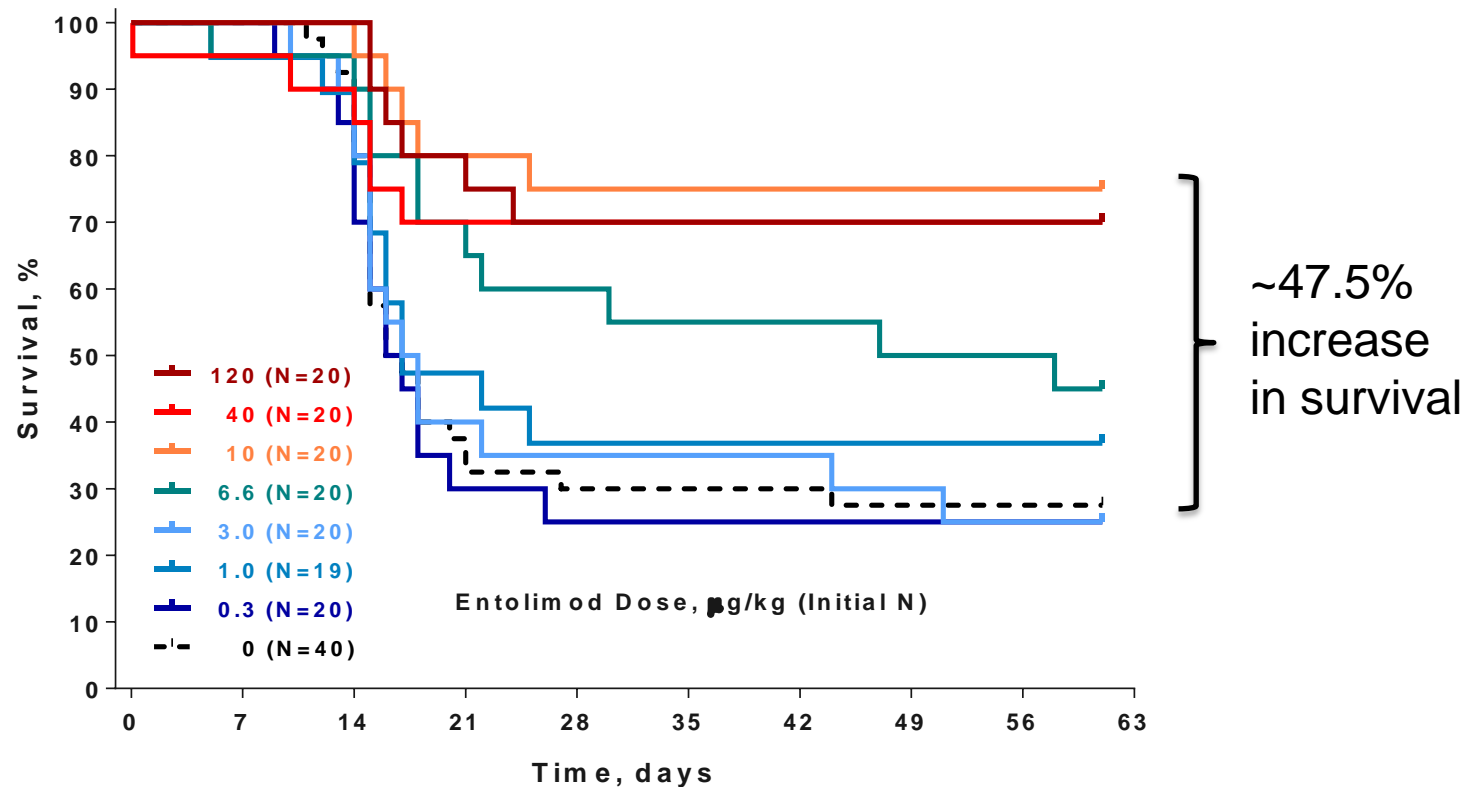


- A 10-kT detonation in Washington DC would irradiate >136,000 people
- Medical care would be very limited (only 2800 hospital beds would remain operational)
- >82,000 victims would die of radiation injuries without a highly effective, easy-to-administer medical radiation countermeasure

