

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT PURSUANT TO
SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **May 11, 2016**

AMICUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

001-33497

(Commission File Number)

71-0869350

(IRS Employer Identification No.)

1 Cedar Brook Drive, Cranbury, NJ

(Address of Principal Executive Offices)

08512

(Zip Code)

Registrant's telephone number, including area code: **(609) 662-2000**

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

The senior management of Amicus Therapeutics, Inc. (the "Company") is using the presentation attached as Exhibit 99.1 to this Current Report in its current meetings with investors and analysts.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits: The Exhibit Index annexed hereto is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

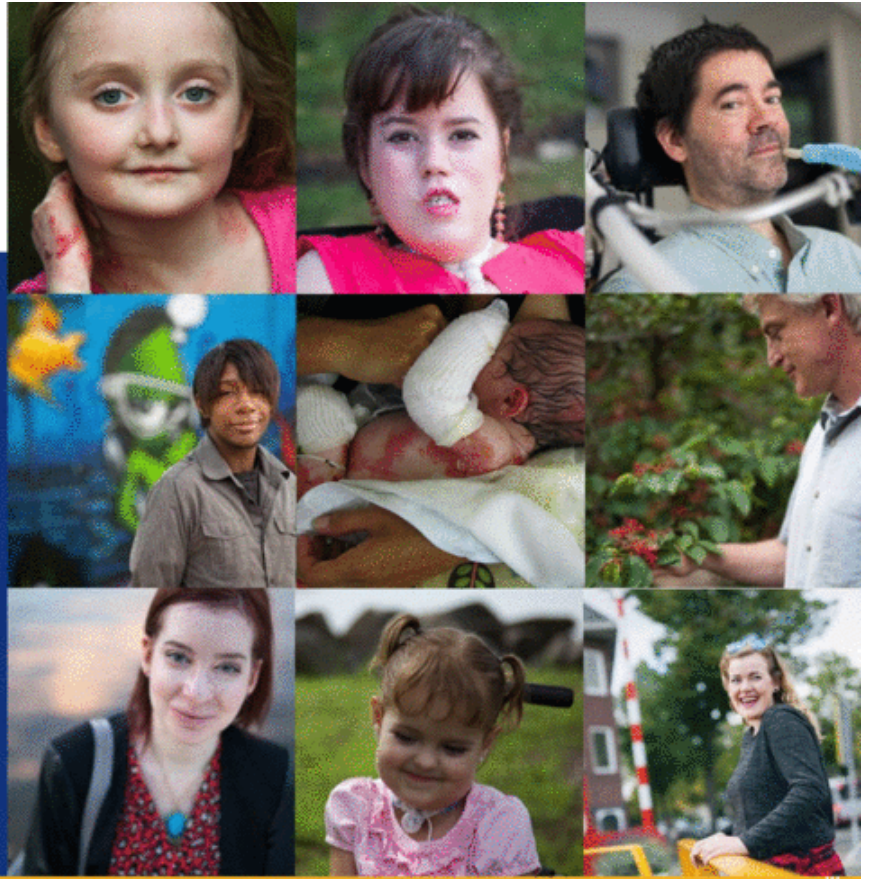
Amicus Therapeutics, Inc.

Date: May 11, 2016

By: /s/ Ellen S. Rosenberg
Ellen S. Rosenberg
General Counsel and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Presentation Materials



Bank of America
Merrill Lynch 2016
Health Care Conference

Chip Baird, Chief Financial Officer
May 11, 2016

Safe Harbor

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, financing plans, and the projected cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this presentation may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials and the expected timing of the EMA's final decision with respect to regulatory approval of migalastat in the European Union, actual results may differ materially from those set forth in this presentation due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities, including the EMA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing our product candidates if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; and the potential that we will need additional funding to complete all of our studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With respect to statements regarding projections of the Company's cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2015. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

Amicus Vision

Amicus Therapeutics is a global biotechnology company at the forefront of developing advanced therapies to treat a range of devastating rare and orphan diseases

