

### **AMAG Analyst Day 2016**



# **AMAG Management Team**



Bill Heiden
Chief Executive Officer



Frank Thomas
President &
Chief Operating Officer



Nik Grund Chief Commercial Officer



Julie Krop, M.D.

Chief Medical Officer



Ted Myles Chief Financial Officer



Todd Van Horn General Manager, CBR



Melissa Klug SVP, Business Development & Strategy



# Agenda – AMAG Analyst Day 2016 (8:30 AM – 12:00 PM)

Registration and continental breakfast		
Welcome & agenda	Linda Lennox, VP, Investor Relations	
Strategic overview & outlook	Bill Heiden, CEO	
Makena franchise	Nik Grund, CCO	
	Julie Krop, CMO	
	Makena Q&A	
Cord Blood Registry	Todd Van Horn, CBR General Manager	
	CBR Q&A	
Severe preeclampsia option (Velo)	Julie Krop, CMO	
Panel of 3 outside experts	Moderated by Frank Thomas, President & COO	
Feraheme	Nik Grund, CCO	
	Julie Krop, CMO	
	Feraheme Q&A	
Business development strategy	Frank Thomas, President & COO	
Financial strategy and guidance	Ted Myles, CFO	
Closing Remarks and Q&A	AMAG executive team - led by Bill Heiden, CEO	



## **Forward-Looking Statements**

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including among others, statements regarding the future market opportunity and growth drivers for Makena, including a new partnership with a provider of home nursing services, share gains from compounders, formulary expansions, the impact of the increased size of the sales force and support services and their effect on physician and patient brand loyalty; expectations for the single-dose formulation of Makena, including its benefits, launch strategy, positive indicators on Makena growth after the commercial launch of the single-dose formulation of Makena and estimated prescriptions; expectations for the Makena subcutaneous auto-injector, including estimated revenue, expectations of improved patient care, its development and advantages, estimated filing timeline of the sNDA and FDA review period and potential extension of orphan drug exclusivity; the future market opportunity and growth drivers for CBR, including expanded market penetration and the impact of a shift in value proposition and of connecting to the research community; expectations regarding the severe preeclampsia candidate, including the timing of initiation of a Phase 2b/3a study, potential orphan drug exclusivity, the future market opportunity and the impact on the Company's portfolio and position in the maternal health market; the future market opportunity and growth drivers for Feraheme, including plans to grow market share in the hospital and hematology/oncology segments; plans and expectations, including the size, timing of data and potential commercial launch of the head-to-head Phase 3 clinical trial for the broad IDA indication for Feraheme and the potential increase in size of the addressable market for Feraheme; 2016 financial guidance, including revenues, adjusted EBITDA, net income and cash flow; expectations regarding near and long-term intentions related to debt, equity and cash on hand; and AMAG's key milestones, including plans to achieve commercial, clinical, financial and portfolio expansion objectives are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, among others, those risks identified in AMAG's filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2015, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and subsequent filings with the SEC. Any of the above risks and uncertainties could materially and adversely affect AMAG's results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on AMAG's stock price. Use of the term "including" in this paragraph shall mean in each case "including, but not limited to." AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.





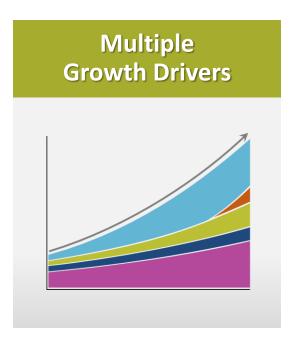
### **AMAG Analyst Day 2016**



# **Building a Growth-Oriented Biopharma Company**





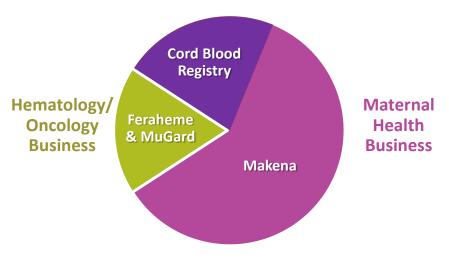






# **AMAG Today: Diversified and Financially Strong**

# 2016 Forecasted Product Revenue of \$545M<sup>1</sup>







# **Key Facts:** (March 31, 2016)

Marketed products	4
Market cap	~\$809M
Cash & investments	\$480M
Total net leverage ratio <sup>2</sup>	~2.6x
Employees	~600



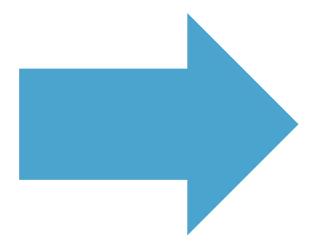
- 1. Reflects midpoint of AMAG's 2016 total product revenue guidance.
- 2. Debt minus cash divided by LTM adjusted EBITDA (\$1,041M-\$480M/\$214M)

# **A Transformed Company**

From: A single product company in 2012



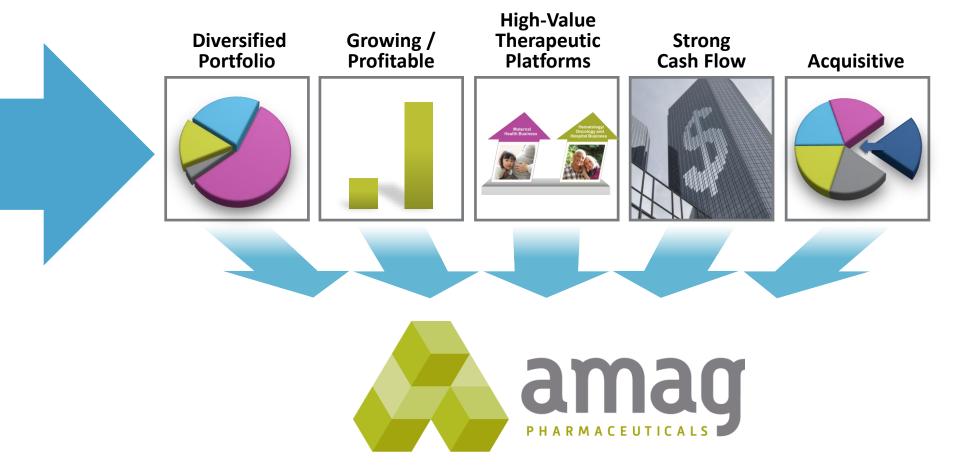
- Feraheme
- Operating loss





## **A Transformed Company**

To: A biopharma company with a portfolio of differentiated growth products





### **Last 18 Months – Significant Progress**



### Drove Makena business expansion

- 2015 expanded access, enlarged sales team, gained market share, Q1-2016 sales up 17%
- FDA approved single-dose, preservative-free formulation







#### **Grew Feraheme business**

Returned to double digit growth in 2016; sales up 13% in Q1-2016





### Completed and integrated acquisitions

- Makena, Cord Blood Registry, combined sales teams
- Option to acquire rights to orphan drug candidate for treatment of severe preeclampsia (Velo)





### Strengthened management team

- Chief Medical Officer (June 2015)
- Chief Commercial Officer (January 2016)
- Chief Financial Officer (April 2016)





# Growing, Cash Generating Business Model → Will Fuel Long-Term Growth



Strong Q1-2016 balance sheet: \$480M cash & investments, low net leverage ratio

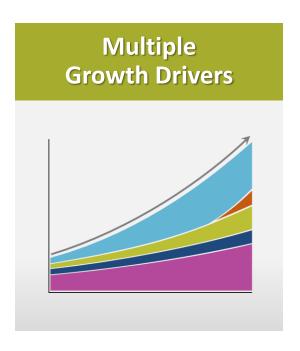


# **Building a Growth-Oriented Biopharma Company**











## **Building on Two Strong Platforms**

# Growth-Oriented Biopharmaceutical Company

# Maternal Health Business



- ~78% of revenues
- Products:
  - Makena
  - CBR
  - Severe preeclampsia option (Velo)

# Hematology / Oncology and Hospital Business



- ~22% of revenues
- Products:
  - Feraheme
  - MuGard

• Financial Strength • Corporate Infrastructure • Commercial & Digital Expertise



# Proven Commercial Execution Capabilities Consistently Maximize Product Growth Opportunities



#### **Proven Capabilities**

- Clear & compelling product differentiation: e.g. "Easy as 1-2-3"
- Optimizing pricing & contracting strategies
- Growing hospital segment

#### **Future**

- Potential label expansion
- Market expansion



#### **Proven Capabilities**

- Enhancing commercial & Medicaid patient access
- Premium customer service Makena Care Connection; educational programs
- Partnership with leading provider of home nursing services
- Partnerships with former compounders
- Optimization of sales force size

#### **Future**

- Additional physician & patient support programs
- Developing next generation products

### Next up...

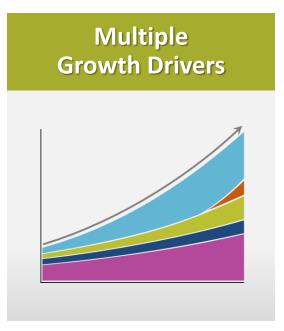




# **Building a Growth-Oriented Biopharma Company**











# Ambitious Future Growth Plan



### **Key Plan Pillars**



**GROWING:** 

Organic growth of current products through excellence in execution and ability to leverage key strengths and differentiators to expand use



**BUILDING:** 

Disciplined, patient-centric approach to portfolio expansion that complements our current strengths and differentiators

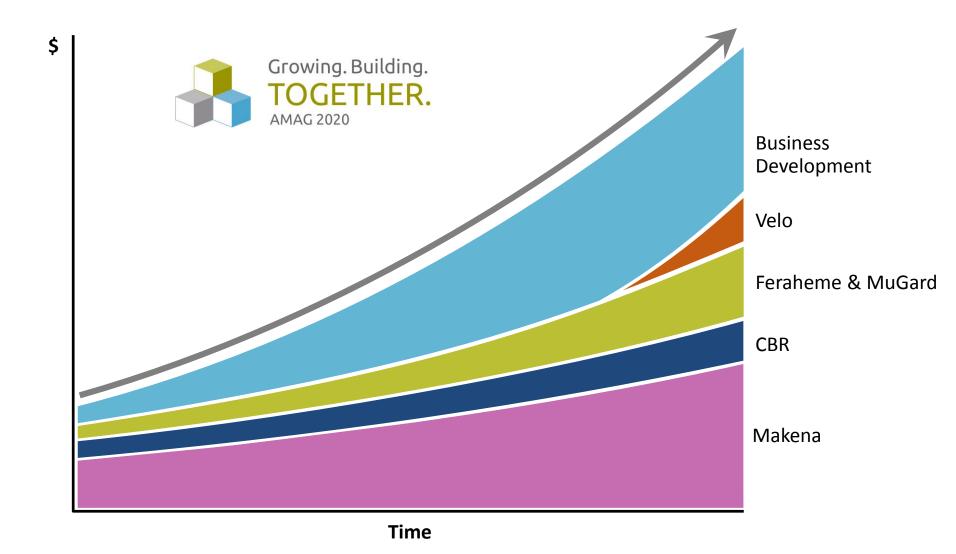


**TOGETHER:** 

Continued development of a best-in-class workforce with a strong, unified culture through investment in infrastructure and people



## Multiple, Growing Revenue Streams







### **AMAG Analyst Day 2016**



# Makena Agenda

- Status today building on two strong foundational platforms
- Market opportunities
- Competitive landscape
- Next generation development









## **Building on Two Strong Platforms**

# Growth-Oriented Biopharmaceutical Company

# Maternal Health Business



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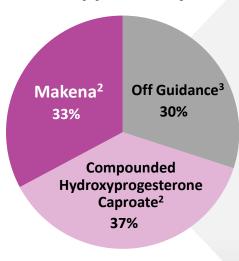






## **Growth Drivers in 2016 and Beyond**

# \$1B Market Opportunity<sup>1</sup>



Q1-2016 market share

- New partnership with a leading provider of home nursing services
  - One of the largest former sources of compounded Makena
- Continued market share gains from compounders
  - Preservative-free launch could expand conversion of additional compounding pharmacies to Makena distributors
- Continue to pull through formulary expansions
- Maternal health sales force increased to 104 reps from 76 reps (+37%) in Q3-2015
  - Target physician base doubled to 16,000 OB/GYNs
- Enhance physician and patient brand loyalty with valued support services, such as Makena Care Connection and nurse-supported adherence program

- 1. Based on 140,000 patients, >16 injections/patient and net revenue of ~\$425/injection.
- 2. Company estimates Makena market share based on distributor dispensing data and all other market share estimates based on physician market research data conducted by AMAG.
- 3. Off-guidance represents patients treated outside guidance of Society for Maternal Fetal Medicine (SMFM), including patients treated with unapproved therapies and untreated patients.





