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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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 13, 2008

**AMICUS THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33497**  
(Commission  
File Number)

**20-0422823**  
(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 (see General Instruction A.2. below):

- 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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EX-99.1: PRESS RELEASE

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**Item 2.02. Results of Operations and Financial Condition.**

On May 13, 2008, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2008. 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 13, 2008

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**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 13, 2008

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

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 13, 2008

## Amicus Therapeutics Announces First Quarter 2008 Financial Results

Strong financial position supports clinical focus on advancing drug candidates  
for treatment of lysosomal storage disorders

**Cranbury, NJ, May 13, 2008** — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company developing small molecule, orally-administered pharmacological chaperones for the treatment of human genetic diseases, today announced financial results for the first quarter of 2008. 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 \$0.34 per share (\$0.28 per share on a non-GAAP basis) for the three months ended March 31, 2008. As of March 31, 2008, cash, cash equivalents, and marketable securities totaled \$154.6 million.

“In the first quarter of 2008, we continued to advance our three lead clinical development programs. We also reported data from multiple clinical trials that add to the growing body of evidence demonstrating that treatment with our oral pharmacological chaperone drug candidates has the potential to benefit patients with Fabry, Gaucher and Pompe disease,” said John F. Crowley, President and CEO of Amicus Therapeutics. “In the months ahead in 2008, we will be focused on advancing the global regulatory plan for Amigal Phase 3 development, evaluating opportunities for additional clinical studies in Gaucher and Pompe disease, as well as on identifying new therapeutic areas for applying our pharmacological chaperone technology platform.”

### Program Advancements

#### Fabry Disease:

Amigal™ (migalastat hydrochloride) is an investigational, oral therapeutic being developed for the treatment of Fabry disease. In March, clinical investigators presented positive results from Phase 2 clinical trials of Amigal at the American College of Medical Genetics (ACMG) meeting. The data showed that Amigal was generally safe and well-tolerated at all doses evaluated and no drug-related serious adverse events were reported. In addition, Amigal increased the level of the enzyme deficient in Fabry patients in 24 of 26 study subjects and in a majority of study subjects the treatment resulted in a reduction of kidney GL-3 as measured in urine.

Amicus, along with its partner Shire, has initiated discussions with the U. S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regarding its plans for Phase 3 clinical evaluation of Amigal. Amicus expects to complete these interactions and provide an update in the second half of 2008, and subject to the outcome of the discussions, the Company plans to initiate the Phase 3 clinical trial in the first half of 2009.

In parallel with the regulatory process, 23 of the original 26 patients continue to be treated with Amigal in the voluntary Phase 2 extension study to monitor long term safety and efficacy. In addition, the Company will evaluate modified doses and dose regimens in these 23 patients. Data from this extension study are expected to be available by Q1 2009, prior to finalization of the Phase 3 protocol.

#### Gaucher Disease:

Plicera™ (isofagomine tartrate) is an investigational, oral therapeutic being developed for the treatment of Gaucher disease. At the ACMG meeting in March, clinical investigators presented full data from a 4 week

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Phase 2 study in Gaucher patients who switched from enzyme replacement therapy (ERT) with imiglucerase to the pharmacological chaperone Plicera. Results showed that Plicera was generally safe and well tolerated at all doses and increased target enzyme activity levels in a majority of patients. In the trial, GCCase activity, as measured in white blood cells, was increased in 20 of the 26 patients with evaluable GCCase data, and 5 of the 6 patients without a clear increase were either in the lowest dose cohort or the cohort dosed least frequently. As expected in this short term study, the levels of relevant hematological markers of Gaucher disease remained stable.

Amicus has amended the protocol for the 6-month Phase 2 clinical trial of Plicera patients naive to ERT to include modified doses and dose regimens. Amicus expects the results of this study to be available in 2009. In addition, in the second half of 2008, the Company expects to initiate a longer-term study in individuals switching from ERT to Plicera.

#### Pompe Disease:

AT2220 (1-deoxynojirimycin HCl) is an investigational, oral therapeutic drug candidate being developed for the treatment of Pompe disease. At the ACMG meeting in March clinical investigators presented encouraging results from an ex vivo response study in cells from patients with Pompe disease as well as three Phase 1 clinical trials of AT2220 in healthy volunteers. The ex vivo response study was designed to test the effect of AT2220 on various Pompe mutations. Blood and skin samples were collected from 30 Pompe patients (26 adults, 3 juveniles and 1 infant) with a variety of different mutations in acid alpha-glucosidase (GAA), the target enzyme in Pompe disease. Cells from these samples were then treated with AT2220. Of the 26 patients with available data, 24 had cells that showed a dose responsive increase in GAA levels including 22 patients who had at least 1 copy of the common splice site mutation IVS1-13T>G. Data from the Phase 1 trials in a total of 72 healthy volunteers showed that AT2220 was generally safe and well tolerated at all doses.