# Entolimod Has Achieved Pivotal Development Status Under the FDA Animal Rule

- Successful completion of a pivotal efficacy study in non-human primates
- Characterization of safety in 150 healthy subjects and 26 patients with advanced cancers
- Completion of formal animal-to-human dose conversion to select a human dose
- Development of a high-yield cGMP manufacturing process
  - Manufacturing of drug substance for >1,000,000 doses
  - Demonstration of prolonged drug stability
  - Formulation in single-use vials suitable for stockpiling
- Pre-Emergency Use Authorization dossier was filed with FDA in June 2015

# Entolimod Prevents Radiation-related Death in Non-human Primates



A single dose of entolimod, administered 25 hours *after* irradiation without any supportive care protects against radiation-related mortality occurring 2-3 weeks later

# Entolimod Development Addresses FDA Pre-EUA Criteria

- The condition for which the drug will be used (eg, potentially lethal irradiation) is serious or life-threatening
- The drug has been shown in adequate, well-controlled studies to be effective in treating the serious condition
- The potential benefits outweigh the potential risks in the context of the indication for use
- No adequate, approved alternative drug is available for treating the serious condition

FDA invited CBLI to submit a pre-EUA application; dossier filed June 2015

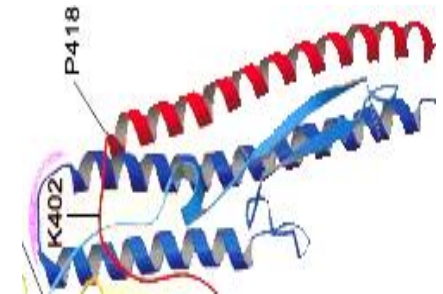


# The Market Potential for Entolimod as a Medical Radiation Countermeasure Is Significant

- Project BioShield established the Strategic National Stockpile (SNS)
  - Funded through Strategic Reserve Fund (\$560M annual budget)
- Procurement contracts to date have totaled \$3.3B
  - Mean/median awards of \$301M/\$220M (range \$18M-\$700M) for anthrax, botulism, smallpox, nerve agents
  - Award for filgrastim analogues of \$171M in 2013, despite their clinical limitations
- Most purchases have been based on pre-EUA approval
  - Most drugs did not have a BLA/NDA for the proposed indication

# The Road to Entolimod Commercialization Is Defined





# Entolimod-Oncology

Cancer Immunotherapy



# Cancer Immunotherapy is a Growing Opportunity

- Global market for cancer immunotherapies to reach \$67.9 billion in 2018<sup>1</sup>
- Pharma companies are focusing on cancer immunotherapy
  - Merck, BMS, Roche, Novartis, AstraZeneca and others are developing checkpoint inhibitors for multiple solid tumors
- Combination approaches may offer the potential for improved therapeutic outcomes in a broader range of tumor types<sup>2</sup>



# Entolimod Offers Potential as an Alternative or Adjunctive Immunotherapy

- Activation of TLR5 induces innate immune response in normal tissues and potent antitumor activity in preclinical models
  - Immunocytes mobilize to organs with high TLR5 expression (liver, lungs, bladder)
- Entolimod induces a secondary adaptive response for prolonged antitumor effect
- May offer therapeutic benefit via two different routes
  - Systemic administration – potential for combinations with other emerging immunotherapy agents (eg, immune checkpoint inhibitors)
  - Local (intravesical) administration for bladder cancer

