

**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): **April 29, 2014**

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 7.01. Regulation FD Disclosure.

On April 29, 2014, Amicus Therapeutics, Inc. (the "Company") hosted a conference call and webcast to discuss the positive 12 and 24 month data results from its Phase 3 Fabry Monotherapy Study 011. A copy of conference call presentation materials is attached hereto as Exhibit 99.1.

Item 8.01. Other Events.

On April 29, 2014, the Company issued a press release announcing the positive 12 and 24 month data results from its Phase 3 Fabry Monotherapy Study 011. A copy of this press release is attached hereto as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

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

Exhibit No.	Description
99.1	April 29, 2014 Conference Call Presentation Materials
99.2	Press Release dated April 29, 2014 titled "Amicus Therapeutics Announces Positive 12- and 24-Month Data from Phase 3 Fabry Monotherapy Study 011."

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: April 29, 2014

By: /s/ WILLIAM D. BAIRD III

Name: William D. Baird III

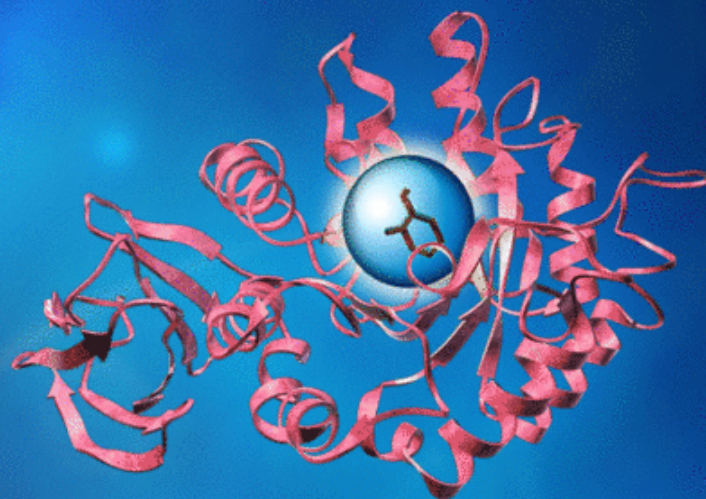
Title: Chief Financial Officer

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EXHIBIT INDEX

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99.2	Press Release dated April 29, 2014 titled "Amicus Therapeutics Announces Positive 12- and 24-Month Data from Phase 3 Fabry Monotherapy Study 011."

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***Phase 3 Fabry Monotherapy Study
(Study 011) Results Conference Call***

April 29, 2014

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

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, ongoing collaborations 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, 2013. 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.



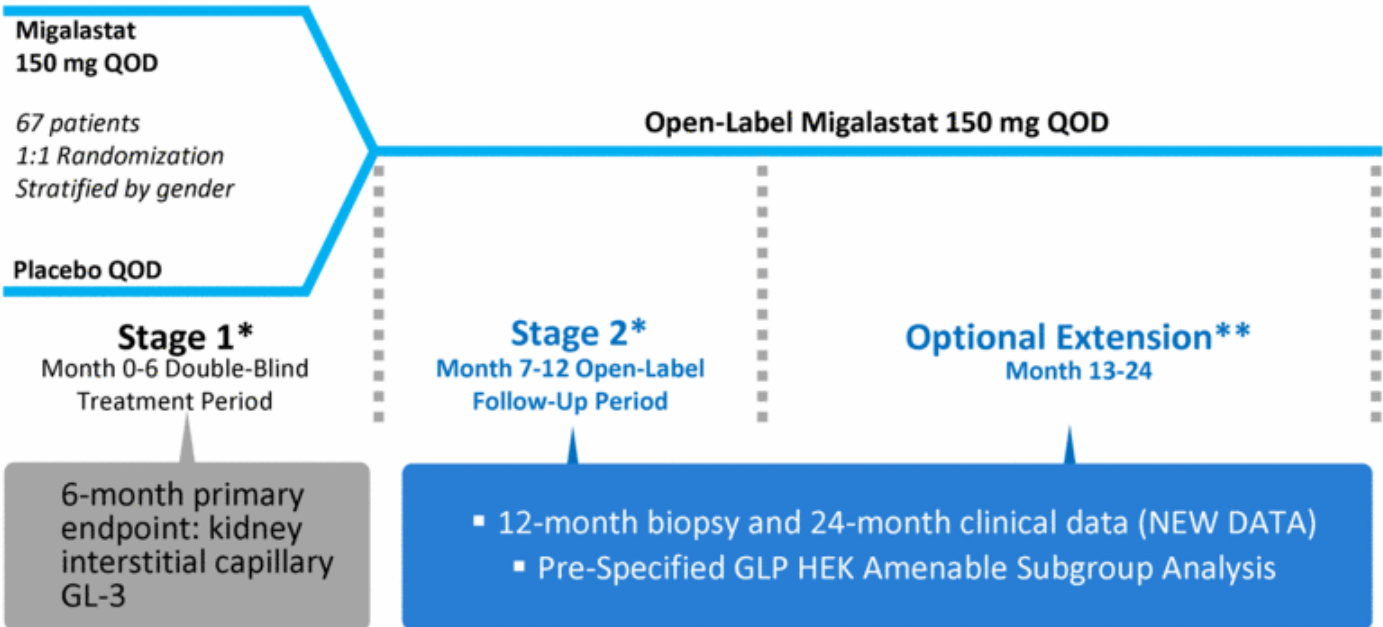
Study 011 12- and 24-Month Data - Key Findings