In the second quarter of 2008, Amicus plans to initiate a Phase 2 clinical trial of AT2220 in patients with Pompe disease. The Company also plans to consider the initiation of a clinical trial of AT2220-ERT combination treatment in Pompe patients later in 2008.

#### Other Chaperone Programs:

Amicus is accelerating its investment in research and development to assess the potential for using pharmacological chaperones to treat a broader range of human genetic diseases beyond lysosomal storage diseases. As part of this effort, Amicus continues to conduct preclinical studies in Parkinson's disease, funded in part by a grant from the Michael J. Fox Foundation. In addition to the work in Parkinson's, Amicus is investing in new research aimed at evaluating disease targets for other neurodegenerative disorders and metabolic disorders.

#### Shire Collaboration:

In November 2007, Amicus entered into a strategic collaboration with Shire Human Genetic Therapies (HGT), a business unit of Shire plc, to jointly develop Amicus' three lead pharmacological chaperone compounds for lysosomal storage disorders, Amigal, Plicera and AT2220. In this collaboration valued at up to \$440 million including an up front payment and success based clinical and sales milestones and excluding royalties and cost sharing, Shire also reimburses worldwide development costs on a 50/50 basis. Under the agreement, Shire received rights to commercialize these products outside of the United States. Amicus retains all rights to commercialize these products in the United States. Amicus will lead development operations through the end of Phase 2 clinical trials. The companies will 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.

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## Additional Financial Results & Notes

On a reported basis, the net loss attributable to common stockholders for the three months ended March 31, 2008, was \$7.7 million as compared to \$9.7 million for the same period in 2007. On a non-GAAP basis, the net loss for the three months ended March 31, 2008, was \$6.4 million as compared to \$8.9 million and the same period in 2007.

Amicus recorded revenue during the first quarter of 2008 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 2008, Amicus recognized \$0.7 million of the Shire upfront payment and \$2.5 million of research revenue on reimbursed research and development costs.

Amicus today reiterated its guidance for 2008 cash burn of \$40 million to \$60 million. The Company also stated that it does not expect to raise cash from any equity financings in 2008.

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
- Pre-tax charges for preferred stock accretion
- Pre-tax charges for changes in the fair value of warrant liability

## 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.
  - (2) Other items — Non-GAAP net loss and diluted net loss per common share exclude other unusual or non-recurring items that are evaluated on an individual basis. Amicus' evaluation of whether to exclude an item for purposes of determining its non-GAAP financial measures considers both the quantitative and qualitative aspects of the item, including, among other things (i) its size and nature, (ii) whether or not it relates to its ongoing business operations, and (iii) whether or not Amicus expects it to occur as part of its normal business on a regular basis. Items excluded for purposes of determining non-GAAP net loss and diluted net loss per common share include deemed dividends, preferred stock accretion, and changes in the fair value of warrant liability.
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## **Conference Call and Webcast: First Quarter Financial Results**

Amicus Therapeutics will host a conference call and webcast today, Tuesday, May 13, 2008, at 5:00 P.M. EDT to review financial results and recent developments. Interested participants and investors may access the teleconference call by dialing 877-397-0284 (U.S./Canada) or 719-325-4871 (international).

The webcast of the call can be accessed on the Investor section of Amicus' Web site at [www.amicustherapeutics.com](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 replay will remain available in the Investors section of Amicus' Web site for 90 days.

A telephonic replay will also be available for seven days beginning at 8 p.m. EDT. Access numbers for this replay are 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 4106309.

Amicus' press releases are available at [www.amicustherapeutics.com](http://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 completed Phase 2 clinical trials of Amigal for the treatment of Fabry disease and is conducting Phase 2 clinical trials of Plicera for the treatment of Gaucher disease. The Company recently completed Phase I clinical trials of AT2220 for the treatment of Pompe disease.