# Entolimod Is in Phase 1 Testing in Cancer Patients to Evaluate Safety and Systemic Immune Cell Response

## Phase 1 Study United States

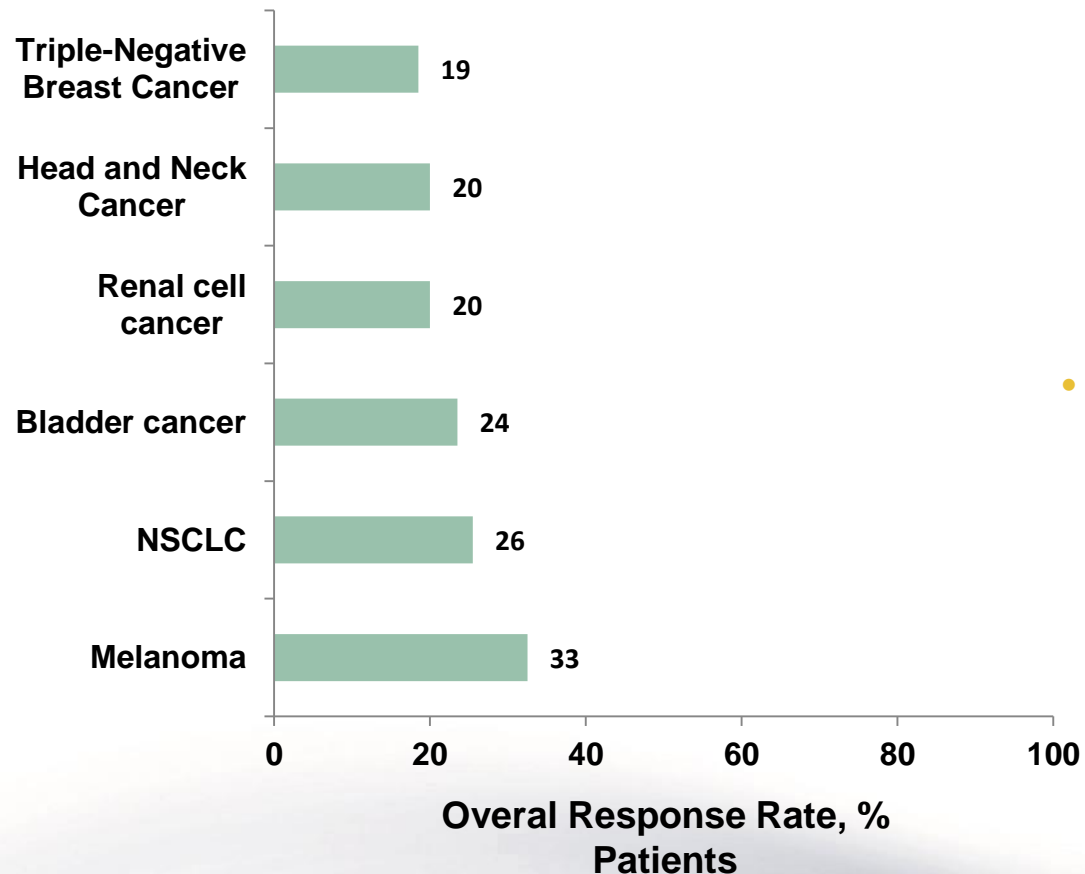
- Tolerability profile similar to that observed in healthy volunteers
- Induction of TLR5-dependent immune cells (T-cell subsets, neutrophils, NK cells), as assessed at higher dose levels
- Stable disease in several patients with heavily pretreated cancers
- Data presented at 2015 American Society of Clinical Oncology (ASCO) annual meeting

## Phase 1 Study Russian Federation

- Enrollment of additional patients at the highest doses achieved in the US study
- Further evaluation of immune cell activation planned
- Supported by Russian government contract
- Data expected 1H16

# Combinations with Emerging Immunotherapeutics Represent Important Platforms for Future Development

## Pembrolizumab (Keytruda®) Anti-PD-1 Antibody Antitumor Activity in Multiple Cancers

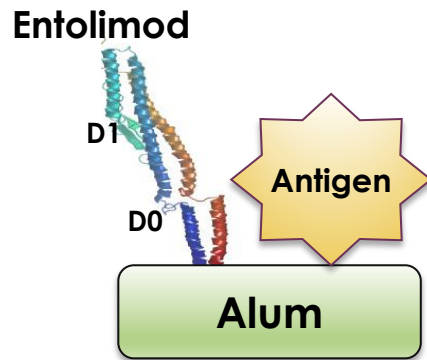


- Immune checkpoint inhibitors
  - Show important clinical efficacy in multiple cancer types
  - However, 65 to 80% of patients have tumors that do not respond
  - Novel combinations of immunotherapies are needed to improve outcomes
- Entolimod
  - Mobilizes antitumor innate and adaptive immunity to several body sites (particularly, liver)
  - Entolimod stimulation of T-cells was confirmed in the Phase 1 trial
  - Preclinical combination studies are ongoing in breast, colon, and bladder cancer tumor models

