

**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): **August 5, 2015**

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 2.02. Results of Operations and Financial Condition.

On August 5, 2015, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2015. A copy of this press release is attached hereto as Exhibit 99.1. The Company will also host a conference call and webcast on August 5, 2015 to discuss its first quarter results of operations. A copy of the conference call presentation materials is also attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

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

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: August 5, 2015

By: /s/ William D. Baird III
William D. Baird III
Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 5, 2015
99.2	August 5, 2015 Conference Call Presentation Materials

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Amicus Therapeutics Announces Second Quarter 2015 Financial Results and Corporate Updates

Marketing Submissions for Galafold® (migalastat HCl) for Fabry Disease Under Review in Europe and on Track for Filing in 2H15 in United States

2Q15 Equity Financing Significantly Strengthens Balance Sheet; More Than \$350M Cash on Hand

International Commercial Leadership Team Nearly Complete

Phase 1/2 Clinical Study Initiation of Next-Generation Pompe ERT in 2H15

CRANBURY, NJ, August 5, 2015 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of therapies for rare and orphan diseases, today announced financial results for the second quarter ended June 30, 2015. The Company also provided program updates and reiterated full-year 2015 net cash spend guidance of \$100 million to \$110 million.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, “During the second quarter we made great progress towards our vision of building one of the world’s leading biotechnology companies focused on rare and orphan diseases. As part of fulfilling that vision and mission, we now have in place a world class international business and commercial leadership team. Our first marketing application for Galafold for Fabry disease is now under review in Europe, and we plan to submit our U.S. marketing application in the second half of this year. We have also made significant progress toward clinical studies with our next-generation Pompe enzyme replacement therapy. I am proud to report that this next-generation biologic has now completed the first GMP production run and has maintained its exceptionally high levels of mannose-6 phosphate and proper glycosylation. The Pompe program remains on track with all IND-enabling toxicology studies also nearly complete as we advance towards initiation of clinical studies in patients by the end of 2015.”

Financial Highlights for Second Quarter Ended June 30, 2015

- Cash, cash equivalents, and marketable securities totaled \$361.4 million at June 30, 2015, compared to \$169.1 million at December 31, 2014.
- Total operating expenses increased to \$26.9 million compared to \$14.7 million for the second quarter 2014, primarily due to increases in preclinical and clinical development costs on the Fabry monotherapy and Pompe ERT programs.
- Net loss was \$27.1 million, or \$0.27 per share, compared to a net loss of \$14.6 million, or \$0.22 per share, for the second quarter 2014.

2015 Financial Guidance

Cash, cash equivalents, and marketable securities totaled \$361.4 million at June 30, 2015 compared to \$169.1 million at December 31, 2014. The Company’s balance sheet was strengthened during the second quarter of 2015 with a \$258.8 million follow-on public offering. Amicus continues to expect full-year 2015 net cash spend between \$100 million and \$110 million. The current cash position is projected to fund operations into 2017.

Organizational Update

Amicus is building its commercial infrastructure in both the U.S. and Europe to support the potential 2016 launch of the oral pharmacological chaperone Galafold as a personalized medicine for Fabry patients who have amenable mutations. The Company continues to hire industry leaders who are experienced in building commercial teams to launch innovative therapies at some of the most successful and respected companies in biotechnology and orphan diseases. There are currently regional leaders in place who are responsible for the key commercial regions around the globe as well as functional heads in the areas of commercial operations, medical affairs, and marketing among others who are actively preparing to launch Galafold.

Program Highlights

Fabry Franchise

Amicus has made significant progress executing its global regulatory and launch strategy for Galafold. During the second quarter, the Company submitted a marketing authorization application (MAA) for Galafold under accelerated assessment.

On June 25, 2015, the MAA was validated by the European Medicines Agency (EMA) and review began under the Centralized Procedure. The MAA validation also triggered the initiation of the global regulatory process in several additional geographies. In the U.S., a pre-New Drug Application (pre-NDA) meeting is scheduled for the third quarter with the Food and Drug Administration (FDA) to discuss the content of the planned NDA (Subpart H) and proposed Phase 4 post-marketing commitments for Galafold in the second half of this year.

Positive Phase 3 data in both treatment-naïve and ERT-switch patients have shown that treatment with Galafold has resulted in reductions in disease substrate, stability of kidney function, reduction in cardiac mass, and a positive impact in patient-reported outcomes in patients with amenable mutations. For Fabry patients who do not have amenable mutations and cannot take monotherapy, Amicus is advancing migalastat in combination with ERT.

Anticipated 2015 Fabry Franchise Milestones:

- Pre-NDA meeting with FDA (3Q15)
- NDA submission for Galafold in U.S. (2H15)
- Initiation of Phase 2 study of oral migalastat co-administered with currently marketed ERTs (2H15)
- Internal development underway of next-generation ERT (Fabry cell line for co-formulation with migalastat)

Next-Generation ERT for Pompe Disease (ATB200 + Chaperone)

During the second quarter, Amicus completed the first good manufacturing practice (GMP) production run of ATB200, a next-generation Pompe ERT. This is a significant milestone as Amicus advances toward clinical study initiation in Pompe patients. Additional GMP manufacturing runs will occur during the second half of 2015 to build further supply for clinical studies.

Amicus is leveraging its biologics capabilities and CHART™ (Chaperone-Advanced Replacement Therapy) platform to develop ATB200. This next-generation ERT consists of a uniquely engineered recombinant human acid alpha-glucosidase (rhGAA) enzyme with an optimized carbohydrate structure to enhance uptake, administered with a pharmacological chaperone enhancer to improve activity and stability.

