

AMICUS THERAPEUTICS INC

FORM 8-K

(Current report filing)

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Address	6 CEDAR BROOK DRIVE CRANBURY, NJ 08512
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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): October 26, 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 1.01 Entry into a Material Definitive Agreement.

On October 29, 2009, Amicus Therapeutics, Inc. (the "Company") and Shire Pharmaceuticals Ireland Ltd. ("Shire") entered into a Mutual Termination Agreement (the "Termination Agreement") immediately terminating the License and Collaboration Agreement dated as of November 7, 2007 (the "Original Agreement") between the parties. The Company and Shire agreed to terminate the Original Agreement upon concluding that it is in their respective best interests to no longer collaborate on the development of the Company's three lead pharmacological chaperone compounds for the treatment of lysosomal storage disorders, which were being jointly developed by the parties under the Original Agreement.

Pursuant to the Termination Agreement, Shire has agreed to pay \$5.2 million to the Company as full and final payment for any amounts that may be due to the Company under the Original Agreement. The Termination Agreement relieves both parties of all other future obligations under the Original Agreement, financial or otherwise, other than those select provisions of the Original Agreement that survive termination. As a result of the Termination Agreement, the Company has reacquired all global development and commercialization rights for its three lead compounds. A copy of the Termination Agreement is attached as Exhibit 10.1 to this Current Report.

Item 1.02 Termination of a Material Definitive Agreement.

The information set forth in Item 1.01 of this Current Report is incorporated herein by reference.

Item 2.02 Results of Operations and Financial Condition.

On October 29, 2009, the Company issued a press release announcing its financial results for the quarter ended September 30, 2009. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and 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 2.05 Costs Associated with Exit or Disposal Activities.

On October 28, 2009, the Company committed to a restructuring in order to better align its workforce with its revised operating plans following the previously announced disappointing results of its Phase 2 study of Plicera (afegostat tartrate) for the treatment of Gaucher disease and the termination of its license and collaboration agreement with Shire discussed above. The Company's workforce will be reduced by approximately 20 percent, or 26 employees, through layoffs across all departments and levels throughout the organization. Affected employees are eligible for a severance package that includes severance pay and temporary continuation of benefits. The Company estimates that its costs associated with the workforce reduction will be \$0.9 million, comprised principally of one-time severance payments, unused vacation payments and benefits continuation. These payments will be primarily made in the fourth quarter of 2009. The Company expects the restructuring to be completed during the fourth quarter of 2009.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) In connection with the reduction in workforce discussed in Item 2.05, the Company's Chief Financial Officer, James E. Dentzer, is leaving the Company effective as of October 30, 2009.

(c) On October 28, 2009, the Company appointed John M. McAdam, Senior Director, Finance & Accounting and Corporate Controller of the Company, as its Principal Accounting and Principal Financial Officer and Treasurer. Mr. McAdam, 34, joined the Company in March 2006 as Director of Finance & Accounting and Corporate Controller, and in April 2007 was named Senior Director of Finance & Accounting and Corporate Controller. Mr. McAdam served as the Company's Interim Principal Accounting and Principal Financial Officer from March 2006 to September 2006. From September 2001 to March 2006, Mr. McAdam worked at Quest Diagnostics Incorporated where he served in a variety of financial positions, most recently as Director of Accounting and Reporting. Mr. McAdam is a certified public accountant and member of the New Jersey Society of Public Accountants. Mr. McAdam received a B.S. in Accountancy from Villanova University and an M.B.A. from Rutgers Business School.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits: The Exhibit Index annexed hereto is incorporated herein by reference.

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: October 29, 2009

By: /s/ Geoffrey P. Gilmore
Geoffrey P. Gilmore
Senior Vice President and General Counsel

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1	Mutual Termination Agreement dated as of October 29, 2009 between Amicus Therapeutics, Inc. and Shire Pharmaceuticals Ireland Ltd.
99.1	Press Release dated October 29, 2009

MUTUAL TERMINATION AGREEMENT

This Mutual Termination Agreement (this "Agreement") is entered as of October 29, 2009, between Amicus Therapeutics, Inc., a Delaware corporation ("Amicus"), and Shire Pharmaceuticals Ireland Ltd., a corporation organized under the laws of Ireland ("Shire").

