

# Advancing Medicines for Neglected and Rare Diseases Through Innovative Business Models

OTC: KBIO  
[www.kalobios.com](http://www.kalobios.com)



# Forward-Looking Statements

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Words such as "will," "expect," "intend," "plan," "predict," "potential," "possible," and similar expressions identify forward-looking statements, including, without limitation, statements related to the scope, progress, expansion, and costs of developing and commercializing our product candidates, anticipated regulatory incentives for product candidates, and anticipated expenses related to development activities, clinical trials and the development and potential commercialization of product candidates.

Forward-looking statements are subject to risks and uncertainties including, but not limited to, the Company's ability to execute its revised strategy and business plan; the ability of the Company to list its common stock on a national securities exchange; the Company's access to limited cash reserves and its ability to obtain additional capital, including the additional capital which will be necessary to complete the clinical trials that the Company has initiated or plans to initiate; the potential timing and outcomes of clinical studies of benznidazole, lenzilumab, ifabotuzumab or any other product candidates; the commercial viability of the Company's proposed drug pricing program; the ability of the Company to timely source adequate supply of its development products from third-party manufacturers on whom the Company depends; the potential, if any, for future development of any of its present or future products; the Company's ability to successfully progress, partner or complete further development of its programs; the ability of the Company to identify and develop additional products; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals and reaching other development milestones; the Company's ability to apply or receive Priority Review Vouchers; the Company's ability to protect the Company's intellectual property; competition; and changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the various risks described in the "Risk Factors" and elsewhere in the Company's periodic and other filings with the Securities and Exchange Commission.

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# Compelling Investment Opportunity

- Turnaround focused on high-value neglected and rare diseases, including pediatric
- Pipeline with multiple potential near- and longer-term catalysts
  - Benznidazole: 505(b)(2) development pathway for Chagas disease; possible PRV
  - Lenzilumab: recombinant mAb; possible PRV
  - Ifabotuzumab: recombinant mAb; pediatric and orphan blood and solid cancers; possible PRV; ready for partnering
- Experienced, focused new management with track record of efficient execution, commitment to leadership in responsible, transparent pricing

# Leadership



## **Cameron Durrant, MD, MBA**

### **Chairman and CEO**

- Senior pharmaceutical and biotech exec, turnaround specialist
- Senior exec roles at Pharmacia/Pfizer, J+J in US, Merck, GSK in Europe; experience as Exec Chairman, CEO and CFO; CEO roles at three specialty pharma groups
- Expertise in anti-infectives, pediatrics, oncology



## **Morgan Lam**

### **Chief Scientific Officer**

- Extensive industry experience in clinical research
- Head of Clinical Operations and Development KaloBios
- Executive Director, Medical Affairs, Geron



## **Dave Tousley, MBA, CPA**

### **Interim Chief Financial Officer**

- More than 35 years experience in biotech, spec pharma, big pharma
- Senior exec roles, President, COO, CFO
- Pasteur, Merieux, Connaught, AVAX, airPharma, PediaMed, DARA Biosciences



## **Tariq Arshad, MD, MBA**

### **Consultant focused on medical affairs**

- Extensive industry experience in clinical development
- Experienced in orphan, pediatrics, oncology, pediatric oncology, immunology
- Pharmacia/Pfizer, Genentech, Xoma



## **Niv Caviar, MBA**

### **Consultant focused on corporate/business development**

- Senior functional roles in marketing, business development, strategic planning
- Senior exec roles, CEO, EVP-CBO, CFO, VP Bus Dev
- La Jolla Pharma, Allergan, Suneva, SpineOvations, Affymetrix, Accenture



## **Christopher Bowe**

### **Consultant focused on corporate affairs**

- Deep experience advising CEOs on articulating, executing strategy through corporate affairs
- Former Strategic Affairs advisor at Schering-Plough
- Industry thought leader, prior award-winning writer Financial Times