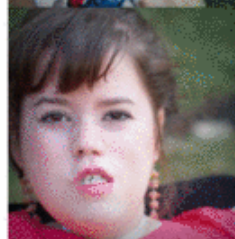
Rare &
Devastating
Diseases



Potential
First-in-Class
/ Best-in-
Class



Meaningful
Benefits for
Patients



Key Drivers of Value

3 Novel Product Candidates Each with \$500M to \$1B+ Market Potential

Fabry

- Migalastat Personalized Medicine (Small Molecule)
- Positive CHMP Opinion (April 1, 2016)
- EC Adoption and EU Launch*
- FDA meeting expected mid-year 2016

Epidermolysis Bullosa (EB)

- Phase 3 Novel Topical Treatment (SD-101)
- U.S. Breakthrough Therapy Designation
- Rolling NDA
- Phase 3 Data Expected in 2H16

Pompe

- Novel ERT + Chaperone Treatment Paradigm
- Biologics Manufacturing
- Clinical Study Initiated with Interim Data Anticipated in 2016

R&D Engine and Continued Business Development Activity

*Pending Approval



Migalastat Personalized Medicine for Fabry Disease

Positive CHMP Opinion Recommending Broad Label for Migalastat

Migalastat Indicated for Long-Term Treatment of Adults and Adolescents Aged ≥ 16 years with a Confirmed Diagnosis of Fabry Disease and Who have an Amenable Mutation



“The evaluation of EMA’s Committee for Medicinal Products for Human Use (CHMP) was based on the results of two phase III clinical trials in about 110 patients with Fabry disease who had a genetic mutation which responds to migalastat. Galafold demonstrated its efficacy compared to placebo (a dummy treatment) and to ERT in a long-term comparative study.

- EMA Press Release

Fabry Disease Overview

Fabry Disease is a Fatal Genetic Disorder that Affects Multiple Organ Systems

Leading Causes of Death

TRANSIENT ISCHEMIC
ATTACK (TIA) & STROKE¹

HEART DISEASE²

KIDNEY DISEASE³

Life-Limiting Symptoms

GASTROINTESTINAL³

Key Facts

- Deficiency of α -Gal A enzyme leading to GL-3 accumulation
- >800 known mutations
- 5-10K diagnosed WW (51% female/49% male⁴)
- Newborn screening studies suggest prevalence of ~1:1000 to ~1:4000

1. Desnick R, et al. *Ann Intern Med.* 2003 2. Yousef Z, et al. *Eur Heart J.* 2013 3. Germain D. *Orphanet J Rare Dis.* 2010 4. Fabry Registry 2011

Summary of Clinical Data

Favorable Efficacy and Safety Data in Two Largest Phase 3 Studies Ever Completed in Fabry Disease



Reduction in Disease Substrate

IC GL-3 (Study 011¹)*
Plasma Lyso Gb-3 (Study 011^{2,1} and 012³)*

Stability of Kidney Function

Estimated Glomerular Filtration Rate (eGFR) and Measured GFR
(Study 011⁴ and Study 012^{4,3})

Reduction in Cardiac Mass

Left Ventricular Mass Index (LVMI) (Study 011² and 012)*

Improvement in GI Symptoms

Gastrointestinal Symptoms Rating Scale (GSRS) (Study 011¹)*

Low Rate of Fabry-Associated Clinical Events

Renal, Cardiac and Cerebro-Vascular Events (Study 012³)

1: Improvement versus placebo over 6 months in amenable patients
2: Improvement from baseline over 18+ months
3: Comparable to ERT over 18 months
4: Stabilization from baseline over 18 months with favorable comparison to natural history in literature

*Analyses in this endpoint achieved statistical significance. For more complete clinical data go to amicusrx.com/posters.aspx

Launch Preparation Activities



Medical education and patient advocacy ongoing on behalf of Fabry patients



Experienced commercial leadership team with established international operations



Patient and physician mapping



Global value dossier complete and local submissions initiated



International distribution system

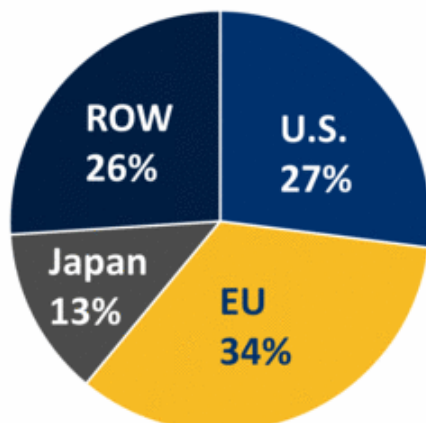
Amicus is Prepared for 2016 Launch



Fabry Market Today

Amicus is Prioritizing EU, Japan, US and Other Large Fabry Markets for Initial Launch

