

# Near-Term Value Creation for Neglected and Rare Diseases Through Innovative Business Models

OTC: KBIO  
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# Unique Investment Opportunity

- Turnaround story focused on delivering value to shareholders
- Clinical stage neglected and rare disease assets with clear development pathway and modest investment needed to reach potentially significant value inflection points
  - Benznidazole franchise: potential approval with market exclusivity plus potential PRV sale in latter half of 2018; standalone, focused commercial opportunity in US that can be leveraged with synergistic products in adjacent therapeutic areas to Chagas; larger patient market opportunity in LATAM; compelling strategic partnership opportunity; lifecycle management plan
  - Lenzilumab franchise: multiple potential indications plus potential PRV; significant markets in Orphan areas; multiple licensing and commercial opportunities; lifecycle management plan
- Experienced, focused management with track record of efficient execution and 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**

**Head of Clinical and Medical Affairs**

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



**Niv Caviar, MBA**

**Head of 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**

**Head of 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**

**Head of Commercial**

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



# Management Experience Developing, Launching Products in Infectious Diseases, Cardiovascular, Oncology, Other Markets



# Two-Pronged Value Model: Near-Term Return, Propelling Long-Term Value Creation

## Hunt

Late-stage, neglected, rare/orphan assets



## Value Creation

Potential robust commercial return: PRV returns fuel pipeline development



## Smart

Investment in underappreciated assets: speed to market and unmet need in neglected and rare/orphan areas



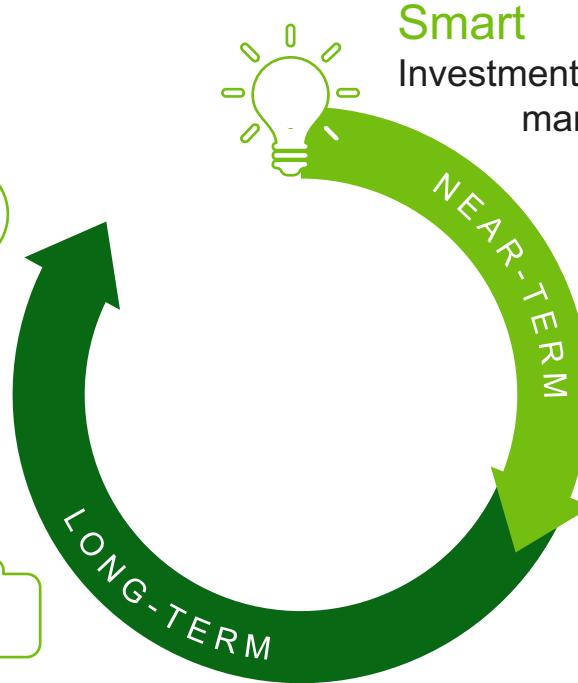
## Leverage

Existing FDA incentives for efficiency: 505(b)(2), Orphan, Priority Review, Fast-Track, Breakthrough

