

**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 10, 2012**

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 08512
(Address of principal executive offices, including 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 (see General Instruction A.2. below):

- 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 May 10, 2012, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2012. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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: May 10, 2012

By: /s/ Geoffrey P. Gilmore
Geoffrey P. Gilmore
Senior Vice President and General
Counsel

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 10, 2012

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**Amicus Therapeutics Announces
First Quarter 2012 Financial Results**

*Continues to Advance Programs and Technology
for Chaperone-ERT Combination Products*

Migalastat HCl Monotherapy Phase 3 Results for Fabry Disease on Track for 3Q12

CRANBURY, NJ, US, May 10, 2012 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of developing therapies for rare and orphan diseases, today announced financial results for the first quarter ended March 31, 2012. The Company also highlighted recent and upcoming milestones related to its pharmacological chaperone development pipeline and reiterated full-year 2012 operating expense guidance.

Corporate Highlights and Upcoming Milestones

- Balance sheet strengthened by \$62.0 million in net proceeds from public offering of common stock. Cash, cash equivalents and marketable securities totaled \$108.2 million at March 31, 2012
- Significant progress enrolling patients in ongoing clinical studies
 - o A majority of patients enrolled in second global registration study (Study 012) of migalastat HCl monotherapy for Fabry disease. Final enrollment on track by YE12
 - o Current enrollment in Phase 2 Study 013 for Fabry disease includes patients in higher dose group of migalastat HCl (450 mg) co-administered with Fabrazyme and in lower dose group of migalastat HCl (150 mg) co-administered with Replagal
 - o Two ascending dose groups fully enrolled in Phase 2 Study 010 of AT2220 co-administered with enzyme replacement therapy (ERT) for Pompe disease
- Results from Phase 3 Study 011 of migalastat HCl monotherapy for Fabry disease anticipated in 3Q12
- Multiple expected milestones for Chaperone-ERT combination products and preclinical pipeline in 2012
 - o Preliminary results from Phase 2 Study 010 for Pompe disease in 2Q12
 - o Update from Phase 2 Study 013 in patients receiving migalastat HCl co-administered with ERT in 3Q12
 - o Final results from Study 013 at Fall 2012 scientific conference
 - o Evaluation of ERT-related immunogenicity in Pompe disease now underway, supported by grant from Muscular Dystrophy Association. Data expected 3Q12.

John F. Crowley, Chairman and Chief Executive Officer of Amicus stated, “With the recent closing of our public offering, Amicus is well-positioned to support ongoing programs, expand our chaperone-ERT combination platform, and continue our advancement toward becoming a fully-integrated biopharmaceutical company. We are encouraged by the current pace of enrollment in our ongoing clinical studies. We are also looking forward to Phase 3 results of migalastat HCl for Fabry disease to support a U.S. marketing application, particularly given the lack of treatment alternatives for Fabry patients in the U.S. We also expect additional results this year from our ongoing Phase 2 Fabry and Pompe studies to further support the potential of chaperone-ERT therapy for lysosomal storage diseases.”

First Quarter 2012 Financial Highlights

- Total revenue of \$7.8 million compared to \$6.0 million in 1Q11
- Research revenue of \$6.1 million compared to \$4.3 million in 1Q11
- Collaboration revenue of \$1.7 million was flat from 1Q11
- Total operating expenses of \$18.5 million compared to \$16.0 million in 1Q11 on higher research and development expenses
- Net loss attributable to common stockholders of \$13.1 million, or \$0.35 per share, compared to a net loss of \$13.3 million, or \$0.39 per share, in 1Q11

Cash, cash equivalents, and marketable securities totaled \$108.2 million at March 31, 2012 compared to \$60.0 million at the beginning of 2012. On March 7, 2012, Amicus received net proceeds of approximately \$62.0 million from a public offering of 11.5 million shares of common stock priced at \$5.70 per share.

Total revenue for the three months ended March 31, 2012 consisted of payments received from GlaxoSmithKline (GSK) for shared development costs for migalastat HCl (research revenue) and the recognized portion of the \$33.2 million upfront cash payment received from GSK (collaboration revenue). In October 2010, Amicus and GSK entered into an agreement pursuant to which GSK received an exclusive worldwide license to develop, manufacture and commercialize migalastat HCl for the treatment of Fabry disease.

Financial Guidance

Amicus continues to expect full-year 2012 operating expenses will total between \$37 million to \$43 million, net of anticipated cost sharing and milestones related to the GSK collaboration. Amicus and GSK equally shared development costs for migalastat HCl (monotherapy and co-administration) in 2011, and GSK is responsible for 75% of these costs in 2012 and beyond, subject to annual and aggregate caps. Amicus is also eligible to receive up to a total of \$170 million in development, regulatory and commercial milestones as part of the Fabry collaboration with GSK.