# Non-invasive Bladder Cancer Represents a Major Opportunity for Entolimod Therapy



- Bladder cancer is the 4th most common cancer in the world
  - US incidence of 73,000 per year
- Following surgery, patients receive TLR4 agonist immunotherapy with intravesical BCG
  - 50% of patients recur in <2 years and can require total cystectomy and may develop life-threatening metastases
- TLR5 expression in bladder and bladder tumors supports development of entolimod for BCG-refractory disease
  - Focused IND-enabling toxicology program builds on known drug profile
  - Cystoscopy data could provide rapid clinical proof of concept (6-12 months)
  - FDA focus on finding new bladder cancer therapies offers potential for accelerated regulatory approval

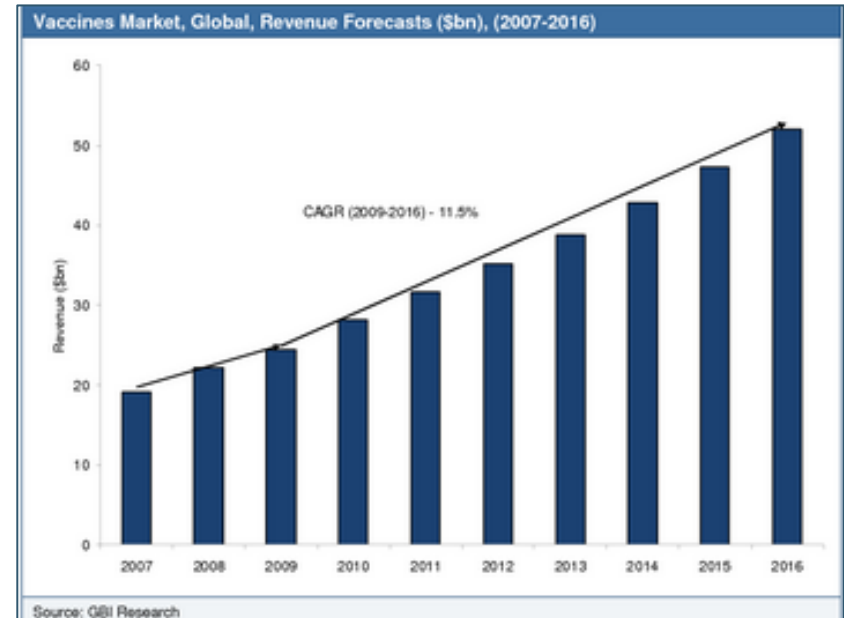


# SA-702

Vaccine Superadjuvant

# There Is a Growing Need for Effective Vaccine Adjuvants

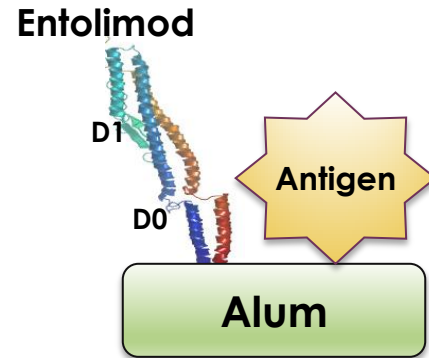
- Vaccine development is rapidly expanding in diverse indications
- Many vaccines require an adjuvant to induce sufficient immune response
- ~50% of the 30 most commonly used FDA-approved vaccines contain alum (aluminum salts) as an adjuvant
  - Alum alone is often not sufficiently immunopotentiating
- A shortage of effective and safe adjuvants is a major bottleneck in vaccine development
  - Until recently, Alum was the only adjuvant approved by FDA
  - GSK AS004 immunoadjuvant (monophosphoryl lipid A + alum; TLR4 agonist) as a component of CERVARIX (anti-HPV vaccine) confirms the immunoadjuvant utility of TLR activation