Migalastat Demonstrated Statistically Significant and Durable Substrate Reductions on 12-Month Pre-Specified Primary Analysis in Fabry Patients with Amenable Mutations

- Subjects who switched from placebo to migalastat after month 6 demonstrated a statistically significant reduction in kidney interstitial capillary GL-3 at month 12 (p=0.013*)
- Subjects who remained on migalastat for 12 months demonstrated a durable reduction in kidney interstitial capillary GL-3
- Reduction in disease substrate also observed in plasma lyso-Gb3 in subjects who switched from placebo to migalastat (p<0.0001**). Subjects who remained on migalastat demonstrated a durable reduction in lyso-Gb3
- Kidney function (estimated glomerular filtration rate (eGFR), iohexol mGFR) remained stable over 18-24 months
- Migalastat was generally safe and well-tolerated
- Of 41 subjects with GLP HEK amenable mutations who completed Study 011, 35 (85%) remain in voluntary extension study (Study 041)

Phase 3 FACETS Study (Study 011)

12-Month Biopsy and 24-Month Clinical Data Are Being Reported Today

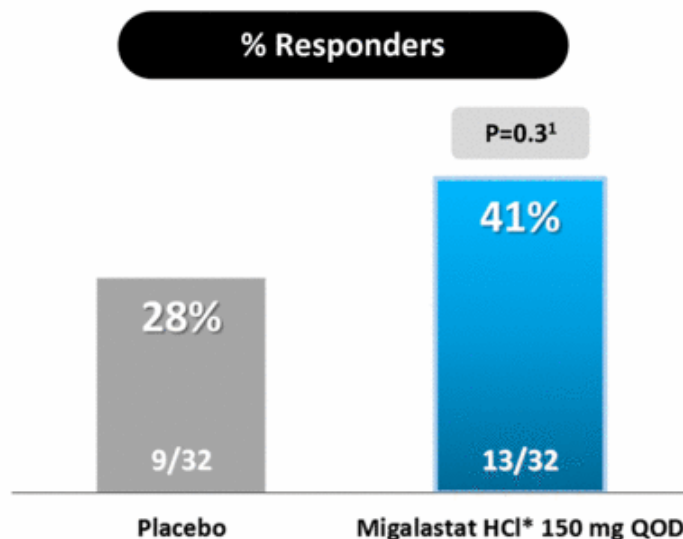


4 *GL-3 Substrate Measured by Histology in Kidney Biopsies **Clinical Outcomes Assessed, Including eGFR and Proteinuria



Top-Line Stage 1 (6-Month) Results (Reported December 2012)

Primary Endpoint - Responder Analysis (ITT):
≥ 50% Reduction from Baseline in Kidney Interstitial Capillary GL-3

