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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 3, 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)

**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 3, 2008, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 3, 2008

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 3, 2008

## Amicus Therapeutics Announces Third Quarter 2008 Financial Results

### Amicus Makes Steady Progress Toward Achievement of Milestones

**Cranbury, NJ, November 3, 2008** — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the third 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 \$0.36 per share (\$0.29 per share on a non-GAAP basis) for the three months ended September 30, 2008. As of September 30, 2008, cash, cash equivalents, and marketable securities totaled \$136.3 million.

“The third quarter of 2008 was another quarter of strong progress for Amicus as we focused on clinical and regulatory execution on our three lysosomal storage disease programs,” said John F. Crowley, President and CEO of Amicus Therapeutics. “In recent months, we have continued the process with regulatory authorities in the United States and Europe in order to define the global development plan for Amigal™ in Fabry, and we remain on track to provide an update by the end of the year. In our Gaucher and Pompe disease programs, we continue to focus on advancing our ongoing Phase 2 clinical trials with the goal of reporting data in Gaucher in 2009. Finally, our financial position remains strong based on a healthy balance sheet and on the economics from our strategic alliance with Shire, which funds 50% of development costs for our lead programs in addition to success-based clinical and regulatory milestone payments.”

#### Program Advancements

Fabry Disease:

Amigal (migalastat hydrochloride) is an investigational, oral therapeutic being developed for the treatment of Fabry disease. Amicus, along with its partner Shire Human Genetic Therapies, Inc. (“Shire”), is engaged in ongoing discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and will provide an update by the end of the year. A final decision on the global development strategy will follow the conclusion of the discussions with both agencies. Subject to the outcome of the discussions, the Company expects to initiate Phase 3 development of Amigal in the first half of 2009.

In addition, 23 of the original 26 patients continue to be treated in a voluntary Phase 2 extension study designed to monitor long-term safety and efficacy and to evaluate additional doses and dose regimens. Data from this extension study are expected in Q1 2009 prior to the start of the Phase 3 study.

Gaucher Disease:

Plicera™ (isofagomine tartrate) is an investigational, oral therapeutic in Phase 2 development for the treatment of Gaucher disease. As previously disclosed, a 6-month Phase 2 clinical trial of Plicera in patients naive to ERT is ongoing and Amicus expects the results of this study to be available in 2009.

#### Pompe Disease:

AT2220 (1-deoxynojirimycin HCl) is an investigational, oral therapeutic being developed for the treatment of Pompe disease. As previously disclosed, a Phase 2 clinical trial of AT2220 in adult Pompe patients is ongoing and includes an 11 week treatment period with an optional extension study.

In addition, Amicus is conducting preclinical animal studies to evaluate the effects of administering AT2220 in combination with enzyme replacement therapy. Based on the results of the preclinical work, Amicus will consider initiating a clinical trial of the AT2220-ERT combination treatment in Pompe patients.

#### Other Chaperone Programs:

Amicus continues to invest 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 and is investing in new research aimed at evaluating disease targets for other neurodegenerative and genetic disorders. In September 2008, the Company entered into a lease for laboratory space for a small scale research facility in San Diego, Calif. This facility will complement Amicus' core research and development activities in New Jersey, while allowing closer access to the significant scientific and biotechnology resources in the San Diego community.

#### Shire 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. 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 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 September 30, 2008, was \$8.2 million as compared to \$10.3 million for the same period in 2007. On a non-GAAP basis, the net loss for the three months ended September 30, 2008, was \$6.6 million as compared to \$9.2 million in the same period in 2007.

Amicus recorded revenue during the third 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 third quarter 2008, Amicus recognized \$0.7 million of the Shire upfront payment and \$3.0 million of research revenue on reimbursed research and development costs.

Amicus today reiterated its most recent guidance for 2008 cash burn of \$40 million to \$50 million. The Company also reiterated 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.

## 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.

## Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, Monday, November 3, 2008, at 5:00 P.M. EST to review financial results and recent developments. Interested participants and investors may access the conference call at 5 P.M. EST by dialing 877-419-6591 (U.S./Canada) or 719-325-4858 (international).

An audio webcast 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 90 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 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 4499321.

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 and AT2220 for the treatment of Pompe disease.

