
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): November 1, 2011

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**

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

On November 1, 2011, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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: November 1, 2011

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated November 1, 2011



**Amicus Therapeutics Announces
Third Quarter 2011 Financial Results**

Final Enrollment in Amigal Phase 3 Study on Track for 4Q11

CRANBURY, N.J., November 1, 2011 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of developing therapies for rare diseases, today announced financial results for the third quarter ended September 30, 2011. The Company also highlighted recent and upcoming milestones surrounding Phase 3 global registration studies of Amigal™ (migalastat HCl) for Fabry disease, and ongoing Phase 2 studies to evaluate the co-administration of pharmacological chaperones with enzyme replacement therapy (PC-ERT) for Fabry and Pompe diseases.

Development Pipeline Progress and Upcoming Milestones

- Patient recruitment closed in first Phase 3 study of migalastat HCl (Study 011) — final enrollment on track for 4Q11
- First patient dosed in second Phase 3 study of migalastat HCl (Study 012)
- Seventeen subjects treated with migalastat HCl for up to five years in Phase 2 and Phase 2 extension studies
- Preliminary Phase 2 migalastat HCl-ERT co-administration study (Study 013) results anticipated in 4Q11
- Patient recruitment underway for Phase 2 study (Study 010) of AT2220 (duvoglustat HCl) co-administered with ERT for Pompe disease — dosing of first patient anticipated in 4Q11
- Results from preclinical proof-of-concept study of AT3375 for Parkinson's disease expected in 4Q11

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics said, "With the close of recruitment in Study 011 and patient dosing underway in Study 012, we continue toward the objective of global registration of migalastat HCl for Fabry disease. These achievements reflect our dedication to the Fabry program and the strength of our collaboration with GSK. Additionally, the co-administration of chaperones with ERT has the potential to be an important expansion of our technology that may provide additional treatment options for lysosomal storage disorders. Based on our current cash position and migalastat HCl cost-sharing under the GSK agreement, we are well-capitalized to continue advancing our pipeline as we head toward major catalysts this quarter and into next year."

Third Quarter 2011 Financial Summary

As of September 30, 2011, cash, cash equivalents, and marketable securities totaled \$69.5 million, compared to \$83.0 million at June 30, 2011.

Total revenue was \$5.8 million for the third quarter 2011, compared to no revenue in the prior year period. Total revenue consists of collaboration and research revenues recognized under the Company's collaboration with Glaxo Group Limited (GSK). 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.

Research revenue for the third quarter 2011 was \$4.1 million, and reflects payments received from GSK for shared development costs. Amicus and GSK are equally sharing development costs for migalastat HCl in 2011, and GSK will be responsible for 75% of these costs in 2012 and beyond.

Collaboration revenue for the third quarter 2011 was \$1.66 million, and reflects the recognized portion of the \$33.2 million upfront payment received from GSK upon signing the agreement.

Total operating expenses in the third quarter 2011 were \$18.9 million, compared to \$13.3 million in the prior year period. The increase was primarily attributed to higher expenses for research and development, one-time stock-based compensation and severance.

Net loss attributable to common stockholders for the three months ended September 30, 2011 was \$9.8 million, or \$0.28 per share, compared to a net loss of \$15.4 million, or \$0.56 per share, for the same period in 2010. Weighted-average common shares outstanding were 35.0 million and 27.6 million for the three months ended September 30, 2011 and September 30, 2010, respectively.

2011 Financial Guidance

Amicus continues to expect to spend a total of \$50 million to \$55 million on 2011 operating expenses, net of cost sharing and milestones related to the GSK collaboration.

The Company continues to expect that the current cash position, including anticipated collaboration payments from GSK, will be sufficient to fund the Company's operations and capital expenditure requirements through at least the end of 2012.

Pipeline Highlights

Migalastat HCl for Fabry Disease: Phase 3 Global Registration Program

Amicus and its collaborator GSK are conducting two Phase 3 registration studies ([Study_011](#) and [Study_012](#)) to support the global approval of migalastat HCl for the treatment of Fabry disease. Both studies are evaluating Fabry patients with genetic mutations that may be amenable to migalastat HCl monotherapy.

Study 011 is a six-month, randomized, double-blind, placebo-controlled study to support marketing applications to the U.S. Food and Drug Administration (FDA) and other regulatory agencies. Patient recruitment has closed at 37 centers worldwide and final enrollment is expected by year-end.

"Based on the number of patients currently in screening and randomized in Study 011, we are on track to exceed our target enrollment of 60 patients," added Mr. Crowley. "There has been positive momentum in this study, particularly over the past few months, and we believe that each and every patient plays a very important role in building our data set for migalastat HCl."

