
**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): **August 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 August 5, 2009, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 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: August 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 August 5, 2009

**Amicus Therapeutics Announces Second Quarter
2009 Financial Results**

**Company Successfully Transitions into Late-Stage Development with Amigal for Fabry Disease
Entering Phase 3**

CRANBURY, N.J., August 5, 2009 — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the second 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 \$0.60 per share (\$0.51 per share on a non-GAAP basis) for the three months ended June 30, 2009. As of June 30, 2009, cash, cash equivalents, and marketable securities totaled \$100.4 million.

John F. Crowley, President and CEO of Amicus stated, "The second quarter was marked by a significant achievement for Amicus with our lead program, Amigal for Fabry disease, entering Phase 3 development." Crowley continued, "This is a major step for the Company as we have now transitioned to a late-stage biopharmaceutical company and are one step closer to bringing to market an important, novel treatment to patients who suffer with Fabry disease."

Clinical Program Updates

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

In the second quarter of 2009, Amicus announced that the Company reached agreement with the U.S. Food and Drug Administration (FDA) on the key protocol design elements of its pivotal trial, including the use of the surrogate primary endpoint of the change in the amount of kidney interstitial capillary GL-3, the substrate that accumulates in the cells of Fabry patients. In addition, the FDA is in agreement that the Company is eligible to seek Accelerated Approval for Amigal according to Subpart H regulations. Amicus has begun submitting the Phase 3 protocol to investigational sites worldwide and expects to begin the dosing of subjects in the second half of this year.

As previously announced, the Phase 3 trial will evaluate the efficacy, safety and pharmacodynamics of Amigal in males and females with Fabry disease. The trial will consist of a six-month double-blind, randomized, placebo-controlled treatment stage and will enroll approximately 60 subjects who are naïve to enzyme replacement therapy (ERT) or who have not received ERT for at least six months prior to the start of treatment with Amigal. The Amigal treatment arm dose and regimen will be 150 mg every other day.

The primary endpoint will be the change in the amount of kidney interstitial capillary GL-3 as measured in kidney biopsies using histology. Secondary endpoints will include safety and tolerability, kidney GL-3 as measured in urine, and an assessment of renal function (including glomerular filtration rate (GFR) and 24-hour urine protein).

Additionally, the FDA and Amicus reached agreement on an improved methodology for the histological evaluation of GL-3 in the kidney biopsies. An analysis of the Phase 2 and Phase 2 extension study biopsies using the improved methodology demonstrated that all of the evaluable baseline samples had detectable interstitial capillary GL-3 and that reductions were observed in 8 of the 9 responders.

It is expected that approximately 30 clinical sites worldwide will participate in this trial.

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, dosing, and preliminary efficacy, as measured by the standard endpoints in Gaucher disease. The Company expects to report the results early in the fourth quarter of 2009.

Amicus continues 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

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 continues to work closely with the FDA to determine appropriate next steps for advancing the development of AT2220 and expects to provide guidance on this progress over the upcoming months.

Additionally, Amicus continues to be encouraged with its preclinical studies with AT2220 in combination with ERT. As previously announced, the Company expects to report additional data from these activities throughout the remainder of 2009.

Preclinical Chaperone Programs

Amicus continues to invest in research to assess the potential for applying its versatile chaperone technology platform to the treatment of a broad 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.

Appointment of New Director

The Company announced today the election of James Barrett, Ph.D., to its Board of Directors. Dr. Barrett currently serves as General Partner of New Enterprise Associates (NEA), the Company's single largest shareholder, where he specializes in biotechnology and works with members of NEA's healthcare investment group on medical devices, healthcare information systems and healthcare services companies. Prior to joining NEA in 2001, Dr. Barrett served as Founder, Chairman and CEO of Sensors for Medicine and Science (1997 — 2001) where he remains Chairman. Prior to that, he led three NEA-funded companies, serving as Chairman and CEO of Genetic Therapy, Inc. (1987 — 1995), President and CEO of Life Technologies (1985 — 1987), and President and CEO of Bethesda Research Labs (1982 — 1983). He currently serves on the Board of Directors for several life sciences companies including Inhibitex, Inc. (NASDAQ: INHX) and Targacept, Inc. (NASDAQ: TRGT).

Dr. Barrett received a Ph.D. in Biochemistry at the University of Tennessee, his MBA from the University of Santa Clara, and a BS in Chemistry from Boston College.

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 June 30, 2009, was \$13.6 million as compared to \$9.3 million for the same period in 2008. On a non-GAAP basis, the net loss for the three months ended June 30, 2009, was \$11.5 million as compared to \$7.4 million in the same period in 2008.

Amicus recorded revenue during the second 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 second quarter of 2009, Amicus recognized \$0.7 million of the Shire upfront payment and \$4.7 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 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.
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Conference Call and Webcast

We will host a conference call to discuss financial and operational results for the second quarter 2009, today, August 5, 2009 at 5 p.m. EDT. Interested participants and investors may access the conference call by dialing 877-591-4949 (U.S./Canada) or 719-325-4889 (international). A telephonic replay of the call will 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 4035217.

