
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 7, 2009

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 May 7, 2009, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2009. 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.

(c) Exhibits.

99.1 — Press Release, dated May 7, 2009

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 7, 2009

By: /s/ GEOFFREY P. GILMORE
Name: Geoffrey P. Gilmore
Title: Senior Vice President and General
Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated May 7, 2009

Amicus Therapeutics Announces First Quarter 2009 Financial Results

Company Remains on Track to Advance Amigal for Fabry Disease into Phase 3 in Second Quarter

CRANBURY, N.J., May 7, 2009 — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the first quarter 2009.

On a reported basis calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP), Amicus announced a net loss attributable to common stockholders of \$0.55 per share (\$0.46 per share on a non-GAAP basis) for the three months ended March 31, 2009. As of March 31, 2009, cash, cash equivalents, and marketable securities totaled \$109 million.

“Our first quarter was highlighted by positive Phase 2 extension data and continued progress towards our final Phase 3 development plan for Amigal in Fabry Disease,” said John F. Crowley, Amicus’ President and CEO. “We look forward to announcing our final protocol over the upcoming weeks and starting the trial later this quarter.”

Clinical Program Updates

Amigal™ (migalastat hydrochloride) for the treatment of Fabry disease

In the first quarter of 2009, Amicus continued to work closely with the U.S. and E.U. regulatory authorities in an effort to finalize its Phase 3 development plan for Amigal. The Company remains on track to announce the final Phase 3 protocol intended to support U.S. approval and to initiate Phase 3 development of Amigal in the second quarter of 2009.

Additionally, in March 2009 at the American College of Medical Genetics (ACMG) 2009 Annual Meeting in Tampa, FL, the Company presented positive results from its Phase 2 extension study with Amigal.

Amicus reported that treatment with Amigal was generally well-tolerated, with no drug-related serious adverse events. The most common adverse events were headache, arthralgia and diarrhea.

Subjects identified as responders to Amigal at the completion of the Phase 2 studies continued to maintain elevated levels of the target enzyme (α-Gal A), as measured in white blood cells, and reduced levels of the target substrate (kidney GL-3), as measured in urine.

A reduction of GL-3 levels was also observed in interstitial capillary cells from kidney biopsies. Previously reported Phase 2 results indicated that little to no GL-3 was detected in these cells in most subjects prior to treatment with Amigal. The new data were obtained from the retesting of biopsies using an improved methodology.

Preliminary results from the evaluation of modified doses and a new dosing regimen were also presented.

Plicera™ (afegostat tartrate) for the treatment of Gaucher Disease

A Phase 2 clinical trial of the Company’s investigational drug Plicera is ongoing. This 6-month study is designed to evaluate safety and to demonstrate trends of efficacy, as measured by the standard endpoints in Gaucher disease. The Company expects to report the results late in the third quarter of 2009.

Amicus will continue to work closely with its partner, Shire HGT, to prepare for Phase 3 development of Plicera pending the results of the ongoing Phase 2 trial.

Furthermore, during the first quarter, the Company announced the issuance of United States Patent No. 7,501,439, titled "Tartrate Salt of Isofagomine and Methods of Use." The patent covers the tartrate salt form of isofagomine, the active ingredient in the Plicera, and its use for the treatment of Gaucher disease. The patent will expire in 2027.

AT2220 (1-deoxynojirimycin HCl) for the treatment of Pompe Disease

As previously reported, the Company suspended enrollment for the Phase 2 clinical trial of its investigational drug AT2220 for the treatment of Pompe Disease and received notice from the U.S. Food and Drug Administration (FDA) that the trial is on clinical hold.

The Company is currently evaluating all data and continues to work closely with the FDA to determine appropriate next steps for advancing the development of AT2220.

The events have no impact on Amicus' ongoing studies with Amigal™ for Fabry disease and Plicera™ for Gaucher disease.