## **Steve Pal, MBA**

### **Consultant focused on commercial**

- Global pharma and consumer healthcare product commercialisation
- Former Corporate VP Global Strategic Marketing, Health Outcomes, Strategy and Research, Global Medical Affairs, Allergan

# Board of Directors

## **Cameron Durrant, MD, MBA**

**Chairman**

## **Ronald Barliant, JD**

- Of Counsel at Goldberg Kohn, extensive experience representing debtors and creditors in complex bankruptcy cases
- United States bankruptcy judge for the Northern District of Illinois 1988 to 2002

## **Dale Chappell, MD, MBA**

- Managing member of Black Horse Capital Management, LLC
- Previously associate at Chilton Investment Company specializing in healthcare

## **Timothy Morris, CPA**

- CFO AcetRx Pharmaceuticals; also Head of Business Development
- CFO, SVP Finance and Global Corporate Development VIVUS, Inc.

## **Ezra Friedberg**

- Founder and general partner of Multiplier Capital, LP
- >20 years investing experience across public and private companies

# Two-Pronged Value Model: a Unique Approach To Near-Term Return Propelling Long-Term Value Creation

## Hunt

Late-stage, neglected, rare/orphan assets



## Value Creation

Potential robust commercial return



## Smart

Investment in underappreciated assets



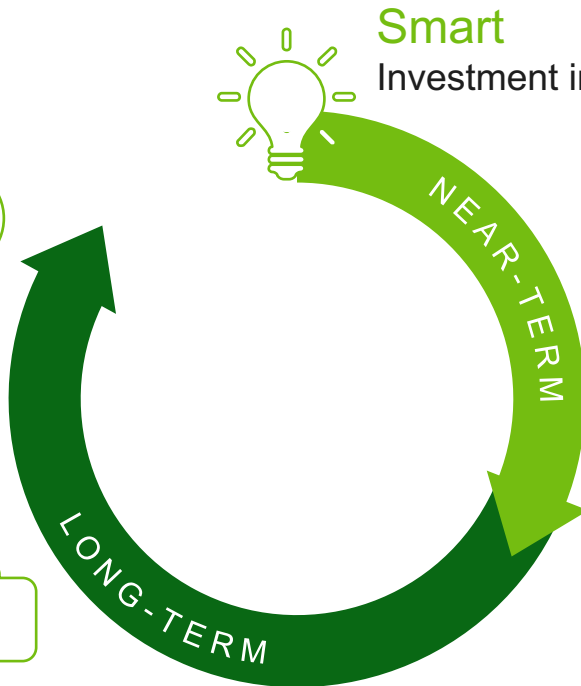
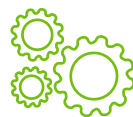
## Leverage

FDA incentives for better efficiency



## Value Options

From multiple FDA catalysts like PRV

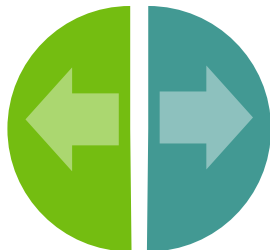


# Priority Review Vouchers (PRVs)

## Create Options For Significant Potential Return

Highest disclosed sale price so far for PRV is \$350MM

Neglected  
Tropical  
Diseases  
(NTD)



Rare  
Pediatric  
Diseases  
(RPD)

- Holder of PRV can receive priority review for any NDA/BLA
- PRV can be sold to company seeking a competitive jump
- KaloBios open to novel potential PRV transaction structures