WITNESSETH:

WHEREAS, Shire and Amicus entered into that certain License and Collaboration Agreement (the "Original Agreement") dated as of November 7, 2007; and

WHEREAS, Shire and Amicus have determined that it is in their respective best interests to terminate the Original Agreement effective immediately rather than upon the one hundred eighty (180) days' notice provided under such Section 15.3.1 of the Original Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements contained in this Agreement and intending to be legally bound, the Parties hereto agree as follows:

1. Termination of Original Agreement. Effective as of the date hereof, the Original Agreement shall be terminated in its entirety, including that Sections 15.5 and 15.6 shall be of no further force or effect, except that Sections 14.1-14.4 (and all definitions in the Original Agreement that give meaning to the capitalized terms in such Sections) shall survive such termination. Except for the obligations set forth under this Agreement and the survival of the obligations under the Original Agreement set forth above, all obligations between Shire and Amicus as defined in the Original Agreement are terminated as of the date of this Agreement.

2. Termination of Licenses. Effective as of the date hereof, the licenses granted by Amicus to Shire under the Original Agreement shall be terminated and of no further force or effect.

3. Termination Payment. Shire shall pay to Amicus Five Million One Hundred and Ninety-Seven Thousand Four Hundred and Twenty-Five Dollars (\$5,197,425.00) within ten (10) Business Days after the date hereof in full and fair settlement of all development cost sharing obligations through the date of this Agreement and any and all other liabilities or obligations that Shire may have under the Original Agreement. Without limiting the foregoing, Amicus acknowledges that it shall not be entitled to any further payment or reimbursement of costs or expenses from Shire under the Original Agreement.

4. Data, Regulatory Filings, and Regulatory Correspondence. Within thirty (30) days after the date hereof, Shire shall disclose (to the extent Shire has not already disclosed to Amicus) all data and regulatory correspondence in Shire's or its Affiliates' possession or Control with respect to the Licensed Products Developed under the Original Agreement. Amicus shall be perpetually and irrevocably free to use, disclose and sublicense, on a fully paid-up, royalty free basis such data and regulatory correspondence to Develop, Commercialize, Manufacture and otherwise exploit the Licensed Products, or other products containing a Compound in Amicus's sole discretion. Shire shall assign and transfer, or cause to be assigned and transferred, to Amicus all Regulatory Filings solely for the Licensed Products, including without limitation all orphan drug designations currently held by Shire related to all Licensed Products (the "Orphan Drug Designations"), and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Filings, including with out limitation the Orphan Drug Designations, to Amicus. In each case, unless otherwise prohibited by any applicable Laws, the foregoing assignment shall be made within thirty (30) days after the date hereof.

5. Press Release . On or shortly after the effective date of this Agreement, each Party shall have the right to release a press release announcing (or incorporating an announcement of) this Agreement and the termination of the relationship of the Parties. The parties will share the contents of such releases that relate to the termination sufficiently in advance of the announcement to permit comment, and each party shall make reasonable efforts to accommodate such comments.

6. Representations and Warranties of Amicus . Amicus represents and warrants to Shire as follows:

a. Organization . Amicus is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware.

b. Authorization . The execution, delivery and performance by Amicus of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders or (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter documents.

c. Binding Agreement . This Agreement is a legal, valid and binding obligation of Amicus enforceable against it in accordance with its terms.

7. Representations and Warranties of Shire . Shire hereby represents and warrants to Amicus as follows:

a. Organization . Shire is a corporation duly organized, validly existing and in good standing under the laws of Ireland.

b. Authorization . The execution, delivery and performance by Shire of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders or (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter documents.

c. Intellectual Property . Shire has not (i) granted any sublicenses to any one or more of its Affiliates or Third Parties in connection with the Compounds or the Licensed Products, (ii) made or developed any Shire Inventions in connection with its activities under the Original Agreement or the Licensed Products, and (iii) filed any patent applications directly related to the Licensed Compounds.

d. Binding Agreement. This Agreement is a legal, valid and binding obligation of Shire enforceable against it in accordance with its terms.

8. Miscellaneous.

a. Definitions. Unless otherwise defined in this Agreement, all capitalized terms used herein shall have the meanings ascribed to them in the Original Agreement.

b. Severability. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement or the validity or enforceability of this Agreement in any other jurisdiction.

c. Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by telephone), postage prepaid (where applicable), addressed to such other party at its address indicated below, or to such other address as the addressee shall have furnished in writing to the addressor and shall be effective upon receipt by the addressee.

