

AMICUS THERAPEUTICS INC

FORM 8-K (Current report filing)

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Address	6 CEDAR BROOK DRIVE CRANBURY, NJ 08512
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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 14, 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 February 14, 2011, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2010. 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 14, 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 February 14, 2011



Amicus Therapeutics Announces Fourth Quarter and Full Year 2010 Financial Results

Company expects to achieve multiple key milestones advancing rare disease product pipeline during 2011

CRANBURY, N.J., February 14, 2010 — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the fourth quarter and full year 2010. The Company also provided a review of planned key milestones for 2011, which includes the announcement of top line results from the ongoing Phase 3 Study of Amigal™ (migalastat HCl) for Fabry Disease.

Fourth Quarter and Full-Year 2010 Financials Summary

Amicus announced net loss attributable to common stockholders of \$0.48 per share for the three months ended December 31, 2010. For the year ended December 31, 2010, the net loss attributable to common stockholders was \$1.98 per share. As of December 31, 2010, cash, cash equivalents, and marketable securities totaled \$107.4 million.

“We have started 2011 on a very positive note and intend to build on our momentum through the achievement of multiple key milestones across all of our programs during the year,” said John F. Crowley, Chairman and CEO of Amicus. “We are advancing and expanding the use of pharmacological chaperone technology and as a result have established ourselves as a leader in the development of new treatments for rare diseases.”

2011 Key Milestones

In 2011 Amicus expects to achieve multiple key milestones across its three areas of focus: Amigal (migalastat HCl) for the treatment of Fabry Disease, the evaluation of pharmacological chaperones co-administered with enzyme replacement therapy (ERT), and the investigation of pharmacological chaperones for the treatment of diseases of neurodegeneration. Among the milestones expected this year are results from the following studies:

- Phase 3 study of Amigal for Fabry Disease in 2H11
- Phase 2 study of Amigal co-administered with ERT for Fabry Disease in 2H11
- Phase 2 study of AT2220 co-administered with ERT for Pompe Disease in 2H11
- Late-stage preclinical proof of concept studies of AT3375 for Parkinson’s Disease, including completion of additional IND-enabling activities, in 2H11.

Amigal™ (migalastat HCl) for the Treatment of Fabry Disease

On October 29, 2010, Amicus announced a definitive agreement with GlaxoSmithKline PLC (GSK) to develop and commercialize Amigal (migalastat HCl), currently in Phase 3 for the treatment of Fabry disease. Under the terms of the agreement, GSK received an exclusive worldwide license to develop, manufacture and commercialize migalastat HCl. Additionally, as part of the agreement, GSK and Amicus also intend to advance clinical studies exploring the co-administration of migalastat HCl with ERT for the treatment of Fabry disease.

The Phase 3 study (Study 011) of migalastat HCl remains the Company’s number one priority. Study 011 is ongoing and patients are being enrolled at 36 investigational sites worldwide. A majority of the planned 60 patients have been enrolled in the study. The Company expects to complete enrollment in the first half of 2011 and to report preliminary results from this study in the second half of the year.

Amicus and GSK intend to commence an additional Phase 3 study (Study 012) in the first half of 2011. Study 012 will be an 18-month, randomized, open-label study comparing migalastat HCl to enzyme replacement therapy (ERT) in approximately 60 subjects. The primary outcome of efficacy will be renal function as measured by glomerular filtration rate (GFR).

Seventeen subjects continue to receive treatment in the ongoing Phase 2 long-term extension study. Amicus plans to provide a data update from this study at the Lysosomal Disease Network WORLD Symposium in Las Vegas, Nevada February 16-18th, 2011.

Chaperone-ERT Combination Therapy

Amicus previously reported promising preclinical data demonstrating that the co-administration of a pharmacological chaperone with ERT has the potential to address key limitations of ERT. The addition of a pharmacological chaperone has been shown to prevent the loss of activity of ERT in the circulation, increase tissue uptake, and increase substrate reduction. Preclinical proof of concept has been established for Fabry disease and Pompe disease. Amicus plans to present a review of historical and new data from these studies at the Lysosomal Disease Network WORLD Symposium in Las Vegas, Nevada February 16-18th, 2011.

Amicus and its partner GSK are sponsoring an ongoing Phase 2 study evaluating the co-administration of migalastat HCl with ERT for Fabry disease. Results from this study are expected in the second half of 2011.

Additionally, the Company expects to initiate a Phase 2 study with its pharmacological chaperone AT2220 co-administered with ERT for Pompe disease in the first half of 2011 and expects results from this study to be available in the second half of the year. The Company intends to seek U.S. FDA approval to lift the current hold on the AT2220 program as part of its development plan.

Diseases of Neurodegeneration

Amicus is investigating the potential use of pharmacological chaperones for the treatment of genetically defined sub-populations of patients with Parkinson's Disease and Alzheimer's Disease. Amicus previously reported encouraging results from preclinical studies evaluating the use of a pharmacological chaperone for the treatment of Parkinson's Disease. In 2011 it expects to complete late-stage preclinical proof of concept studies, including IND-enabling activities, for its molecule AT3375, which is in development for the treatment of Parkinson's Disease. The Amicus Parkinson's Disease program is funded in part by a grant from The Michael J. Fox Foundation (MJFF).