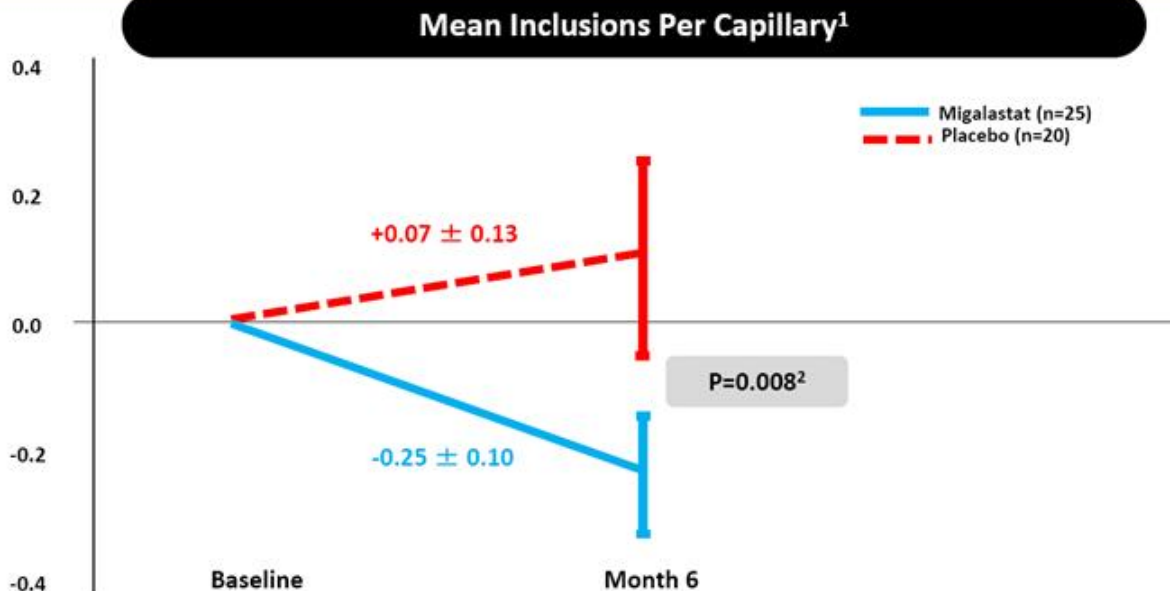


¹ Difference=12.5% (95% CI: -13.4, 37.3). Migalastat HCl minus placebo in % responders. P-value based on exact Cochran-Mantel-Haenszel test stratified by gender. Subjects with baseline biopsy but missing month 6 biopsy counted as a failure.



6-Month Post-Hoc Analysis (Reported February 2014)

Statistically Significant Mean Change in Kidney Interstitial Capillary GL-3
Compared to Placebo (GLP HEK Amenable)*