Program Updates

Fabry Disease Program

Phase 3 Global Registration Studies (Study 011 and Study 012) — Migalastat HCl Monotherapy

Amicus and GSK are conducting two Phase 3 global registration studies (Study 011 and Study 012) of migalastat HCl monotherapy. Study 011 and Study 012 are investigating migalastat HCl at

an oral dose of 150 mg, administered every-other-day (QOD) to Fabry patients identified as having alpha-Gal A mutations amenable to migalastat HCl as a monotherapy.

Study 011 is a six-month, placebo-controlled Phase 3 study of migalastat HCl that completed enrollment of 67 patients with Fabry disease. Results from this study are anticipated in the third quarter of 2012 to support subsequent marketing applications for the U.S. Food and Drug Administration (FDA) and other regulatory agencies.

Study 012 is a randomized, open-label, 18-month Phase 3 study investigating the safety and efficacy of migalastat HCl compared to current standard-of-care ERTs Fabrazyme (agalsidase beta) or Replagal (agalsidase alfa) for Fabry disease. A majority of patients have been enrolled in this study, which is targeting approximately 50 total patients (30 to switch to migalastat HCl and 20 to remain on ERT). Study 012 is currently underway at 25 clinical sites worldwide, including U.S. sites that are now able to enroll patients who have resumed full-dose Fabrazyme. Strong global interest in this study has resulted in the initiation of several new sites and robust patient screening and enrollment since the beginning of this year. Amicus and GSK continue to anticipate that enrollment in this study will be completed by year-end 2012.

Phase 2 and Phase 3 extension studies continue to evaluate long-term safety with migalastat HCl monotherapy in Fabry patients. As of April 30, 2012, 38 of 40 patients who have completed the six-month treatment and six-month follow-up periods in Study 011 are currently enrolled in a Phase 3 extension study. An additional 17 subjects continue in the ongoing Phase 2 extension study and have been receiving migalastat HCl for up to six years. There are also more than 150 patient-years of experience from the Phase 2 and Phase 2 extension studies, and ongoing Phase 3 and Phase 3 extension studies of migalastat HCl for Fabry disease.

Phase 2 Study 013 — Drug-Drug Interaction Study of Migalastat HCl and ERT

Study 013 is an ongoing open-label Phase 2 study to investigate a single oral dose of migalastat HCl (150 mg or 450 mg) co-administered two hours prior to ERT (Fabrazyme or Replagal) in males diagnosed with Fabry disease. When co-administered with ERT, migalastat HCl is designed to bind to and stabilize the enzyme in the circulation, independent of alpha-Gal A mutation type.

Positive preliminary results from Study 013 were announced in the first quarter 2012 in patients who received migalastat HCl 150 mg co-administered with Fabrazyme (0.5 mg/kg or 1.0 mg/kg). The Company expects to provide an update from this study in the third quarter 2012 and to present final results at a Fall 2012 scientific conference. Both Amicus and GSK are committed to working together to advance this Fabry co-administration program, which has been recognized as having significant medical interest and importance. A repeat-dose global study of migalastat HCl co-administered with ERT is currently being designed as the next step in U.S. and global development. Following the withdrawal of the U.S. marketing application for Replagal, Fabrazyme remains the only ERT with conditional approval in the U.S.

Chaperone-ERT Combination Program for Pompe Disease and Other LSDs

Outside the Fabry collaboration with GSK, Amicus owns exclusive rights to the rest of its pipeline and applications of its platform technology. In addition to the ongoing work in Fabry, Amicus is investigating chaperone-ERT combinations as potential next-generation treatments for Pompe, Gaucher, and other undisclosed lysosomal storage diseases where the Company believes there are significant opportunities to improve treatment outcomes.

Preclinical chaperone-ERT co-administration studies in animal models of Fabry, Pompe and Gaucher have shown that a pharmacological chaperone can selectively bind to and stabilize the enzyme, prevent deactivation in the circulation, and increase uptake of active enzyme into key tissues of disease. In Fabry and Pompe animal models, chaperone-ERT co-administration has also been shown to lead to greater substrate reduction compared to ERT alone.

Chaperone-ERT Combination for Pompe Disease

Amicus is investigating four ascending doses of AT2220 co-administered with the ERT alglucosidase alfa (Myozyme or Lumizyme) in a Phase 2 open-label study (Study 010) for Pompe disease. Approximately 22 patients will receive one infusion of ERT alone, and a single oral dose of AT2220 prior to the next ERT infusion. In addition to safety and pharmacokinetic effects, Study 010 will measure uptake of active enzyme in muscle tissue with and without the chaperone, three or seven days following each infusion. Enrollment has been completed for the first two dose groups, and preliminary results from Study 010 continue to be anticipated in the second quarter of 2012.

In parallel with Study 010, Amicus is evaluating ERT-related immunogenicity in Pompe disease. Immune responses occur in a majority of Pompe patients receiving alglucosidase alfa infusions⁽¹⁾ which have the potential to limit treatment outcomes with ERT. Preclinical results to date suggest that AT2220 when co-administered with Myozyme may mitigate immunogenicity induced by this ERT by stabilizing the enzyme in its properly folded and active form.