Anticipated 2015 Pompe Program Milestones:

- Start of observational clinical study in Pompe patients (3Q15)
- Meetings with US and EU regulatory authorities to discuss clinical development plan (3Q15)
- Phase 1/2 clinical study initiation to investigate the next-generation treatment paradigm for Pompe patients, ATB200 + chaperone (4Q15)

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, August 5, 2015 at 5:00 p.m. ET to discuss second quarter 2015 financial results and program updates. Interested participants and investors may access the conference call at 5:00 p.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

An audio webcast and slide presentation can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at <http://www.amicusrx.com>, and will be archived for 30 days. Web participants are encouraged to go to the web site 15 minutes prior to the start of the call to register, download and install any necessary software. A telephonic replay of the call will be available for seven days beginning at 8:00 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 98584713.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq:FOLD) is a biopharmaceutical company at the forefront of therapies for rare and orphan diseases. The Company is developing novel, first-in-class treatments for a broad range of human genetic diseases, with a focus on delivering new benefits to individuals with lysosomal storage disorders. Amicus' lead programs in development include the small molecule pharmacological chaperone Galafold as a monotherapy for Fabry disease, as well as next-generation enzyme replacement therapy (ERT) products for Fabry disease, Pompe disease, and MPS I.

Forward-Looking Statements

This press release contains, and the accompanying conference call will contain, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of Amicus' candidate drug products, the timing and reporting of results from preclinical studies and clinical trials evaluating Amicus' candidate drug products, financing plans, and the projected cash position for the Company. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "potential," "plan," "targets," "likely," "may," "will,"

"would," "should" and "could," and similar expressions or words identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation by Amicus that any of its plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Amicus 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 the potential goals, progress, timing and results of preclinical studies and clinical trials, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the business of Amicus, including, without limitation: the potential that results of clinical or pre-clinical 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 may not grant or may delay approval for our product candidates; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we will need additional funding to complete all of our studies and, our dependence on third parties in the conduct of our clinical 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, 2014. 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 Amicus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

CONTACTS:

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Media:

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Table 1

Amicus Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Research revenue	—	\$ 475	—	\$ 931
Total revenue	—	475	—	931
Operating Expenses:				
Research and development	\$ 17,234	\$ 9,978	\$ 33,347	\$ 19,970
General and administrative	8,278	4,753	14,705	9,929
Changes in fair value of contingent consideration payable	100	(305)	1,100	200
Restructuring charges	26	(81)	36	(89)
Loss on extinguishment of debt	952	—	952	—
Depreciation	353	396	861	808
Total operating expenses	26,943	14,741	51,001	30,818
Loss from operations	(26,943)	(14,266)	(51,001)	(29,887)
Other income (expenses):				
Interest income	158	36	329	78
Interest expense	(338)	(374)	(710)	(729)
Other expense	(10)	(10)	(39)	(19)
Net loss	\$ (27,133)	\$ (14,614)	\$ (51,421)	\$ (30,557)
Net loss per common shares — basic and diluted	\$ (0.27)	\$ (0.22)	\$ (0.53)	\$ (0.46)
Weighted-average common shares outstanding — basic and diluted	99,994,125	67,212,764	97,888,573	65,799,059

Table 2

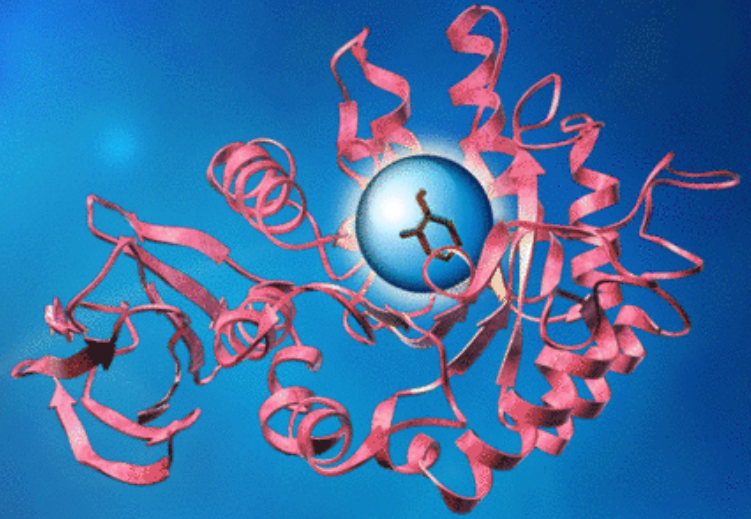
Amicus Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	June 30, 2015	December 31, 2014
Assets:		
Current assets:		
Cash and cash equivalents	\$ 249,023	\$ 24,074
Investments in marketable securities	112,396	127,601
Prepaid expenses and other current assets	3,578	2,902
Total current assets	364,997	154,577
Investments in marketable securities	—	17,464
Property and equipment, less accumulated depreciation of \$12,381 and \$11,520 at June 30, 2015 and December 31, 2014, respectively	3,379	2,811
In-process research & development	23,000	23,000
Goodwill	11,613	11,613
Other non-current assets	924	502
Total Assets	\$ 403,913	\$ 209,967
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 16,901	\$ 16,345
Current portion of secured loan	—	3,840
Total current liabilities	16,901	20,185
Deferred reimbursements	36,620	36,620
Secured loan, less current portion	—	10,510
Contingent consideration payable	11,800	10,700
Deferred tax liability	9,186	9,186
Other non-current liability	504	588
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value, 250,000,000 shares authorized, 118,367,319 shares issued and outstanding at	1,241	1,015