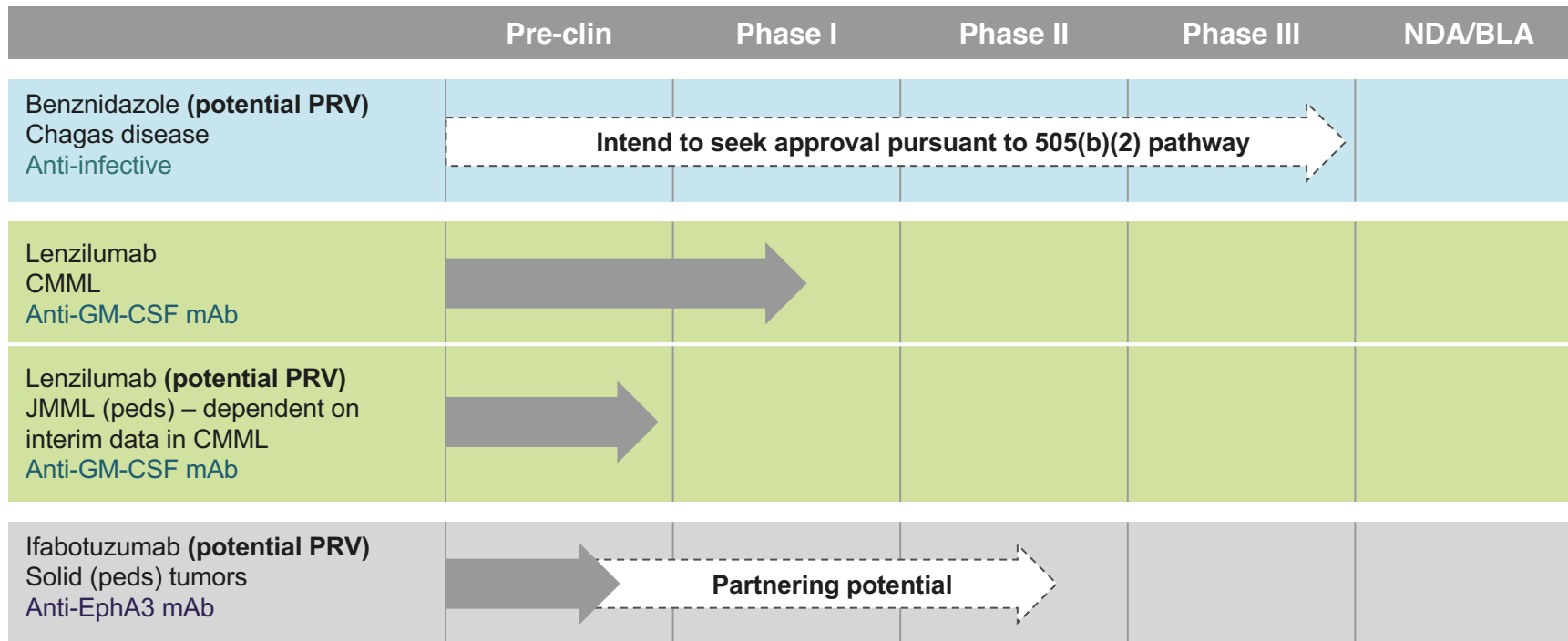


## Value Options

From multiple FDA catalysts like PRV, licensing, commercialization, international opportunities



# Current Pipeline



# Benznidazole



a potential treatment for Chagas disease (CD)

# CHAGAS disease

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



Insect carries the parasite called *Trypanosoma cruzi*

350,000



Infected individuals in US\*



Significant portion of chronic patients progress to serious heart illness



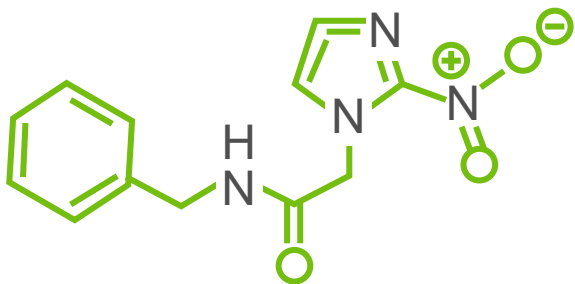
Can also affect swallowing, digestion and cause neurological complications