## Forward-Looking Statements

This Press release contains and the accompanying conference call will contain “forward-looking statements” as that term is defined in 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, progress and expected timing of clinical studies, including the progress, timing and design of Phase 3 clinical development for Amigal, the progress and timing of the availability of data from the Phase 2 extension study of Amigal, the progress and timing of Phase 2 clinical trials for Plicera for the treatment of Gaucher disease, the timing of the release of data from the Phase 2 clinical trials for Plicera, the initiation of Phase 2 clinical development of AT2220 for the treatment of Pompe disease, 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 other genetic 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,
- a change in strategy by our collaboration partners,
- delays or failure to achieve final agreement with regulatory authorities on the design of phase 3 program for Amigal and the regulatory pathway for approval of Amigal,
- delays or failure to achieve regulatory approvals for our products,
- risks of relying on third party manufacturers for the supply of our product candidates,
- our or licensors inability 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 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:

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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
	Ended September 30, 2007	2008	Ended September 30, 2007	2008	February 4, 2002 (inception) to September 30, 2008
<b>Revenue:</b>					
Research revenue	\$ —	\$ 2,959	\$ —	\$ 8,539	\$ 9,913
Collaboration revenue	—	694	—	2,083	2,491
Total revenue	<u>—</u>	<u>3,653</u>	<u>—</u>	<u>10,622</u>	<u>12,404</u>
<b>Operating Expenses:</b>					
Research and development	7,537	8,200	21,404	23,989	113,867
General and administrative	3,954	4,371	9,994	14,676	52,745
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	315	382	924	1,036	3,829
In-process research and development	—	—	—	—	418
Total operating expenses	<u>11,806</u>	<u>12,953</u>	<u>32,322</u>	<u>39,701</u>	<u>171,889</u>
Loss from operations	(11,806)	(9,300)	(32,322)	(29,079)	(159,485)
<b>Other income (expenses):</b>					
Interest income	1,593	1,019	3,346	4,053	11,993
Interest expense	(90)	(49)	(269)	(179)	(1,608)
Change in fair value of warrant liability	—	—	(149)	—	(454)
Other expense	—	—	—	—	(1,180)
Loss before tax benefit	(10,303)	(8,330)	(29,394)	(25,205)	(150,734)
Benefit from income taxes	—	150	—	—	695
Net loss	(10,303)	(8,180)	(29,394)	(25,205)	(150,039)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	(351)	—	(802)
Net loss attributable to common stockholders	<u>\$ (10,303)</u>	<u>\$ (8,180)</u>	<u>\$ (29,745)</u>	<u>\$ (25,205)</u>	<u>\$ (170,265)</u>
Net loss attributable to common stockholders per common share —					
basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.36)</u>	<u>\$ (2.92)</u>	<u>\$ (1.12)</u>	
<b>Weighted-average common shares outstanding —</b>					
basic and diluted	<u>22,291,832</u>	<u>22,517,431</u>	<u>10,177,449</u>	<u>22,465,981</u>	

Table 2

**Amicus Therapeutics, Inc.**  
**Reconciliation of GAAP to non-GAAP Measures for the**  
**Statement of Operations Information for Three Months Ended September 30, 2008**  
**(Unaudited)**  
(In thousands, except share and per share amounts)

	<u>Non-GAAP</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
<b>Income Statement Classifications:</b>			
Revenue	\$ 3,653		\$ 3,653
Research and development	(7,597)	\$ (603)	(8,200)
General and administrative	(3,358)	(1,013)	(4,371)
Depreciation and amortization	(382)		(382)
Interest income	1,019		1,019
Interest expense	(49)		(49)
(Provision for)/benefit from income taxes	<u>150</u>		<u>150</u>
<b>Summary:</b>			
Net loss:	<u>\$ (6,564)</u>	<u>\$ (1,616)</u>	<u>\$ (8,180)</u>
Net loss per share — basic and diluted:	<u>\$ (0.29)</u>	<u>\$ (0.07)</u>	<u>\$ (0.36)</u>
Weighted average number of shares outstanding:	<u>22,517,431</u>		<u>22,517,431</u>

Table 3

**Amicus Therapeutics, Inc.**  
**Reconciliation of GAAP to non-GAAP Measures for the**  
**Statement of Operations Information for Three Months Ended September 30, 2007**  
**(Unaudited)**  
(In thousands, except share and per share amounts)

	<u>Non-GAAP</u>	<u>Stock Compensation</u>	<u>GAAP as Reported</u>
<b>Income Statement Classifications:</b>			
Research and development	\$ (7,090)	\$ (447)	\$ (7,537)
General and administrative	(3,293)	(661)	(3,954)
Depreciation and amortization	(315)		(315)
Interest income	1,593		1,593
Interest expense	<u>(90)</u>	<u>                    </u>	<u>(90)</u>
<b>Summary:</b>			
Net loss:	<u>\$ (9,195)</u>	<u>\$ (1,108)</u>	<u>\$ (10,303)</u>
Net loss per share — basic and diluted:	<u>\$ (0.41)</u>	<u>\$ (0.05)</u>	<u>\$ (0.46)</u>
Weighted average number of shares outstanding:	<u>22,291,832</u>		<u>22,291,832</u>

Source: FOLD -G