June 30, 2015, 125,000,000 shares authorized, 95,556,277 shares issued and outstanding at December 31, 2014

Additional paid-in capital	826,582	568,743
Accumulated other comprehensive income	(52)	(132)
Accumulated deficit	(498,869)	(447,448)
Total stockholders' equity	<u>328,902</u>	<u>122,178</u>
Total Liabilities and Stockholders' Equity	\$ <u>403,913</u>	\$ <u>209,967</u>

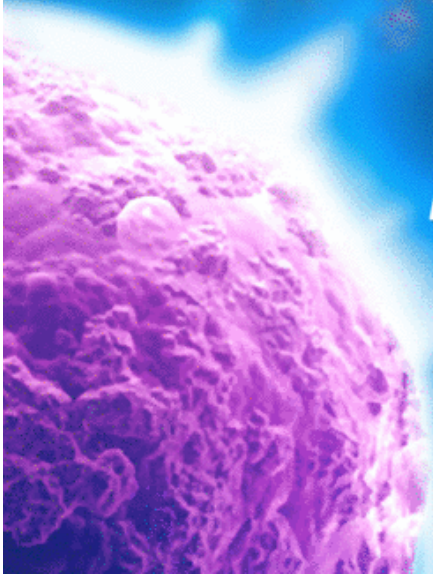
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***2Q15 Corporate and Program
Highlights and Financial Results***

August 5, 2015

*at the forefront of therapies
for rare and orphan diseases*



Safe Harbor

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 relating to business, operations and financial conditions of Amicus including but not limited to preclinical and clinical development of Amicus’ candidate drug products, cash runway, and the timing and reporting of results from clinical trials evaluating Amicus’ candidate drug products. Words such as, but not limited to, “look forward to,” “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “would,” “should” and “could,” and similar expressions or words, identify forward-looking statements. Although Amicus believes the expectations reflected in such forward-looking statements are based upon reasonable assumptions, there can be no assurance that its expectations will be realized. Actual results could differ materially from those projected in Amicus’ forward-looking statements due to numerous known and unknown risks and uncertainties, including the “Risk Factors” described in our Annual Report on Form 10-K for the year ended December 31, 2014. All forward-looking statements are qualified in their entirety by this cautionary statement, and Amicus undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

Agenda

- 2Q15 corporate and program highlights
- Fabry market overview
- Pompe global strategy overview
- 2Q15 financial results and FY15 guidance
- Summary and upcoming milestones
- Q&A

2Q15 Corporate and Program Highlights

Successful Achievement of Multiple Corporate and Program Milestones in 2Q15

- Galafold® (migalastat HCl) for Fabry
 - MAA submitted and validated (EU review under accelerated assessment)
 - Pre-NDA meeting and NDA submission on track for 2H15 in U.S.
 - Global regulatory process initiated in additional geographies
 - Amicus commercial team in key regions
- Next-generation ERT (ATB200 + chaperone) for Pompe
 - First GMP production run successfully completed
 - IND-enabling studies nearly complete
 - Clinical study initiation on track for 2H15
- Well-capitalized to build leading patient-centric rare disease company
 - \$361.4M cash position on 6/30
 - Balance sheet strengthened with \$258.8M follow-on public offering in 2Q
- International commercial leadership team in place

Agenda

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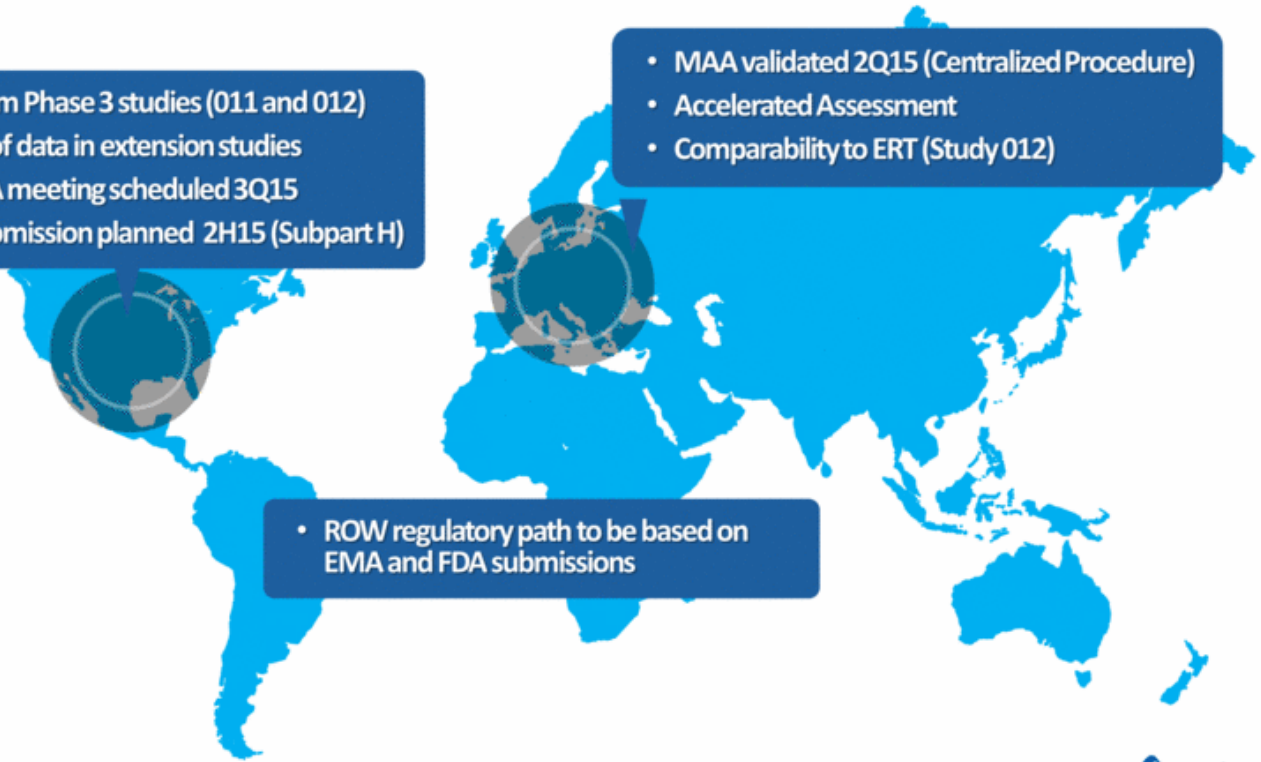
Global Regulatory Strategy