\$1.2B in FY15 ERT Sales¹



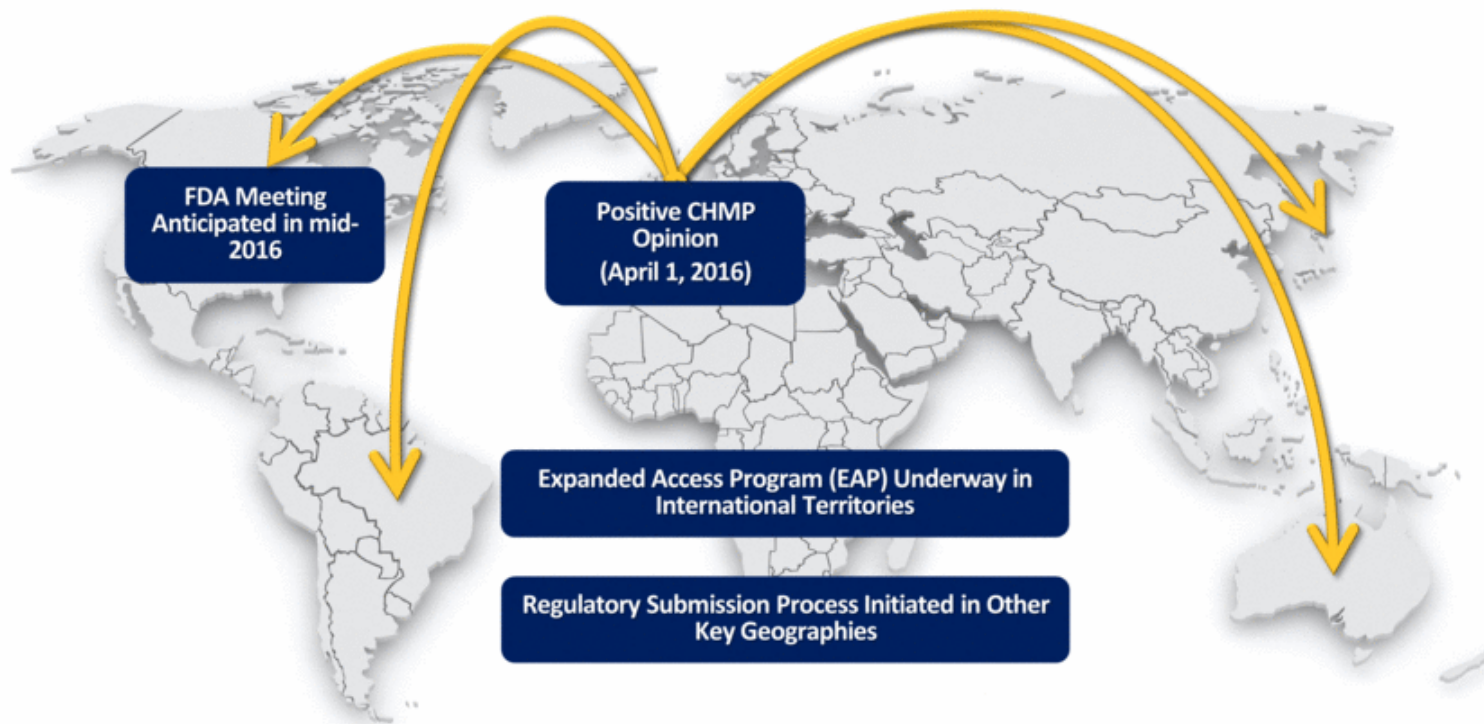
- **First** new product in > 10 years
- **First** oral therapy
- **First** targeted therapy for amenable patients (30%-50% of population)

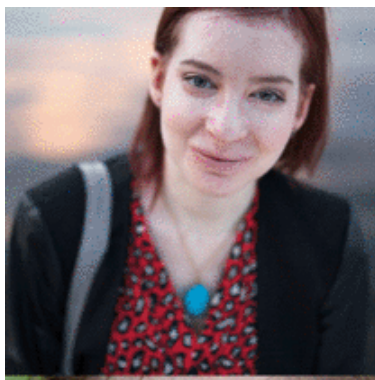
- 40-50% of Diagnosed Patients Not on ERT Today
- Market Continues to Grow > 10% / Year
- ERT Infused Once Every 2 Weeks