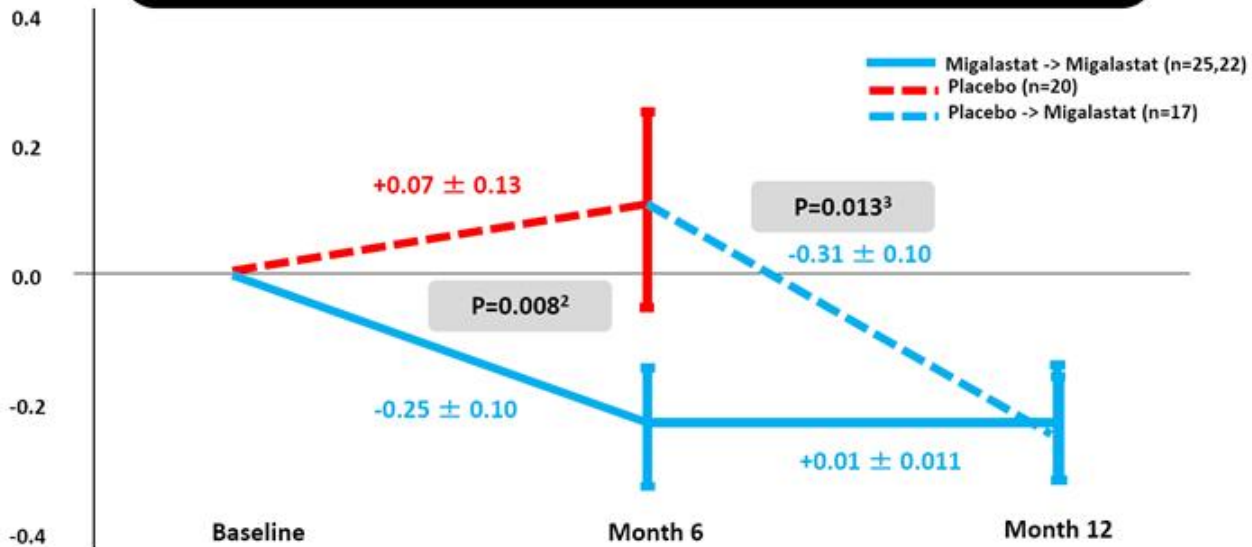


*All patients with evaluable paired biopsies and amenable GLA mutations in GLP-validated HEK assay – post hoc at month 6 and pre-specified at month 12 ¹Data points are baseline corrected; represent mean \pm standard error (SEM) change from baseline in the mean number of GL-3 inclusions per capillary after 6 months of treatment with migalastat or placebo. ²Analysis of covariance (ANCOVA) model with covariate adjustment for baseline value and factors for treatment group and treatment by baseline interaction. P-value corresponding to least-square mean difference between migalastat and placebo is displayed.

12-Month Pre-Specified Primary Analysis

Statistically Significant Mean Change in Kidney Interstitial Capillary GL-3 in Patients Switching from Placebo to Migalastat HCl (GLP HEK Amenable)*

Mean Inclusions Per Capillary¹



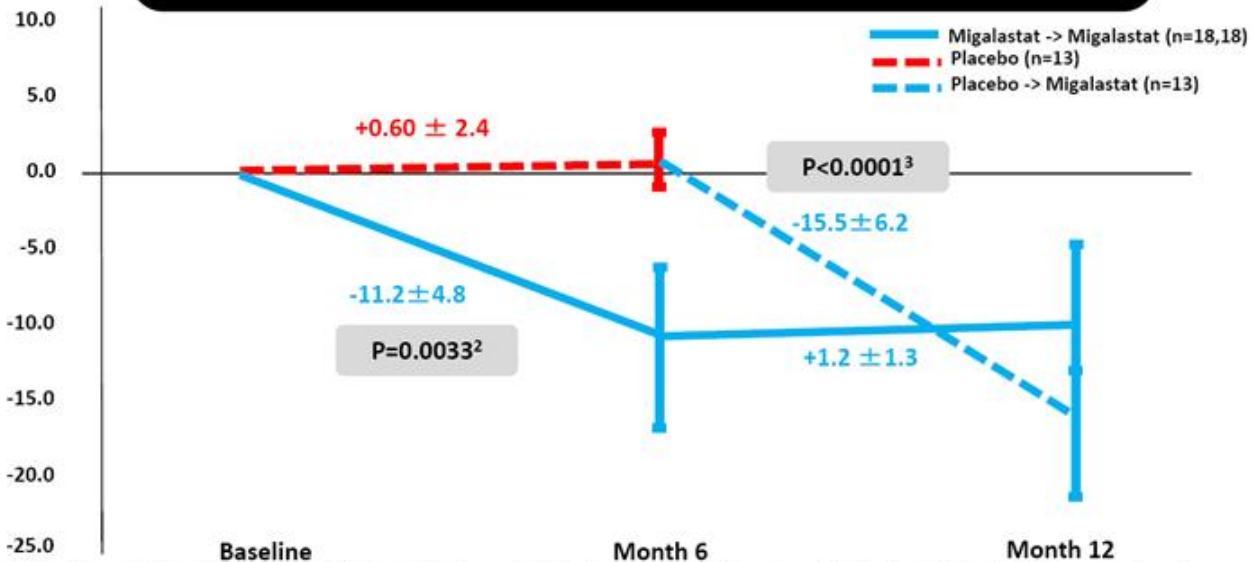
*All patients with evaluable paired biopsies and amenable GLA mutations in GLP-validated HEK assay – post hoc at month 6 and pre-specified at month 12 ¹Data points are baseline corrected; represent mean ± standard error (SEM) change from baseline in the mean number of GL-3 inclusions per capillary after 6 months of treatment with migalastat or placebo. ²Analysis of covariance (ANCOVA) model with covariate adjustment for baseline value and factors for treatment group and treatment by baseline interaction. P-value corresponding to least-square mean difference between migalastat and placebo is displayed. ³MMRM Pbo change M6 to M12.