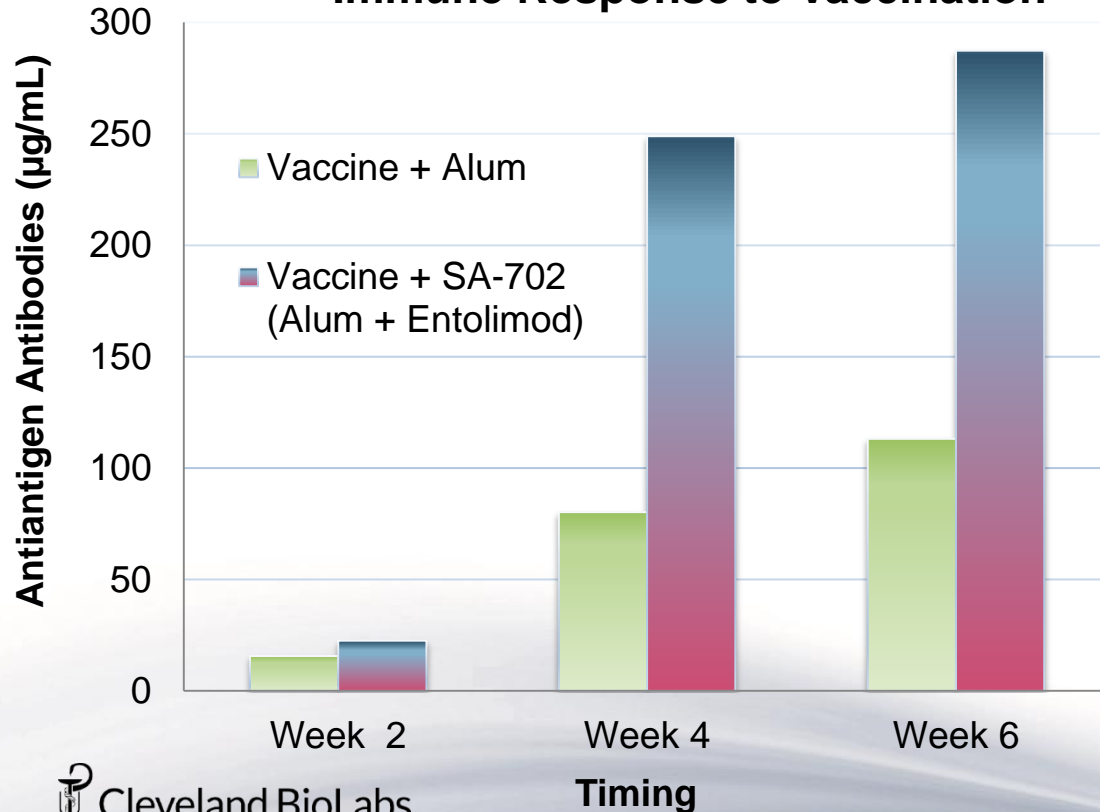


# SA-702 Offers a Next-Generation Novel Proprietary Immune Adjuvant Platform

SA-702 comprises a tight complex of alum and entolimod that boosts immune responses



**Immune Response to Vaccination**



Addition of low doses of entolimod boosts antibody generation in preclinical models

Vaccination at Weeks 0, 3, 6  
(N=5 mice/group)