### **Single-Dose Makena: Gain Share and Convert Market**

### **Launch Strategy**

**Convert ALL prescribers to single-dose Makena (new and current prescribers)** 

**Priority #1: GROW** 

HCPs who prescribe compounded IM HPC

(Includes home healthcare opportunity)

**Priority #2: PROTECT** 

HCPs who prescribe multi-dose Makena

### Benefits of Single-Dose Vial of Makena

- Preservative free
- Convenient for healthcare providers (HCPs)
- 4-pack aligns with insurers' policies







### **Single-Dose Execution Priorities**

### Access



Ramped up staffing to process Rxs

#### **Market Access Team**

- ✓ Contracting under both medical & pharmacy benefit
- ✓ Reducing access barriers

#### Demand

#### **Field Sales**

- ✓ Converting physicians from compounded HPC
- ✓ Adding new prescribers
- ✓ Leveraging home health opportunities
- Expanding former compounding distributor network

### **Distribution**

# **Distribution Team Channel Expansion**

- ✓ Adding new partners >50
- ✓ Compounded product more difficult to acquire

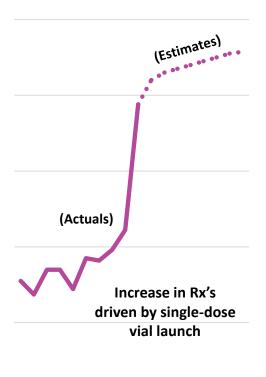






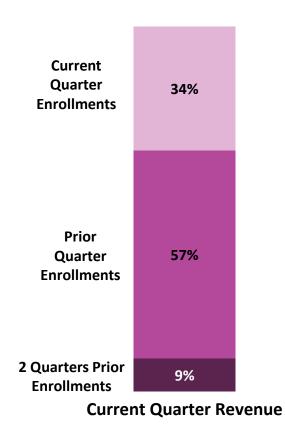
### Makena Revenue Lags Enrollment by ~1-4 Months

### Rx's Received in Makena Care Connection



7/15 10/15 1/16 4/16 7/16 10/16

### % of Revenue From Prior Quarter Enrollments



# Estimated 2016 Makena Revenue (\$M)





# Why We are Confident in the Long-Term Future of the Makena Franchise

- Only FDA approved drug to reduce risk of preterm birth
  - Minimal competitive pipeline activity







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- Significant room to continue growing market share
  - Gained 11 market share points since product acquired in November 2014
  - Vs. compounded 17P segment (esp. with single-dose vial launch)
  - Vs. untreated or treated with vaginal progesterone

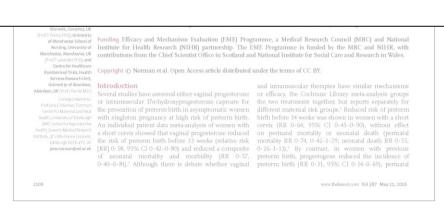








Interpretation Vaginal progesterone was not associated with reduced risk of preterm birth or composite neonatal adverse outcomes, and had no long-term benefit or harm on outcomes in children at 2 years of age.





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- Vs. untreated or treated with vaginal progesterone
- Opportunity to increase number of paid injections per patient
  - From current average ~13.7 to a maximum of 16-18 paid injections







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- Next generation Makena will drive 2018 growth and beyond
  - Single-dose; subcutaneous auto injector







## Makena Agenda

- Status today building on two strong foundational platforms
- Market opportunities
- Competitive landscape
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## **Competitive Landscape: Barriers for Generic Delalutin**

# Generic Delalutin Barriers to Use

- X Label indication
- X Limited ability to promote
- X Risk of off-label use
- X High-risk patient population
- Value proposition vs. compounded HPC

# Makena Business Model Advantages

- >100 sales representatives
- Makena Care Connection
- Broad distribution network
- Single-dose, preservative-free formulation



# Competitive Landscape: Market Research<sup>1</sup> on Durability of Makena Access

### **Key Payer Perspectives on Future HPC Market**

#### C-HPC Weakens Delalutin Value Prop.

 When C-HPC allowed, generic Delalutin may be duplicative or disadvantageous depending on price

"I want to like this generic, but it comes down to dollars and cents vs. C-HPC."

### Spec Pharma is King, Retail not Opportunity

- Makena is increasingly specialty pharma driven;
   Delalutin should follow suit
- Retail to be limited due to liability and waste

"Why would I not allow it to go through retail? I mean, why would I?!"

#### **Payers Also Awaiting Makena LOE**

 Select payers are thinking longer term and may wait to enact management until indicated generic entry

"If Makena will be off patent in 2018, not sure it's worth risk of managing now."

### **Clinical Support for Generic is Key**

 Many plans would need clinical data and/or society backing to advantage Delalutin (e.g., Avastin in AMD)

"We're putting ourselves at real risk without equivalence data or ACOG okay."



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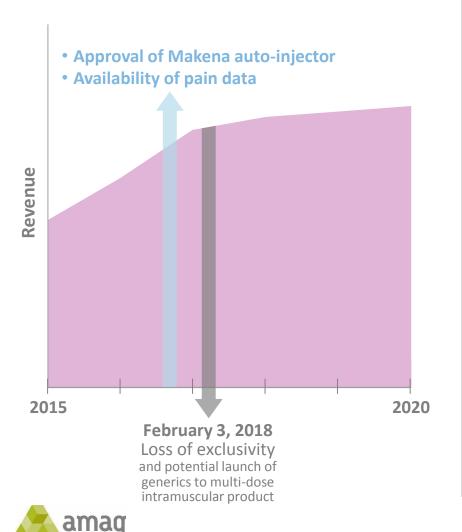




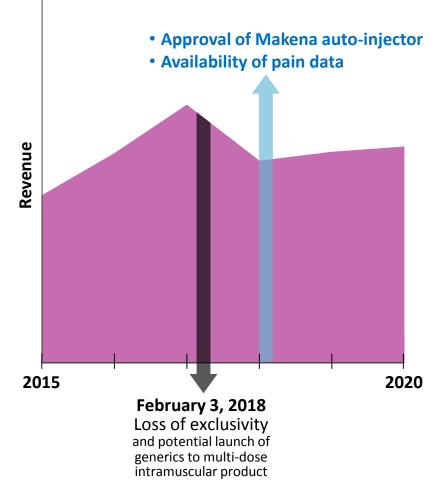


# Subcutaneous Auto-Injector Will Provide Significant Value to Makena Franchise – Pre or Post February 2018 Launch





# Estimated Revenue with Launch Delay<sup>1</sup>: Even if Delayed, Franchise is Protected & Grows



<sup>1.</sup> Estimates based on analogues and market research conducted by AMAG with physicians and payers.





# Makena Subcutaneous Development Pathway & Timeline

Julie Krop, M.D.
Chief Medical Officer & SVP, Clinical
Development & Regulatory Affairs

### **Subcutaneous Auto-Injector Expected to Improve Patient Care**

#### **Current Intramuscular (IM) Injections**

 At-risk patients are treated weekly for approximately 5 months with a deep IM injection into the buttocks

#### **Subcutaneous (SC) Injections**

- SC injection administered via auto-injector with shorter and smaller width needle
- Multiple studies have shown significantly less pain and higher patient preference for SC injections vs. IM injections
- Auto-injector easy to use prefilled syringe, no needle contact



# Injection Site Pain is Most Frequent Adverse Event of the Current IM Therapy

#### Viscous Oil-Based Vehicle

- Withdraw drug with 18G needle, switch to 21G needle for injection
- Slow injection due to high viscosity (up to 1 minute)



# Adverse Reactions Occurring in ≥ 2% of IM Makena-Treated Subjects and at a Higher Rate than Control Subjects<sup>1</sup>

Preferred Term	Makena N=310 %	Control N=153 %
Injection site pain	34.8	32.8
Injection site swelling	17.1	7.8

Pain with Makena AND placebo: associated with injection, not drug





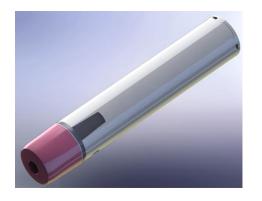
# Several Studies Show Reduced Pain and Greater Preference for SC Injection over IM Injection

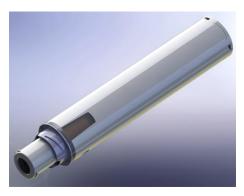
- Zackheim et al conducted study in patients on chronic IM Methotrexate and then switched them to SC injection<sup>1</sup>
  - SC injections were deemed less painful and easier to administer
- Singham et al examined patient preference for SC vs. IM Hepatitis B immunoglobulin<sup>2</sup>
  - All patients preferred SC to IM
  - 78% described SC route as much less painful
- Hahner et al evaluated patient preference for SC vs. IM hydrocortisone<sup>3</sup>
  - 92% of patients preferred SC over IM injections
- Russo and Moore compared patient acceptance of SC vs. IM growth hormone injections in a crossover study in children with growth hormone deficiency<sup>4</sup>
  - Overwhelming preference for SC route
  - Several patients refused future therapy if it required IM injections
    - 1. Zackheim HS. Subcutaneous administration of methotrexate. J Am Acad Dermatol. 1992 Jun; 26(6):1008.
    - 2. Singham J, Greanya ED, Lau K, Erb SR, Partovi N, Yoshida EM. Efficacy of maintenance subcutaneous hepatitis B immune globulin (HBIG) post-transplant for prophylaxis against hepatitis B recurrence. Ann Hepatol. 2010 Apr-Jun; 9(2):166-71.
    - 3. Hahner S, Burger-Stritt S, Allolio B. Subcutaneous hydrocortisone administration for emergency use in adrenal insufficiency. Eur J Endocrinol. 2013 Aug; 169(2):147-54.
    - . Russo L, Moore WV. A comparison of subcutaneous and intramuscular administration of human growth hormone in the therapy of growth hormone deficiency. J Clin Endocrinol Metab. 1982 Nov;55(5):1003-6.