Additionally, Amicus continues to advance its preclinical program evaluating a pharmacological chaperone approach for the treatment of Alzheimer's disease. The Company expects to continue preclinical proof of concept studies during 2011. The Amicus Alzheimer's Disease program is funded in part by a grant from the Alzheimer's Drug Discovery Foundation (ADDF).

Amicus plans to present new information from both its Parkinson's Disease and Alzheimer's Disease programs at the Lysosomal Disease Network WORLD Symposium in Las Vegas, Nevada February 16-18th, 2011.

2011 Financial Guidance

As previously reported, the Company expects to spend a total of \$45 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.

In 2011, the Company will continue to evaluate additional business development opportunities to further build shareholder value. The Company is actively exploring a range of opportunities with multiple potential partners.

Additional Financial Results & Notes

Net loss attributable to common stockholders for the three months ended December 31, 2010, was \$15.1 million as compared to a net income of \$33.0 million for the same period in 2009, which included recognition of \$45 million of previously deferred revenue on the upfront payment we received from our prior partner, Shire, in 2007.

Upon the signing the GSK collaboration agreement, Amicus received an upfront payment of \$30 million and a premium of \$3.2 million related to GSK's purchase of an equity investment in Amicus. The total upfront consideration received of \$33.2 million will be recognized as revenue on a straight-line basis over the development period of the collaboration agreement which is approximately 5.2 years. In the fourth quarter of 2010, Amicus recognized \$0.9 million of the total upfront consideration as Collaboration Revenue.



Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, Monday, February 14, 2010, at 5:00 P.M. EST to review financial results and provide a corporate update. Interested participants and investors may access the conference call at 5 p.m. EST by dialing 877-303-5859 (U.S./Canada) or 678-224-778 (international).

An audio webcast and archive can also be accessed via the investor section of the Amicus Therapeutics Web site at <http://www.amicustherapeutics.com> under Investors: Events and Presentations. 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. After the live webcast, a webcast replay will remain available in the Investors section of the Amicus Therapeutics Web site for 30 days.

A telephonic replay of the call will be available for seven days beginning at 8 p.m. EST. Access numbers for this replay are 800-642-1687 (U.S./Canada) and 706-645-9291 (international); participant code 43466317.

Amicus' press releases are available at www.amicustherapeutics.com.

About Amicus Therapeutics

Amicus Therapeutics is a biopharmaceutical company focused on developing treatments 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 is in Phase 3 for the treatment of Fabry disease.

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, the projected cash position for the Company, including achievement of development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline, and business development and other transactional activities that seek to strengthen the Company's financial position. 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. Additionally, with respect to statements relating to potential business development opportunities and other transactions that seek to strengthen our financial position, we may not be successful in identifying suitable collaborators, establishing and implementing such collaborations or completing other transactions that could improve our financial position. 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, 2009. 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:
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(609) 662-2000

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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		Twelve Months		Period from
	Ended December 31, 2009	2010	Ended December 31, 2009	2010	February 4, 2002 (inception) to Dec 31, 2010
Revenue:					
Research revenue	\$ 4,746	\$ —	\$ 17,545	\$ —	\$ 31,108
Collaboration revenue	44,730	922	46,813	922	50,922
Total revenue	<u>49,476</u>	<u>922</u>	<u>64,358</u>	<u>922</u>	<u>82,030</u>
Operating Expenses:					
Research and development	10,126	13,154	48,081	39,042	214,764
General and administrative	4,338	3,823	19,973	15,660	93,369
Restructuring charges	1,522	—	1,522	—	1,522
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	548	481	2,132	2,058	8,478
In-process research and development	—	—	—	—	418
Total operating expenses	<u>16,534</u>	<u>17,458</u>	<u>71,708</u>	<u>56,760</u>	<u>319,581</u>
Income/(loss) from operations	32,942	(16,536)	(7,350)	(55,838)	(237,551)
Other income (expenses):					
Interest income	73	35	997	156	13,913
Interest expense	(123)	(57)	(278)	(260)	(2,185)
Change in fair value of warrant liability	—	(946)	—	(1,410)	(1,864)
Other income	64	1,277	64	1,277	161
Income/(loss) before tax benefit	<u>32,956</u>	<u>(16,227)</u>	<u>(6,567)</u>	<u>(56,075)</u>	<u>(227,526)</u>
Benefit from income taxes	—	1,139	—	1,139	1,834
Net Income/(loss)	32,956	(15,088)	(6,567)	(54,936)	(225,692)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net Income/(loss) attributable to common stockholders	<u>\$ 32,956</u>	<u>\$ (15,088)</u>	<u>\$ (6,567)</u>	<u>\$ (54,936)</u>	<u>\$ (245,918)</u>
Net Income/(loss) attributable to common stockholders per common share — basic					
	<u>\$ 1.46</u>	<u>\$ (0.48)</u>	<u>\$ (0.29)</u>	<u>\$ (1.98)</u>	
— diluted	<u>\$ 1.45</u>	<u>\$ (0.48)</u>	<u>\$ (0.29)</u>	<u>\$ (1.98)</u>	
Weighted-average common shares outstanding — basic					
	<u>22,643,507</u>	<u>31,320,453</u>	<u>22,624,134</u>	<u>27,734,797</u>	
— diluted	<u>22,781,090</u>	<u>31,320,453</u>	<u>22,624,134</u>	<u>27,734,797</u>	

Source: FOLD -G