**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 4, 2011**

# AMICUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-33497** | **71-0869350** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **6 Cedar Brook Drive, Cranbury, NJ** | **08512** |
|---|---|
| (Address of principal executive offices) | (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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 4, 2011, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 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: May 4, 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 May 4, 2011 |

**Exhibit 99.1**

**Amicus Therapeutics Announces First Quarter 2011 Financial Results and Continued Progress of Development Programs**

**Enrollment Nearing Completion in Phase 3 Study of Amigal™ for Fabry Disease**

**Phase 2 Co-Administration Studies Advancing in Fabry Disease and Pompe Disease**

**CRANBURY, N.J., May 4, 2011** — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of developing therapies for rare diseases, today announced financial results for the first quarter ended March 31, 2011. The Company also highlighted recent and upcoming milestones, including an update on patient enrollment in the ongoing Phase 3 study of its lead program Amigal™ (migalastat HCl) for Fabry disease.

**Development Pipeline Highlights**

- Enrollment in Phase 3 Amigal study (Study 011) is nearing completion and is expected to be fully enrolled in 2Q11 or 3Q11
- Phase 2 Amigal extension study continues to provide encouraging safety and renal function data following up to four years of treatment
- Patient dosing commenced in Phase 2 study of Amigal co-administered with enzyme replacement therapy (ERT) for Fabry disease
- Moving forward with Phase 2 study of AT2220 (1-deoxynojirimycin HCl) co-administered with ERT for Pompe disease

Matthew R. Patterson, President and Acting Chief Executive Officer of Amicus Therapeutics said, “We continue to make excellent progress across all parts of our business. Our Phase 3 study of Amigal for Fabry disease remains our top priority and we are close to enrolling the final patient. We are also excited to have dosed our first patient in a Phase 2 study evaluating pharmacological chaperones co-administered with ERT. We see this approach as an important extension of our science and a validation of the broader therapeutic potential of our pharmacological chaperone technology. Amicus is in a position of strategic and financial strength due to the positive momentum of our development programs and the successful collaboration with our partner, GSK Rare Diseases. Our team is focused on the achievement of multiple key milestones during 2011.”

**First Quarter 2011 Financial Summary**

As of March 31, 2011, cash, cash equivalents, and marketable securities totaled $93.8 million, compared to $107.4 million at December 31, 2010.

Total revenue of $6.0 million for the first quarter 2011 consisted of $4.3 million in research revenue and $1.7 million in collaboration revenue, compared to no revenue in the prior year period. Research revenue reflects payments received from GlaxoSmithKline (GSK) for shared development costs of Amigal as part of the Company’s collaboration with GSK. Amicus entered into an agreement with GSK in October 2010 pursuant to which GSK received an exclusive worldwide license to develop, manufacture and commercialize Amigal for the treatment of Fabry disease. Collaboration revenue reflects the recognized portion of the upfront payment received from GSK upon signing the agreement.

Total operating expenses in the first quarter 2011 were $16.0 million, compared to $13.4 million in the prior year period. The increase was primarily attributed to an increase in research and development expenses to $11.1 million in the first quarter from $8.9 million in the prior year period, as a result of contract research and manufacturing costs within the Fabry program.

Net loss attributable to common stockholders for the three months ended March 31, 2011, was $13.4 million, compared to a net loss of $13.2 million for the same period in 2010.

**2011 Financial Guidance**

Amicus is reiterating previously announced guidance on 2011 operating expenses and the current cash position. The Company expects to spend a total of $45 million to $55 million on 2011 operating expenses, net of cost sharing and milestones related to the GSK collaboration. The current cash position, including anticipated payments from GSK in connection with the collaboration, is expected to be sufficient to fund the Company's operations and capital expenditure requirements through the anticipated commercial launch of Amigal in the United States.

**Upcoming Milestones**

Amicus expects to achieve multiple near-term milestones across its three areas of focus: Amigal for the treatment of Fabry disease, pharmacological chaperones co-administered with ERT, and pharmacological chaperones for the treatment of diseases of neurodegeneration. Planned upcoming milestones include the following:

- Complete enrollment in Study 011, the Phase 3 U.S. registration study of Amigal for Fabry disease, in 2Q11 or 3Q11
- Begin patient dosing in Study 012, the Phase 3 EU registration study of Amigal for Fabry disease, in 2Q11 or 3Q11
- Report Phase 2 results for Amigal co-administered with ERT for Fabry disease in 2H11
- Begin patient dosing in Phase 2 study of AT2220 co-administered with ERT for Pompe disease in 3Q11, with results expected in 1H12
- Complete late-stage preclinical proof-of-concept studies of AT3375 for Parkinson's disease, including additional investigational new drug (IND)-enabling activities, in 2H11

**Amigal for the Treatment of Fabry Disease**

Updated data from an ongoing Phase 2 extension study continue to support the potential of Amigal as an important new treatment option for patients with Fabry disease. Seventeen subjects are receiving treatment in an extension study designed to evaluate the long-term safety and efficacy of Amigal. Preliminary data suggest that Amigal remains generally well tolerated following up to four years of treatment. In patients who have a genetic mutation responsive to Amigal, these data also suggest that treatment may result in maintenance of renal function as measured by estimated glomerular filtration rate (eGFR). In addition, reduced 24-hour urine protein continues to be observed in multiple subjects.

Amicus and GSK are conducting Phase 3 registration studies to support the global approval of Amigal for the treatment of Fabry Disease.