## **Forward-Looking Statements**

This Press release contains and the accompanying conference call will contain "forward-looking statements" within the meaning of Section 21E 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. Examples of such statements include: (i) statements regarding the goals and expected timing of clinical studies, including the effect of the completion of the Phase 2 clinical trial for Amigal for the treatment of Fabry disease, the timing and design of Phase 3 clinical development for Amigal, the Phase 2 clinical trials for Plicera for the treatment of Gaucher disease, the effect of the completion of the Phase 1 clinical trials for AT2220 for the treatment of Pompe disease, the start of Phase 2 studies for AT2220 and the possibility and timing of conducting clinical trials of AT2220 and ERT combination therapy; (ii) statements regarding the timing and goals of discussions with US and EU regulatory authorities on the Phase 3 study and regulatory pathway for Amigal; (iii) statements on the goals, progress and timing of preclinical studies in Parkinson's disease and other research efforts aimed at evaluating disease targets in neurodegenerative and metabolic disorders; (iv) statements on the range of "cash burn" for Amicus in 2008, the need to raise additional capital in 2008 and the trends for incurring research and development expense in 2008; and (v) statements regarding expected milestone and research reimbursement payments from Shire. These forward looking statements are based on the current estimates and assumptions of the management of Amicus as of the date of this press release and the conference call and are subject to risks, changes in circumstances, assumptions and uncertainties and other factors that may cause the actual results of Amicus to be materially different from those reflected in the forward looking statements. Important factors that may cause actual results to differ materially from those indicated by forward looking statements include, among others, the potential that results of clinical or preclinical studies indicate that product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals, risks of relying on third party manufacturers for the supply of our product candidates, we or our licensors may not be able to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our product candidates and risks of collaborating with third parties to

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develop and commercialize products. These and other risks are described in greater detail in our Annual Report on Form 10-K for the year ended December 31, 2007 and our other filings with the Securities and Exchange Commission. You should not place undue reliance on these forward looking statements because of these uncertainties, and the inclusion of forward-looking statements should not be regarded as a representation by Amicus that any of its plans will be achieved. We assume no obligation to update forward looking statements. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

CONTACTS:

Investors:  
John Quirk  
Porter Novelli Life Sciences  
(212) 601-8296

Media:  
Cory Tromblee  
Porter Novelli Life Sciences  
(617) 897-8294

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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, 2008
	2007	2008	2008
<b>Revenue:</b>			
Research revenue	\$ —	\$ 2,466	\$ 3,841
Collaboration revenue	—	694	1,103
<b>Total revenue</b>	<u>—</u>	<u>3,160</u>	<u>4,944</u>
<b>Operating Expenses:</b>			
Research and development	7,085	6,941	96,819
General and administrative	2,850	5,186	43,256
Impairment of leasehold improvements	—	—	1,030
Depreciation and amortization	297	321	3,115
In-process research and development	—	—	418
<b>Total operating expenses</b>	<u>10,232</u>	<u>12,448</u>	<u>144,638</u>
Loss from operations	(10,232)	(9,288)	(139,694)
<b>Other income (expenses):</b>			
Interest income	693	1,702	9,643
Interest expense	(92)	(70)	(1,500)
Change in fair value of warrant liability	(64)	—	(454)
Other expense	—	—	(1,180)
Loss before tax benefit	(9,695)	(7,656)	(133,185)
(Provision for)/benefit from income taxes	—	(75)	620
Net loss	(9,695)	(7,731)	(132,565)
Deemed dividend	—	—	(19,424)
Preferred stock accretion	(41)	—	(802)
<b>Net loss attributable to common stockholders</b>	<u>\$ (9,736)</u>	<u>\$ (7,731)</u>	<u>\$(152,791)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (10.21)</u>	<u>\$ (0.34)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>953,959</u>	<u>22,412,689</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, 2008**  
**(Unaudited)**  
**(In thousands, except share and per share amounts)**

<b>Income Statement Classifications:</b>	<u>Non-GAAP</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
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>
<b>Summary:</b>			
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>

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Table 3

**Amicus Therapeutics, Inc.**  
**Reconciliation of GAAP to non-GAAP Measures for the**  
**Statement of Operations Information for Three Months Ended March 31, 2007**  
**(Unaudited)**  
**(In thousands, except share and per share amounts)**

	<u>Non- GAAP</u>	<u>Change in Fair Value of Warrant Liability</u>	<u>Preferred Stock Accretion</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
<b>Income Statement Classifications:</b>					
Research and development	\$ (6,795)	\$ —	\$ —	\$ (290)	\$ (7,085)
General and administrative	(2,379)			(471)	(2,850)
Depreciation and amortization	(297)				(297)
Interest income	693				693
Interest expense	(92)				(92)
Change in fair value of warrant liability	—	(64)			(64)
Preferred stock accretion	—		(41)		(41)
<b>Summary:</b>					
Net loss:	<u>\$ (8,870)</u>	<u>\$ (64)</u>	<u>\$ (41)</u>	<u>\$ (761)</u>	<u>\$ (9,736)</u>
Net loss per share — basic and diluted:	<u>\$ (9.30)</u>	<u>\$ (0.07)</u>	<u>\$ (0.04)</u>	<u>\$ (0.80)</u>	<u>\$ (10.21)</u>
Weighted average number of shares outstanding:	<u>953,959</u>				<u>953,959</u>

Source: FOLD -G