MAA Submitted in Europe and NDA on Track for 2H15 in U.S.

- Data from Phase 3 studies (011 and 012)
- 9 years of data in extension studies
- Pre-NDA meeting scheduled 3Q15
- NDA submission planned 2H15 (Subpart H)

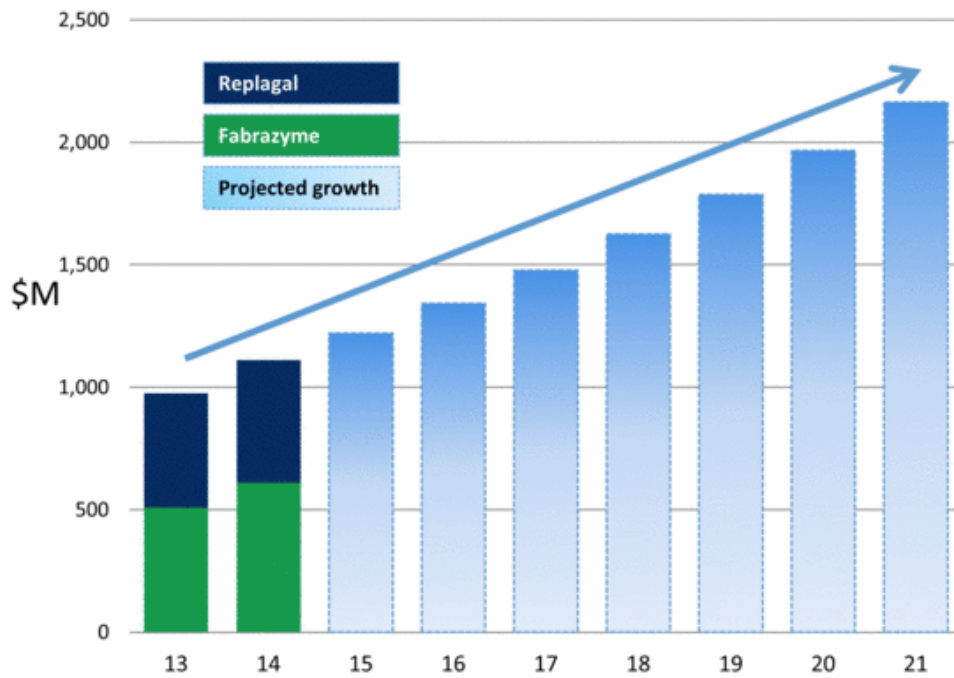
- MAA validated 2Q15 (Centralized Procedure)
- Accelerated Assessment
- Comparability to ERT (Study 012)

- ROW regulatory path to be based on EMA and FDA submissions



Global Fabry Market

Global Fabry Market Exceeded \$1.1B in FY14 and Tracking Toward \$2B by 2021



Fabry ERT sales increased **13.8% in 2014**, continuing trend of double-digit annual growth¹

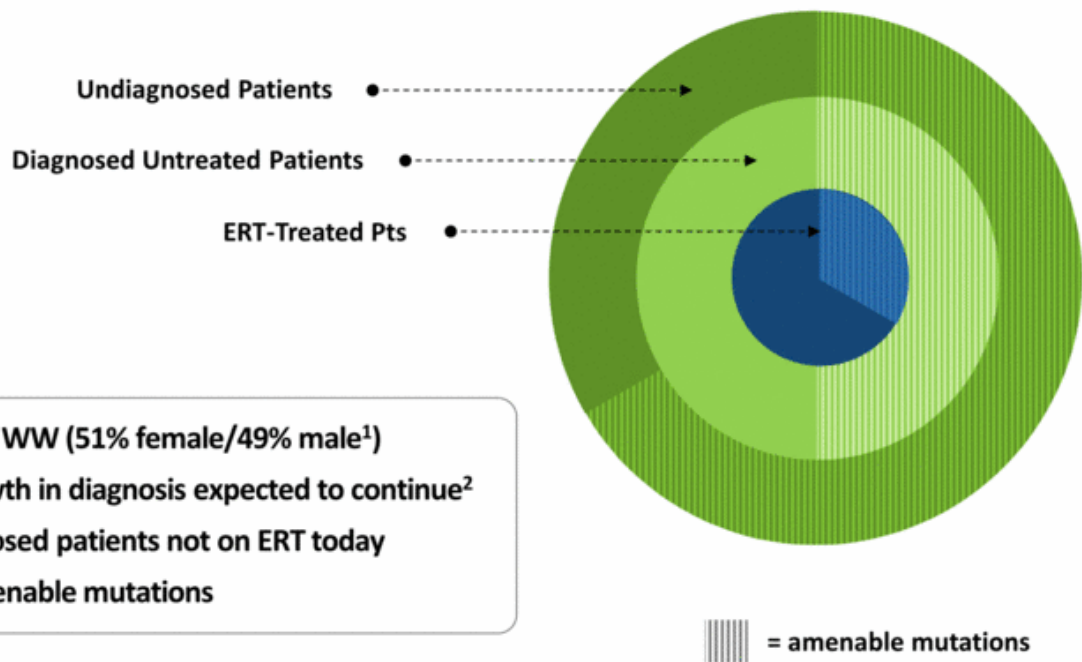
U.S. and Western Europe KOLs expect continued market growth:

"The number of diagnosed patients will increase. We keep identifying new patients, and this number is not decreasing year on year. I would not be surprised if it gets close to doubling in next 10 years."

— UK Fabry KOL

Galafold Commercial Opportunity

Attractive Commercial Opportunity with Significant Number of Patients with Amenable Mutations

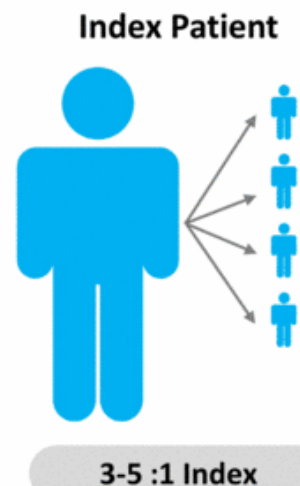


- 5-10K diagnosed WW (51% female/49% male¹)
- 10% annual growth in diagnosis expected to continue²
- 40-50% of diagnosed patients not on ERT today
- 30-50% with amenable mutations

Significant Underdiagnosis of Fabry Disease

Large Number of Patients Identified Through Newborn Screening Suggests Fabry Could Be One of the More Prevalent Human Genetic Diseases

Newborn Screening Study	# Newborns Screened	# Confirmed Fabry Mutations	% Amenable
Burton, 2012, US	8,012	7 [1: ~1100]	TBD
Mechtler, 2011, Austria	34,736	9 [1: ~3,800]	100%
Hwu, 2009, Taiwan	171,977	75 [1: ~2300]	75%
Spada, 2006, Italy	37,104	12 [1: ~3100]	86%
Historic published incidence		1:40,000 to 1:60,000	



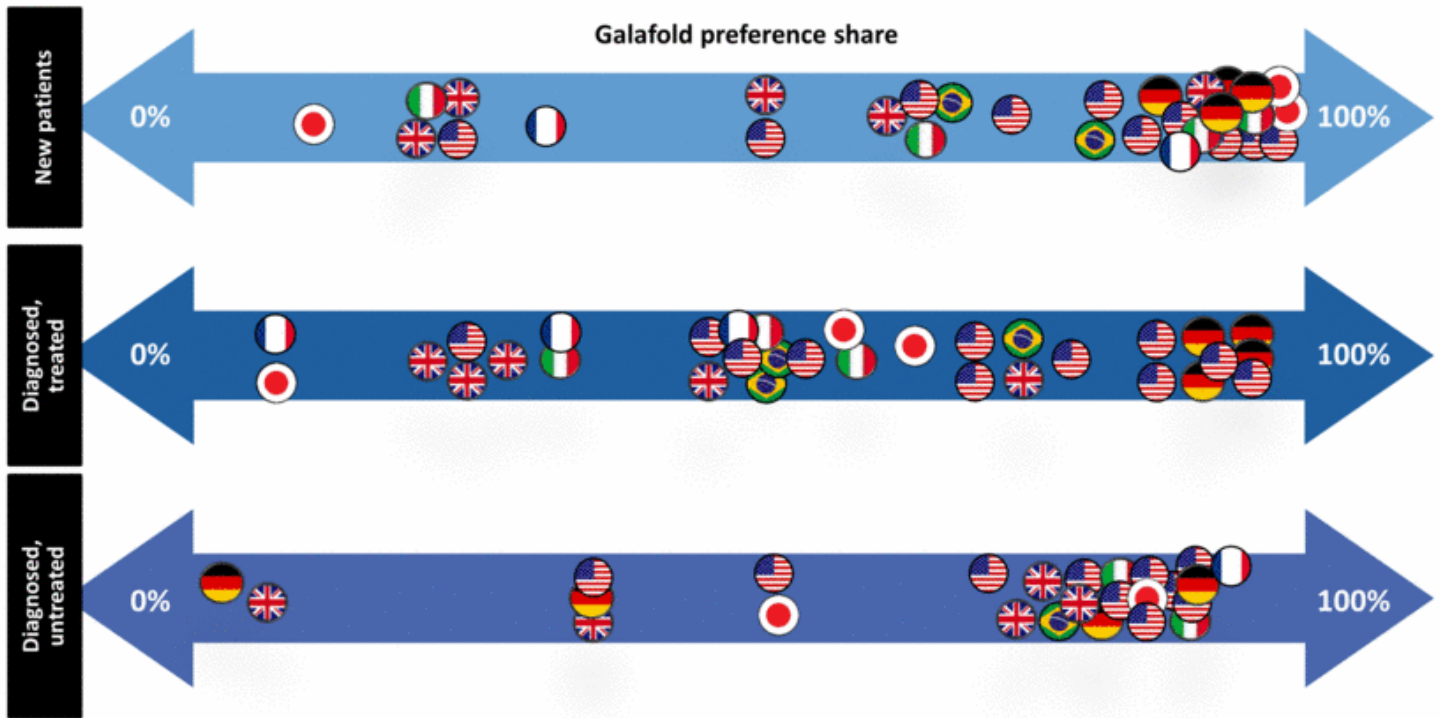
Majority Diagnosed through Newborn Screening Have Amenable Mutations

Burton, LDN WORLD Symposium, 2012 Feb.
Mechtler *et al.*, *The Lancet*, 2011 Dec.