# KaloBios Turnaround Momentum Builds: Rising from the Ashes

San Francisco R&D company, mAb platform

Funding dead-end, winding down Oct 2015

Martin Shkreli investment late Nov 2015

Shkreli arrest, indictment Dec 2015

Chapter 11 filing Dec 2015

Delisted by Nasdaq Jan 2016

FDA meeting Dec 2016 and positive minutes Jan 2017

Current with SEC filings Sept 2016

Shkreli stake extinguished Aug 2016

Lenzilumab Phase 1 start July 2016

Shkreli governance agreement July 2016

Exit from Chapter 11 bankruptcy June 30, 2016

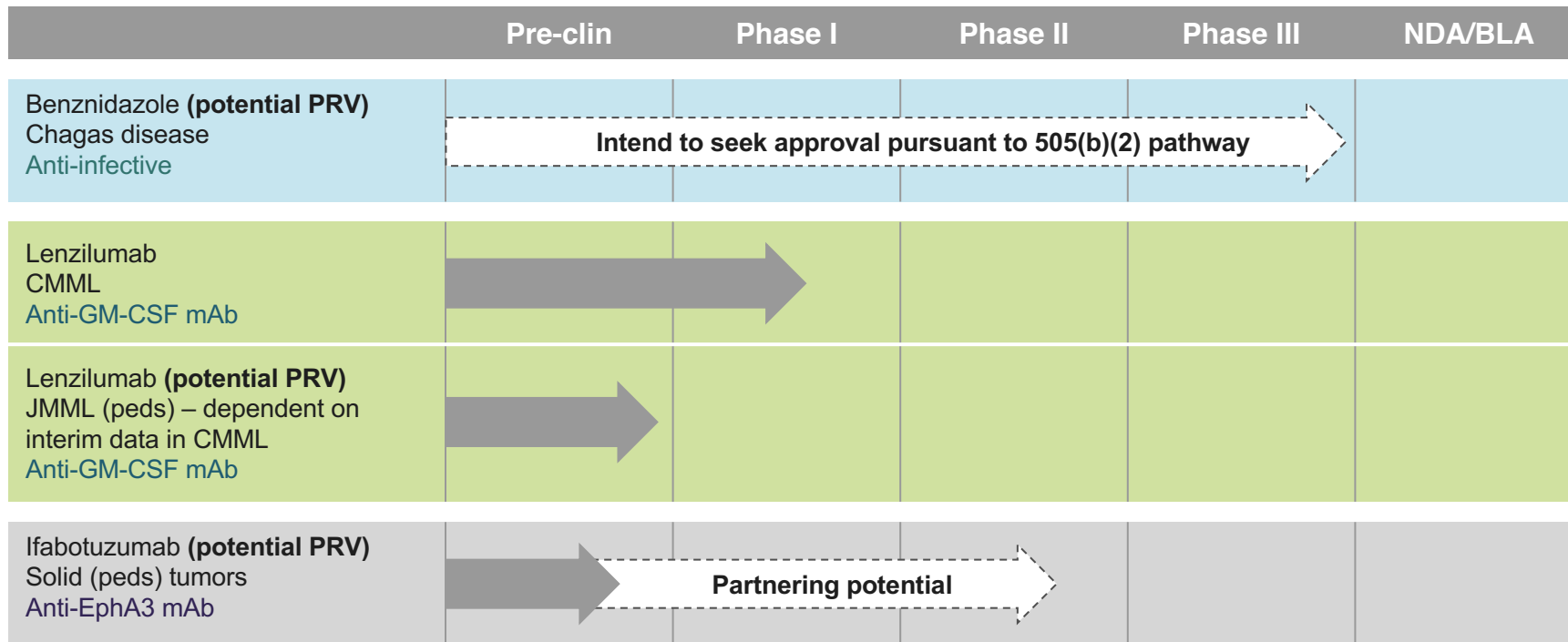
Announced Responsible Pricing Model April 2016

New CEO Mar 2016

Two new board members Jan 2016



# Current Pipeline



# Benznidazole



a potential treatment for Chagas disease

# CHAGAS disease

A chronic, potentially life-threatening infectious disease spread by contact with feces of an infected triatomine insect, called “kissing bugs”



## KEY TAKEAWAYS

- On FDA list of NTDs eligible for PRV
- Neglected tropical disease presenting in the US and other nations
- Currently no FDA-approved treatments
- Immediate need for reliable benznidazole supply in US and abroad