As part of a grant from the Muscular Dystrophy Association, Amicus is using blood samples from healthy volunteers and from Pompe patients in Study 010 to determine if particular human leukocyte antigen (HLA) types are predictive of clinical immunogenicity to ERT. These results may help guide further investigation of the effects of AT2220 on immune response to ERT in future clinical studies.

Chaperone-ERT Combinations for Gaucher Disease

Amicus is also investigating chaperone-ERT combinations as potential next-generation treatments for Gaucher and other undisclosed lysosomal storage diseases where there are significant opportunities to improve treatment outcomes. In Gaucher disease, Amicus is continuing preclinical studies to evaluate two pharmacological chaperones, AT2101 (afegostat tartrate) and AT3375, in combination with ERT (beta-glucosidase). Both of these chaperones target the enzyme deficient in Gaucher disease.

Chaperone for Parkinson's Disease in Gaucher Carriers

Gaucher disease is caused by inherited genetic mutations in the GBA gene, and mutations in this gene that encodes for the GCase enzyme are the most common genetic risk factor for Parkinson's. By targeting GCase in the brain, AT3375 could potentially treat Gaucher, Parkinson's disease in Gaucher carriers, and possibly the general Parkinson's population. By year-end 2012, Amicus expects to complete preclinical and IND-enabling studies of AT3375, which are supported in part by a grant from the Michael J. Fox Foundation.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, May 10, 2012 at 5:00 P.M. ET to review financial results and provide a corporate update. Interested participants and investors may access the conference call at 5 p.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at <http://www.amicustherapeutics.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 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 78252460.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a biopharmaceutical company at the forefront of developing therapies for rare and orphan diseases. The Company is developing orally-administered, small molecule drugs called pharmacological chaperones, a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage disorders and diseases of neurodegeneration. Amicus' lead program migalastat HCl is in Phase 3 for the treatment of Fabry disease.

About Fabry Disease

Fabry disease is an inherited lysosomal storage disease that is currently estimated to affect approximately 5,000 to 10,000 people worldwide. Fabry Disease is caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A). The role of alpha-Gal A within the body is to break down a complex lipid called globotriaosylceramide (GL-3). Reduced or absent levels of alpha-Gal A activity leads to the accumulation of GL-3 in the affected tissues, including the central nervous system, heart, kidneys, and skin. This accumulation of GL-3 is believed to cause the various symptoms of Fabry disease, including pain, kidney failure, and increased risk of heart disorders and stroke.

About Pompe Disease

Pompe disease is a lysosomal storage disease characterized by progressive skeletal muscle weakness and respiratory insufficiency. It is caused by a deficiency in lysosomal alpha-glucosidase (GAA) activity, which leads to accumulation of glycogen in tissues affected by the disease (primarily muscle). Pompe disease affects an estimated 5,000 to 10,000 individuals worldwide and is clinically heterogeneous in the age of onset, the extent of organ involvement, and the rate of progression.

(1) Lacana E, Yao LP, Pariser AR, Rosenberg AS. 2012. The role of immune tolerance induction in restoration of the efficacy of ERT in Pompe disease., **Am J Med Genet C Semin Med Genet. 160C:30-39**

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, including achievement of development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "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, including achievement of development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline. 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, 2011. 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:

Investors/Media:
 Sara Pellegrino
 spellegrino@amicustherapeutics.com
 (609) 662-5044

Table 1

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

	Three Months Ended March 31,		Period from February 4, 2002 (inception) to March 31, 2012
	2011	2012	2012
Revenue:			
Research revenue	\$ 4,306	\$ 6,114	\$ 52,016
Collaboration revenue	1,660	1,660	59,222
Total revenue	<u>5,966</u>	<u>7,774</u>	<u>111,238</u>
Operating Expenses:			
Research and development	11,125	14,004	279,624
General and administrative	4,402	4,095	117,344
Restructuring charges	—	—	1,522
Impairment of leasehold improvements	—	—	1,030
Depreciation and amortization	438	420	10,483
In-process research and development	—	—	418
Total operating expenses	<u>15,965</u>	<u>18,519</u>	<u>410,421</u>
Loss from operations	(9,999)	(10,745)	(299,183)
Other income (expenses):			
Interest income	59	27	14,100
Interest expense	(48)	(43)	(2,376)
Change in fair value of warrant liability	(3,432)	(2,376)	(1,476)
Other income	70	—	231
Loss before tax benefit	<u>(13,350)</u>	<u>(13,137)</u>	<u>(288,704)</u>
Benefit from income taxes	—	—	5,463
Net loss	<u>(13,350)</u>	<u>(13,137)</u>	<u>(283,241)</u>
Deemed dividend	—	—	(19,424)
Preferred stock accretion	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (13,350)</u>	<u>\$ (13,137)</u>	<u>\$ (303,467)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.35)</u>	
Weighted-average common shares outstanding — basic and diluted	34,498,926	37,887,520	

FOLD—G