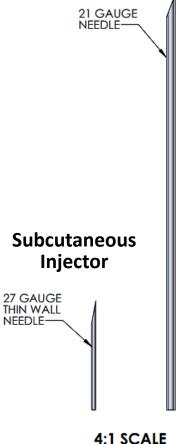
### **Unique Auto-Injector**

- Proprietary auto-injector allows for SC administration of Makena
  - Specifically designed for administration of viscous material through smaller needle - cannot pass Makena through small needle in the absence of device
  - Utilizes shorter and more narrow 27 gauge needle
  - Needle hidden from view less anticipatory pain
  - Prefilled, single use "One & done"





#### **Current Injection** Needle







#### **Experienced Device Partner – Antares Pharma**

- Leader in auto-injector development
- Proven track record 4 drug device products FDA approved since 2012
- Novel drug delivery technology
- Strong patent protection on device through 2026





#### **Advancing the Makena Auto-Injector Program**

February 3, 2018 Loss of orphan drug exclusivity 2015 2016 2019 2017 2018 2020 **Estimated** FDA Approval File sNDA H2-2017 Q2-2017 Device dev/CMC & **Auto-injector Pivotal PK Study** 



Example of drug/device combo



#### Makena: Building a Long-Life Franchise

#### **Executing next generation development program**

- Easier to administer with potential for less painful injections
- Proven device partner, Antares
- Potential orphan exclusivity on drug/device combination if reduction in pain demonstrated
- Franchise longevity past February 2018







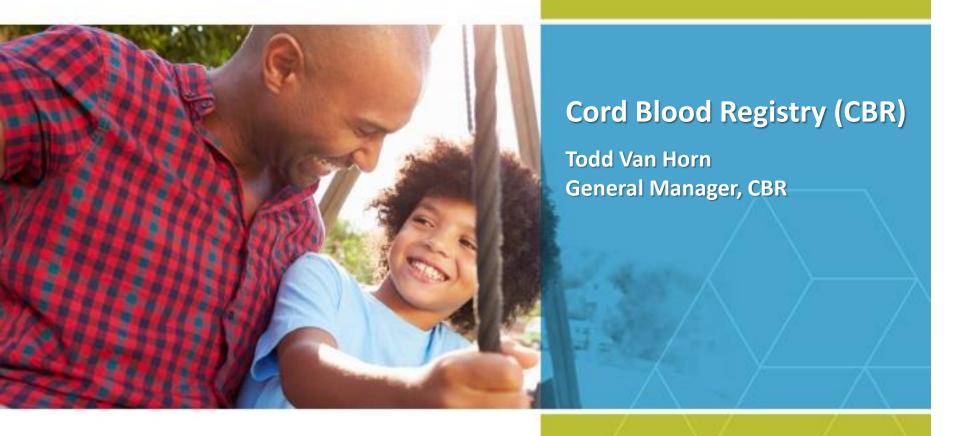








#### **AMAG Analyst Day 2016**



### **Agenda**

- The Business Today
- Market Opportunity and Growth Drivers
- CBR's Digital Consumer Platform







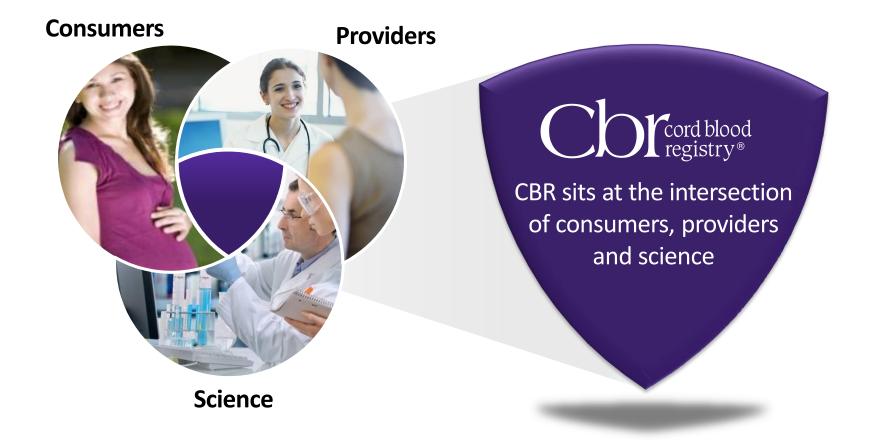


# CBR is the Largest Newborn Stem Cell Bank and #1 Choice of Expectant Parents and OB/GYNs





#### **CBR** is a Leader in Consumer Health





### **CBR Educates Pregnant Mothers through Multiple Channels**



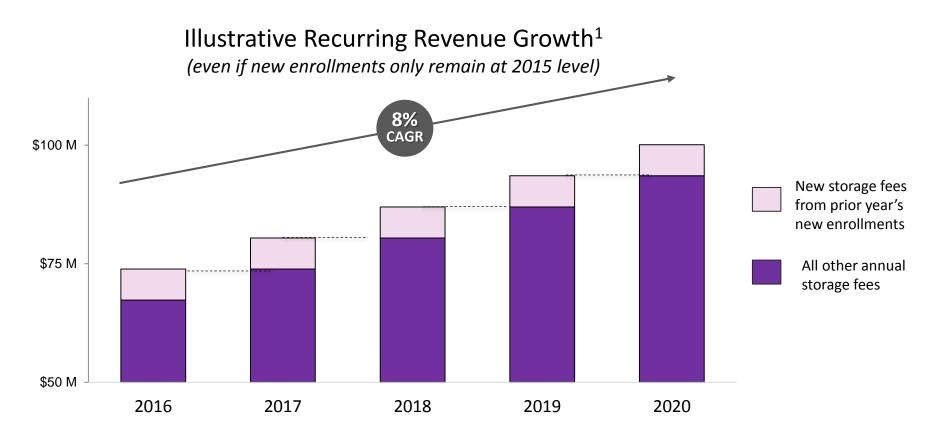








## CBR's Recurring Revenue Growth Drives Significant Value and Cash Flow



- New storages drive steady growth in recurring revenue stream
- <1% attrition of base supports high lifetime value of every new customer</p>



### **Agenda**

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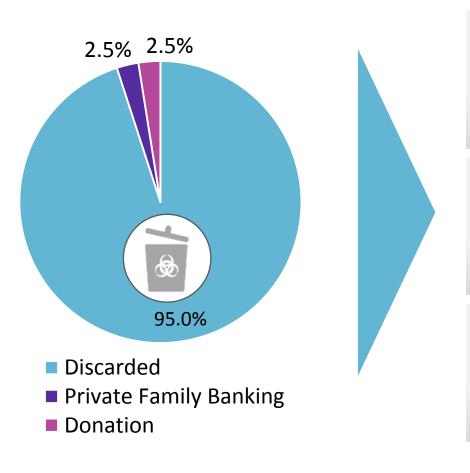






#### **Primary Focus is Category Growth**

#### 4M Annual U.S. Births



#### **Growth Drivers**

- Shift message and pricing approach to capitalize on generational shift
- Optimize product portfolio to address new segments of untapped market
- Enhance and differentiate CBR's offerings



## 1

### **Shifting Value Proposition to Drive Growth**

#### **Prior Approach**

Key message with focus on mitigating risk for child

- Emphasis on technical aspects
   (e.g. cell recovery rates) of service
- Fear-based language

Deep discount-driven, opaque pricing

Message differed by channel

Approach to digital communications and contact strategy broad and uniform

#### **Growth Strategy**

Key message of optimism for child with emphasis on investment in future

- Emphasis on reasons for preserving cells
- Future potential of regenerative medicine

Minimal discounting and transparent and predictable pricing

Single unified message tailored for each channel

Digital approach augmented by predictive modeling and segmentation focused on driving consumer engagement in funnel



## 2

# Optimize Product Portfolio to Segment Market and Drive Category Growth

Customer research and insights around generational shift and segmentation provides foundation to augment product portfolio.

CBR is looking to augment/build on offering to clients in order to:

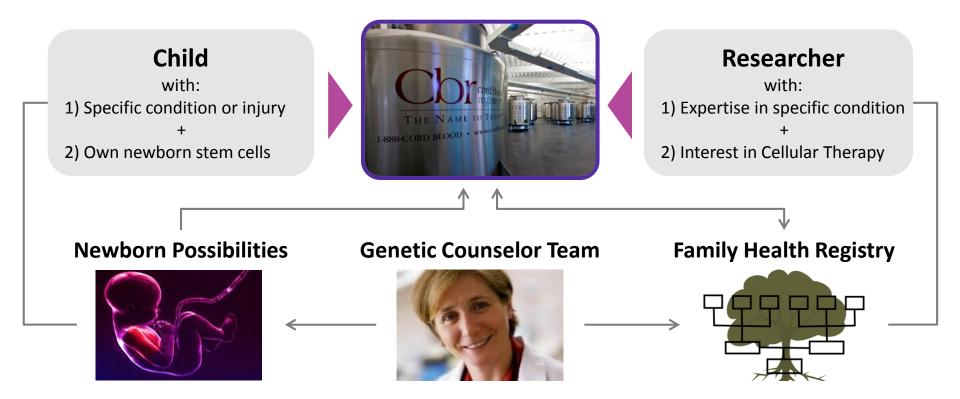
- Increase accessibility to new segments
- Maximize value of currently addressed segments
- Grow revenue and profitability in year one
- Further enhance long-term value of client







## Differentiating Our Offering and Leading the Effort to Connect Researchers and Our Client Families



AMAG partners with institutions to drive research on newborn stem cells

Hearing loss Cerebral Palsy Induced pluripotent stem cells (iPSCs)



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# Digital Platform Drives Product Awareness and Consumer Engagement



## Email/Database Marketing

- Predictive modeling-based
- 2M+ leads per year
- Over 500,000 pregnant moms engaged



## Digital Properties

- Approximately 30% of enrollments from website
- More than 50% of traffic from mobile devices
- Sponsored content through partner sites



#### **Social Media**

- Targeting of pregnant women
- Over 180,000 followers on Facebook with trend indicating growth



## Search Engine Marketing

Critical component of digital strategy to optimize organic and paid search



## Market Leader with Steady Cash Flow Growth and Upside Growth Potential

- Business model that drives steady, high-margin recurring revenue growth
- Substantial untapped market with multi-pronged strategy to address and grow CBR
- CBR's digital platform and expertise will be leveraged across AMAG portfolio, which we believe is a competitive advantage for AMAG