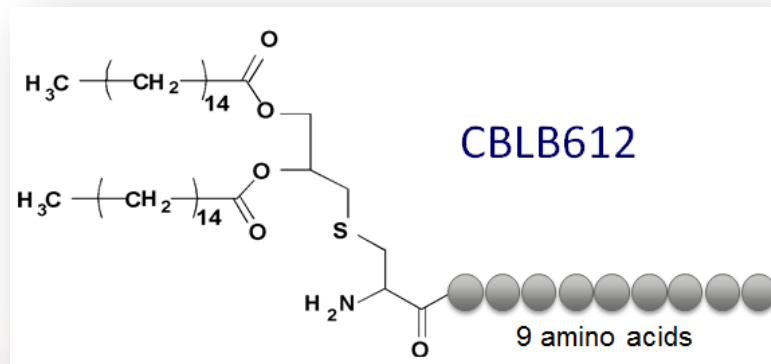


# CBLI Is Pursuing Development of Next-Generation Anti-Addiction Vaccines

- Total estimated US market is >\$1.3B/year for an effective relapse-prevention therapy
  - ~300,000 cocaine addicts are seeking treatment
  - ~100,000 methamphetamine addicts are seeking treatment
- CBLI is entering into co-development with major thought-leader in anti-addiction therapy
  - Thomas Kosten, MD (Baylor College of Medicine; Houston VAMC)
  - Brought 1st-generation anti-cocaine vaccine to Phase 3 clinical trials
  - Funding from NIH/NIDA
- Near-term value-driving activities are in progress
  - Anti-methamphetamine/SA-702 vaccine
    - Clinical proof of concept expected in 4Q2016
  - Anti-cocaine/SA-702 vaccine
    - Clinical proof of concept expected in 2017

# CBLB612

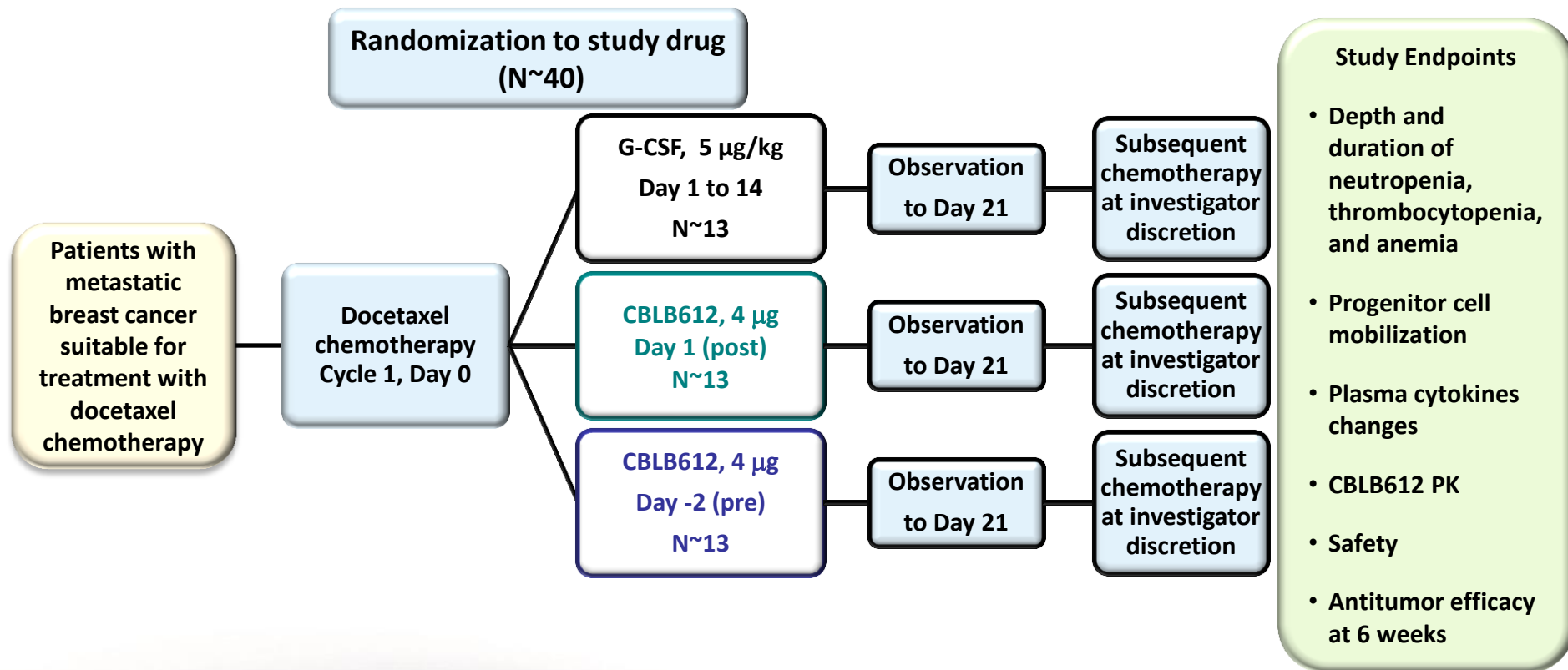
Synthetic Mycoplasma TLR2/6 Agonist  
& Hematorestorative Agent