During the third quarter 2011, the first patient was dosed in Study 012, a randomized, open-label, 18-month Phase 3 study to compare the safety and efficacy of migalastat HCl and ERT in approximately 50 male or female patients (30 to switch from ERT to migalastat HCl and 20 to remain on ERT).

Pharmacological Chaperone-ERT (PC-ERT) Co-Administration: Phase 2 Studies in Fabry and Pompe

Two open-label Phase 2 studies are underway in Fabry and Pompe patients to evaluate safety, pharmacokinetic (PK) and pharmacodynamic (PD) parameters for PC-ERT co-administration versus ERT alone. Patients in each study will receive a regular ERT infusion and on a subsequent occasion will receive an orally administered pharmacological chaperone just prior to the next scheduled ERT infusion.

Amicus and GSK are investigating migalastat HCl co-administered with ERT as part of the global collaboration for Fabry disease. An ongoing Phase 2 study ([Study_013](#)) will evaluate two different doses of migalastat HCl (150 mg and 450 mg) co-administered with ERT in males with Fabry disease. Study 013 will measure ERT plasma PK and enzyme activity in skin biopsies, with and without an oral dose of migalastat HCl. Preliminary results from this study are anticipated in the fourth quarter 2011.

Patient recruitment is also underway for a Phase 2 study ([Study_010](#)) to evaluate four different doses of a second pharmacological chaperone owned exclusively by Amicus, AT2220, co-administered with ERT in approximately 16 Pompe patients. The study will measure ERT plasma PK and enzyme activity in muscle biopsies, with and without an oral dose of AT2220. Dosing of the first patient in Study 010 is anticipated in the fourth quarter of 2011.

Preclinical Pharmacological Chaperones

Amicus is conducting preclinical studies of AT3375 for the treatment of Parkinson's disease. AT3375 is a pharmacological chaperone targeted at glucocerebrosidase (GCase), the enzyme deficient in Gaucher disease. Mutations in the GBA1 gene that encodes for the GCase enzyme are the most common genetic risk factor known for Parkinson's disease.

Posters at Human Genetic Meeting (ICHG/ASHG 2011)

Migalastat HCl for Fabry disease and AT2220 for Pompe disease were featured in posters at the 12th International Congress of Human Genetics (ICHG) and the 61st ASHG Annual Meeting ([ICHG/ASHG 2011](#)), held October 11-15, 2011 in Montreal, Canada.

Phase 2 Study in Female Fabry Patients

Oral migalastat HCl (AT1001/GR181314A) as an investigational therapy evaluated in females with Fabry disease. P. Fernhoff, R. Giugliani, K. Nicholls, *et al.*

One of four open-label Phase 2 studies ([Study_204](#)) evaluated the safety and tolerability of oral migalastat HCl (50, 150, or 250 mg once every other day, or QOD) in a total of nine symptomatic female Fabry patients. All nine females completed the initial 12-week treatment and a 36-week treatment extension period with migalastat HCl. No treatment-related serious adverse events (SAEs) and no treatment-limiting toxicities were identified. No patients interrupted, reduced, or discontinued study drug dosing due to an AE. All treatment-related AEs were mild or moderate in severity, and only two were reported as likely or related to study drug (atrioventricular block, resolved without any intervention while patient continued migalastat HCl treatment, and abdominal discomfort).

After 48 weeks of treatment, females treated with 150 mg or 250 mg migalastat HCl, who were retrospectively identified as having amenable GLA mutations, showed the earliest and most significant declines in urine globotriaosylceramide (GL-3), and also demonstrated decreases in GL-3 inclusions in interstitial capillary cells. In contrast, none of the patients with non-amenable GLA mutations showed a consistent reduction in urine GL-3 at any dose in this study. Kidney and urine GL-3 are biomarkers of Fabry disease.

"In addition to supporting our Phase 3 Fabry registration program, Study 204 demonstrates our ongoing commitment to gathering more data in female Fabry patients, who constitute a significant fraction of the overall Fabry population," said Pol F. Boudes, M.D., Chief Medical Officer of Amicus.

Different doses and regimens of migalastat HCl were previously evaluated in four Phase 2 studies that support the design of ongoing Phase 3 registration studies of migalastat HCl in male and female Fabry patients that have been enrolled on the basis of specific genetic mutation types.

Preclinical PC-ERT Co-administration Results in Fabry and Pompe

Two studies investigated the effects of PC-ERT co-administration *in vitro* and *in vivo* in models of Fabry and Pompe. Results from both studies indicate that PC-ERT co-administration increases ERT stability, enzyme activity, and substrate reduction in disease-relevant tissues compared to ERT alone.