Disease Substrate in Plasma (Plasma Lyso-GB3)

Statistically Significant Reduction in Plasma Lyso-GB3 at Month 6 and Month 12 Following Treatment with Migalastat (GLP HEK Amenable)*

Plasma Lyso-GB3¹



*Patients with amenable GLA mutations in GLP-validated HEK assay ¹Baseline corrected. Error bars are SEM ²ANCOVA comparing migalastat to placebo in Stage 1 ³ANCOVA comparing change from month 6 to month 12 in subjects switching from placebo to migalastat



Kidney Function: Annualized Glomerular Filtration Rate (GFR)

GFR Remained Stable Over 18-24 Months (GLP HEK Amenable)*

Annualized GFR (ml/min/m²/yr) at Month 18 or 24¹

GFR Measure	N*	Mean	(SEM)
eGFR (CKD-EPI)	41	-0.30	(0.66)
eGFR (MDRD)	41	0.79	(1.03)
mGFR (iohexol)	37	-1.51	(1.33)

*Patients with amenable GLA mutations in GLP-validated HEK assay

¹24 Months of Data in Subjects Treated with Migalastat from Baseline, 18 Months of Data in Subjects Switched from Placebo to Migalastat After 6 Months



Safety Summary

Migalastat Generally Safe and Well Tolerated

Most Common Treatment Emergent Adverse Events (≥ 10% of Subjects)

Adverse event	Baseline to Month 6		Months 7-12		Open-Label Extension (Months 13-24)	
	Placebo* (n=33)	Migalastat (n=34)	Placebo-Migalastat* (n=30)	Migalastat (n=33)	Placebo-Migalastat* (n=28)	Migalastat (n=29)
Any Event	91%	91%	80%	79%	86%	83%
Headache	21%	35%			11%	10%
Fatigue	12%	12%				
Nausea	9%	12%				
Nasopharyngitis	6%	15%				
Paresthesia	12%	9%				
Procedural Pain			10%	12%		
Proteinuria					18%	14%
Bronchitis					11%	10%



Global Regulatory Strategy

- Totality of clinical data
- 8+ years of data in extension studies
- Complete data from Phase 3 Studies (011 and 012)

- Clear regulatory pathway
- Non-inferiority to ERT (Study 012)

Patient Experience

97 Patients Today Take Migalastat HCl as Only Therapy for Fabry Disease¹



¹ All patients are receiving migalastat as part of ongoing clinical trials as of March 1, 2014.
*Retention defined as # of patients who complete a study and chose to enter extension, e.g., 011 12-mo into 24-mo extension



Key Milestones

Timing	Milestone	
3Q09	Phase 3 Study 011 initiation	✓
3Q11	Phase 3 Study 012 initiation	✓
4Q12	Interim 6-month data from first Phase 3 Study (011)	✓
2Q13	FDA meeting (Type C)	✓
2Q14	12-month Study 011 data (kidney biopsies)	✓
2Q14	24-month Study 011 data (clinical outcomes)	✓
3Q14	18-month Study 012 data (kidney function)	





Amicus Therapeutics Announces Positive 12- and 24-Month Data from Phase 3 Fabry Monotherapy Study 011

Migalastat Demonstrated Statistically Significant ($p=0.013$) and Durable Substrate Reductions on 12-Month Pre-Specified Primary Analysis in Fabry Patients with Amenable Mutations

Statistically Significant ($p<0.0001$) Reduction Also Seen in Important Fabry Disease Biomarker, Plasma Lyso-Gb3

Kidney Function Remained Stable Up to 24 Months in Fabry Patients with Amenable Mutations

85% of Patients with Amenable Mutations Completing Month 24 Remain in Ongoing Voluntary Extension Study (Study 041)

Conference Call and Webcast Today at 8:00 a.m. ET

CRANBURY, NJ, April 29, 2014 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of therapies for rare and orphan diseases, today announced positive 12- and 24-month data from its first Phase 3 study (Study 011) of the oral small molecule chaperone migalastat HCl (“migalastat”) monotherapy in Fabry patients with amenable mutations. Detailed results are available in a slide presentation that will be shared by the Amicus management team on a conference call today at 8:00 a.m. ET. Please visit <http://ir.amicustherapeutics.com/events.cfm>.

Study 011 was designed to measure the reduction of disease substrate (Globotriaosylceramide, or GL-3) following treatment with migalastat. The 24-month study began with a 6-month double-blind, placebo-controlled treatment period, after which all patients were treated with migalastat for a 6-month open-label follow-up period and a subsequent 12-month open-label extension phase. The study also measured clinical outcomes, including renal function, as secondary endpoints.