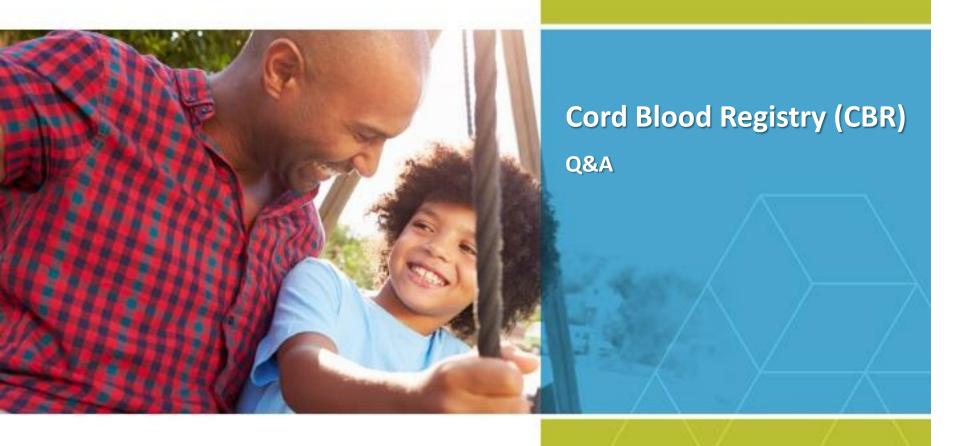




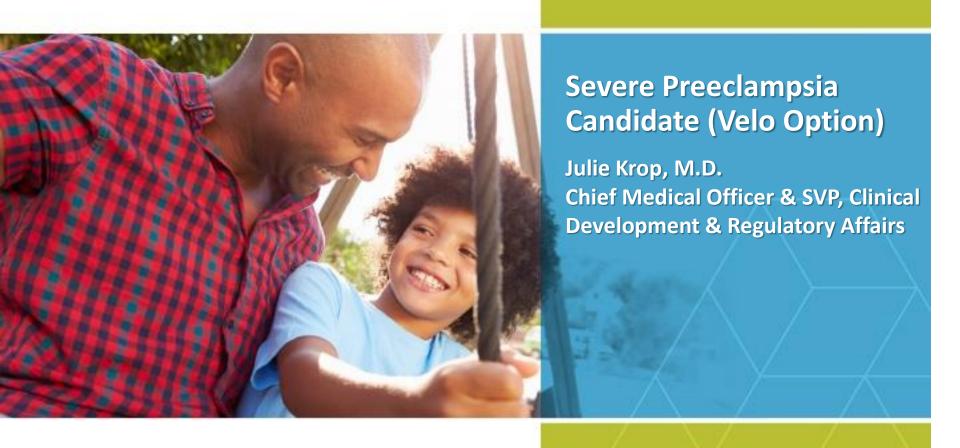




### **AMAG Analyst Day 2016**







### **Agenda**

- Severe Preeclampsia (sPE) Candidate with High Unmet Medical Need
- Mechanism of Action, Prior Trial Results & Timeline
- Large Market Opportunity









### **Severe Preeclampsia Candidate: Exciting Opportunity**

- Significant unmet medical need with large market potential
- Mid to late-stage development opportunity
  - Proof-of-principal clinical data
  - Velo to initiate Phase 2b/3a study by year-end
- ✓ Fast Track designation
- ✓ Patent protection and orphan drug exclusivity if approved
- Option deal structured to mitigate financial risk
  - Small upfront cash payment of \$10M in 2015
  - After completion of 2b/3a study, AMAG may exercise, extend or terminate option

- Expands product portfolio
- Strengthens leadership in Maternal Health





#### SEVERE PREECLAMPSIA

#### **High Unmet Medical Need**

- Disorder of pregnancy associated with hypertension and end organ damage in the mother
- No "cure" other than delivery of the baby
  - Current interventions only treat symptoms, not underlying pathophysiology
  - Near term: Induction of labor is treatment of choice
  - Earlier stage pregnancy: Attempts to delay delivery
- Associated with significant morbidity and mortality in the mother and baby
  - Accounts for 15% of all premature deliveries<sup>1</sup>
  - Can lead to life threatening conditions:
    - HELLP (Hemolysis, Elevated Liver enzymes, Low Platelet counts):
       10%-20% preeclampsia cases





### **Agenda**

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### Pathophysiology of Severe Preeclampsia: EDLFs May Play Role

- Endogenous digitalis-like factors (EDLFs) have been recognized as key circulating factors that may be involved in preeclampsia
  - EDLFs are increased in the circulation of majority of women with preeclampsia, and activity has been positively correlated with severity of preeclampsia
- EDLFs inhibit sodium pump at the cellular level leading to vasoconstriction and elevated blood pressure
- DIF is an antibody fragment developed as treatment for digoxin toxicity –
   marketed product for over 25 years
  - Binds to digoxin preventing its effect
- Polyclonal antibody not specific for digoxin
  - Also binds to EDLFs, blocking their activity





### **Proof-of-Concept Study (DEEP Trial)**<sup>1</sup>

- Placebo-controlled antepartum trial
- Study population (DIF n=24, placebo n=27)
  - Severe PE (BP>160/90; evidence of end organ damage)
  - ≤ 32 weeks gestational age
  - Delivery required within 72 hours
- Two primary outcome measures:
  - Change in creatinine clearance (statistically significant improvement)
  - Use of antihypertensive drugs (no apparent effect)
- Pre-planned subset analysis of patients who were EDLF+ at baseline<sup>2</sup>





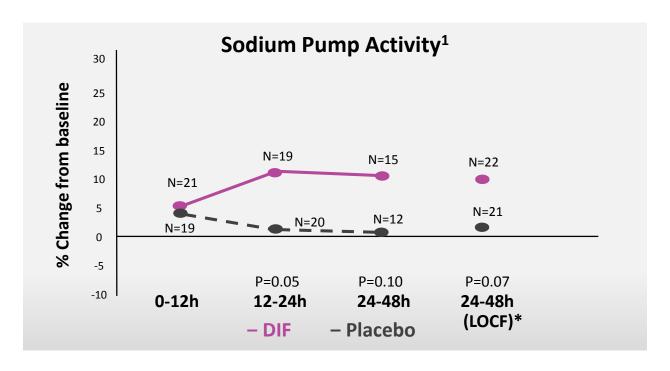
<sup>.</sup> Adair CD, Buckalew VM, Graves SW, et al. Digoxin immune fab treatment for severe preeclampsia. Am J Perinatol. 2010;27:655-62.

<sup>2.</sup> Lam GK et al, a secondary analysis of the DEEP Trial. American Journal of Obstetrics & Gynecology. August 2013, pp119.e1- 119.e6

#### **DIF Inhibits EDLF Activity**

#### DIF significantly decreased EDLF activity (increased sodium pump function)

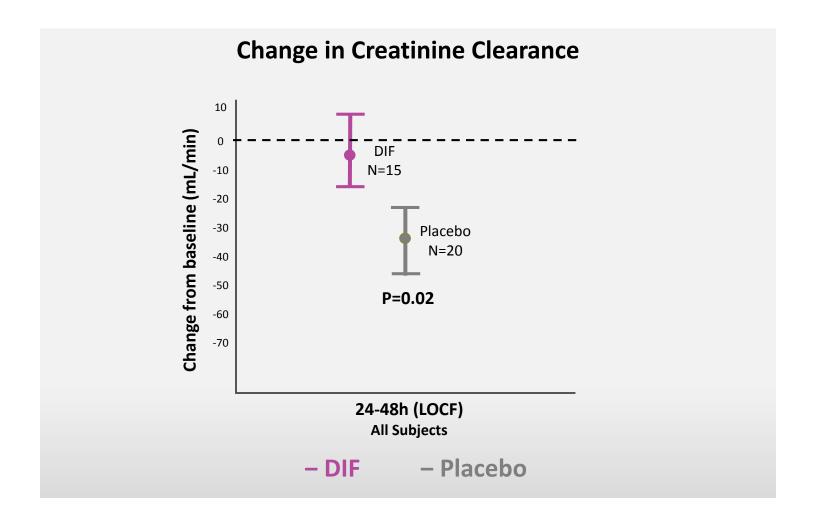
- Sodium pump activity was used to measure EDLF activity
- Majority of study subjects had EDLF activity at baseline (78%)
- No difference between groups at baseline
- Sodium pump activity improved with DIF





<sup>1.</sup> Adair CD, Buckalew VM, Graves SW, et al. Digoxin immune fab treatment for severe preeclampsia. Am J Perinatol. 2010;27:655-62 \* LOCF = Last Observation Carried Forward

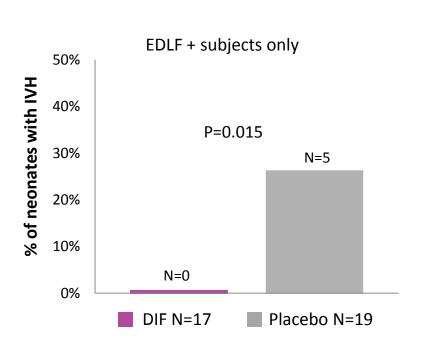
## Statistically Significant Preservation of Renal Function in DIF Treated Women<sup>1</sup>



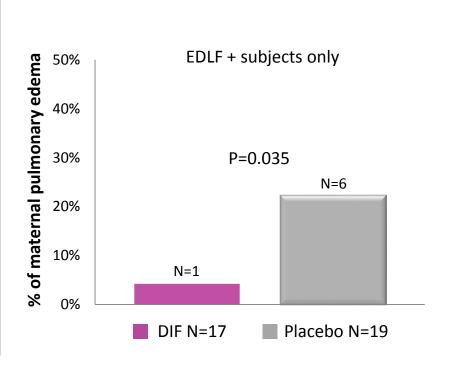


# DIF Demonstrates Promising Key Clinical Outcomes in Subset Analysis of EDLF-Positive Patients<sup>1</sup>

## Incidence of Neonatal Intraventricular Hemorrhage



### Incidence of Maternal Pulmonary Edema



Compared to all-subjects analysis, the difference between treatment and placebo for use of antihypertensives was greater, although the differences did not reach statistical significance.<sup>1</sup>



### **Agenda**

- Severe Preeclampsia (sPE) Candidate with High Unmet Medical Need
- Mechanism of Action, Prior Trial Results & Timeline
- Large Market Opportunity









#### SEVERE PREECLAMPSIA

#### **Large Market Opportunity**

- Leading cause of maternal and perinatal mortality/morbidity worldwide:
  - Major cause of premature birth
    - Admission of babies into NICUs
    - Death or life-long developmental abnormalities of premature infants (e.g., cerebral palsy, mental retardation, hearing loss and vision impairment)
    - Affects approximately 2% of pregnancies in U.S. annually
- Significant economic burden (~\$7B annual U.S.) as a result of premature babies due to preeclampsia<sup>1</sup>
  - Estimated incremental cost per case of severe preeclampsia approximately \$70k for babies born <24 weeks for mother and infant<sup>2</sup>



Estimated U.S. market opportunity



<sup>.</sup> Preeclampsia Foundation. Statistics. 2000–2010. Retrieved July 13, 2009 from http://www.preeclampsia.org/statistics.

UCLA Center for Health Policy Research. Costs of Gestational Hypertensive disorders In California: Hypertension, Preeclampsia, and Eclampsia. October 2013.