Insect carries the parasite called *Trypanosoma cruzi*

300,000



Infected individuals in US\*



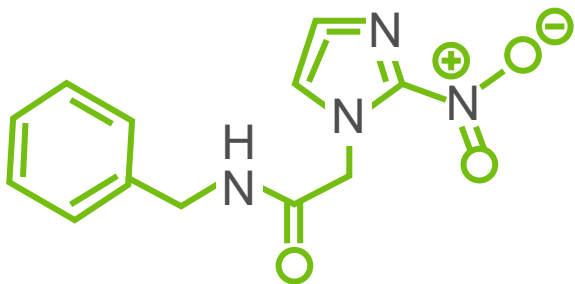
Significant portion of chronic patients progress to serious heart illness



Can also affect swallowing, digestion and cause neurological complications

\* Source: CDC

# Benznidazole: the Preferred Treatment Globally for Chagas



40 years of clinical experience, primarily in Latin America

- Used in tens of thousands of patients

Efficacy ~60% or more in children and can be higher in young children, according to published studies

- Believed to work by inducing free radicals damaging DNA within parasite
- Better tolerated in children; side effect profile extremely well known

Only available in US via special protocol with CDC

Drug supply believed to be sporadic, product difficult to obtain

# Benznidazole Strategy, Development Plan On Track



## Positive FDA Guidance

- Received minutes from productive meeting

## 505(b)(2) Pathway

- Acceptable to FDA
- Expect no clinical efficacy or safety studies

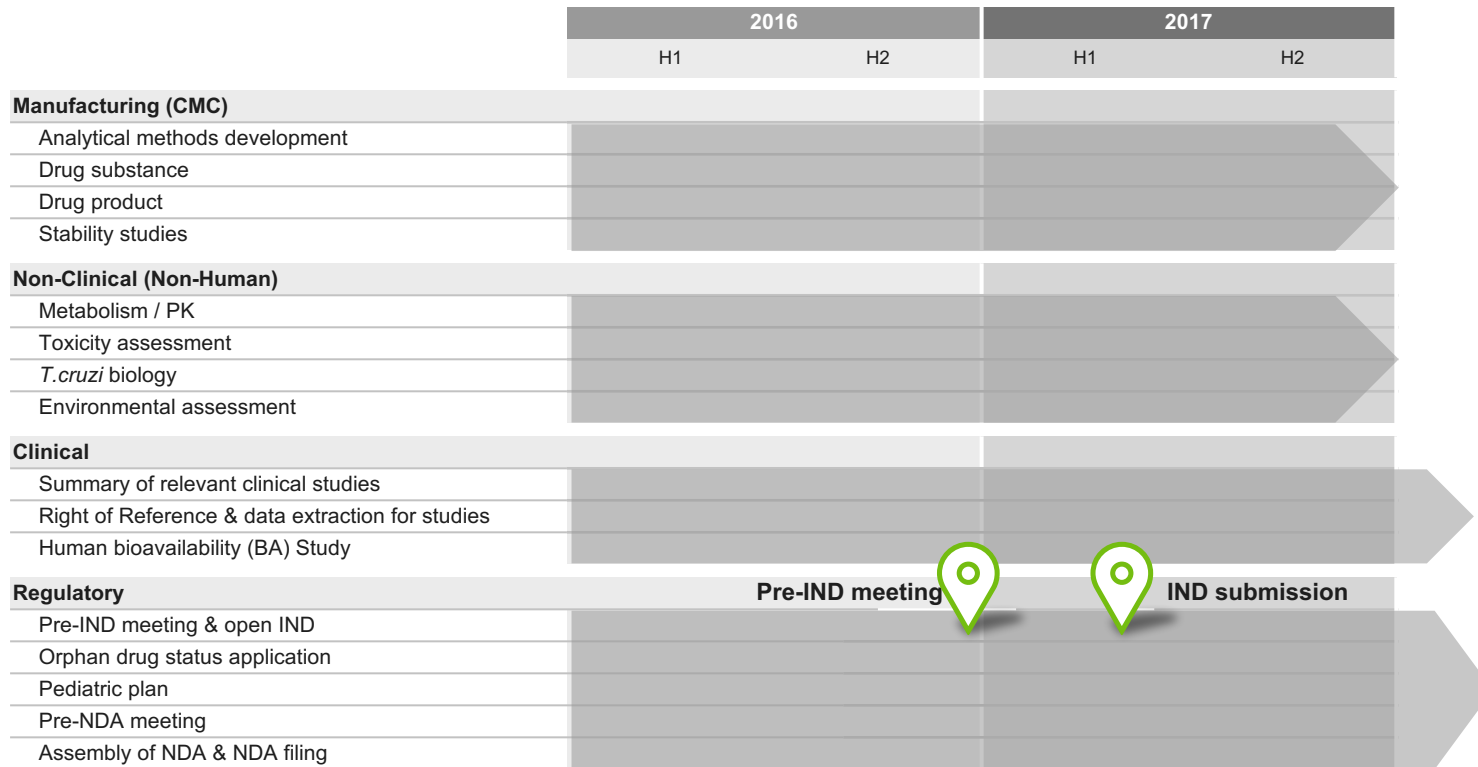
## PRV Eligibility Confirmed

- Currently expected to be eligible if approved for Chagas disease