Preclinical Chaperone Programs

Amicus continues to invest in research and development to assess the potential for applying its versatile chaperone technology platform to the treatment of a broader range of human genetic diseases. As part of this effort, Amicus continues to conduct preclinical studies in Parkinson's disease and is investing in new research aimed at evaluating disease targets for other neurodegenerative and genetic disorders.

Shire HGT Collaboration

In November 2007, Amicus entered into a strategic collaboration with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Shire plc, to jointly develop Amicus' three lead pharmacological chaperone compounds for lysosomal storage disorders, Amigal, Plicera and AT2220. Under the terms of the collaboration Shire will pay development and sales milestones up to a maximum of \$390 million, and will also pay tiered, double digit royalties on net sales of the products. Shire also reimburses world-wide development costs on a 50/50 basis, and in return Shire received rights to commercialize these products outside of the U.S. while Amicus retains all rights to commercialize these products in the U.S. In addition, Amicus leads development operations through the end of Phase 2 clinical trials. The companies then share responsibility for Phase 3 clinical trial development leveraging Shire's significant ex-US regulatory and clinical experience as well as its commercial infrastructure.

Additional Financial Results & Notes

On a reported basis, the net loss attributable to common stockholders for the three months ended March 31, 2009, was \$12.5 million as compared to \$7.7 million for the same period in 2008. On a non-GAAP basis, the net loss for the three months ended March 31, 2009, was \$10.5 million as compared to \$6.4 million in the same period in 2008.

Amicus recorded revenue during the first quarter of 2009 representing two different revenue streams from the Shire agreement. Upon signing the agreement, Amicus received an upfront payment of \$50 million that will be recognized as revenue on a straight-line basis over 18 years from the date of the agreement. In the first quarter of 2009, Amicus recognized \$0.7 million of the Shire upfront payment and \$3.9 million of research revenue on reimbursed research and development costs.

The differences between U.S. GAAP and non U.S. GAAP financial results are itemized in Tables 2 and 3 and are primarily due to pre-tax stock compensation expense.

Use of Non-GAAP Financial Measures

Amicus' "non-GAAP net loss" and "non-GAAP diluted net loss per common share" financial measures are defined as reported, or GAAP, net loss and diluted net loss per common share excluding certain items further discussed below. Amicus' management uses these non-GAAP financial measures to establish financial goals and to gain an understanding of the comparative financial performance of Amicus from year to year and quarter to quarter. Accordingly, Amicus believes investors' understanding of Amicus' financial performance is enhanced as a result of disclosing these non-GAAP financial measures. Non-GAAP net loss and diluted net loss per common share should not be viewed in isolation or as a substitute for reported, or GAAP net loss and diluted net loss per common share.

- (1) Stock option expense — Non-GAAP net loss and diluted net loss per common share exclude the impact of the stock option expense recorded in accordance with SFAS No. 123R. Amicus believes that excluding the impact of expensing stock options better reflects the recurring economic characteristics of its business.

Conference Call and Webcast

Interested participants and investors may access the conference call at 5 p.m. EST by dialing 877-874-1565 (U.S./Canada) or 719-325-4830 (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 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 5114983.

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 developing novel, oral therapeutics known as pharmacological chaperones for the treatment of a range of human genetic diseases. Pharmacological chaperone technology involves the use of small molecules that selectively bind to and stabilize proteins in cells, leading to improved protein folding and trafficking, and increased activity. Amicus is initially targeting lysosomal storage disorders, which are severe, chronic genetic diseases with unmet medical needs.

Amicus has a strategic collaboration with Shire Human Genetic Therapies, Inc., a wholly-owned subsidiary of Shire Limited, to develop and commercialize Amicus' three lead pharmacological chaperone compounds for lysosomal storage disorders. Under the agreement, Shire received commercial rights outside of the United States. Amicus retains all U.S. rights.