Hwu *et al.*, *Hum Mutation*, 2009 Jun
Spada *et al.*, *Am J Human Genet.*, 2006 Jul

Positive KOL Feedback

Based on Target Product Profile, KOLs Would Use Galafold in Most Naïve and Switch Patients with Amenable Mutations with Signs and Symptoms if Approved



Payor Feedback Supports Reimbursement

Interviews with 20 Payors in Major Markets Suggest Broad Reimbursement and Coverage for Amenable Patients if Approved

Coverage supported by clinical trial data...

Based on Target Product Profile, payors interviewed in all studied countries believe there is sufficient evidence to support reimbursement of Galafold

- Payor, UK: I think the level of evidence is good enough here for reimbursement, at least at [pricing] parity to ERT

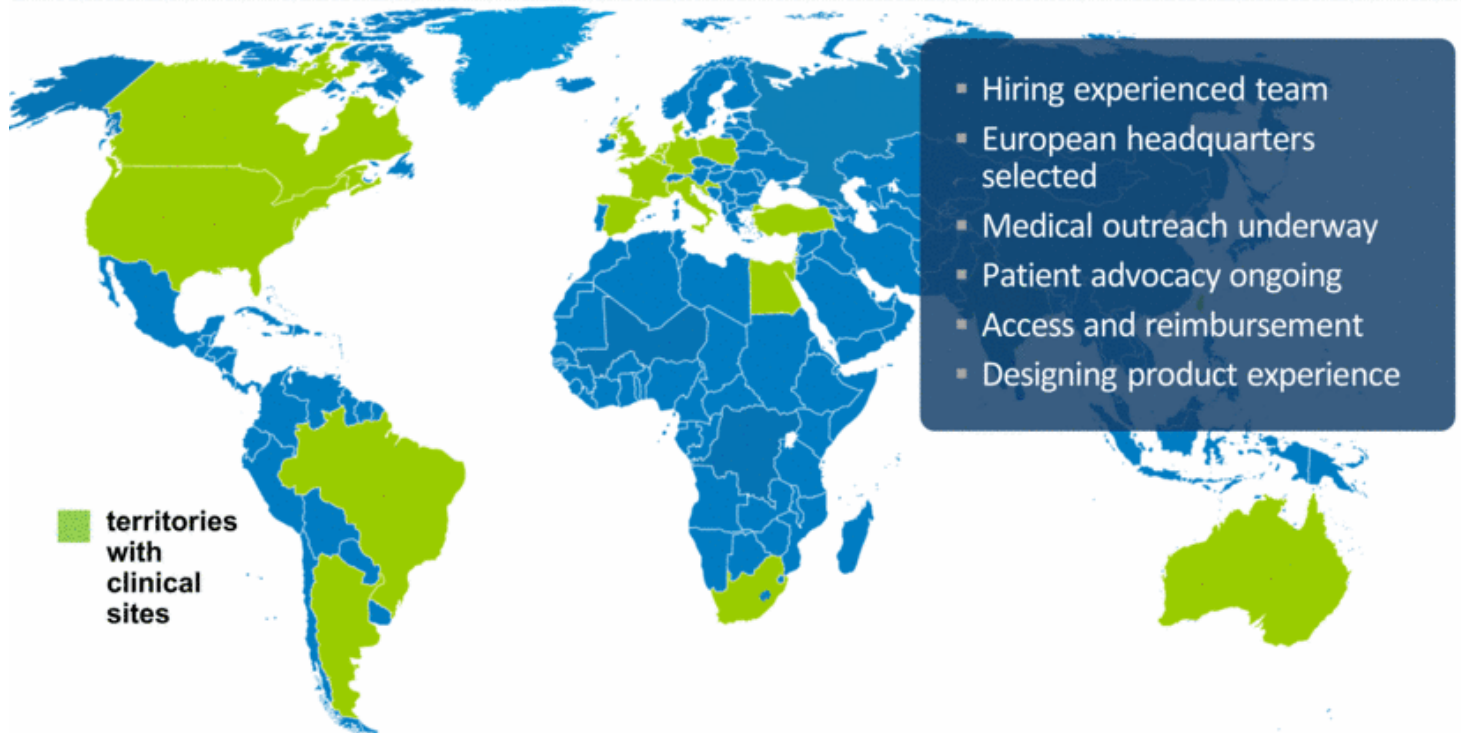
...and more convenient route of administration

Additionally, assuming parity pricing to ERT, payors generally expressed high interest in including Galafold in their formulary as they believe most patients would prefer oral route of administration over infusion

- Payor, U.S: If it was priced at parity with ERT, there would be zero restrictions on its use

Global Pre-Commercial Activities

Amicus is Building on Global Galafold Experience to Prepare for Successful Launch