## Progress to Submission

- Expect to progress expeditiously toward a submission

# Benznidazole Target Approval Plan





# Lenzilumab

a potential pipeline in a product



# CMML overview

a rare hematologic cancer



Recently classified as separate disease with distinct natural history\*



~1,100



Newly diagnosed US patients per year

60+

Age at diagnosis



Median overall survival rate in months

*\* Formerly classified as subtype of the myelodysplastic syndromes (MDS)*

## KEY TAKEAWAYS



- High unmet need
- Patients typically unsuitable for stem cell transplant
- 40-90% patients show hypersensitivity to GM-CSF



# JMML overview

very rare, frequently lethal pediatric leukemia

~420



New US cases per year



Age of majority of patients at diagnosis is 4 years or younger

~52%

Event-free survival rate at 5 years (with bone marrow transplant)

## KEY TAKEAWAYS

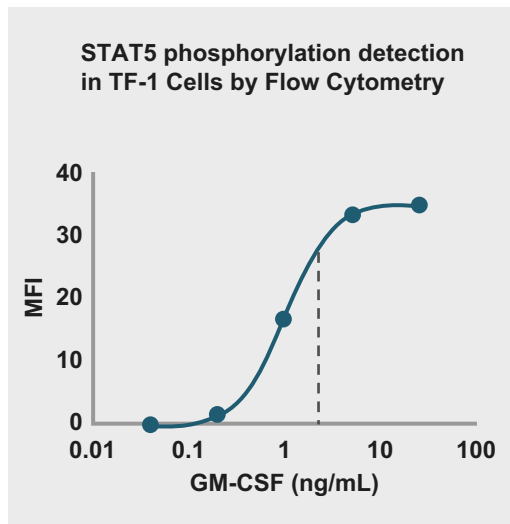


- No FDA-approved treatment
- Clear unmet need
- Potential for a rare pediatric disease PRV
- GM-CSF hypersensitivity is hallmark
- Pediatric oncology largely ignored in clinical development