1. Company filings and Amicus estimates

Global Regulatory Strategy

EU Approval Lays the Foundation to Address ~70% of Global Fabry Market





SD-101 for Epidermolysis Bullosa (EB)

Poised to deliver pivotal data for a
devastating rare disease in 2016

EB Disease Overview

Rare, Devastating, Connective Tissue Disorder with No Approved Treatments



- Multiple genes cause disease which results in fragility of skin and can affect internal organs
- Diagnosed from infancy to adulthood
- Severe blistering, open wounds, and scarring in response to minor friction to the skin
- Disfiguring, excruciatingly painful, and can be fatal
- Given the lack of approved treatment options, any reduction in disease symptoms would be considered meaningful
- 30,000 – 40,000 diagnosed patients in major global regions

Three Major EB Types Represent ~99% of EB Population

Multiple Types...Single Devastating and Fatal Genetic Disorder

Simplex



~75% of EB Population

Dystrophic



~20% of EB Population

Junctional



~5% of EB Population

INCREASING SEVERITY

No Approved Therapies Today

SD-101 in Development for All 3 Major Types

30,000 - 40,000 Diagnosed in Major Markets

Phase 2b Design (Study 003)

3-Month, Double-Blind Treatment Period¹

SD-101 6% (n=15)

SD-101 3% (n=16)

Placebo (n=17)

Optional Extension (SD-004)

Open-Label SD-101 6%

42/44 Patients entered extension study

\$400K FDA Grant for Extension Study

Primary Efficacy Endpoint: Target Wound Healing at Month 1

- Baseline wound: Chronic (≥ 21 days), size 5-50 cm²

Secondary Efficacy Endpoints Include:

- Time to target wound closure
- Change in Body Surface Area (BSA) of lesional skin

48 EB patients (age ≥ 6 months)¹ - 1:1:1 Randomization - Daily Topical Application

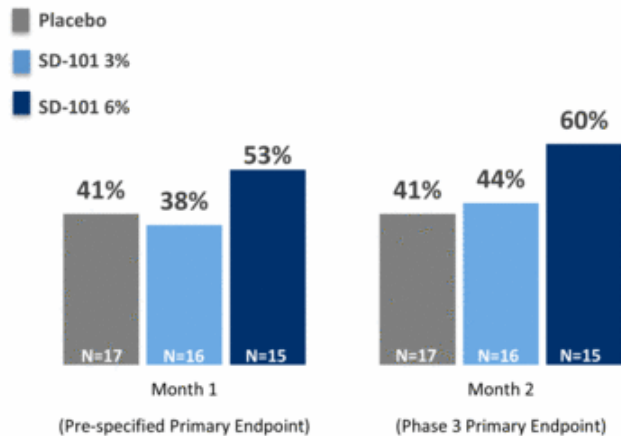
1. Assessments: 0, 14, 30, 60, 90 Days. 2. Initial Disease Severity: Mean target lesion size (cm²) 14.0 (range 5-39); mean lesional BSA: 19.4% (range 0.4-48%); mean wound age (days): 182 (range 21-1,639). EB types enrolled: Simplex (n=11), Dystrophic (n=29), and Junctional (n=8)

Phase 2b Results

SD-101 6% Demonstrated Higher Proportion of Complete Target Wound Closure

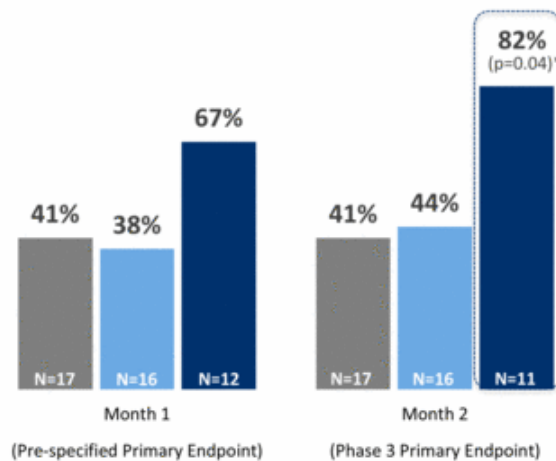
ITT Population (n=48)