## KEY TAKEAWAYS

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

# 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 sporadic, product difficult to obtain

# Benznidazole Strategy, Development Plan on Track



## Positive FDA Guidance

- Received minutes from productive meeting December 6, 2016

## 505(b)(2) Pathway

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

## PRV Eligibility Confirmed

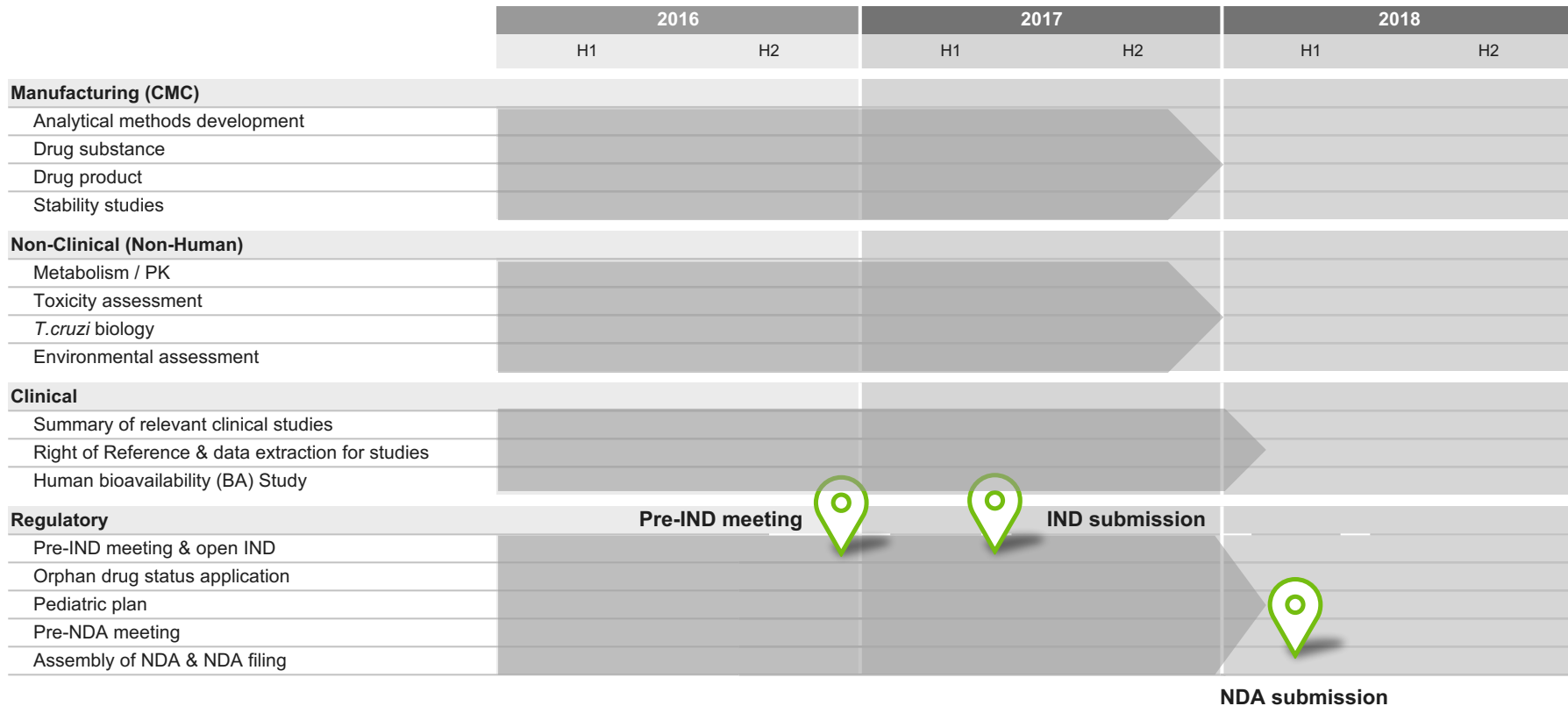
- Currently expected to be eligible if approved for Chagas disease

## Progress to Submission

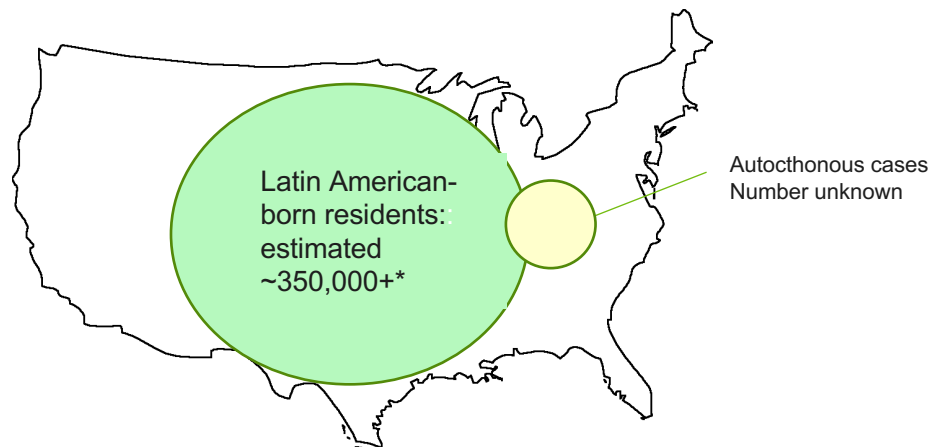
- Manufacturing batches of drug complete, prototype tablets made
- Secured safety/efficacy databases
- Next FDA meeting already scheduled