# Lenzilumab is a Potent Inhibitor of GM-CSF Function *In Vitro*

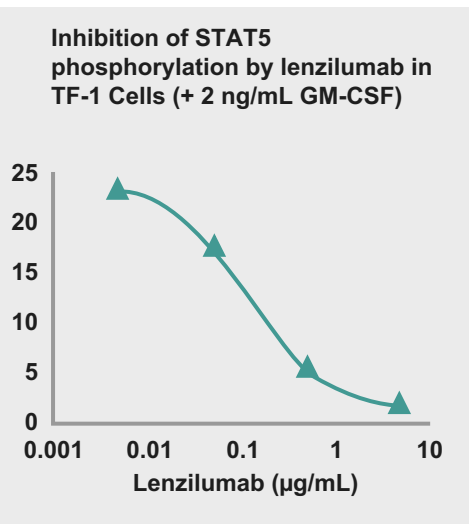


Blocks GM-CSF-induced STAT5 Phosphorylation in Human TF-1 Leukemia Cells

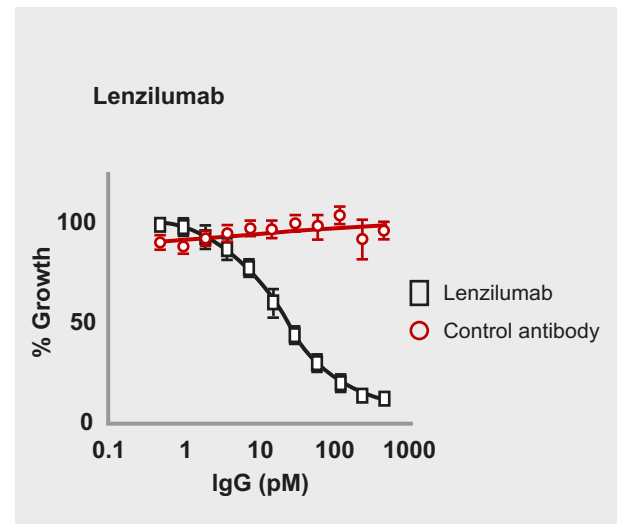


MFI = mean fluorescence intensity

Source: KaloBios laboratory notebook

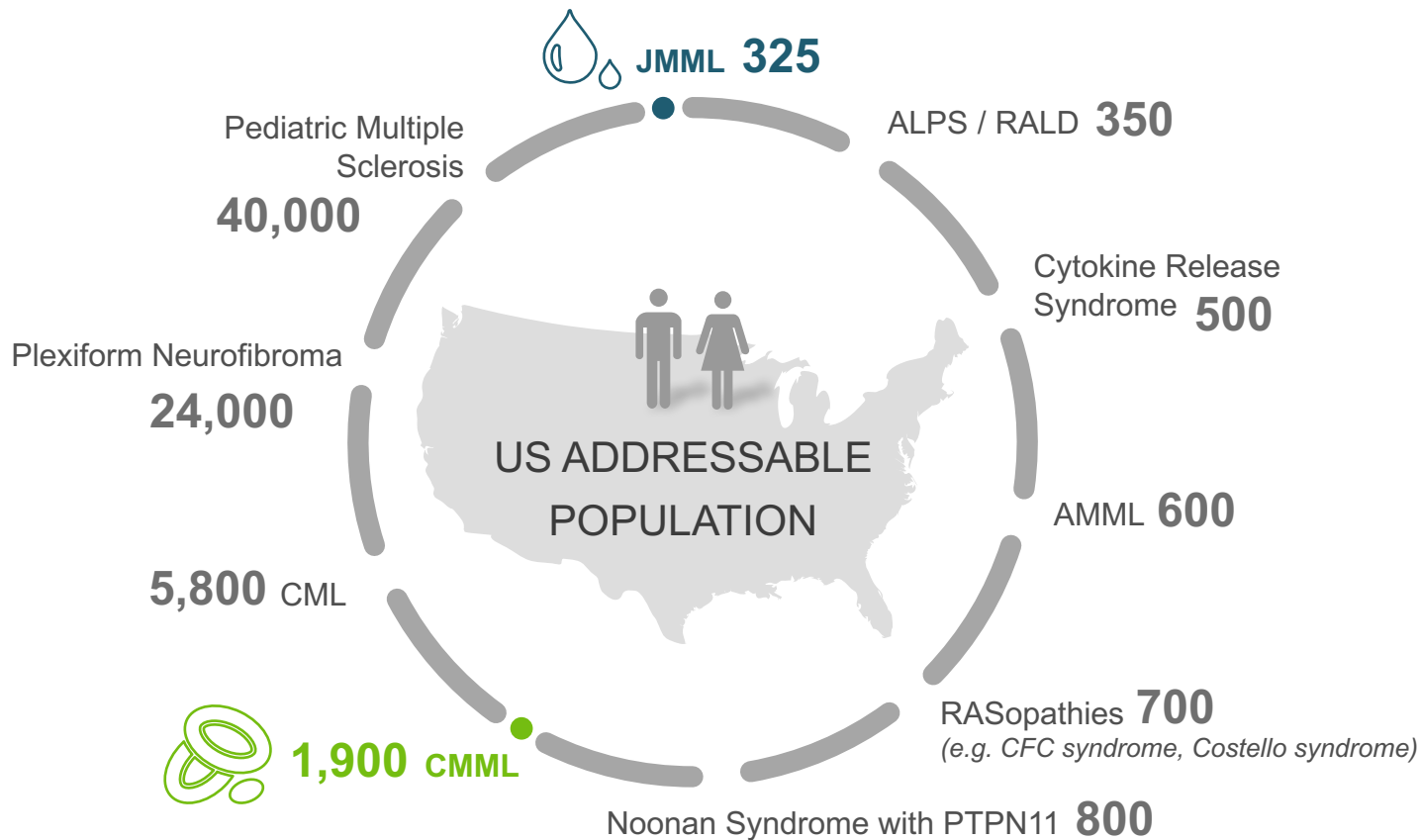


Inhibits GM-CSF-dependent Proliferation of Human TF-1 Leukemia Cells



Source: KaloBios pre-clinical study

# Lenzilumab: a Pipeline in a Drug Opportunity



# Ifabotuzumab



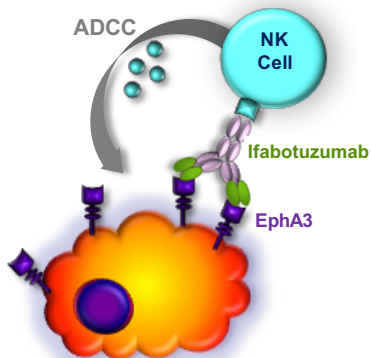
significant potential for partnering and development

# Ifabotuzumab Has Four Postulated Mechanisms of Action

Humaneered® monoclonal antibody for Ephrin type-A receptor 3 (EphA3)