Proportion of Complete Target Wound Closure (%)



Evaluable Population¹ (n=45)

Proportion of Complete Target Wound Closure (%)



*SD-101 6% vs placebo, unadjusted p=0.04

1. Excluded from Evaluable population: 1 patient (due to lost to follow-up), 2 patients (did not have single identified and qualified target lesion). 1 additional patient lost to follow up after Month 1 visit and is excluded from target wound assessment at later time points

Phase 3 Design (SD-005)

Phase 3 Initiated in 2Q15 and >50% Enrolled
Top-Line Data Expected 2H16

3-Month, Double-Blind Treatment Period¹



Primary Endpoint: Target Wound Healing at Month 2

- U.S. and EU regulatory authorities agreed on primary endpoint
- Baseline wound: Chronic (≥ 21 days), size ≥ 10 cm²

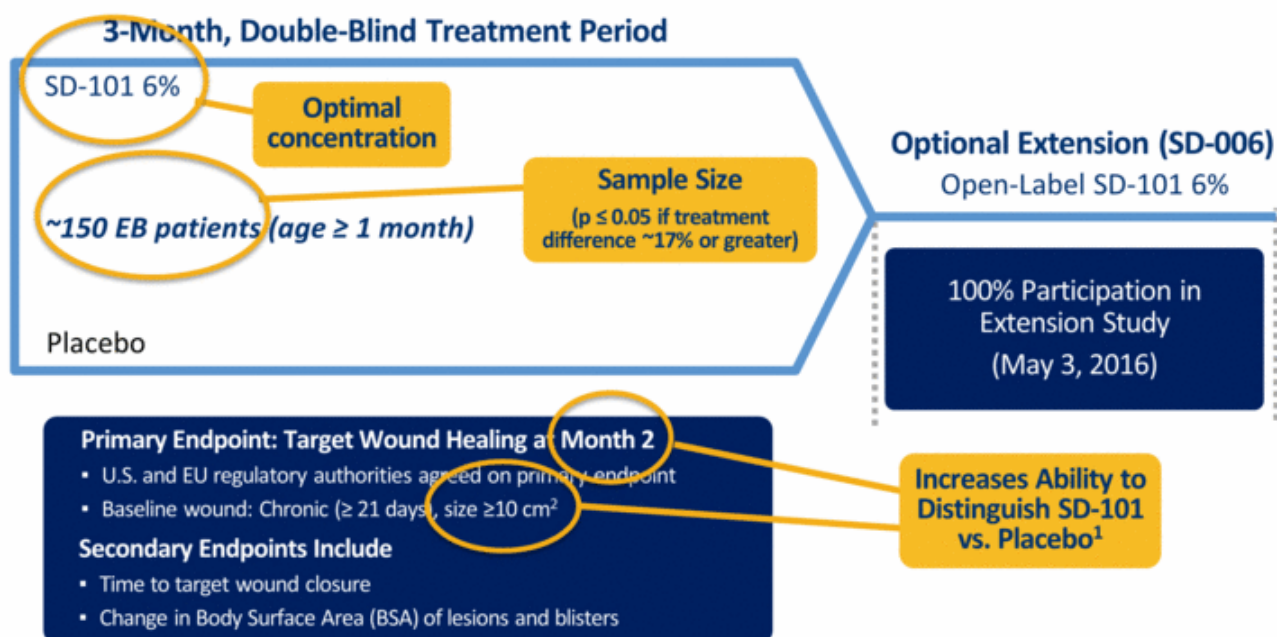
Secondary Endpoints Include

- Time to target wound closure
- Change in Body Surface Area (BSA) of lesions and blisters

1. Assessments: 0, 14, 30, 60, 90 Days. 1:1 randomization, daily topical application

Phase 3 Design (SD-005)

Study Design Incorporates Key Learnings from Phase 2b Study



1. Complete target wound closure in patients with target wounds ≥ 10 cm² at Month 2 in Phase 2b: SD-101 6% - 50% (n= 4) vs. Placebo - 12.5% (n=8)