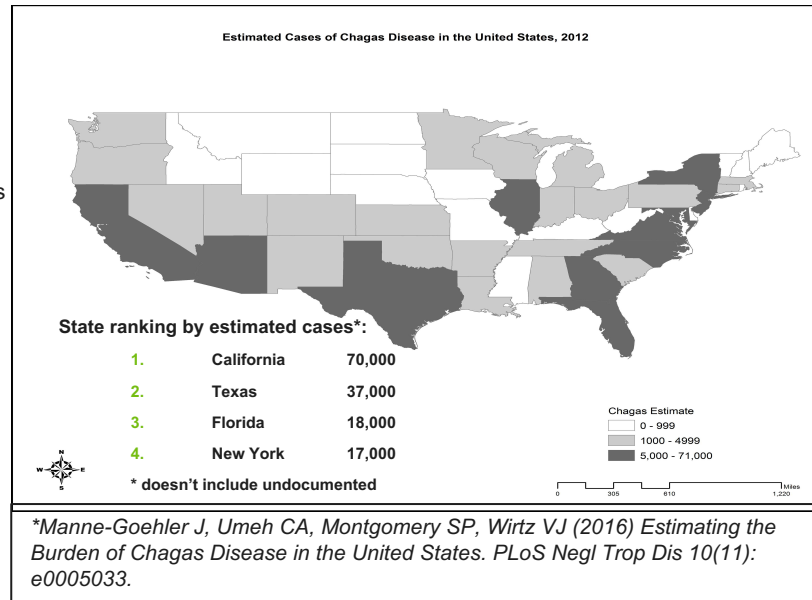
# Benznidazole Target Approval Plan



# The Burden of Chagas Disease in the US: ~350,000 patients



\*Sources: Bern and Montgomery 2009, Manne-Goehler et al. 2016



Acute Phase + Congenital  
Prevalence

Less than 1000

Chronic Indeterminate Phase  
Prevalence

200,000-250,000

Chronic / Symptomatic Phase  
Prevalence

60,000-100,000

Currently less than 1% diagnosed and less than 0.2% treated

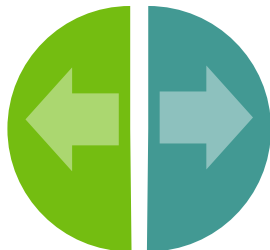
# Building the Benznidazole Franchise: LATAM Commercial

- 8-10 million estimated patients, 120 million people at risk, 300,000 new cases a year, 12-14,000 deaths
- Large volume, lower cost commercial opportunity vs. US; potential for pricing differentiation with multiple KBIO benz versions according to manufacturing source
- US FDA approved product has significant advantages in this market to local companies
- Significant market opportunity
- Synergies with other anti-infectives product or cardiovascular companies
- HF companies have begun local Chagas heart failure market expansion programs
- Potential for strategic licensing/partnership with an anti-infectives or HF company with LATAM presence

# Building the Benznidazole Franchise: Priority Review Voucher (PRV) May Create Options for Significant Potential Return

Range of disclosed sale prices for PRVs is \$67.5MM - \$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
- PRV sale could be part of an overall partnering package alongside other elements of the benz franchise

# Benznidazole Franchise Conclusions

- Comprises US commercial (+/- HF linkages), LATAM commercial, manufacturing potential partnerships, LCM upside and PRV sale
- US commercial footprint may allow for leverage with synergistic products and is small, focused and scalable
- Overall package valuable and significant portion of that value may be unlocked near-term, with PRV sale potentially occurring in late 2018



# 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%

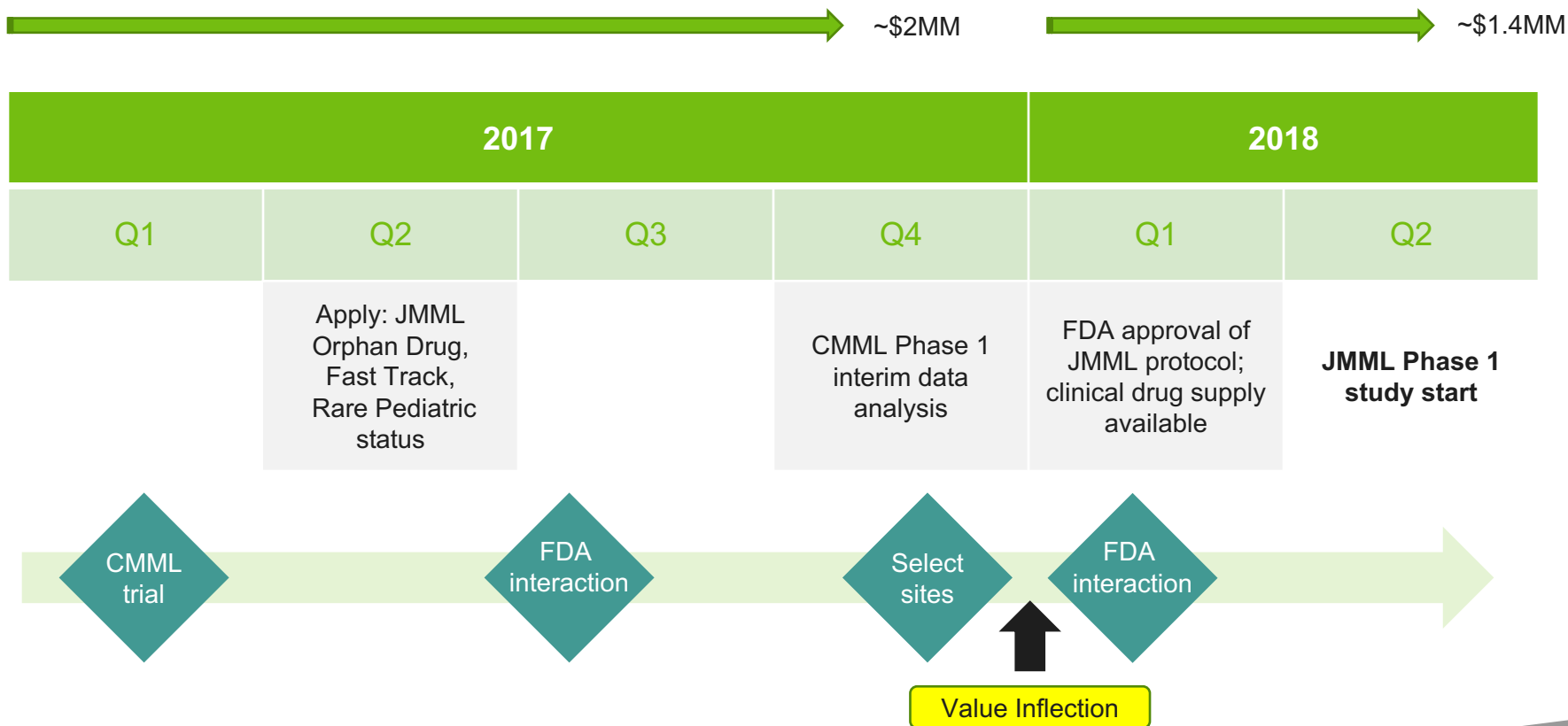
Event-free survival rate at 5 years (with bone marrow transplant)