Agenda

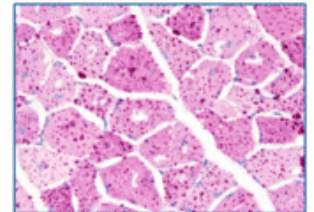
- 2Q15 corporate and program highlights
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Pompe Disease Overview

Severe, Fatal, Progressive Neuromuscular Disease with Significant Unmet Need Despite Availability of ERT



- 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
- Incidence 1:28,000¹



Elevated Glycogen
in Muscle

Amicus Biologics Platform Technologies

Multiple Complementary Amicus Platform Technologies
With Potential to Address The Challenges with Existing ERTs Today

Activity/
Stability



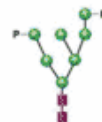
CHAPERONE-ADVANCED
REPLACEMENT THERAPY

Tolerability /
Immunogenicity



CHAPERONE-ADVANCED
REPLACEMENT THERAPY

Uptake/
Targeting



Uniquely Engineered rhGAA
Optimized M6P & Carbohydrates

Amicus Biologics Capabilities

Significant Progress From Pompe Master Cell Banking to GMP Manufacturing in < 2 Years While Maintaining High Levels of M6P and Proper Glycosylation



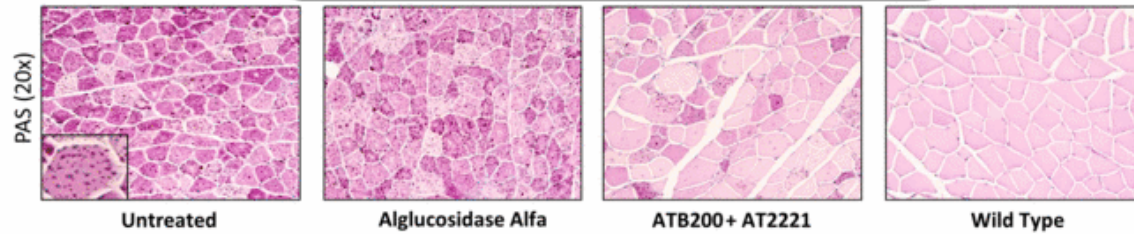
- Master cell banking in 2013
- Cell line scaled to 250 L in 2014
- First GMP batch completed 2Q15
- Additional GMP runs underway for clinical supply
- IND-enabling tox studies nearing completion by 4Q15

Image from Satorius Stedim

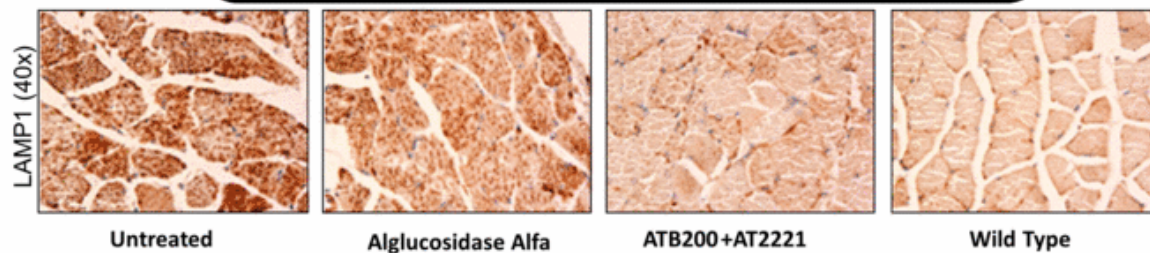
ATB200 + Chaperone Preclinical Proof-of-Concept

Glycogen Clearance Correlates with Endocytic Vesicle Turnover in Skeletal Muscle of *Gaa* KO Mice¹