Global Regulatory Strategy

Positive FDA and EMA Feedback on Phase 3 Study Design

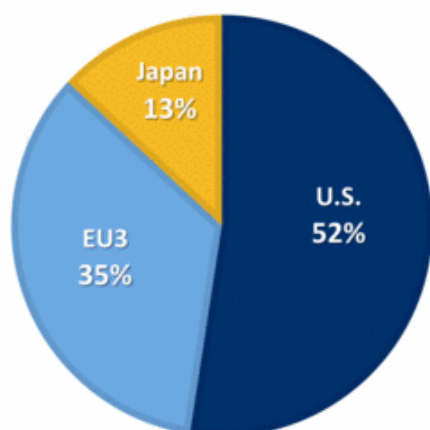


\$1B+ Commercial Potential

KOL Feedback Supports Profound Unmet Medical Need and Broad Usage in All EB Types

Diagnosed EB Patients by Geography

(U.S., EU3, Japan)



Significant Unmet Clinical Need

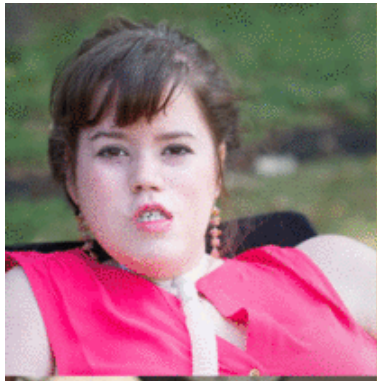
- No approved treatments, opportunity for first-in-class
- Promising proof of concept in all EB types

Strong Support Among Surveyed Stakeholders

- Physicians indicate usage in 100% patients
- Payers indicate support for broad reimbursement if approved

Large Commercial Opportunity

- 30,000 – 40,000 diagnosed patients in major markets
- KOLs expect diagnosis rates to increase



ATB200 Novel ERT for Pompe Disease

A Proprietary, Clinical-Stage Biologics Program

Pompe Disease Overview

Severe, Fatal, Genetic Disorder with Significant Unmet Medical Need



- Deficiency of GAA leading to glycogen accumulation
- Age of onset ranges from infancy to adulthood
- Symptoms include muscle weakness, respiratory failure, and cardiomyopathy
- Respiratory and cardiac failure are leading causes of morbidity and mortality
- 5,000 – 10,000 patients diagnosed WW¹
- ~\$800M+ Global Pompe ERT sales in FY15²

1. National Institute of Neurological Disorders and Stroke (NIH). 2. Sanofi Press Release & 10-K

Pompe ERT - 3 Challenges

Amicus Technology Platforms with Potential to Address Challenges with Existing Pompe ERT

Activity/ Stability

Rapid denaturation of ERT in pH of blood¹

Protein Aggregation



CHAPERONE-ADVANCED REPLACEMENT THERAPY

Tolerability / Immunogenicity

Infusion-associated reactions in >50% of late-onset patients³

Antibody titers shown to affect treatment outcomes^{4,5}

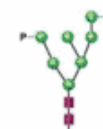


CHAPERONE-ADVANCED REPLACEMENT THERAPY

Uptake/ Targeting

Low M6P receptor uptake into skeletal muscle²

Vast majority of rhGAA not delivered to lysosomes²



Uniquely Engineered rhGAA Optimized M6P & Carbohydrates

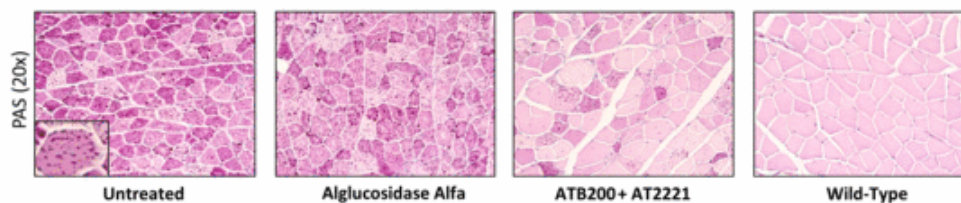
¹Khanna et al., PLoS ONE, 2012; ²Zhu et al., Amer. Soc. Gene Therapy, 2009 June; ³Banati et al., Muscle Nerve, 2011 Dec.; ⁴Banugaria et al., Gen. Med., 2011 Aug.; ⁵de Vries et al., Mol Genet Metab., 2010 Dec.