As previously reported, patients on migalastat experienced greater reductions in GL-3 as compared to placebo during the initial 6-month period, however, this difference was not statistically significant under the original study primary endpoint (responder analysis with a 50% reduction threshold at month 6). Following a Type C Meeting with the U.S. Food and Drug Administration (FDA) in the second quarter of 2013, and based on feedback from the agency at that meeting, Amicus revised the Statistical Analysis Plan to pre-specify the primary analysis at month 12 as the mean change in GL-3 in patients with amenable mutations in a GLP-validated human embryonic kidney (HEK) cell-based *in vitro* assay (“GLP HEK amenable”).

Summary of Study 011 12- and 24-Month Data in GLP HEK Amenable Patients

- Subjects who switched from placebo to migalastat after month 6 demonstrated a statistically significant reduction in kidney interstitial capillary GL-3 at month 12 ($p=0.013$).
- Subjects who remained on migalastat for 12 months demonstrated a durable reduction in kidney interstitial capillary GL-3.
- Reduction in disease substrate was also observed in plasma lyso-Gb3, another important biomarker of disease, in subjects who switched from placebo to migalastat ($p<0.0001$). Subjects who remained on migalastat demonstrated a durable reduction in lyso-Gb3.
- Kidney function (estimated glomerular filtration rate (eGFR), iohexol mGFR) remained stable over 18-24 months
- Migalastat was generally safe and well-tolerated.
- Of 41 subjects with GLP HEK amenable mutations who completed Study 011, 35 (85%) remain in the voluntary extension study (Study 041).

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, “Today is a great day for Amicus and the Fabry community. We are pleased to report that the 12 and 24 month results from Study 011 have met our pre-defined criteria for success in terms of substrate reduction at 12 months, as well as clinical measures of kidney function maintained out to 24 months. We believe these data provide important validation that a small-molecule chaperone can restore the function of a patient’s own enzyme in patients with amenable mutations, and that our pharmacogenomic assays can identify these patients. Together these results demonstrate the power of personalized

medicine in rare diseases and offer the prospect of a new treatment option that differs from traditional enzyme replacement therapy. Pending positive data from our second Phase 3 study we expect to meet with regulatory authorities to discuss these data and determine the fastest registration pathway for migalastat.”

Raphael Schiffmann, M.D., M.H.Sc., Director of the Institute of Metabolic Disease, Baylor Research Institute, stated, “As an investigator experienced in treating patients with migalastat for up to 8 years in clinical studies, I believe the results from Study 011 show a positive treatment effect of migalastat in Fabry patients with amenable mutations. The reductions in substrate levels in the kidney and in plasma, combined with stabilization of renal function, strongly suggest that migalastat may become an important new oral treatment option for Fabry patients.”

Migalastat monotherapy is being investigated in two Phase 3 registration studies (Study 011 and Study 012) and an open-label extension study (Study 041) in Fabry patients with amenable mutations. Top-line data are anticipated in the third quarter of 2014 from Study 012. The primary analysis in Study 012 will evaluate GFR, a clinical measure of kidney function, over 18-months of treatment with migalastat compared to enzyme replacement therapy (ERT), the current standard of care for Fabry disease.

Robert Desnick, M.D., Dean for Genetics and Genomic Medicine, Professor and Chairman Emeritus, Genetics and Genomic Sciences at Icahn School of Medicine at Mount Sinai stated, “Over 40 years of working with patients with Fabry disease, participating in the development of enzyme replacement therapy, and as an early advocate of chaperone therapy, I believe there remains an unmet medical need among these patients. Study 011 has generated an impressive data set demonstrating that patients with amenable mutations respond to migalastat as a chaperone monotherapy.”

Study 011 Substrate Reduction Data in GLP HEK Amenable Patients

Migalastat has demonstrated significant and durable reductions in GL-3 in Study 011 in patients with GLP HEK amenable mutations. Reductions in plasma Lyso-Gb3, another important disease biomarker, were also observed in patients with GLP HEK amenable mutations. GL-3 is the substrate that accumulates in patients with Fabry disease. Reduction in kidney interstitial capillary GL-3 is a surrogate biomarker that was used to support U.S. approval of ERT for Fabry disease.