#### **Velo – Extends Market Leadership in Maternal Health**

- Significant health and economic consequences related to severe preeclampsia
- Unmet medical need is substantial
- Large untapped market opportunity
- Option structured to mitigate financial risk associated with clinical development
- DIF would further expand AMAG's portfolio in maternal health





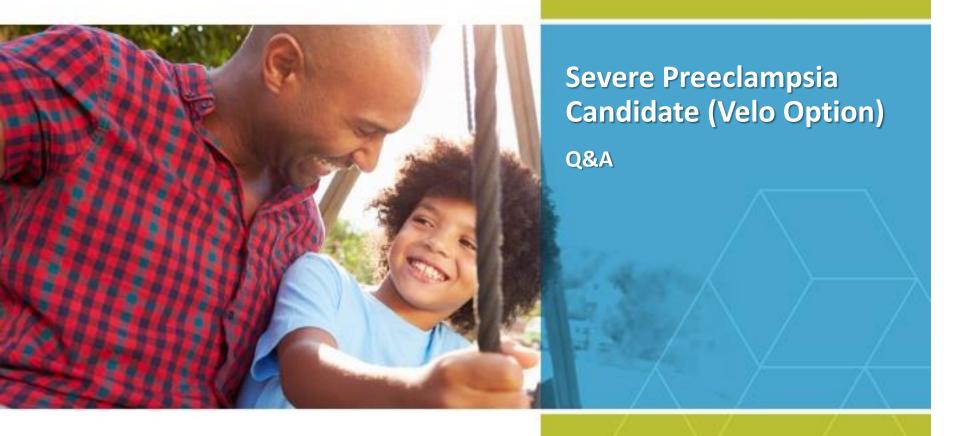








## **AMAG Analyst Day 2016**





## **AMAG Analyst Day 2016**



# **Independent Panel of Experts<sup>1</sup>**



David Gandell, MD

Dr. Gandell is a Board Certified
Obstetrician/ Gynecologist, and a Fellow
in the American College of Obstetricians
and Gynecologists. He holds the position
of Clinical Professor of Obstetrics and
Gynecology at the University of
Rochester. As a co-founder of the Parallel
Support Group for Pregnancy Loss, Dr.
Gandell has particular interest in family
planning, infertility treatment, preterm
birth prevention, and other areas of
maternal health. He currently practices
at Rochester Gynecologic and Obstetric
Associates, P.C. in Rochester, NY.



Lisa Latts, MD, MBA, MSPH, FACP

Dr. Latts is an expert in value-based payment and health system transformation and has served on the **National Commission for Physician** Payment Reform. She has earned multiple awards for her work to improve member and community health by building coalitions between plans, pharma companies, community organizations and non-profit organizations. Dr. Latts was formerly Chief Medical Officer at University of California, Vice President, Public Health Policy at WellPoint, Inc./Anthem, Inc., and Regional Medical Director at Anthem Blue Cross and Blue Shield.



Mahendra Rao, MD, PhD

Dr. Rao was the founding Director of the NIH Center of Regenerative Medicine and the Chief of the Laboratory of Stem cell Biology at the NIH. Previously, he was Vice President of regenerative medicine at the New York Stem Cell Foundation. Dr. Rao was named one of the top ten influential people in the stem cell field and was honored by the Federation of Biologists (FABA) India for his achievements in the stem cell field and the NBRI medal (India) for his contributions to neuroscience research.



Panel members were compensated for their time and participation on this panel; Dr. Gandell and Dr. Rao periodically provide consulting services to AMAG.



## **AMAG Analyst Day 2016**

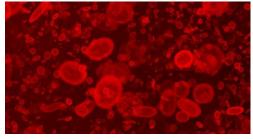


# **Feraheme Agenda**

- Status Today
- Competitive Landscape
- Next Generation Development
- Market Opportunities









## Feraheme: It's as Easy as 1-2-3



#### **Feraheme**

Used for the treatment of iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD)

1 gram

2 doses

3 days apart



Attribute	Feraheme 1 gram Dose <sup>1</sup>
Dosing <sup>1</sup> Schedule:	2 x 510 mg doses
Delivery:	IV infusion
Regimen (1 g):	2 treatments, 3 to 8 days apart
Observation Period:	30 minutes post dosing

#### Why iron therapy is important

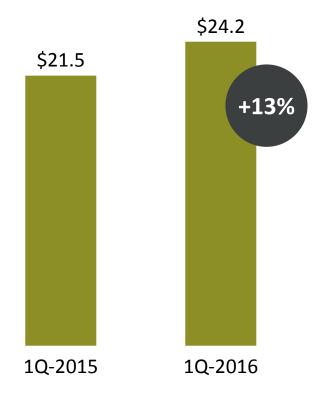
- Iron is a critical factor in the production of red blood cells
- 4.5 million Americans diagnosed and suffering from IDA<sup>2</sup>
  - Daily oral iron is first line therapy for most IDA patients
  - Many patients fail oral iron therapy – compliance, efficacy and/ or side effects (constipation, GI upset)



- . One gram of IV iron is the usual therapeutic course and that which was studied in the Feraheme clinical trials.
- Global Intravenous (I.V.) Iron Drugs Market Report: 2015 Edition.

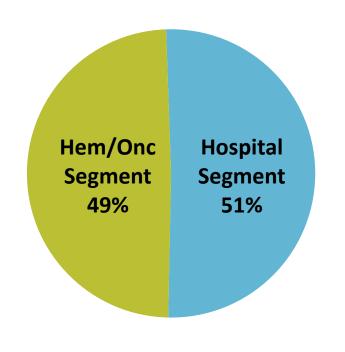
# **Record Sales in Q1-2016**

# Feraheme Sales Growth (GAAP)



Growth from volume +7% and price +6%

# Breakdown of Feraheme Sales Q1-2016



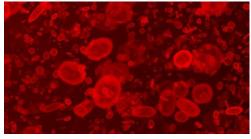


# **Feraheme Agenda**

- Status Today
- Competitive Landscape
- Next Generation Development
- Market Opportunities

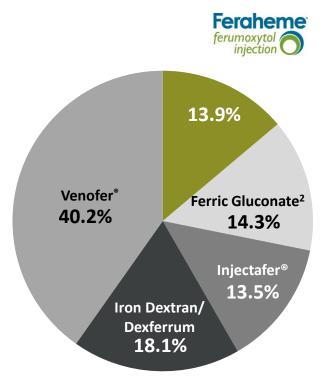




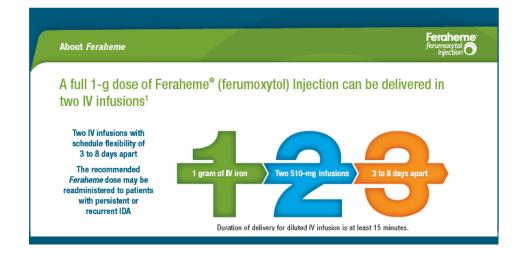




# **Differentiated Product with Unique Positioning**



2015 U.S. share of non-dialysis IV iron market: ~1M grams<sup>1</sup>



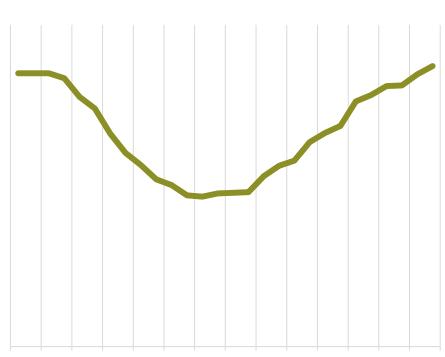


<sup>1.</sup> IMS DDD Data through week ending 01/01/2016

<sup>2.</sup> Aggregate of Ferrlecit® Brand + Generic Ferric Gluconate

# **Feraheme Strong Pricing & Contracting Strategy**

# Quarterly History of Published Feraheme Payment Allowance Limit

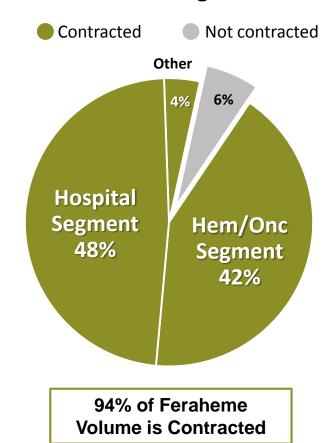


3Q09 1Q10 3Q10 1Q11 3Q11 1Q12 3Q12 1Q13 3Q13 1Q14 3Q14 1Q15 3Q15 1Q16

#### **Effective Quarter**

Source: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

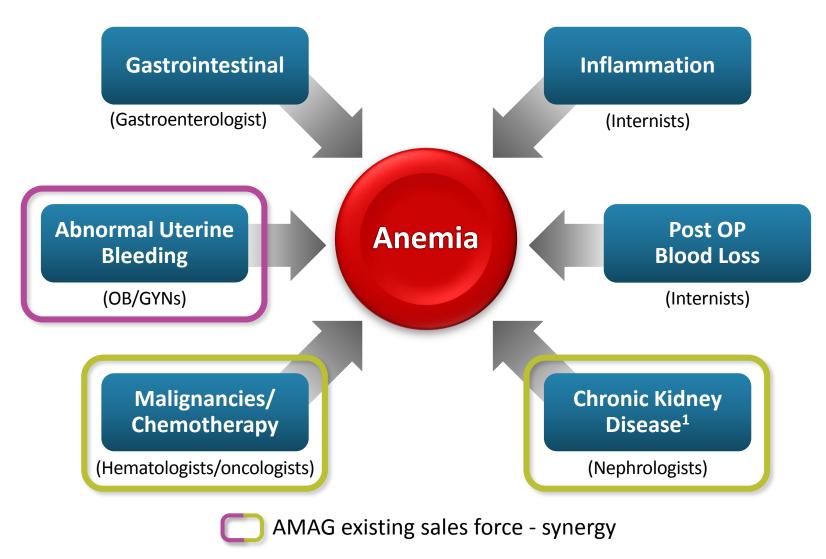
# Allocation of Feraheme Volume by Contract Segment



Source: AMAG sales/chargebacks from 3Q15-1Q16



# Multiple Causes of Iron Deficiency Anemia: Potential for Synergies with AMAG's Two Sales Forces

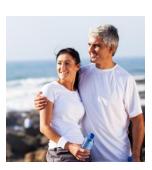




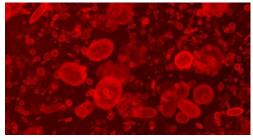
1. Approved indication.

