
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 5, 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 February 5, 2009, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 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 February 5, 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: February 5, 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 February 5, 2009

**Amicus Therapeutics Announces Fourth Quarter
and Full Year 2008 Financial Results**

**Company Advancing Core Lysosomal Storage Disorder Programs to Key Milestones in 2009; Expects Continued Strong
Financial Position**

CRANBURY, N.J., February 5, 2009 – Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the fourth quarter and full year 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 \$0.63 per share (\$0.55 per share on a non-GAAP basis) for the three months ended December 31, 2008. For the year ended December 31, 2008, on a GAAP basis, the net loss attributable to common stockholders was \$1.75 per share (\$1.46 per share on a non-GAAP basis). As of December 31, 2008, cash, cash equivalents, and marketable securities totaled \$121 million.

“In 2008, we made great strides in advancing our lead clinical development programs for Fabry, Gaucher and Pompe diseases while maintaining a strong financial position. We plan to continue this momentum and believe 2009 will be a transformational year for Amicus, as we are committed to achieving several key milestones and to transitioning into a late-stage biopharmaceutical company,” said John F. Crowley, Amicus’ president and CEO.

Clinical Program Advancements

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

In the fourth quarter of 2008, Amicus continued to work closely with the U.S. and E.U. regulatory authorities to advance its lead program, Amigal, into Phase 3 development. As previously announced, the Company plans to initiate Phase 3 development of Amigal for the treatment of Fabry disease in the second quarter of 2009.

In January 2009, the Company announced that the FDA supports a Phase 3 clinical trial comparing Amigal to placebo based on a surrogate primary endpoint of the change in the amount of kidney GL-3, the substrate that accumulates in the cells of Fabry patients. Amicus is continuing discussions with the FDA through a Special Protocol Assessment (SPA) procedure that commenced in the fourth quarter of 2008 to finalize how the primary endpoint will be measured. The Company is expecting to finalize the protocol in the second quarter of this year.

Based on discussions with the European Medicines Agency (EMA) in the fourth quarter of 2008, the Company plans to initiate a separate clinical trial designed to evaluate the safety and efficacy of Amigal versus enzyme replacement therapy (ERT) in Fabry patients. Amicus and its partner Shire Human Genetic Therapies, Inc. (Shire HGT) plan additional discussions with the EMA to finalize the design of this study.

In parallel with the Phase 3 regulatory discussions, 23 of the original 26 patients from the Phase 2 studies continue to be treated in a voluntary extension study to characterize the long-term safety and efficacy of Amigal and to evaluate additional doses and dose regimens. Amicus expects data from this extension study to be available in the first quarter of 2009.

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

During the fourth quarter, Amicus also focused on executing its ongoing Phase 2 clinical trial of Plicera in Gaucher disease. This 6-month study is designed to evaluate safety and to demonstrate trends of efficacy, as measured by the standard endpoints in Gaucher disease. Amicus previously reported that target enrollment is expected to be surpassed in the study and the Company expects the results to be available 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.

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

Amicus continued to make progress throughout the fourth quarter with its ongoing Phase 2 clinical trial of AT2220 in adult Pompe patients. The trial includes an 11-week treatment period with an optional extension study. The objectives of the trial include the evaluation of the safety and pharmacodynamics of multiple doses and regimens of AT2220. The results of this study are expected to be available in the second half of 2009.

In addition, Amicus is continuing to conduct preclinical animal studies to evaluate the effects of administering AT2220 in combination with ERT. Results announced at the American Society of Human Genetics conference in November 2008 indicate that AT2220 in combination with ERT has the potential to increase the stability and tissue uptake of ERT. Amicus is conducting additional preclinical proof-of-concept studies to determine the feasibility of a combination that may be appropriate for Pompe patients who are not amenable to chaperone monotherapy. Amicus expects to discuss additional results at relevant scientific conferences during 2009.

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.

2009 Financial Guidance

In 2009, Amicus expects to report approximately \$70 million in operating expenses, which it expects to be offset by approximately \$50 million in program cost-sharing reimbursements and clinical milestone payments from Shire. The Company's 2009 net cash burn is expected to be approximately \$20 million. Amicus anticipates ending 2009 with approximately \$100 million in cash.

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. 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 December 31, 2008, was \$14.2 million as compared to \$11.8 million for the same period in 2007. On a non-GAAP basis, the net loss for the three months ended December 31, 2008, was \$12.5 million as compared to \$10.7 million in the same period in 2007.

Amicus recorded revenue during the fourth 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 fourth quarter 2008, Amicus recognized \$0.7million of the Shire upfront payment and \$3.7 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 through 5 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, Thursday, February 5, 2009, at 5:00 P.M. EST to review financial results and recent developments. Interested participants and investors may access the conference call by dialing 877-675-4756 (U.S./Canada) or 719-325-4870 (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 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 8627644.

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 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.

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 use of a surrogate endpoint and 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.

