
**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): February 13, 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.)

6 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))
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Item 2.02. Results of Operations and Financial Condition.

On February 13, 2012, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2011. 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: February 13, 2012

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

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated February 13, 2012



Amicus Therapeutics Announces Fourth Quarter and Full-Year 2011 Financial Results

Phase 3 Results of Migalastat HCl Monotherapy for Fabry Disease Expected in 3Q12

*Multiple Chaperone-Enzyme Replacement Therapy (ERT)
Combination Programs Advancing*

Positive Phase 2 Preliminary Results in Fabry Patients Previously Reported

Current Cash Expected to Fund Operations into Mid-3Q13

CRANBURY, NJ, US, February 13, 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 fourth quarter and full-year ended December 31, 2011. The Company also highlighted recent and upcoming milestones related to its pharmacological chaperone development pipeline and reiterated full-year 2012 financial guidance.

Fourth Quarter and Full-Year 2011 Financial Summary

Cash, cash equivalents, and marketable securities totaled \$56 million at December 31, 2011 and \$60 million at the beginning of 2012, compared to \$70 million at September 30, 2011 and \$107 million at December 31, 2010.

Net of cost-sharing related to the agreement with GlaxoSmithKline (GSK), full-year 2011 operating expenses were \$47.2 million, below management's guidance of \$50 million to \$55 million.

Total revenue for the three and twelve months ended December 31, 2011 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.

Fourth Quarter 2011 Financial Highlights

- Total revenue of \$5.6 million, compared to \$0.9 million in 4Q10
- Research revenue of \$4.0 million compared to no research revenue in 4Q10
- Collaboration revenue of \$1.7 million compared to \$0.9 million in 4Q10
- Total operating expenses of \$18.7 million, an increase from \$17.5 million in 4Q10 on higher expenses for research and development
- Net loss attributable to common stockholders of \$8.7 million, or \$0.25 per share, compared to a net loss of \$15.1 million, or \$0.48 per share, in 4Q10

Full-Year 2011 Financial Highlights

- Total revenue of \$21.4 million compared to \$0.9 million in FY10
- Research revenue of \$14.8 million compared to no research revenue in FY10
- Collaboration revenue of \$6.6 million compared to \$0.9 million in FY10
- Total operating expenses of \$72.3 million, an increase from \$56.8 million in FY10 on higher expenses for research and development and stock options
- Net loss attributable to common stockholders of \$44.4 million, or \$1.28 per share, compared to a net loss of \$54.9 million, or \$1.98 per share, in FY10

John F. Crowley, Chairman and Chief Executive Officer of Amicus stated, "During 2011, we laid the foundation for many of the important milestones we expect to achieve during 2012. These upcoming results include data from our Phase 3 study of migalastat HCl for Fabry disease. We also continue to build momentum for our chaperone-ERT combination platform to potentially improve treatment outcomes for patients with multiple lysosomal storage diseases. We have reported positive preliminary results from our ongoing Phase 2 Fabry co-administration study, and have a Phase 2 Pompe co-administration study underway. We believe that as we advance our technology and programs throughout this year we will have the opportunity to create many potential sources of shareholder value. We are off to a great start in 2012, with much more work to be done."

2012 Financial Guidance

Amicus reiterated its guidance that full-year 2012 operating expenses are expected to 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 will be responsible for 75% of these costs in 2012 and beyond, subject to annual and aggregate caps.

The Company anticipates that its current cash position will be sufficient to fund operations into the middle of third quarter 2013. This projection includes anticipated Fabry program reimbursements and development milestones but excludes potential regulatory milestones under its agreement with GSK. Amicus is eligible to receive up to \$170 million in development, regulatory and commercial milestones as part of the Fabry collaboration.

2012 Anticipated Milestones

Several expected milestones related to the Company's pharmacological chaperone monotherapy and chaperone-ERT combination programs have the potential to make 2012 a transformative year for Amicus, including:

- Preliminary results from Phase 2 Study 010 of AT2220 (duvoglustat HCl) co-administered with ERT for Pompe disease in 1H12;

- Completion of Phase 2 Study 013 of migalastat HCl co-administered with ERT for Fabry disease in 1H12;
- Results from Phase 3 Study 011 of migalastat HCl monotherapy for Fabry disease in 3Q12;
- Completion of preclinical and IND-enabling studies of AT3375 for Parkinson's disease in Gaucher carriers by YE12; and
- Enrollment of final patient in second Phase 3 Study 012 of migalastat HCl monotherapy for Fabry disease in 4Q12.

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 for Fabry disease. Enrollment of 67 patients was completed in December 2011. [Information](#) on patients screened for Study 011 was presented at the 8th Annual Lysosomal Disease Network WORLD Symposium ([LDN WORLD](#)) in February 2012. 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 to compare the safety and efficacy of migalastat HCl and ERT (agalsidase beta or agalsidase alfa) for Fabry disease. The first patient in Study 012 was dosed in September 2011 and enrollment of approximately 50 patients (30 to switch to migalastat HCl and 20 to remain on ERT) is anticipated 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 January 31, 2012, 26 of 28 patients who have completed the six-month treatment and six-month follow-up periods in Study 011 are 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.