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. 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 ongoing discussions with regulatory authorities and the potential goals, progress, timing and results of 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 inability to reach final agreement with regulatory agencies on the phase 3 trial design for Amigal; the potential that results of clinical or pre-clinical studies indicate that the product candidates are unsafe or ineffective; and, our dependence on third parties in the conduct of our clinical studies. Further, the results of earlier clinical trials may not be predictive of future results. Additionally, with respect to statements regarding projections of the Company’s cash position and expected use of cash during 2009, actual results may differ based on market factors, the company’s ability to execute its operational and budget plans, and its achievement of milestones and receipt of milestone payments from Shire. Additionally, all forward looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2008, and our other public filings with the Securities and Exchange Commission. 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.

CONTACT:

Investors:
Jenene Thomas
Director, Investor Relations
Amicus Therapeutics
609-662-5084

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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 March 31,		Period from February 4, 2002 (inception) to March 31, 2009
	2008	2009	
Revenue:			
Research revenue	\$ 2,466	\$ 3,912	\$ 17,476
Collaboration revenue	694	694	3,881
Total revenue	<u>3,160</u>	<u>4,606</u>	<u>21,357</u>
Operating Expenses:			
Research and development	6,941	11,875	139,517
General and administrative	5,186	5,195	62,931
Impairment of leasehold improvements	—	—	1,030
Depreciation and amortization	321	505	4,792
In-process research and development	—	—	418
Total operating expenses	<u>12,448</u>	<u>17,575</u>	<u>208,688</u>
Loss from operations	(9,288)	(12,969)	(187,331)
Other income (expenses):			
Interest income	1,702	526	13,286
Interest expense	(70)	(29)	(1,677)
Change in fair value of warrant liability	—	—	(454)
Other expense	—	—	(1,180)
Loss before tax benefit	(7,656)	(12,472)	(177,356)
(Provision for)/benefit from income taxes	(75)	—	695
Net loss	(7,731)	(12,472)	(176,661)
Deemed dividend	—	—	(19,424)
Preferred stock accretion	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (7,731)</u>	<u>\$ (12,472)</u>	<u>\$ (196,887)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.55)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>22,412,689</u>	<u>22,613,850</u>	

See accompanying notes to consolidated financial statements

Table 2

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Three Months Ended March 31, 2009
(Unaudited)
(In thousands, except share and per share amounts)

	<u>Non-GAAP</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
Income Statement Classifications:			
Revenue	\$ 4,606		\$ 4,606
Research and development	(11,060)	\$ (815)	(11,875)
General and administrative	(4,038)	(1,157)	(5,195)
Depreciation and amortization	(505)		(505)
Interest income	526		526
Interest expense	(29)		(29)
Summary:			
Net loss:	<u>\$ (10,500)</u>	<u>\$ (1,972)</u>	<u>\$ (12,472)</u>
Net loss per share - - basic and diluted:	<u>\$ (0.46)</u>	<u>\$ (0.09)</u>	<u>\$ (0.55)</u>
Weighted average number of shares outstanding:	<u>22,613,850</u>		<u>22,613,850</u>

Table 3

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Three Months Ended March 31, 2008
(Unaudited)
(In thousands, except share and per share amounts)

	<u>Non-GAAP</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
Income Statement Classifications:			
Revenue	\$ 3,160		\$ 3,160
Research and development	(6,412)	\$ (529)	(6,941)
General and administrative	(4,368)	(818)	(5,186)
Depreciation and amortization	(321)		(321)
Interest income	1,702		1,702
Interest expense	(70)		(70)
(Provision for)/benefit from income taxes	<u>(75)</u>		<u>(75)</u>
Summary:			
Net loss:	<u>\$ (6,384)</u>	<u>\$ (1,347)</u>	<u>\$ (7,731)</u>
Net loss per share - - basic and diluted:	<u>\$ (0.28)</u>	<u>\$ (0.06)</u>	<u>\$ (0.34)</u>
Weighted average number of shares outstanding:	<u>22,412,689</u>		<u>22,412,689</u>

Source: FOLD -G