# CBLB612 Offers Opportunity as a Single-Dose Alternative to Existing Hematopoietic Growth Factors

- Worldwide use of granulocyte colony-stimulating factor (G-CSF) (eg, filgrastim, peg-filgrastim, lenograstim) comprises a multi-billion-dollar market in support of chemotherapy administration
- G-CSF modestly ameliorates chemotherapy-related neutropenia but does not improve thrombocytopenia, anemia, or antitumor efficacy
- Through stimulation of TLR-2/6, CBLB612 offers the potential for multilineage hematorestoration and antitumor efficacy
  - Potential for use before or after chemotherapy (G-CSF only works after chemotherapy)
  - Possible improvements in neutrophil, platelet, and red blood cell counts while mobilizing progenitor cells
  - Potential for antitumor effects
- Results of a recently completed Phase 1 healthy-subject study support Phase 2 development

# A Phase 2 Study Will Evaluate CBLB612 as Myelosuppressive Prophylaxis in Patients Receiving Docetaxel Chemotherapy

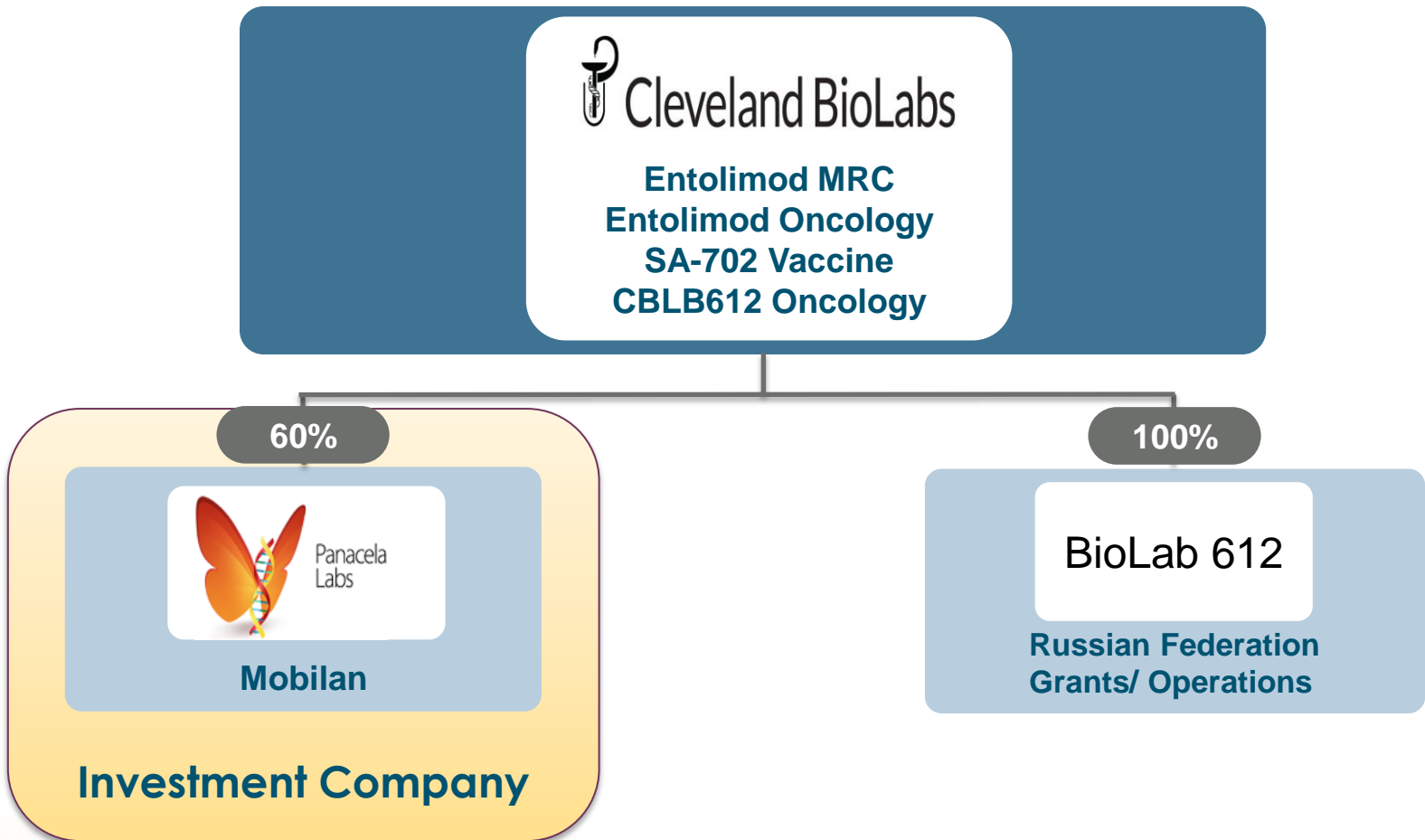


Anticipated to start in 2H2015 with support from a Russian government contract

# CBLI

## Financial Summary and Development Milestones

# CBLI's Corporate Structure



# Pro Forma Financial Summary

(as of June 30, 2015)

\$s in millions <sup>(1)</sup>

	CBLI & BioLab 612	Majority-Owned Joint Venture (Panacela)	Total
Cash & investments - actual	\$ 2.3	\$ 1.3	\$ 3.6
Davidovich private placement, net proceeds	23.5		23.5
Sale of Incuron joint venture	1.0		1.0
Payment of outstanding Hercules debt	(2.0)		
<b>Total Pro forma Cash &amp; Investments</b>	<b>24.8</b>	<b>1.3</b>	<b>26.1</b>
Contract & grant funding available <sup>(2)</sup>	0.9	0.5	1.4