# **Feraheme Agenda**

- Status Today
- Competitive Landscape
- Next Generation Development
- Market Opportunities









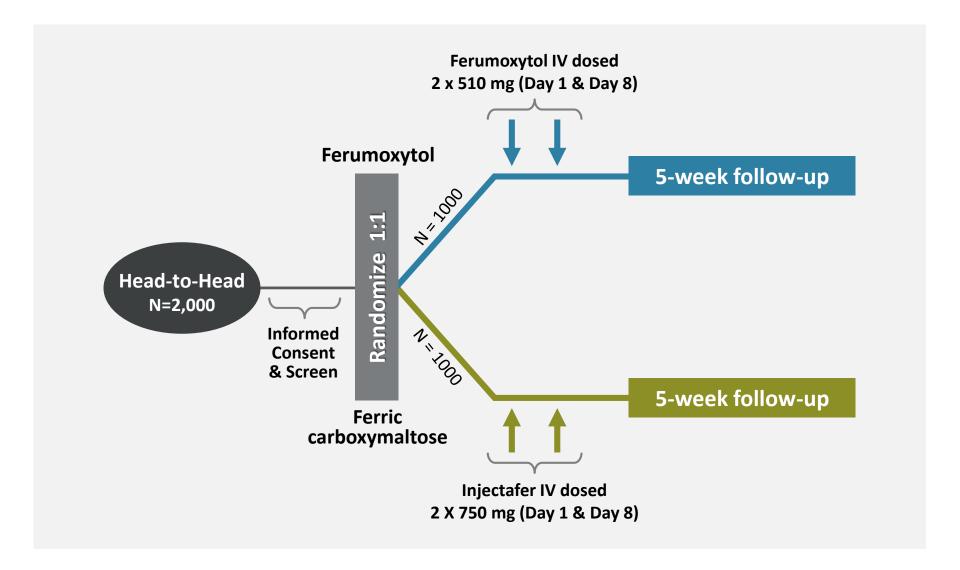
# **Phase 3 Label Expansion Trial Underway**

Randomized, Multicenter, Double-Blind, Safety Study of Ferumoxytol Compared to FerrIc Carboxymaltose for the TReatment of Iron Deficiency AneMia (IDA) (FIRM)

Sample Size (N)	N = 2,000 Main Study
Key Entry Criteria	Subjects with IDA and in whom intravenous iron treatment is indicated and have failed previous course of oral iron
Primary Endpoint	<ul> <li>Safety</li> <li>Incidence of moderate to severe hypersensitivity reactions, including anaphylaxis, and moderate to severe hypotension</li> </ul>
Secondary Endpoint	<ul><li>Efficacy</li><li>Mean change in hemoglobin from baseline to week 5</li><li>Mean change in hemoglobin/mg iron delivered</li></ul>
# Sites/Region	200 Sites, International (US, Canada, Europe)



# **Head-to-Head Trial Design**





# **Estimated Timeline to Market**

	2016	2017	2018
<ul><li>First patient</li></ul>	Feb.		
<ul><li>Enrollment</li></ul>			
<ul><li>Filing</li></ul>			
<ul><li>Targeted FDA Approval</li></ul>			



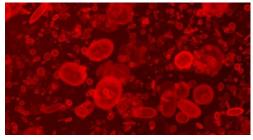


# **Feraheme Agenda**

- Status Today
- Competitive Landscape
- Next Generation Development
- Market Opportunities









# Rationale for Injectafer as the Comparator



- Competitor with a broader label
- Similar dosing regimen allows for blinded study
- Injectafer requires 50% higher iron dose to achieve similar rise in hemoglobin levels
- More expensive than Feraheme

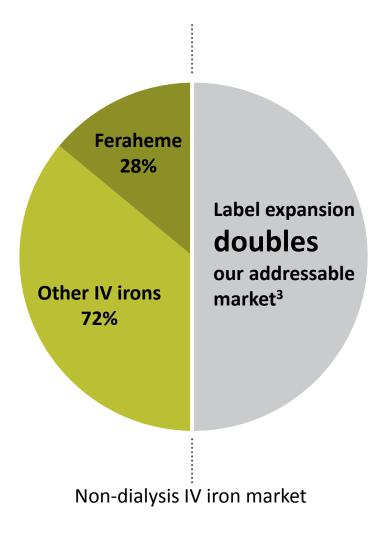




# Large IV Iron Market Opportunity of \$600M

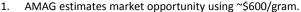
Current Addressable Market: \$300M<sup>1</sup>

 Iron deficiency anemia caused by Chronic Kidney Disease



Additional Addressable Market: \$300M<sup>2</sup>

 Iron deficiency anemia caused by other diseases



- 2. 1Q-2016 IMS Health data annualized.
- . If regulatory approval is received for broad IDA indication.



**IDA-CKD Patients** 

Majority under the care of current AMAG call points;

hematology / oncology &

hospital infusion centers

# IV Iron Market Represents Small Subset of 4.5M Patients Who Suffer from IDA

#### 4.5M Total Patients Diagnosed with Iron Deficiency Anemia<sup>1</sup>

# 600,000 **IV Patients**

#### **Diagnosed IDA Patients**

 Under the care of other physician specialists, including OB/GYNs

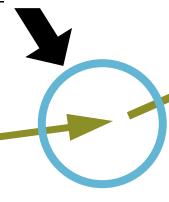
Opportunity to convert from oral to IV treatments



# **Future Growth: Potential to Double Size of Addressable Market**

#### **Label expansion**

iron deficiencyall cause



# **Growth Drivers Next 2-3 Years**

- Grow share in hospital segment
- Maximize opportunity in Hem/Onc segment
- Continue to gain share

# Growth Beyond 2018

- Initiated Phase 3 trial Q1-2016 vs. Injectafer
  - Potential approval 2018<sup>1</sup>
- Doubles addressable market to \$600M
- Future IV iron market expansion opportunities





#### IN SUMMARY

## **Feraheme Franchise is Strong and Growing**

- Overall IV iron market is growing double digits (+13% in 2015)
- Differentiated IV iron replacement therapy
- Clinical trial offers opportunity to show similar safety profile and equivalent efficacy with lower dose
- Label expansion provides opportunity to double size of Feraheme addressable market





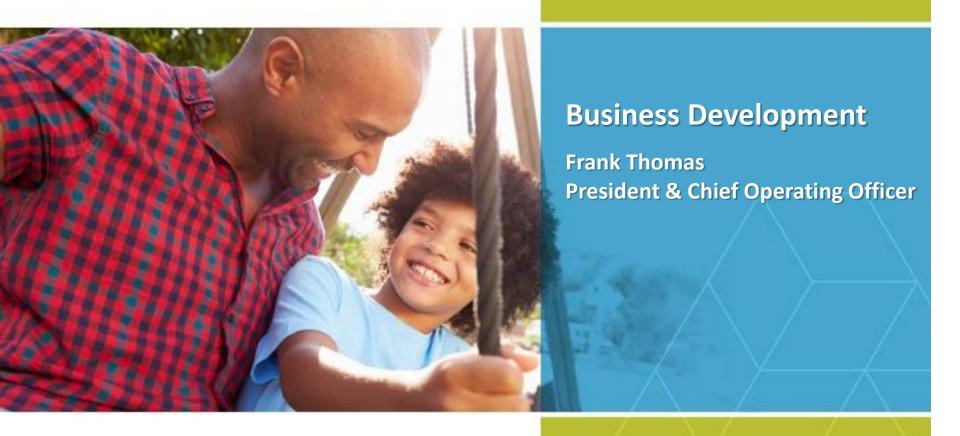








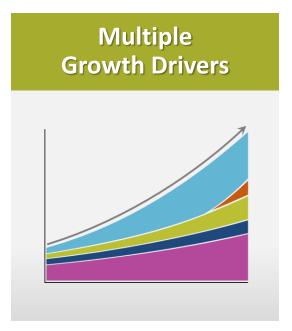




# **Building a Growth-Oriented Biopharma Company**



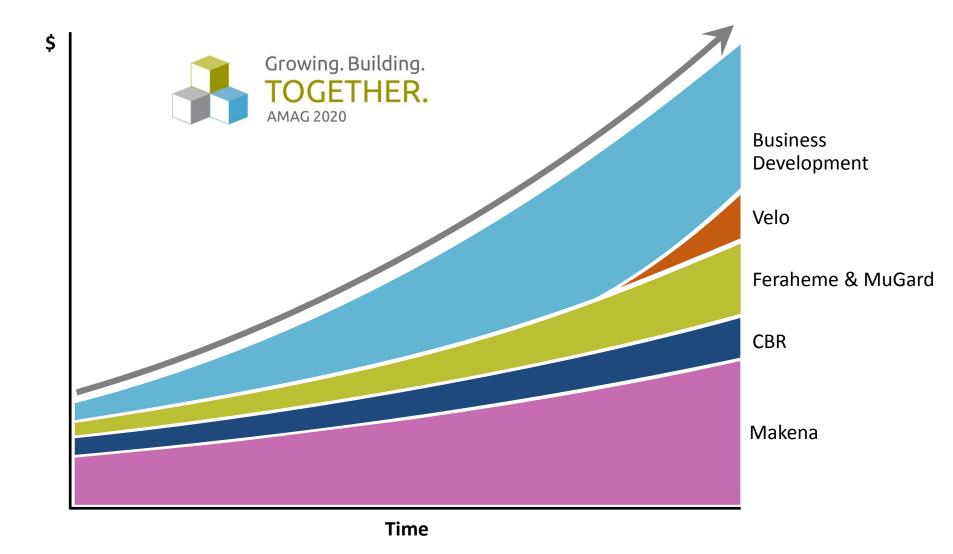








# Multiple, Growing Revenue Streams





# **Recent Transactions Fit Our Criteria**

	Makena	Cord blood registry®	Velo Option
Fits with core platforms		V	V
Differentiated assets with growth potential		V	V
Potential to add value, enhance growth	V	V	V
Strong ROI, accretive	V	V	
Long-life assets 5+ years (with Makena next generation dev. progran	<b>1</b> )		V
Unmet medical need	V		V



# **Building Our Portfolio: Search and Evaluate Criteria**

Therapeutic Criteria

- Core therapeutic areas (TAs) (maternal health, hem/onc & select hospital)
- Adjacent TAs (women's health, nephrology)





Financial Criteria

- Differentiated & durable
- Stage of development
- Cash payback period and IRR





Leverage Core Capabilities

- Physician relationships
- Commercial execution skills
- Consumer/digital platform





## **Asset Screening Process Resulted in a List of 180 Prioritized Products**



# Initial Product Database

- Marketed Products:
  - Branded products
  - Unique Branded
     Generics
- Pipeline Products:
   Phase 2 or later

~7,500 Products



#### Indication Fit

 Screened products, relevant indications for each target market

~2,000 Products

Prioritized List

#### Prioritized List

Prioritized products
 based on several key
 factors such as indication,
 validated mechanism,
 stage of development and
 clinical need and market
 size

~180 Products

5-10 active



# Example of How We Expand the Search Criteria Across the Continuum of Care in Women's Health

# **Decision to Get Pregnant**

- Contraception
- Prenatal Vitamins
- Infertility



#### **Current Bull's Eye**

#### Maternal Health

- Preterm Birth
- Placenta Disorders
- Labor Induction
- Preeclampsia
- Maternal Vitamins



#### Birth / Post Birth

- Umbilical cord dermatitis
- Postpartum Hemorrhage
- Postpartum depression
- Nutrition



# Women's Wellness

- Endometriosis
- Human papillomavirus
- Migraine
- Vaginal/Yeast infections
- Contraception



#### Post Menopausal

- Hot flashes
- Vulvar and vaginal atrophy
- Female sexual dysfunction
- Osteoporosis





# Portfolio Expansion: Leverage Expertise – Acquire Products/Companies with Durable Growth Opportunities





IN SUMMARY

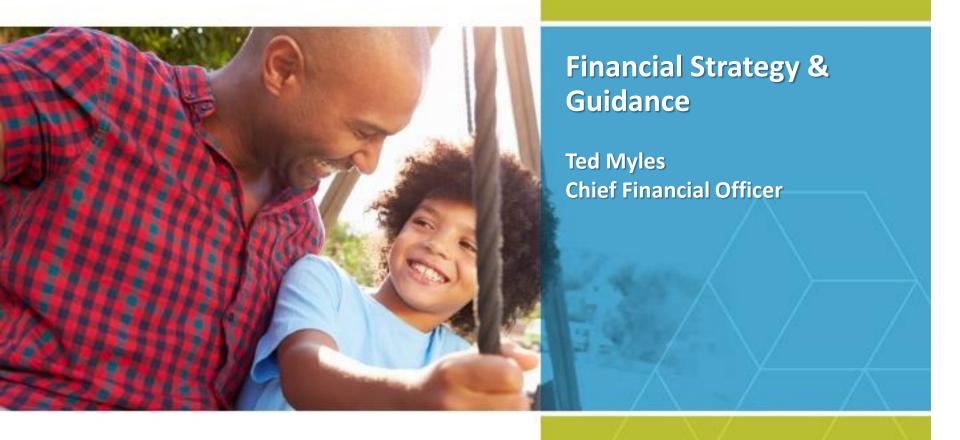
# **Disciplined Criteria, Multiple Growth Opportunities**

