



Amicus Therapeutics Announces Second Quarter 2008 Financial Results

Successful End of Phase 2 Meeting with the FDA for the Fabry Program and Initiation of Phase 2 Clinical Trial in Pompe are Highlights for the Quarter

CRANBURY, N.J., Aug 07, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- 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 second 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 \$0.41 per share (\$0.33 per share on a non-GAAP basis) for the three months ended June 30, 2008. As of June 30, 2008, cash, cash equivalents, and marketable securities totaled \$145.0 million.

"The second quarter of 2008 was significant for Amicus. We initiated a Phase 2 trial of AT2220 for the treatment of Pompe disease, which is the third product from our pharmacological chaperone platform to enter Phase 2 development. We also successfully completed an End of Phase 2 meeting with the FDA related to our development of Amigal for the treatment of Fabry Disease," said John F. Crowley, President and CEO of Amicus Therapeutics. "In the second half of 2008, we will be focused on finalizing the regulatory plan in Fabry as well as executing on our Gaucher and Pompe Phase 2 clinical programs, and we have tightened our financial outlook as well by reducing our anticipated 2008 cash burn."

Program Advancements

Fabry Disease:

Amigal(TM) (migalastat hydrochloride) is an investigational, oral therapeutic being developed for the treatment of Fabry disease. Previously, Amicus announced that it had successfully completed an End of Phase 2 meeting for Amigal with the U.S. Food and Drug Administration (FDA). The FDA indicated that the data from the completed Phase 2 clinical studies of Amigal support the start of Phase 3 development and agreed that Amigal meets the criteria to be considered for accelerated approval. The Agency further indicated that it is not opposed to the use of a surrogate primary endpoint, pending further discussion and final agreement on the Phase 3 trial design.

Amicus, along with its partner Shire Human Genetic Therapies, Inc. ("Shire"), is engaged in ongoing discussions with FDA and the European Medicines Agency (EMA) regarding plans for a global Phase 3 clinical development program for Amigal. In line with previous guidance, Amicus expects to complete these interactions in the second half of 2008, and subject to the outcome of the discussions, the Company plans to initiate Phase 3 development of Amigal in the first half of 2009.

In parallel with the regulatory process, 23 of the original 26 patients will continue to be treated with Amigal in a voluntary Phase 2 extension study to monitor long term safety and efficacy and to evaluate additional doses and dose regimens. Data from this extension study are expected to be available by Q1 2009. In addition, Amicus expects to conduct clinical pharmacology studies to support the Phase 3 program.

Gaucher Disease:

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

The Company has modified its development plan for Plicera to include a study of the pharmacokinetics of Plicera in Gaucher patients. In addition, the company no longer plans to conduct a longer-term Phase 2 study in patients switching from ERT to Plicera as previously disclosed. The design of the pharmacokinetics study is currently under development.

Pompe Disease:

AT2220 (1-deoxynojirimycin HCl) is an investigational, oral therapeutic being developed for the treatment of Pompe disease. In the second quarter of 2008, Amicus announced that it had initiated a Phase 2 clinical trial of AT2220 (1-deoxynojirimycin HCl). Amicus is conducting the study in adult Pompe patients in clinical centers throughout North America and Europe. AT2220 is the third compound based on Amicus' pharmacological chaperone technology platform to enter Phase 2 clinical development.

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

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, Inc., a wholly-owned subsidiary of Shire Limited, 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 June 30, 2008, was \$9.3 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 June 30, 2008, was \$7.4 million as compared to \$8.3 million in the same period in 2007.

Amicus recorded revenue during the second 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 second quarter 2008, Amicus recognized \$0.7 million of the Shire upfront payment and \$3.1 million of research revenue on reimbursed research and development costs.

Amicus today updated its previous guidance for 2008 cash burn of \$40 million to \$60 million to a new range of \$40 million to \$50 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.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, Thursday, August 7, 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 877-340-7913 (U.S./Canada) or 719-325-4847 (international).

The webcast of the call can be accessed on the Investor section of Amicus' 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 replay will remain available in the Investors section of Amicus' Web site for 90 days.

A telephonic replay will also be available beginning today at 8 P.M. EDT for seven days through Thursday, August 14. Access numbers for this replay are 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 8324472.

Amicus' press releases are available at <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 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 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 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 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.

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Source: FOLD -G

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, 2008
	2007	2008	2007	2008	
Revenue:					
Research revenue	\$-	\$3,113	\$-	\$5,579	\$6,954
Collaboration revenue	-	694	-	1,389	1,797
Total revenue	-	3,807	-	6,968	8,751
Operating Expenses:					
Research and development	6,783	8,848	13,867	15,789	105,667
General and administrative	3,189	5,118	6,040	10,305	48,374
Impairment of leasehold improvements	-	-	-	-	1,030
Depreciation and amortization	312	332	609	653	3,447
In-process research and development	-	-	-	-	418
Total operating					

expenses	10,284	14,298	20,516	26,747	158,936
Loss from operations	(10,284)	(10,491)	(20,516)	(19,779)	(150,185)
Other income (expenses):					
Interest income	1,060	1,331	1,753	3,034	10,974
Interest expense	(86)	(59)	(179)	(129)	(1,559)
Change in fair value of warrant liability	(86)	-	(149)	-	(454)
Other expense	-	-	-	-	(1,180)
Loss before tax benefit	(9,396)	(9,219)	(19,091)	(16,874)	(142,404)
(Provision for)/ benefit from income taxes	-	(75)	-	(150)	545
Net loss	(9,396)	(9,294)	(19,091)	(17,024)	(141,859)
Deemed dividend	-	-	-	-	(19,424)
Preferred stock accretion	(310)	-	(351)	-	(802)
Net loss attributable to common stockholders	\$(9,706)	\$(9,294)	\$(19,442)	\$(17,024)	\$(162,085)
Net loss attributable to common stockholders per common share - basic and diluted	\$(1.37)	\$(0.41)	\$(4.80)	\$(0.76)	
Weighted-average common shares outstanding - basic and diluted	7,083,748	22,467,198	4,051,709	22,439,893	

Table 2

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)

	Non-GAAP	Preferred Stock Accretion	Stock Compensation	GAAP as Reported
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:	\$(7,438)	\$-	\$(1,856)	\$(9,294)
Net loss per share - basic and diluted:	\$(0.33)	\$-	\$(0.08)	\$(0.41)
Weighted average number of shares outstanding:	22,467,198		22,467,198	

Table 3

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

Income Statement Classifications:	Non- GAAP	Change in Fair Value of Warrant Liability	Preferred Stock Accretion	Stock Compensation	GAAP as Reported
Research and development	\$(6,361)	\$-	\$-	\$(422)	\$(6,783)
General and administrative	(2,607)			(582)	(3,189)
Depreciation and amortization	(312)				(312)
Interest income	1,060				1,060
Interest expense	(86)				(86)
Change in fair value of warrant liability	-	(86)			(86)
Preferred stock accretion	-		(310)		(310)
Summary:					
Net loss:	\$(8,306)	\$(86)	\$(310)	\$(1,004)	\$(9,706)
Net loss per share - basic and diluted:	\$(1.17)	\$(0.01)	\$(0.05)	\$(0.14)	\$(1.37)
Weighted average number of shares outstanding:	7,083,748			7,083,748	

SOURCE Amicus Therapeutics

<http://www.amicustherapeutics.com>

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