Contract awards, not yet funded <sup>(3)</sup>	0.7	0.7	1.4
Financial Partner options <sup>(4)</sup>	-	15.5	15.5
<b>Total Financial Resources</b>	<b>\$ 26.4</b>	<b>\$ 18.0</b>	<b>\$ 44.4</b>

<sup>(1)</sup> Amounts payable in foreign currencies are quantified based on the period-end exchange rate.

<sup>(2)</sup> Amounts represent contract & grant funded awards, less cash receipts to date.

<sup>(3)</sup> Amount represents awards made for future periods of currently active contracts, not yet funded.

<sup>(4)</sup> Amount represents optional future contributions the financial partner can make to subsidiary.

# Capitalization Summary

(as of August 12, 2015)

Security	Shares	Notes
Common Stock	10,729,123	
Warrants	2,227,232	Wtd. Avg. exercise price of \$13.95
Stock Options	365,784	Wtd. Avg. exercise price of \$48.89
<b><i>TOTAL</i></b>	<b>13,322,139</b>	



# CBLI Development Milestones

	2015				2016			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Entolimod - MRC:</b>								
Pre-EUA submission		X						
Potential DoD development contracts			X					
Potential Pre-EUA Review/Feedback from FDA*				X				
Potential US/foreign pre-EUA sale							X	
<b>Entolimod- Oncology:</b>								
Ph 1 advanced cancers data reported at ASCO (US)		X						
Ph 1 advanced cancers data reported (RF)					X			
<b>SA-702 Vaccine Superadjuvant:</b>								
Ph 1 Anti-meth/SA-702 vaccine started							X	
Ph 1 Anti-cocaine/SA-702 vaccine started								X
Ph 1 Anti-meth/SA-702 vaccine data reported								X
<b>CBLB612:</b>								
Ph 1 healthy subject data reported (RF)		X						
Ph 2a myelosuppression prophylaxis started (RF)			X					
Ph 2a myelosuppression prophylaxis data reported (RF)							X	

\* Estimate (no PDUFA timeline)