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 NEA

New Enterprise Associates, Inc. (NEA) is a leading venture capital firm focused on helping entrepreneurs create and build major new enterprises that use technology to improve the way we live, work and play. Since its founding in 1978, the firm has followed the same core principles: supporting its entrepreneurs, providing an excellent return to its limited partners, and practicing its profession with the highest standards and respect. Through its affiliated funds, NEA focuses on investments at all stages of a company's development, from seed stage through IPO. With approximately \$8.5 billion in committed capital, NEA's experienced management team has invested in over 650 companies, of which more than 160 have gone public and more than 250 have been acquired. NEA has U.S. offices in Chevy Chase, Maryland; Menlo Park, California; and Baltimore, Maryland. In addition, New Enterprise Associates (India) Pvt. Ltd. has offices in Bangalore and Mumbai, India and New Enterprise Associates (Beijing), Ltd. has offices in Beijing and Shanghai, China. For additional information, visit www.nea.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 relating to preclinical and clinical development of Amicus’ candidate drug products, the timing and reporting of results from preclinical studies and clinical trial evaluating Amicus’ candidate drug products, and the timing of updates on the interactions with the FDA on the AT2220 program. 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 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 inability to reach final agreement with regulatory agencies on the lifting of the clinical hold on the AT2220 program; 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 preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; 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. 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:

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 June 30,		Six Months Ended June 30,		Period from February 4, 2002 (inception) to June 30, 2009
	2008	2009	2008	2009	2009
Revenue:					
Research revenue	\$ 3,113	\$ 4,667	\$ 5,579	\$ 8,580	\$ 22,143
Collaboration revenue	694	694	1,389	1,389	4,576
Total revenue	<u>3,807</u>	<u>5,361</u>	<u>6,968</u>	<u>9,969</u>	<u>26,719</u>
Operating Expenses:					
Research and development	8,848	13,470	15,789	25,345	152,987
General and administrative	5,118	5,223	10,305	10,419	68,154
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	332	519	653	1,024	5,311
In-process research and development	—	—	—	—	418
Total operating expenses	<u>14,298</u>	<u>19,212</u>	<u>26,747</u>	<u>36,788</u>	<u>227,900</u>
Loss from operations	(10,491)	(13,851)	(19,779)	(26,819)	(201,181)
Other income (expenses):					
Interest income	1,331	269	3,034	795	13,555
Interest expense	(59)	(41)	(129)	(71)	(1,718)
Change in fair value of warrant liability	—	—	—	—	(454)
Other expense	—	—	—	—	(1,180)
Loss before tax benefit	(9,219)	(13,623)	(16,874)	(26,095)	(190,978)
(Provision for)/benefit from income taxes	(75)	—	(150)	—	695
Net loss	(9,294)	(13,623)	(17,024)	(26,095)	(190,283)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (9,294)</u>	<u>\$ (13,623)</u>	<u>\$ (17,024)</u>	<u>\$ (26,095)</u>	<u>\$ (210,509)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.60)</u>	<u>\$ (0.76)</u>	<u>\$ (1.15)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>22,467,198</u>	<u>22,618,026</u>	<u>22,439,893</u>	<u>22,615,951</u>	

Table 2

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Three Months Ended June 30, 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	\$ 5,361		\$ 5,361
Research and development	(12,628)	\$ (842)	(13,470)
General and administrative	(3,968)	(1,255)	(5,223)
Depreciation and amortization	(519)		(519)
Interest income	269		269
Interest expense	<u>(41)</u>		<u>(41)</u>
Summary:			
Net loss:	<u>\$ (11,526)</u>	<u>\$ (2,097)</u>	<u>\$ (13,623)</u>
Net loss per share — basic and diluted:	<u>\$ (0.51)</u>	<u>\$ (0.09)</u>	<u>\$ (0.60)</u>
Weighted average number of shares outstanding:	<u>22,618,026</u>		<u>22,618,026</u>

Table 3

Amicus Therapeutics, Inc.
Reconciliation of GAAP to non-GAAP Measures for the
Statement of Operations Information for Three Months Ended June 30, 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	\$ 3,807		\$ 3,807
Research and development	(8,151)	\$ (697)	(8,848)
General and administrative	(3,959)	(1,159)	(5,118)
Depreciation and amortization	(332)		(332)
Interest income	1,331		1,331
Interest expense	(59)		(59)
(Provision for)/benefit from income taxes	(75)		(75)
Summary:			
Net loss:	<u>\$ (7,438)</u>	<u>\$ (1,856)</u>	<u>\$ (9,294)</u>
Net loss per share — basic and diluted:	<u>\$ (0.33)</u>	<u>\$ (0.08)</u>	<u>\$ (0.41)</u>
Weighted average number of shares outstanding:	<u>22,467,198</u>		<u>22,467,198</u>

Source: FOLD -G