*Phase 3 U.S. Registration (Study 011)*

Study 011 is a six-month, randomized, double-blind, placebo controlled study of Amigal for Fabry disease. Amicus and GSK are close to achieving target enrollment of 60 patients at 37 centers worldwide. The study is on track to complete enrollment by the end of the second quarter or during the third quarter of this year.

"This Phase 3 study of Amigal is designed to maximize our potential for success, primarily through strict entry criteria," added Mr. Patterson. "In addition, the latest data from our ongoing Phase 2 extension study continue to demonstrate the potential long-term safety and efficacy of Amigal for Fabry disease. The combination of the data from Phase 2 studies and the robust design of the Phase 3 protocol give us a high degree of confidence in the study."

*Phase 3 EU Registration (Study 012)*

Amicus and its partner GSK have opened multiple sites globally for the Phase 3 EU registration study (Study 012) of Amigal for Fabry disease. Patient screening is expected to begin in the second quarter, and dosing of the first patient is anticipated in the second or third quarter of this year. Based on prior interactions with the European Medicines Authority (EMA), Study 012 is designed to be an 18-month, randomized, open-label study comparing the efficacy and safety of Amigal and ERT in male and female patients with Fabry disease who are currently receiving ERT, and who have a genetic mutation responsive to Amigal.

*Phase 2 Amigal-ERT Co-Administration Study*

In February 2011, Amicus and its partner GSK dosed the first patient in a Phase 2 study evaluating the co-administration of Amigal with ERT for Fabry disease. The announcement of results is on track for the second half of 2011. The open-label Phase 2 study is investigating drug-drug interactions between Amigal and the ERTs Fabrazyme® and Replagal® in approximately 18 male patients with Fabry disease, ages 18-65, who have been receiving ERT for at least one month before study entry. Two cohorts of nine patients will receive ERT alone and then ERT after a single administration of Amigal at one of two oral dose levels. The primary outcome measure will be safety and a comparison of the ERT activity in plasma, with and without co-administration of Amigal.

**AT2220-ERT Co-Administration for the Treatment of Pompe Disease**

Amicus has commenced activities for a Phase 2 study of AT2220 co-administered with ERT for Pompe disease. The Company expects to dose the first patient during the third quarter of 2011, and anticipates results in the first half of 2012. The broader use of pharmacological chaperones co-administered with ERT represents an important expansion of the Company's chaperone technology platform. Preclinical studies have shown that pharmacological chaperones bind to and stabilize the infused ERT, potentially improving its pharmaceutical and pharmacological properties. Preclinical proof-of-concept studies in Fabry and Pompe diseases have demonstrated that a pharmacological chaperone co-administered with ERT can prevent the loss of activity of ERT in the circulation, increase tissue uptake, and increase substrate reduction.

**Pharmacological Chaperones for the Treatment of Parkinson's Disease**

Amicus is developing AT3375, its lead pharmacological chaperone targeted at glucocerobrosidase (GCase), as a treatment for Parkinson's disease. GCase is the enzyme deficient in Gaucher disease, and mutations in the GBA1 gene for GCase are the most common genetic risk factor known for Parkinson's disease. Gaucher carriers, who have one mutant copy of GCase, are approximately five times more frequent in the Parkinson's disease population. In addition, Gaucher patients, who have two mutant copies of GCase, have an estimated 20-fold increased risk of developing Parkinson's disease. AT3375 is expected to advance through late-stage preclinical proof-of-concept studies, including IND-enabling activities, during the second half of 2011.

**Conference Call and Webcast**

Amicus Therapeutics will host a conference call and webcast today, Wednesday, May 4, 2011, at 5:00 P.M. EDT to review financial results and provide a corporate update. Interested participants and investors may access the conference call at 5 p.m. EDT by dialing 877-303-5859 (U.S./Canada) or 678-224-778 (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. EDT today. Access numbers for this replay are 800-642-1687 (U.S./Canada) and 706-645-9291 (international); participant code 62822099.

**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 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

FOLD—G

**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, 2011 |
|---|---|---|---|
| | 2010 | 2011 | |
| Revenue: | | | |
| Research revenue | $ — | $ 4,306 | $ 35,414 |
| Collaboration revenue | — | 1,660 | 52,582 |
| Total revenue | — | 5,966 | 87,996 |
| Operating Expenses: | | | |
| Research and development | 8,889 | 11,125 | 225,889 |
| General and administrative | 3,925 | 4,402 | 97,771 |
| Restructuring charges | — | — | 1,522 |
| Impairment of leasehold improvements | — | — | 1,030 |
| Depreciation and amortization | 536 | 438 | 8,916 |
| In-process research and development | — | — | 418 |
| Total operating expenses | 13,350 | 15,965 | 335,546 |
| Loss from operations | (13,350) | (9,999) | (247,550) |
| Other income (expenses): | | | |
| Interest income | 53 | 59 | 13,972 |
| Interest expense | (83) | (48) | (2,233) |
| Change in fair value of warrant liability | 204 | (3,432) | (5,296) |
| Other income | — | 70 | 231 |
| Loss before tax benefit | (13,176) | (13,350) | (240,876) |
| Benefit from income taxes | — | — | 1,834 |
| Net loss | (13,176) | (13,350) | (239,042) |
| Deemed dividend | — | — | (19,424) |
| Preferred stock accretion | — | — | (802) |
| Net loss attributable to common stockholders | $ (13,176) | $ (13,350) | $ (259,268) |
| Net loss attributable to common stockholders per common share — basic and diluted | $ (0.54) | $ (0.39) | |
| Weighted-average common shares outstanding — basic and diluted | 24,289,422 | 34,498,926 | |

Source: FOLD -G