- Our recent acquisitions meet our criteria for long-term success
- Our evaluation approach focuses on therapeutic and financial fit within our portfolio, leveraging our core capabilities
- Focus on continuum of care for our patients allows us to examine products in adjacent areas of interest
- There are a number of attractive commercial and late-stage development assets on our prioritized target list









# **Agenda**

- A Transformed Business: Delivering Top- and Bottom-Line Growth
- Well Positioned for Future Value Creation







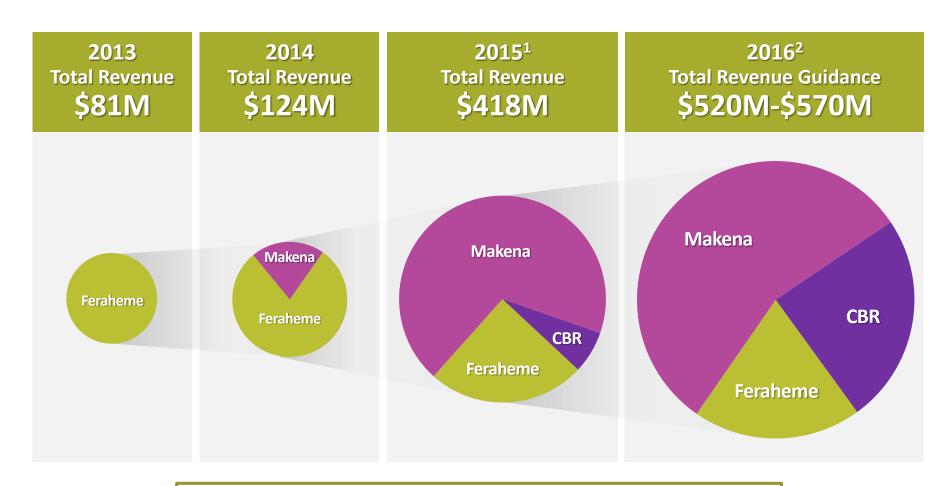








# A Transformed, Diversified, and Growing Revenue Profile



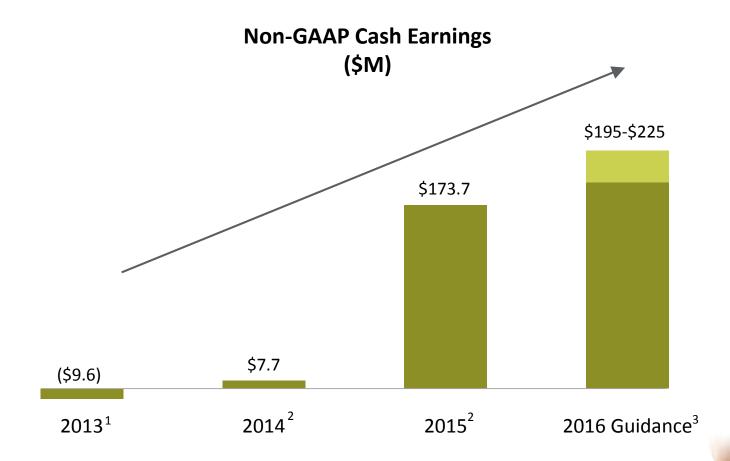
AMAG's transition from one to multiple products has improved its ability to generate consistent cash flow.



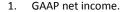
l. Includes approximately \$19M of purchase accounting adjustments related to CBR deferred revenue. CBR was acquired in August 2015.

<sup>2.</sup> Includes approximately \$17M of purchase accounting adjustments related to CBR deferred revenue. See slide 126 for an explanation of CBR deferred revenue adjustments. CBR was acquired in August 2015.

# Cash Earnings in Excess of \$200M Expected in 2016



AMAG's strong cash generation creates flexibility, even in challenging capital markets



See slides 124-125 for a reconciliation of GAAP to non-GAAP financial information.



See slide 123 for a reconciliation of GAAP to non-GAAP financial guidance information.

### **2016 Financial Guidance**

\$M	2015 Actual <sup>1</sup>	2016 Guidance <sup>2</sup>	Increase vs. 2015 <sup>3</sup>
Makena sales	\$251.6	\$310-\$340	+29%
Feraheme and MuGard sales	\$90.2	\$95-\$105	+11%
Cord Blood Registry revenue	\$118.6 <sup>4</sup>	\$115-\$125 <sup>5</sup>	+1%
Total Non-GAAP revenue	\$397.4	\$520-\$570	+42%
Non-GAAP Adjusted EBITDA	\$213.4	\$255-\$285	+27%
Non-GAAP cash earnings	\$173.7	\$195-\$225	+21%

- 1. See slides 124-125 for a reconciliation of GAAP to non-GAAP financial information.
- 2. See slide 123 for a reconciliation of GAAP to non-GAAP financial guidance.
- 3. Reflects midpoint of guidance.
- 4. Includes approximately \$22M of purchase accounting adjustments related to CBR deferred revenue. Revenues shown are pro forma for 2015 and assume CBR was acquired at the beginning of 2015. CBR was acquired in August 2015.
- 5. Includes approximately \$17M of purchase accounting adjustments related to CBR deferred revenue. See slide 126 for an explanation of CBR deferred revenue adjustments. CBR was acquired in August 2015.



### **Agenda**

- A Transformed Business: Delivering Top- and Bottom-Line Growth
- Well Positioned for Future Value Creation















#### **Capital Allocation Principles**

1 Liquidity

 Strong cash position allows us to pursue our strategy, even in challenging markets

2 Conviction to Investments

 Full commitment to value-creating opportunities that we choose to pursue: organic or external

Focus on Shareholder Returns

Key criterion in making investment decisions



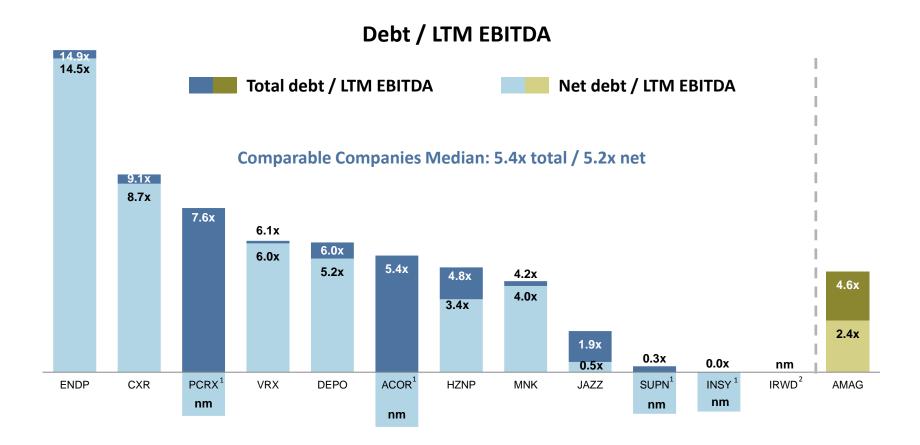
## **Evaluating our Capitalization Against a Wide Range of Opportunities for Value Creation in the Near and Intermediate Term**

(\$M, as of March 31, 2016)	
Cash and investments	\$480
Debt	
Convertible senior notes (2.5%)	\$200
Term loan facility (4.75%)	\$341
2023 senior notes (7.875%)	\$500
Total debt (principal amount outstanding)	\$1,041
Market capitalization (34.6 million shares)	\$809

Expect to generate ~\$200M cash flow in 20161



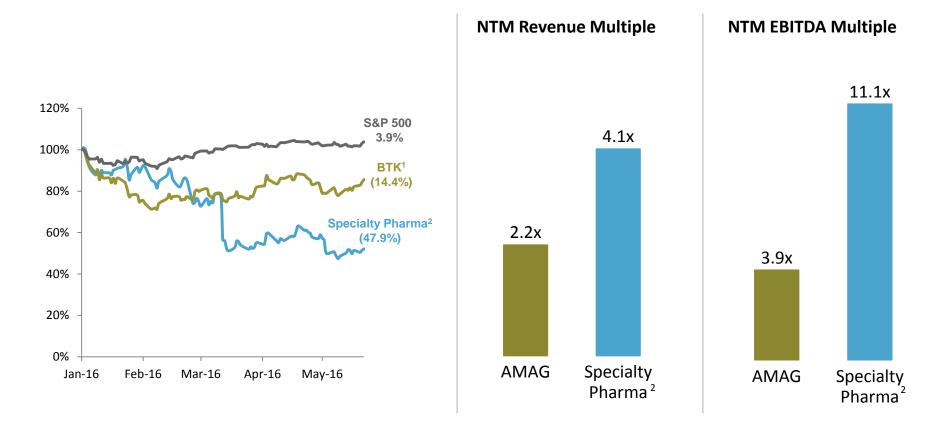
# **Current Debt Balance is Manageable and Well within AMAG Peer Group**

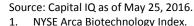




<sup>1.</sup> PCRX, ACOR, SUPN and INSY all have cash balances that exceed total debt.

### **AMAG Share Price Not Reflective of True Value of Company**





Spec Pharma index includes Acorda, AMAG, Concordia, Depomed, Endo, Horizon, Insys, Ironwood, Jazz, Mallinckrodt, Pacira, Supernus and Valeant.



# **Current Cash Balance and Projected Cash Flow Provides Capacity for Transactions**

\$M

Cash and investments – December 31, 2015

\$467

2016 cash earnings guidance<sup>1</sup>

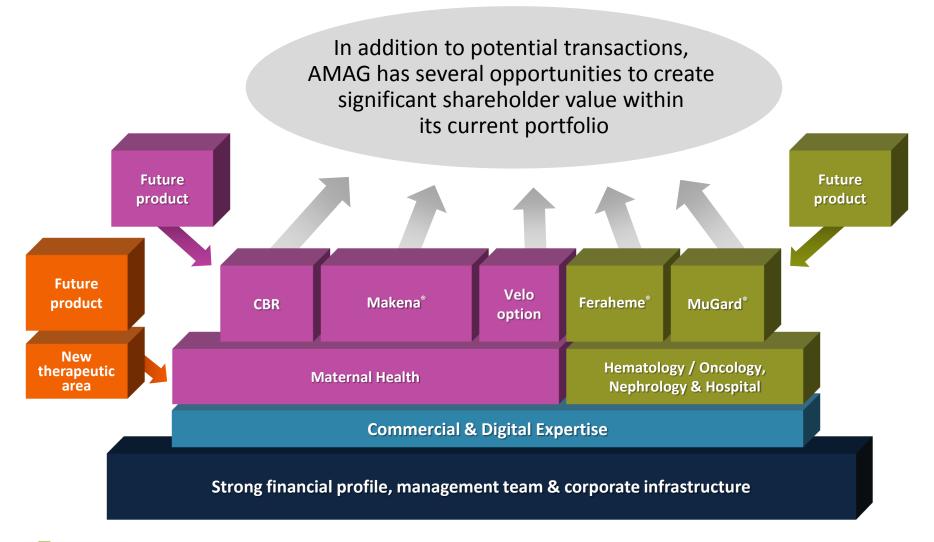
\$195 - \$225

With existing balance and expected near-term generation of cash, deals can be completed without issuing debt or equity.