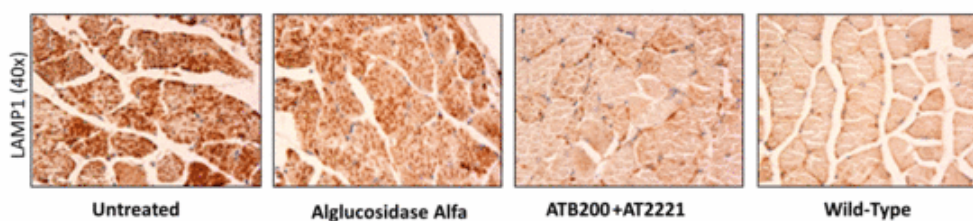
Preclinical Proof of Concept

ATB200 + Chaperone Results in Improved Substrate Clearance in Preclinical Models¹

PAS-glycogen staining in Quadriceps



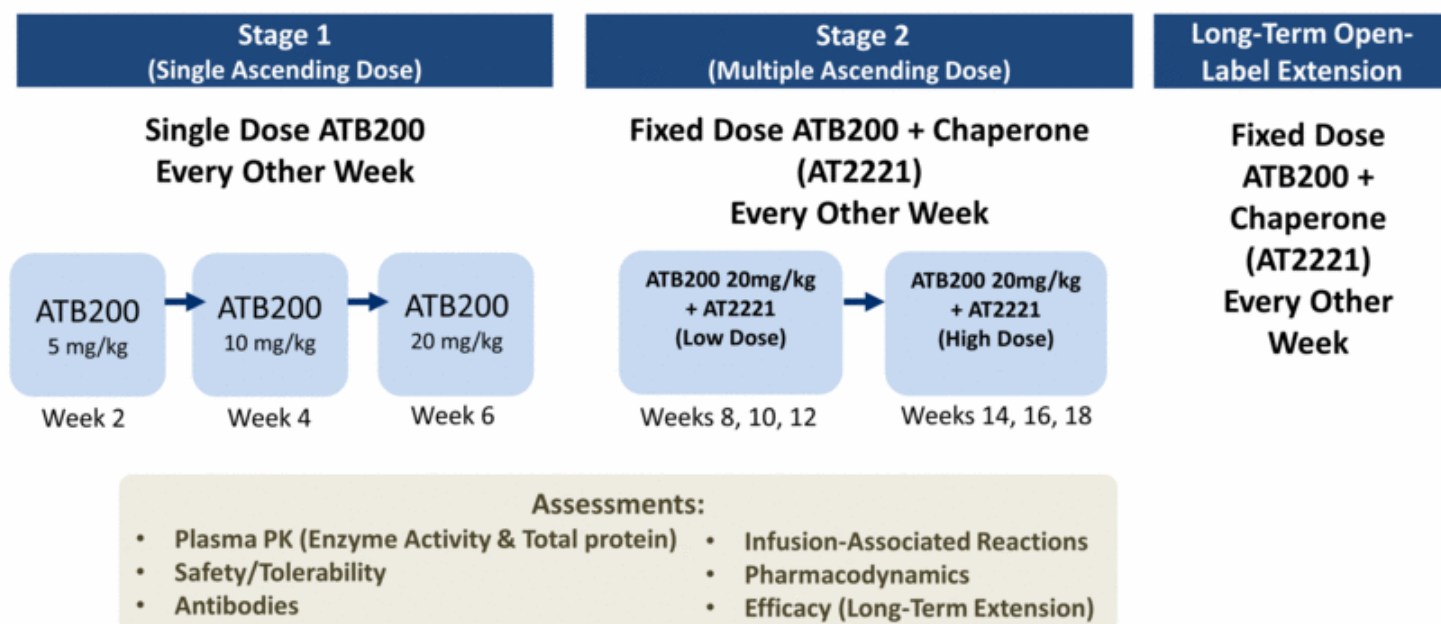
LAMP1 Immunohistochemical staining in Soleus

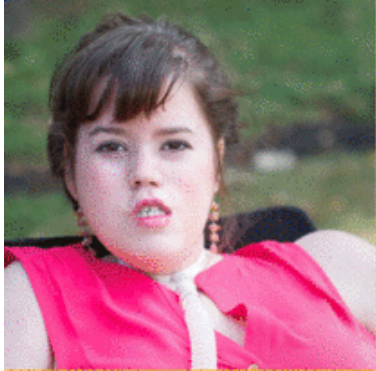


1. Following 2 doses of 20mg/kg alglucosidase alfa or ATB200 + AT2221 in Gaa KO mice, skeletal muscles evaluated for glycogen clearance and proliferated lysosomes. Treatment with alglucosidase alfa modestly reduced glycogen or proliferated lysosomes while ATB200, co-administered with AT2221 significantly decreased the muscle pathology associated with Pompe disease.