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		Twelve Months		Period from
	Ended December 31,		Ended December 31,		February 4,
	2007	2008	2007	2008	2002
					(inception)
					to
					December 31,
					2008
Revenue:					
Research revenue	\$ 1,375	\$ 3,650	\$ 1,375	\$ 12,189	\$ 13,564
Collaboration revenue	409	695	409	2,778	3,187
Total revenue	<u>1,784</u>	<u>4,345</u>	<u>1,784</u>	<u>14,967</u>	<u>16,751</u>
Operating Expenses:					
Research and development	9,670	13,775	31,074	37,764	127,642
General and administrative	5,284	4,990	15,278	19,666	57,736
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	313	457	1,237	1,493	4,287
In-process research and development	—	—	—	—	418
Total operating expenses	<u>15,267</u>	<u>19,222</u>	<u>47,589</u>	<u>58,923</u>	<u>191,113</u>
Loss from operations	(13,483)	(14,877)	(45,805)	(43,956)	(174,362)
Other income (expenses):					
Interest income	1,789	766	5,135	4,819	12,760
Interest expense	(79)	(39)	(348)	(218)	(1,648)
Change in fair value of warrant liability	—	—	(149)	—	(454)
Other expense	—	—	—	—	(1,180)
Loss before tax benefit	(11,773)	(14,150)	(41,167)	(39,355)	(164,884)
Income tax benefit	—	—	—	—	695
Net loss	(11,773)	(14,150)	(41,167)	(39,355)	(164,189)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	(351)	—	(802)
Net loss attributable to common stockholders	<u>\$ (11,773)</u>	<u>\$ (14,150)</u>	<u>\$ (41,518)</u>	<u>\$ (39,355)</u>	<u>\$ (184,415)</u>
Net loss attributable to common stockholders per common share – basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.63)</u>	<u>\$ (3.14)</u>	<u>\$ (1.75)</u>	
Weighted-average common shares outstanding – basic and diluted	<u>22,343,974</u>	<u>22,576,561</u>	<u>13,235,755</u>	<u>22,493,803</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 December 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	\$ 4,345		\$ 4,345
Research and development	(13,112)	\$ (663)	(13,775)
General and administrative	(4,025)	(965)	(4,990)
Depreciation and amortization	(457)		(457)
Interest income	766		766
Interest expense	(39)		(39)
Summary:			
Net loss:	<u>\$ (12,522)</u>	<u>\$ (1,628)</u>	<u>\$ (14,150)</u>
Net loss per share — basic and diluted:	<u>\$ (0.55)</u>	<u>\$ (0.07)</u>	<u>\$ (0.63)</u>
Weighted average number of shares outstanding:	<u>22,576,561</u>		<u>22,576,561</u>

Table 3

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Three Months Ended December 31, 2007
(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	\$ 1,784		\$ 1,784
Research and development	(9,235)	\$ (435)	(9,670)
General and administrative	(4,608)	(676)	(5,284)
Depreciation and amortization	(313)		(313)
Interest income	1,789		1,789
Interest expense	(79)		(79)
Summary:			
Net loss:	\$ (10,662)	\$ (1,111)	\$ (11,773)
Net loss per share — basic and diluted:	\$ (0.48)	\$ (0.05)	\$ (0.53)
Weighted average number of shares outstanding:	<u>22,343,974</u>		<u>22,343,974</u>

Table 4

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Year Ended December 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	\$ 14,967		\$ 14,967
Research and development	(35,272)	\$ (2,492)	(37,764)
General and administrative	(15,711)	(3,955)	(19,666)
Depreciation and amortization	(1,493)		(1,493)
Interest income	4,819		4,819
Interest expense	(218)		(218)
Summary:			
Net loss:	<u>\$ (32,908)</u>	<u>\$ (6,447)</u>	<u>\$ (39,355)</u>
Net loss per share — basic and diluted:	<u>\$ (1.46)</u>	<u>\$ (0.29)</u>	<u>\$ (1.75)</u>
Weighted average number of shares outstanding:	<u>22,493,803</u>		<u>22,493,803</u>

Table 5

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

	Non-GAAP	Change in Fair Value of Warrant Liability	Preferred Stock Accretion	Stock Compensation	GAAP as Reported
Income Statement Classifications:					
Revenue	\$ 1,784				\$ 1,784
Research and development	(29,480)	\$ —	\$ —	\$ (1,594)	(31,074)
General and administrative	(12,887)			(2,391)	(15,278)
Depreciation and amortization	(1,237)				(1,237)
Interest income	5,135				5,135
Interest expense	(348)				(348)
Change in fair value of warrant liability	—	(149)			(149)
Preferred stock accretion	—		(351)		(351)
Summary:					
Net loss:	<u>\$ (37,033)</u>	<u>\$ (149)</u>	<u>\$ (351)</u>	<u>\$ (3,985)</u>	<u>\$ (41,518)</u>
Net loss per share — basic and diluted:	<u>\$ (2.80)</u>	<u>\$ (0.01)</u>	<u>\$ (0.03)</u>	<u>\$ (0.30)</u>	<u>\$ (3.14)</u>
Weighted average number of shares outstanding:	<u>13,235,755</u>				<u>13,235,755</u>

Source: FOLD -G