 2016 financial guidance does not account for \$100M sales milestone payment expected to be paid in 2016 to former shareholders of Lumara Health, as well as working capital.

# While AMAG Continues to be Discriminating in its Evaluation of BD Opportunities, Growth Exists within Current Portfolio





#### **Near-Term Execution Creates Long-Term Opportunities**

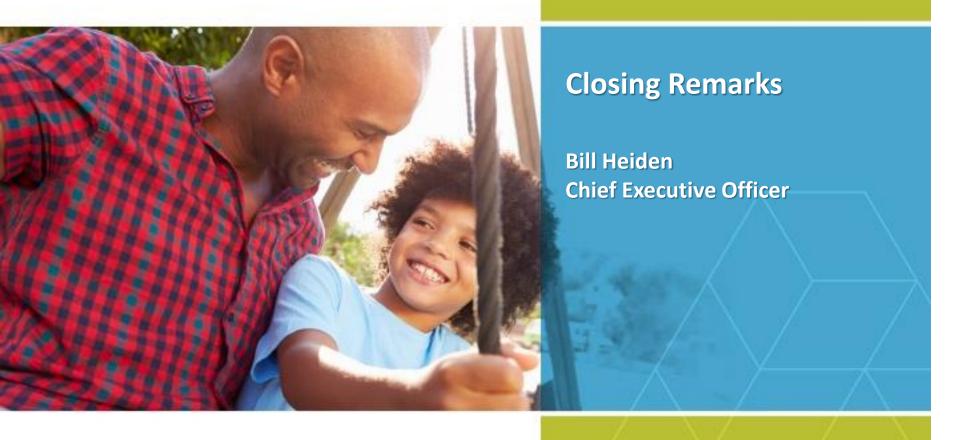
#### Near-term Longer-term Additional cash flow from operations Successful next gen. programs and Asset deals, structured licenses and Cash return of equity and debt markets allow options, and bolt-on acquisitions AMAG to utilize cash more aggressively De-levering with existing cash flows Potential for highly accretive deals Possible refinancing to support larger Debt Excess cash sweep in term loan provides deal and/or lower cost of capital mechanism to de-lever balance sheet As sector issues resolve At current levels, not inclined to Equity AMAG's next gen. programs progress issue equity Execution on plan

Execution of our business plan in the near term expands opportunities for value creation in the long term.





#### **AMAG Analyst Day 2016**



## **Key 2016 Milestones**

	2016
Makena	<ul><li>✓ Commercial launch of single-dose, preservative-free formulation</li><li>☐ Initiate a pharmacokinetic study for the Makena subcutaneous auto-injector</li></ul>
Feraheme	✓ Initiate a head-to-head Phase 3 clinical trial in Q1 2016 evaluating the safety of Feraheme compared to Injectafer in adults with IDA
Financial	<ul> <li>✓ Initiate stock re-purchase program</li> <li>☐ Growing earnings and de-levering adds to borrowing capacity for acquisitions</li> </ul>
Business Development	<ul> <li>Opportunities to further expand company's product portfolio through acquisitions or in-licensing of products or companies</li> </ul>









## **Key Milestones Ahead**

	2017-2019
Makena	☐ Launch Makena subcutaneous auto-injector¹
Feraheme	☐ Launch Feraheme with broad IDA indication <sup>1</sup>
CBR	☐ Accelerate the addition of newly stored units to >750,000 cumulative units
Velo	☐ Phase 2b/3a data in preeclampsia for Velo product
Business Development	☐ Further expand the company's product portfolio through acquisitions or in- licensing of products or companies









### **Building a Growth-Oriented Biopharma Company**



- Transformed into growing, multi-product biopharmaceutical company
- Growing revenues of >\$500M and profitable, while investing in existing & new product development opportunities
- Attractive near and longer term cash generation potential

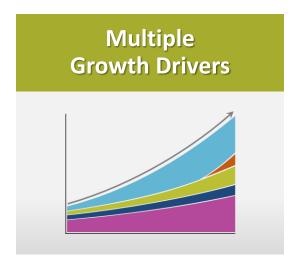


#### Maternal Health

- Makena growing 29% in 2016
- CBR durable, recurring revenue stream

#### Hem/Onc/Hosp

 Feraheme – steady and consistent growth with upside potential



- Makena
  - Single dose vial
  - Subcutaneous auto-injector
- CBR
  - Market segmentation & pricing opportunities
  - Direct-to-consumer platform
- Feraheme IDA broad indication
- New growth opportunities
  - Through acquisition of commercial or late-stage development products





### **AMAG Analyst Day 2016**





### **AMAG Analyst Day 2016**



### **Adjusted EBITDA and Cash Earnings Reconciliation**

(\$M)	2015	2016 GUIDANCE			
GAAP Net income	\$32.8	\$11 - \$41			
CBR deferred revenue purchase accounting adjustments	19.1	17			
Depreciation & amortization	57.5	90			
Interest expense, net	71.4	72			
Provision for income taxes	7.1	20			
EBITDA	\$187.9	\$210 - \$240			
Non-cash collaboration revenue	(40.0)	NA			
Non-cash inventory step-up	13.7	5			
Stock-based compensation	17.2	27			
Adjustment to contingent consideration	4.3	12			
Severance & transaction related costs	20.3	1			
Velo option	10.0	NA			
Adjusted EBITDA	\$213.4	\$255 - \$285			
Cash interest expense	(39.7)	(60)			
Cash earnings	\$173.7	\$195 - \$225			



# **GAAP to Non-GAAP Financials for the Years Ended December 31, 2015 and 2014**

	Twelve Months Ended					Twelve Months Ended								
		December 31, 2015						December 31, 2014						
						Non-						Non-		
		GAAP	Αc	ljustments		GAAP		GAAP	Ad	ljustments	- (	GAAP		
Revenues:														
Makena	\$	251,615	\$	_	\$	251,615	\$	22,513	\$	_		22,513		
Feraheme/MuGard		90,201		_		90,201		87,485		_		87,485		
Cord Blood Registry		24,132		19,136	1	43,268		_		_		_		
License fee, collaboration and other				:	2					2				
revenues		52,328		(39,965)		12,363		14,386		(8,217)		6,169		
Total revenues		418,276		(20,829)		397,447		124,384		(8,217)	1	16,167		
Operating costs and expenses:														
Cost of products sold		78,509		(64,536)		13,973		20,306		(6,706) <sup>3</sup>		13,600		
Cost of services		9,992		(1,563)		8,429		_		_		_		
Research and development		42,878		(14,258)	5	28,620		24,160		(1,662) 5		22,498		
Selling, general and administrative		160,309		(27,324)	6	132,985		72,254		(6,534) <sup>6</sup>		65,720		
Acquisition-related		11,232		(11,232)	7	_		9,478		(9,478) <sup>7</sup>		_		
Restructuring		4,136		(4,136)	8 			2,023		(2,023) 8				
Total costs and expenses		307,056		(123,049)		184,007		128,221		(26,403)		101,818		
Operating income (loss) / adjusted EBITDA		111,220		102,220		213,440		(3,837)		18,186		14,349		
Other income (expense):												_		
Interest expense		(53,251)		12,041 <sup>9</sup>	)	(41,210)		(14,697)		6,967 <sup>9</sup>		(7,730)		
Loss on debt extinguishment		(10,449)		10,449 <sup>1</sup>	.0	_		_		_		_		
Interest and dividend income, net		1,512		_		1,512		975		(17)		958		
Other income, net		(9,188)		9,185 <sup>1</sup>	.0	(3)		217		(103)		114		
Total other income (expense)		(71,376)		31,675		(39,701)		(13,505)		6,847		(6,658)		
Net income (loss) before income taxes		39,844		133,895		173,739		(17,342)		25,033		7,691		
Income tax expense (benefit)		7,065		$(7,065)^1$	.1	_		(153,159)		153,159 <sup>11</sup>		_		
Net income (loss) / cash earnings	\$	32,779	\$	140,960	\$	173,739	\$	135,817	\$	(128,126)	\$	7,691		
Net income (loss) / cash earnings per share														
Basic	\$	1.04		_	\$	5.52	\$	6.06		_	\$	0.34		
Diluted	\$	0.93		_	\$	4.43	\$	5.45		_	\$	0.30		
Weighted average shares outstanding														
Basic		31,471		_		31,471		22,416		_		22,416		
Diluted		35,308		_		39,211		25,225		_		25,225		



# **GAAP to Non-GAAP Financials for the Year Ended December 31, 2015**

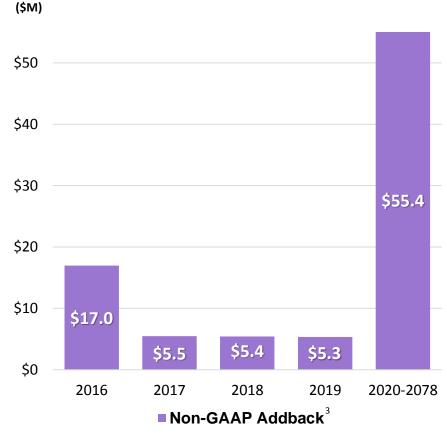
- 1. Adding back period write-down of deferred revenue from purchase accounting.
- 2. Eliminate non-cash revenue related to recognition of previously deferred revenue on Takeda agreement.
- 3. Eliminate the following: (i) non-cash step-up of inventory from purchase accounting; (ii) amortization expense related to intangible assets; (iii) depreciation expense; and (iv) stock-based compensation expense.
- 4. Eliminate the following: (i) depreciation expense; and (ii) certain non-recurring inventory reserves.
- 5. Eliminate the following: (i) non-cash step-up of inventory used in research and development from purchase accounting; (ii) depreciation expense; and (iii) stock-based compensation expense.
- 6. Eliminating the following: (i) non-cash adjustments related to contingent consideration; (ii) amortization expense related to intangible assets; (iii) certain transaction-related expenses; (iv) depreciation expense; and (v) stock-based compensation expense.
- 7. Eliminate non-recurring acquisition costs.
- 8. Eliminate non-recurring restructuring costs.
- 9. Eliminate non-cash interest expense; amortization of debt discount and other non-cash costs.
- 10. Eliminate non-cash or other non-recurring expenses related to the August 2015 term loan financing.
- 11. Eliminate non-cash income tax.



#### **CBR Non-GAAP Revenue Adjustment**



## Addback to calculate non-GAAP revenue to be reported in future periods



- 1. Reflects the GAAP balance sheet adjustment following the 2015 acquisition of CBR by AMAG; prior adjustment due to 2012 acquisition of CBR by GTCR.
- . Write-Off amount is added back in the period it would have been recognized in to arrive at non-GAAP revenue.
- Reflects the addbacks from both the 2015 acquisition of CBR by AMAG and the 2012 acquisition of CBR by GTCR.