## KEY TAKEAWAYS



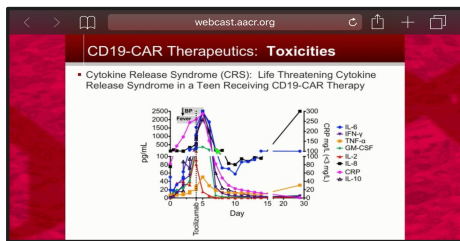
- No FDA-approved treatment
- Clear unmet need
- Potential for a rare pediatric disease PRV
- GM-CSF hypersensitivity is hallmark
- Pediatric oncology largely ignored in clinical development

# Relatively Low Investment To Lenzilumab Inflection Point



# Building the Lenzilumab Franchise: Intentional Choices of What To Develop, To What Stage, and What To Partner; SC Formulation

- Develop CMML to interim data read Q4 2017
- Retain and develop to data inflexion points in ped MS and neurofibromatosis and potentially to approval and commercialize as large market Orphan indications with no FDA-approved therapies
- Pivot to JMML and retain and develop to approval or partner prior, but keep interest in any potential PRV sale proceeds
- Develop in Cytokine Release Syndrome: huge interest in making CAR-T therapy more useful; consider CAR-T partners
- Partner out CMML (and other hem oncology indications, eg, AMML, CML)
- Partner out ultra-Orphan indications ( RAS-opathies, Noonan) with expert ultra-Orphan companies



# Lenzilumab Franchise Conclusions

- Comprises US development and partnering, ex-US partnering, US focused Orphan commercial, LCM upside and PRV sale
- US commercial Orphan footprint could be scaled independently or via partnerships
- Potential opportunity to benefit from CAR-T interest
- US and ex-US ultra-Orphan potential partnerships with expert players adds further value
- Overall potential for significant value through LCM with additional indications around the 'pipeline-in-a-product' strategy, with PRV sale potentially adding non-dilutive capital in 3-4 years

# Capitalization Summary

Debt	<b>\$10.1 million</b>
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Common Shares Outstanding	<b>15.0 million</b>
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Stock Options (WAEP \$3.85)	<b>2.4 million</b>
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Warrants (WAEP \$13.52)	<b>0.4 million</b>
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<b>Fully Diluted Shares Outstanding</b>	<b>17.8 million</b>
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*Note: share and per share amounts as of 3/31/17*

*Debt includes term loan financings*

# Summary

- Attractive asset portfolio with potential to deliver shareholder value quickly
- Unique near-term/long-term potential value creation opportunity
- Business strategy that leverages existing U.S. regulatory and development incentives to build unique, high value franchises around key assets
- Deeply focused new management team with a demonstrated track record of execution