Clinical Study in Pompe Patients

Patient Dosing Underway and Enrollment Ongoing at Multiple Sites





Financial Summary

Strong Balance Sheet to Invest in Rare Disease Pipeline

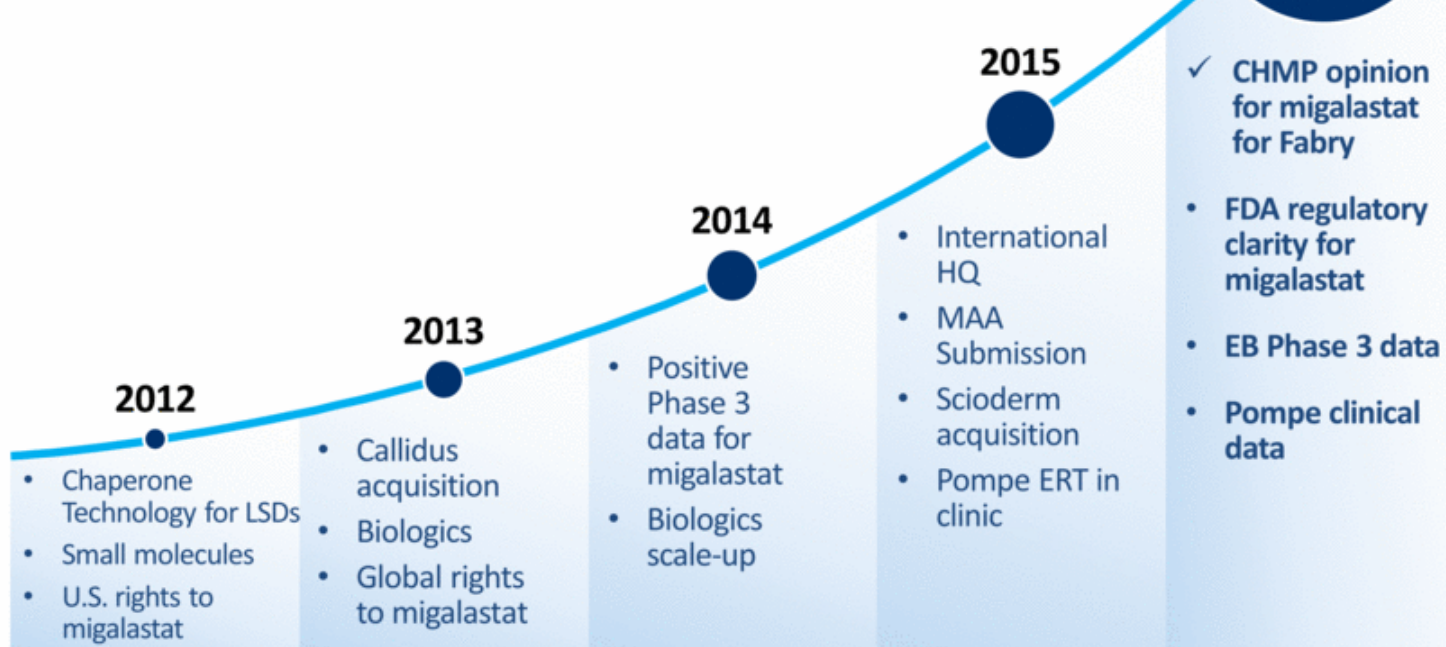
Strong Balance Sheet

Strong Balance Sheet Provides Cash Runway into Mid-2017

Financial Position	March 31, 2016
Current Cash:	\$165.9M
Current Debt	\$50.0M
FY16 Net Cash Spend Guidance:	\$135-\$155M
Cash Runway	Mid-2017
Total Net Proceeds from ATM as of April 29	\$16.2M
Capitalization	
Shares Outstanding	125,221,637

Amicus 2016 – Continuing the Momentum

Significant Milestones in 2016



Thank You

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