

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): November 8, 2010

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 8, 2010, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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: November 8, 2010

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 8, 2010



Amicus Therapeutics Announces Third Quarter 2010 Financial Results

-Global strategic collaboration with GSK Rare Diseases supports potential of Amigal™ for Fabry Disease; Company expects to fund operations and capital expenditure requirements through the anticipated U.S. Amigal commercial launch-

CRANBURY, N.J., November 8, 2010 — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the quarter ended September 30, 2010, provided an update on its product development pipeline, including its Phase 3 program with Amigal (migalastat HCl) for the treatment of Fabry disease and reaffirmed the financial strength of the Company.

John F. Crowley, Chairman and CEO of Amicus Therapeutics stated, "During the third quarter we made significant progress further establishing Amicus as a leader in the research and development of new treatments for rare diseases. Our strategic partnership with GSK not only supports the potential for success with the Amigal program but also provides us with multiple strategic options for continued growth. Moving forward, we intend to judiciously invest in our pipeline and to explore a series of additional partnerships, all while ensuring that our financial strength allows us to fund our operations and capital expenditures through the anticipated US commercial launch of Amigal."

Third Quarter Financial Summary

As of September 30, 2010, Amicus held \$57.6 million of cash, cash equivalents, and marketable securities.

For the three months ended September 30, 2010, Amicus reported a net loss of \$15.4 million, or \$0.56 per share attributable to common stockholders, compared to a net loss of \$13.4 million, or \$0.59 per share attributable to common stockholders for the same period in 2009.

Pipeline Overview

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 enzyme replacement therapy (ERT) for the treatment of Fabry disease.

Under the terms of the Agreement, Amicus will receive an upfront, license payment of \$30M from GSK and is eligible to receive further payments of approximately \$170M upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of migalastat HCl. Amicus will fund development costs for the remainder of 2010, and the parties will begin sharing such costs in 2011 in accordance with an agreed upon development plan. This development plan provides that Amicus and GSK will jointly fund development costs on a 50/50 basis in 2011 and a 25/75 basis, respectively in 2012 and beyond. The Company's obligation to jointly fund development costs is subject to both an annual and an aggregate cap. Additionally, as part of the collaboration, GSK is purchasing 6.9 million shares of Amicus common stock at a price of \$4.56 per share. The total value of the equity investment to Amicus is \$31 million and represents a 19.9% ownership position for GSK in the Company. The total cash up-front to Amicus from GSK for the upfront license payment and equity investment is approximately \$60 million.

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 approximately 40 investigational sites worldwide. The Company expects to complete enrollment in the first quarter of 2011 and to report preliminary results from this study in the second half of 2011.

Amicus and GSK intend to commence an additional Phase 3 study (Study 012) before year end. 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).

Chaperone-ERT Co-administration Therapy Programs

Amicus and GSK intend to initiate a Phase 2 study with migalastat HCl co-administered with ERT for Fabry disease. This open-label phase 2 study to investigate drug-drug interactions between migalastat HCl and ERT for Fabry disease is planned to commence before the end of 2010.

Additionally, Amicus continues to evaluate the co-administration use of AT2220 (1-deoxyinojirimycin HCl) with enzyme replacement therapy (ERT) in mouse models of Pompe disease. The Company previously reported that preclinical studies demonstrated that co-administration of AT2220 with ERT resulted in prolonged half-life of ERT in the circulation, increased enzyme activity in cells and greater substrate reduction in target tissues compared to that seen with ERT alone. Amicus has also completed promising preclinical studies of its chaperone Plicera™ (afegostat tartrate) co-administered with ERT for Gaucher disease.

The Company continues to evaluate options for clinical development of both the combination use of AT2220 and ERT for Pompe disease and afegostat tartrate and ERT for Gaucher disease.

Neurodegenerative Genetic Disease Programs

Amicus continues to advance its preclinical neurodegenerative disease programs. As previously reported, Amicus presented data from preclinical studies that evaluated the chaperone AT2101 in mouse models of Parkinson's disease. The studies demonstrated that treatment with AT2101 increased the activity of β -glucocerebrosidase (GCase), prevented accumulation of α -synuclein in the brain and improved motor function as assessed in various behavioral tests. At that time, the Company also announced that new compounds have been identified that improve on the properties of AT2101 and expand the range of doses and regimens that show motor improvement in mouse models of the disease. Amicus expects to provide details regarding its plans to advance the Parkinson's disease program early in January 2011.

Amicus' second neurodegenerative disease program is for the treatment of Alzheimer's disease. As previously announced, Amicus was awarded a grant of \$210,000 from the Alzheimer's Drug Discovery Foundation (ADDF), which is helping to fund preclinical studies to evaluate the use of pharmacological chaperones for the treatment of Alzheimer's disease.

2010 Financial Guidance

The Company expects to spend a total of \$45 to \$55 million on 2010 operating expenses. The current cash position, including payments from GSK in 2010 and anticipated payments from GSK moving forward, is expected to be sufficient to fund the Company's operations and capital expenditure requirements through the anticipated US commercial launch of Amigal.

Additionally, Amicus announced today that the U.S. Department of the Treasury awarded the Company a total of \$1,466,876 for all six of the Company's applications submitted for the new Therapeutic Discovery Project Program created by the Affordable Care Act. The therapeutic discovery tax credit was targeted, in part, to projects that show significant potential to produce new therapies, address unmet medical needs, and reduce the long-term growth of health care costs.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, November 8, 2010 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 678-224-7784 (international). 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 22575068.

An audio webcast can also be accessed via the investor section of the Amicus Therapeutics Web site at 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, an audio webcast replay will remain available in the Investors section of the Amicus Therapeutics Web site for 30 days.

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 CNS diseases. 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 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, 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:

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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		Nine Months		Period from February 4, 2002 (inception) to Sept 30, 2010
	Ended September 30,		Ended September 30,		
	2009	2010	2009	2010	2010
Revenue:					
Research revenue	\$ 4,219	\$ —	\$ 12,799	\$ —	\$ 31,108
Collaboration revenue	694	—	2,083	—	50,000
Total revenue	<u>4,913</u>	<u>—</u>	<u>14,882</u>	<u>—</u>	<u>81,108</u>
Operating Expenses:					
Research and development	12,609	8,862	37,954	25,888	201,611
General and administrative	5,217	3,892	15,635	11,837	89,546
Restructuring charges	—	—	—	—	1,522
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	561	511	1,585	1,577	7,997
In-process research and development	—	—	—	—	418
Total operating expenses	<u>18,387</u>	<u>13,265</u>	<u>55,174</u>	<u>39,302</u>	<u>302,124</u>
Loss from operations	(13,474)	(13,265)	(40,292)	(39,302)	(221,016)
Other income (expenses):					
Interest income	129	33	924	121	13,878
Interest expense	(84)	(66)	(155)	(203)	(2,127)
Change in fair value of warrant liability	—	(2,059)	—	(464)	(918)
Other expense	—	—	—	—	(1,116)
Loss before tax benefit	(13,429)	(15,357)	(39,523)	(39,848)	(211,299)
Benefit from income taxes	—	—	—	—	695
Net loss	(13,429)	(15,357)	(39,523)	(39,848)	(210,604)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (13,429)</u>	<u>\$ (15,357)</u>	<u>\$ (39,523)</u>	<u>\$ (39,848)</u>	<u>\$ (230,830)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.56)</u>	<u>\$ (1.75)</u>	<u>\$ (1.50)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>22,621,513</u>	<u>27,625,137</u>	<u>22,617,808</u>	<u>26,516,688</u>	

Source: FOLD -G