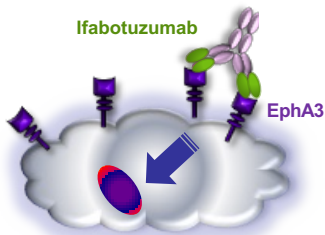
1

ADCC Mediated Killing of  
Tumor Cells



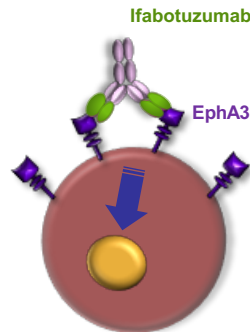
2

Direct Apoptosis of  
Tumor Cells



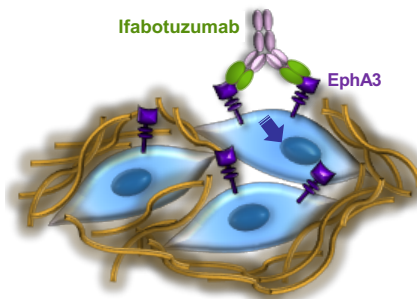
3

Disruption of Tumor  
Vasculature through Cell  
Rounding



4

Anti-fibrotic Effect



# Capitalization Summary as of 1/9/17

Debt	<b>\$4.3 million</b>
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Common Shares Outstanding	<b>14.9 million</b>
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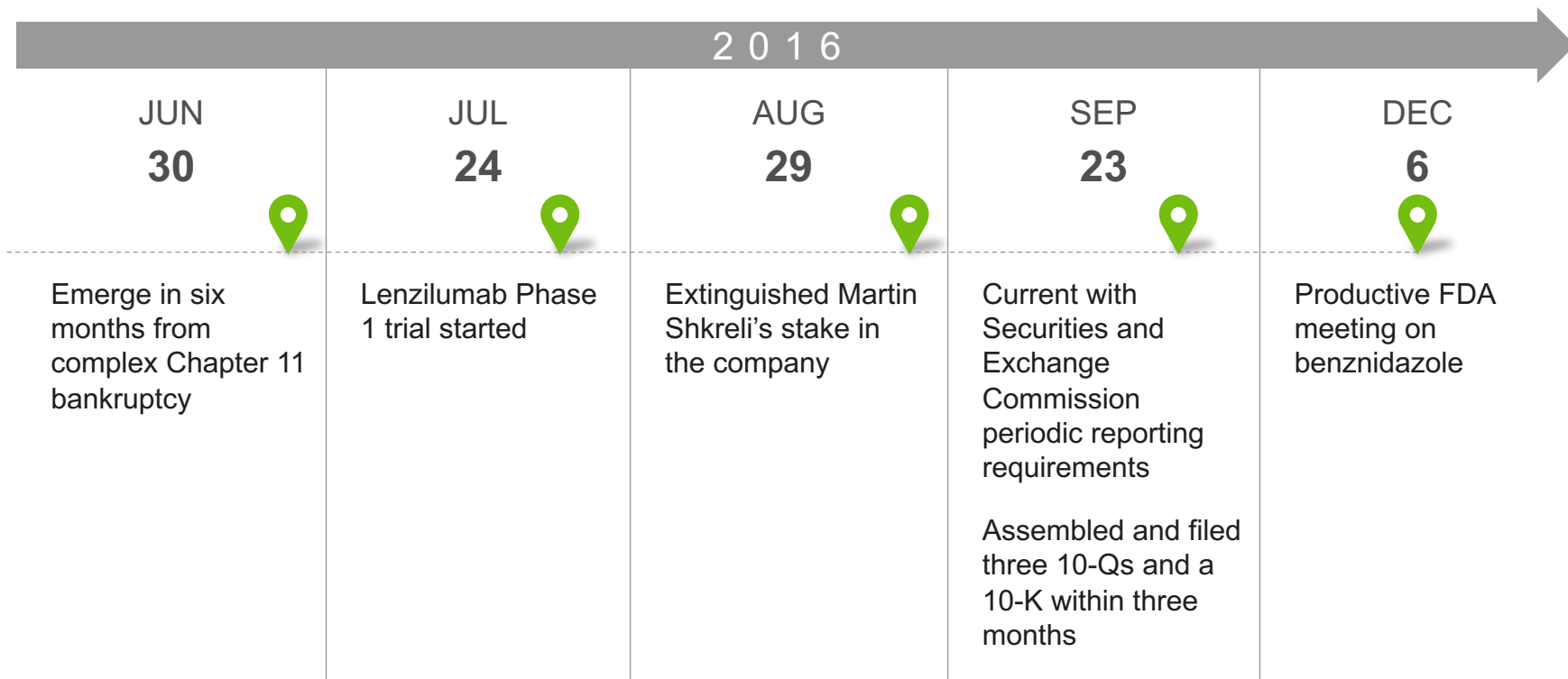
Stock Options (WAEP \$5.82)	<b>2.1 million</b>
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Warrants (WAEP \$14.24)	<b>0.3 million</b>
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<b>Fully Diluted Shares Outstanding</b>	<b>17.3 million</b>
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*Note: share and per share amounts as of 9/30/16 – last 10-Q filing  
Debt includes term loan financing closed on 12/21/16*

# Demonstrated History of Swift Execution in Challenging Circumstances



# Summary

- Unique near-term/long-term potential value creation opportunity
- Thoughtful business strategy that leverages existing U.S. regulatory and development incentives
- Attractive asset portfolio with multiple potential milestones and partnering prospects
- Deeply committed and focused new management team with an unwavering commitment to success