PAS-glycogen staining in Quadriceps

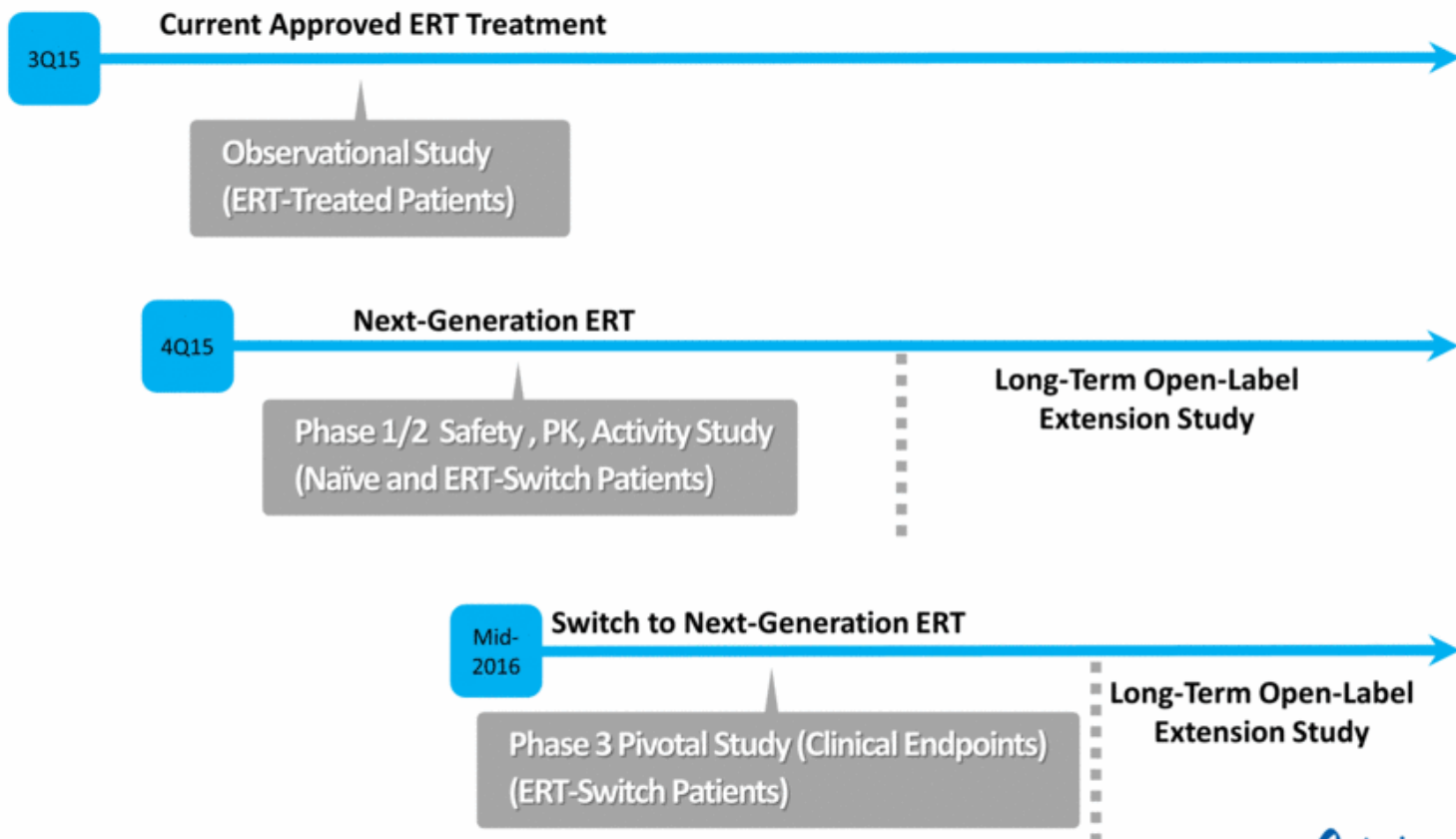


LAMP1 Immunohistochemical staining in Soleus



¹Following 2 doses of 20mg/kg Alglucosidase Alfa and ATB200 +/- AT2221 in *Gaa* KO mice, skeletal muscle evaluated for glycogen clearance and lysosomes. Treatment with ATB200 resulted in greater glycogen reduction and improved muscle physiology. Co-administration of ATB200 with AT2221 had an even greater impact on decreasing the muscle pathology associated with Pompe disease.

Proposed Pompe Clinical Development Plan



Agenda

- 2Q15 corporate and program highlights
- Fabry market overview
- Pompe global strategy overview
- 2Q15 financial results and FY15 guidance
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- Q&A

2Q15 Financial Summary

Cash Position Provides Runway Under Current Operating Plan Into 2H17

Financial Position	June 30, 2015
Current Cash:	\$361.4M
Net Proceeds from 2Q Offering	\$258.8M
2015 Net Cash Spend:	\$100-\$110M
Cash Runway:	2H17
Capitalization	
Shares Outstanding:	118,367,319

2Q15 Financial Results

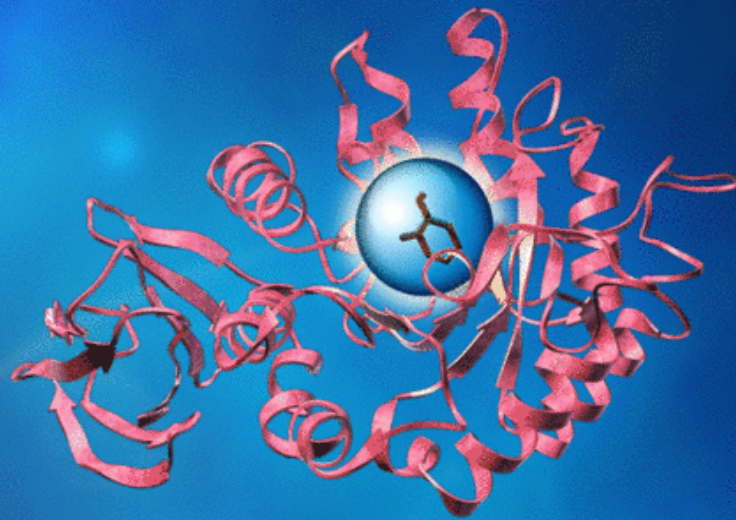
	(\$000s)	June 30, 2015	June 30, 2014
Total Operating Expenses		26,943	14,741
Net Loss		(27,133)	(14,614)
Net Loss Per Share		(0.27)	(0.22)

Agenda

- 2Q15 corporate and program highlights
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2H15 Anticipated Milestones

Milestones	Fabry Franchise	Milestones	Next-Generation Pompe ERT
3Q15	Pre-NDA meeting with U.S. FDA	3Q15	Pre-IND and MHRA Meetings
2H15	NDA Submission	3Q15	FPI in observational study in Pompe patients
2H15	Initiation of Phase 2 co-administration study	3Q15	Pre-IND and MHRA Meetings
Ongoing	Internal Fabry ERT cell line development	4Q15	Completion of IND-Tox Studies
		4Q15	Phase 1/2 PK study initiation (ATB200 + chaperone)



2Q15 Corporate and Program Highlights and Financial Results

August 5, 2015

*at the forefront of therapies
for rare and orphan diseases*