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

Study 013 is an ongoing Phase 2 study to investigate a single oral dose of migalastat HCl (150 mg or 450 mg) co-administered two hours prior to ERT (agalsidase beta or agalsidase alfa) in males diagnosed with Fabry disease. When co-administered with ERT in preclinical studies, migalastat HCl has been shown to bind to and stabilize the infused recombinant enzyme in the circulation; therefore, patients do not need to have alpha-Gal A mutations amenable to migalastat HCl.

Positive preliminary results from Study 013 were announced in January 2012 and during LDN WORLD 2012. Completion of Study 013 is expected in the first half of 2012.

Additional Chaperone-ERT Combination Programs

Outside the Fabry collaboration with GSK, Amicus owns exclusive rights to the rest of its pipeline and the applications of its platform technology. During 2012, Amicus is investigating the broader application of the chaperone-ERT combination technology as a potential next-generation treatment approach for multiple LSDs. In addition to the ongoing work in Fabry, Amicus is investigating chaperone-ERT combinations for Pompe and Gaucher, as well as other undisclosed lysosomal storage diseases where 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 addition, chaperone-ERT co-administration has been shown to lead to greater substrate reduction than ERT alone in Fabry and Pompe animal models.

Chaperone-ERT Combination for Pompe Disease

Amicus is investigating AT2220 co-administered with the ERT alglucosidase alfa in a Phase 2 study (Study 010) in approximately 16 Pompe patients. Preliminary results from Study 010 are anticipated in the first half of 2012. As part of a grant from the Muscular Dystrophy Association, the Company will also obtain blood samples from Pompe patients in Study 010 and from normal donors to further investigate the ability of AT2220 to mitigate ERT-specific immunogenicity.

Chaperone-ERT Combinations for Gaucher Disease

Two pharmacological chaperones, AT2101 (afegostat tartrate) and AT3375, have been studied in combination with ERT (beta-glucosidase) in preclinical models of Gaucher disease. Both of these chaperones target the glucocerebrosidase (GCCase) enzyme deficient in Gaucher disease. Data from initial preclinical studies of AT3375 for Gaucher disease were recently presented at LDN WORLD 2012.

Parkinson's Disease Program – Investigating the Link Between Gaucher and Parkinson's

Mutations in the GBA1 gene that encodes for the GCCase enzyme are the most common genetic risk factor known for Parkinson's disease. AT3375 is a next-generation chaperone designed to improve upon the properties of AT2101. By targeting GCCase in the brain, it is believed that AT3375 has the potential to address Parkinson's disease in Gaucher patients or carriers, and potentially the broader Parkinson's population.

By year-end 2012, Amicus expects to complete preclinical and IND-enabling studies of AT3375, which are funded in part by a grant from the Michael J. Fox Foundation. The MJFF recently announced that Amicus will be featured as part of a pilot Partnering Program designed to showcase research results in the MJFF portfolio to funders who may wish to invest in their continued development.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, February 13, 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 50733384.

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.

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, 2010. 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 Dec. 31,		Twelve Months Ended Dec. 31,		Period from February 4, 2002 (inception) to Dec. 31, 2011
	2010	2011	2010	2011	
Revenue:					
Research revenue	\$ —	\$ 3,970	\$ —	\$ 14,794	\$ 45,902
Collaboration revenue	922	1,660	922	6,640	57,562
Total revenue	<u>922</u>	<u>5,630</u>	<u>922</u>	<u>21,434</u>	<u>103,464</u>
Operating Expenses:					
Research and development	13,154	14,401	39,042	50,856	265,620
General and administrative	3,823	3,917	15,660	19,880	113,249
Restructuring charges	—	—	—	—	1,522
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	481	342	2,058	1,585	10,063
In-process research and development	—	—	—	—	418
Total operating expenses	<u>17,458</u>	<u>18,660</u>	<u>56,760</u>	<u>72,321</u>	<u>391,902</u>
Loss from operations	(16,536)	(13,030)	(55,838)	(50,887)	(288,438)
Other income (expenses):					
Interest income	35	24	156	160	14,073
Interest expense	(57)	(27)	(260)	(148)	(2,333)
Change in fair value of warrant liability	(946)	742	(1,410)	2,764	900
Other income	1,277	—	1,277	70	231
Loss before tax benefit	(16,227)	(12,291)	(56,075)	(48,041)	(275,567)
Benefit from income taxes	1,139	3,629	1,139	3,629	5,463
Net Loss	(15,088)	(8,662)	(54,936)	(44,412)	(270,104)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net Loss attributable to common stockholders	<u>\$ (15,088)</u>	<u>\$ (8,662)</u>	<u>\$ (54,936)</u>	<u>\$ (44,412)</u>	<u>\$ (290,330)</u>
Net Loss attributable to common stockholders per common share – basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.25)</u>	<u>\$ (1.98)</u>	<u>\$ (1.28)</u>	
Weighted-average common shares outstanding – basic and diluted	<u>31,321,066</u>	<u>34,643,722</u>	<u>27,734,797</u>	<u>34,569,642</u>	

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