The pharmacological chaperone AT1001 increases the tissue uptake of agalsidase alfa resulting in greater substrate reduction in a mouse model of Fabry disease. L. Pellegrino, J. Feng, M. Frascella, *et al.*

The pharmacological chaperone AT2220 increases the muscle uptake of recombinant human acid a-glucosidase resulting in greater glycogen reduction in a mouse model of Pompe disease. J. Feng, R. Soska, L. Pellegrino, *et al.*

“Our preclinical PC-ERT co-administration work formed the basis for our ongoing Phase 2 studies in Fabry and Pompe diseases, which we hope will provide initial proof-of-concept for this approach in humans and guide us in the design of later-stage studies,” stated David J. Lockhart, Ph.D., Chief Scientific Officer of Amicus.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, November 1, 2011, 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 22660442.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a biopharmaceutical company at the forefront of developing therapies for rare 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 Amigal™ (migalastat HCl) is in Phase 3 for the treatment of Fabry disease.

About Migalastat HCl

Migalastat HCl is an investigational, orally-administered pharmacological chaperone in Phase 3 development for the treatment of Fabry disease being developed in collaboration with GlaxoSmithKline (GSK). Under the terms of the collaboration, GSK has an exclusive worldwide license to develop, manufacture and commercialize migalastat HCl. Amicus and GSK are conducting two Phase 3 global registration studies ([Study 011](#) and [Study 012](#)) of migalastat HCl monotherapy, along with a Phase 2 study ([Study 013](#)) evaluating migalastat HCl-ERT co-administration for the treatment of Fabry disease.

About Pharmacological Chaperone-ERT (PC-ERT) Co-Administration

The broader use of pharmacological chaperones co-administered with ERT may represent an important extension of the Company's chaperone technology platform. Phase 2 co-administration studies of migalastat HCl-ERT for Fabry disease and AT2220 (duvoglost HCl)-ERT for Pompe disease are currently underway.

About Fabry Disease

Fabry disease is an inherited lysosomal storage disorder 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 attack and stroke.

About Pompe Disease

Pompe disease is an inherited lysosomal storage disorder that affects an estimated 5,000 to 10,000 individuals worldwide and is caused by deficiency in an enzyme called alpha-glucosidase (GAA). Pompe disease is clinically heterogeneous in the age of onset, extent of organ involvement, and rate of progression. The early onset form is most severe, progresses most rapidly, and is characterized by musculoskeletal, pulmonary, gastrointestinal, and cardiac symptoms that usually lead to death between one and two years of age. A high majority of patients develop the late onset form of Pompe disease between childhood and adulthood, which has a slower rate of progression and usually leads to progressive muscle weakness and respiratory insufficiency.

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

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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 Sept. 30,		Nine Months Ended Sept. 30,		Period from February 4, 2002 (inception) to Sept. 30, 2011
	2010	2011	2010	2011	
Revenue:					
Research revenue	\$ —	\$ 4,138	\$ —	\$ 10,824	\$ 41,932
Collaboration revenue	—	1,660	—	4,980	55,902
Total revenue	<u>—</u>	<u>5,798</u>	<u>—</u>	<u>15,804</u>	<u>97,834</u>
Operating Expenses:					
Research and development	8,862	13,711	25,888	36,455	251,219
General and administrative	3,892	4,841	11,837	15,963	109,332
Restructuring charges	—	—	—	—	1,522
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	511	380	1,577	1,243	9,721
In-process research and development	—	—	—	—	418
Total operating expenses	<u>13,265</u>	<u>18,932</u>	<u>39,302</u>	<u>53,661</u>	<u>373,242</u>
Loss from operations	(13,265)	(13,134)	(39,302)	(37,857)	(275,408)
Other income (expenses):					
Interest income	33	31	121	136	14,049
Interest expense	(66)	(32)	(203)	(121)	(2,306)
Change in fair value of warrant liability	(2,059)	3,376	(464)	2,022	158
Other income	—	—	—	70	231
Loss before tax benefit	(15,357)	(9,759)	(39,848)	(35,750)	(263,276)
Benefit from income taxes	—	—	—	—	1,834
Net Loss	(15,357)	(9,759)	(39,848)	(35,750)	(261,442)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net Loss attributable to common stockholders	<u>\$ (15,357)</u>	<u>\$ (9,759)</u>	<u>\$ (39,848)</u>	<u>\$ (35,750)</u>	<u>\$ (281,668)</u>
Net Loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.28)</u>	<u>\$ (1.50)</u>	<u>\$ (1.03)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>27,625,137</u>	<u>34,979,702</u>	<u>26,516,688</u>	<u>34,544,768</u>	

Source: FOLD -G