	Study 011 Stage 1 Data (Baseline to Month 6)			Study 011 Stage 2 Data (Month 6 to Month 12)		
	Migalastat Group(1)	Placebo Group(2)	p-Value	Migalastat Group(1)	Placebo-Migalastat Crossover Group(2)	p-Value
Mean Change in GL-3 (SEM) (Baseline Corrected)(3)	-0.25 ± 0.10 (n=25)	+0.07 ± 0.13 (n=20)	0.008**	+0.01 ± 0.011 (n=22)	-0.31 ± 0.10 (n=17)	0.013*
Plasma Lyso-Gb3 (SEM)	-11.2 ± 4.8 (n=18)	+0.6 ± 2.4 (n=13)	0.0033**	+1.2 ± 1.3 (n=18)	-15.5 ± 6.2 (n=13)	<0.0001**

Study 011 Kidney Function Data in GLP HEK Amenable Patients

Among patients with GLP HEK amenable mutations in Study 011, kidney function by various measures of glomerular filtration rate (GFR) has remained stable for up to 24 months following treatment with migalastat. Decline in kidney function is a key cause of mortality in patients with Fabry disease.

	Mean Annualized Change in GFR (ml/min/m ² /yr) (SEM) Over 18 to 24 Months (Preliminary Data)
Estimated GFR (eGFR) (CKD-EPI) (n=41)	-0.30 (0.66)
eGFR (MDRD) (n=41)	+0.79 (1.03)
Iohexol (Measured) GFR (n=37)	-1.51 (1.33)

About Study 011 Statistical Analyses

The primary endpoint in Study 011 analyzed the percent change in kidney interstitial capillary GL-3 inclusions from baseline to month 6 (responder analysis with a 50% reduction threshold). As previously reported, the variability and low levels of GL-3 at baseline contributed to a higher-than-anticipated placebo response at month 6. Following the unblinding of the 6-month data, and while still blinded to the 12-month data, Amicus identified the mean change in GL-3 as a more appropriate way to control for the variability in GL-3 levels in Study 011 and to measure the biological effect of migalastat.

Amicus analyzed and previously reported the mean change in GL-3 from baseline to month 6 as a post-hoc analysis, including a subgroup analysis in patients with GLP HEK amenable mutations that further supports use of the GLP HEK assay in predicting responsiveness to migalastat. Following a Type C Meeting with the U.S. Food and Drug Administration, Amicus revised the Statistical Analysis Plan to pre-specify the primary analysis at month 12 as the mean change in GL-3 in patients with GLP HEK amenable mutations.

About GLP HEK Amenable Mutations

Amenable mutations are defined as having an absolute increase of 3% of wild type alpha-Gal A enzyme activity and a relative increase of 20% when exposed to migalastat in a cell-based *in vitro* assay. All subjects enrolled in Study 011 had amenable mutations in the clinical trial human embryonic kidney (HEK) assay available at study initiation ("clinical trial assay"). Following the completion of enrollment, a GLP HEK assay was developed with a third party to measure the criteria for amenability with more quality control and rigor. However, approximately 10% of mutations in the HEK database switched categorization between "amenable" and "non-amenable" when moving from the clinical trial assay to the GLP HEK assay. Therefore there were changes in categorization from amenable to non-amenable in 17 patients in Study 011.

Overall based on results from mutations tested in the GLP HEK assay, Amicus continues to believe that approximately 30% to 50% of the Fabry population have mutations that are amenable to migalastat.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, April 29, 2014 at 8:00 a.m. ET to discuss positive 12- and 24-month results from Study 011. Interested participants and investors may access the conference call at 8:00 a.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international). The slide presentation for the conference call is available at <http://ir.amicustherapeutics.com/events.cfm>.

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at <http://ir.amicustherapeutics.com/events.cfm>, 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 11:00 a.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 37179299.

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 diseases. Amicus' lead programs include the small molecule pharmacological chaperones migalastat as a monotherapy and in combination with enzyme replacement therapy (ERT) for Fabry disease; and AT2220 (duvoglustat) in combination with ERT for Pompe disease.

(1)Patients with GLP HEK amenable mutations who received migalastat from baseline to month 24

(2)Patients with GLP HEK amenable mutations who received placebo from baseline to month 6 and switched to migalastat after month 6

(3)Mean change in number of inclusions per capillary as a continuous variable (assessed by histology in kidney biopsies). Scores averaged across all reads at baseline, month 6 and month12.

*MMRM analyzing change in placebo group from month 6 to month 12

**ANCOVA model with covariate adjustment for baseline value and treatment-by-baseline interaction

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 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, 2013. 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.

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