If to Amicus: Amicus Therapeutics, Inc.
6 Cedar Brook Drive
Cranbury, NJ 08512
Fax: (609) 662-2001
Attention: John F. Crowley CEO & President
With a copy to: General Counsel at the same address.

If to Shire: Shire Pharmaceuticals Ireland Ltd.
5 Riverwalk
Citywest Business Campus
Dublin 24
Ireland
Fax: 00 353 1 429 7701
Attention: Legal Department

d. Applicable Law. This Agreement shall be governed by and interpreted under the laws of the State of New York, excluding its conflicts of laws principles.

e. Entire Agreement; Amendments. This Agreement constitutes the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior or contemporaneous oral communications, agreements or discussions with respect to the subject matter hereof including, without limitation, the Original Agreement. This Agreement may be amended or modified only by a writing signed by each of the Parties.

f. Headings. The headings of this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

g. Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

h. Counterparts. This Agreement may be executed in two counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each of the Parties, by their duly authorized officers, has executed this Agreement as of the date first written above.

SHIRE PHARMACEUTICALS IRELAND LTD.

By: /s/ GRAHAM HETHERINGTON

Name: Graham Hetherington

Title: Director

AMICUS THERAPEUTICS, INC.

By: /s/ JOHN F. CROWLEY

Name: John F. Crowley

Title: President and CEO



**Amicus Therapeutics Announces Third Quarter
2009 Financial Results and Strategic Business Updates**

**Amicus Reacquires Global Development and Commercialization Rights to Amigal™,
Plicera™ and AT2220 Through a Mutual Termination Agreement with Shire**

Amicus Identifies Strategic Priorities and Implements Workforce Reduction

CRANBURY, N.J., October 29, 2009 — Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the third quarter 2009. Additionally, Amicus also today announced that it has reacquired all global development and commercialization rights from its partner, Shire for its lead lysosomal storage disease programs as a result of the parties' mutual termination of their collaboration. The Company also announced a workforce reduction of approximately 20 percent and provided cash guidance into the second half of 2011.

Amicus/Shire Collaboration Mutual Termination:

Amicus and Shire have reached a mutual termination agreement with respect to their collaboration to jointly develop Amicus' three lead pharmacological chaperone compounds for the treatment of lysosomal storage disorders, effective immediately. As a result of this agreement, Amicus has regained exclusive worldwide rights to develop and commercialize Amigal™ (migalastat hydrochloride), Plicera™ (afegostat tartrate) and AT2220 (1-deoxynojirimycin HCl) outside of the United States (U.S.) and now owns worldwide rights for these programs. Shire will pay Amicus \$5.2 million in the fourth quarter as full and final payment for any amounts that may be due to the Company under the collaboration, and both parties will be relieved of all other future obligations, financial or otherwise.

John F. Crowley, President & CEO of Amicus Therapeutics stated, "Shire has been an excellent partner to work with during the past two years. However, reacquiring the ex-U.S. commercial rights to Amigal furthers our desire to enhance the value of that program for our shareholders. Since Shire and Amicus mutually concluded that Plicera will not move forward to Phase 3 development in Gaucher disease, having global rights to Amigal was of critical importance to Amicus."

Amicus will continue to manage global clinical operations for Amigal Phase 3 development and expects to initiate more than thirty investigational sites worldwide. As previously announced, the first global Phase 3 Amigal study is a 60 patient randomized, double-blind placebo controlled six month study intended to support U.S. registration. The primary surrogate endpoint agreed to with the U.S. Food and Drug Administration (FDA) is a histological evaluation of the change in GL-3 levels in the interstitial capillary cells of the kidney. The first patient was randomized into this study in mid-October. The Company estimates it will complete enrollment for this trial by the end of 2010 and expects to have data available in mid-2011. A separate Phase 3 study for registration in the European Union comparing Amigal with Fabrazyme® is required by the European Medicines Agency (EMA). Amicus expects to provide a further update on that proposed study for the EMA in 2010 as the supply constraints with Fabrazyme become clearer.

Key Strategic Priorities and Workforce Reduction:

As part of its strategic business plan, Amicus will focus its resources in three key areas:

- The Phase 3 development of Amigal for Fabry disease;
- Advancement of its lead pre-clinical programs that utilize its pharmacological chaperone technology for the treatment of diseases of neurodegeneration. The Company has an advanced pre-clinical program in Parkinson's disease as well as an earlier stage pre-clinical program in an as yet undisclosed neurodegenerative target disease; and
- Advancement of pharmacological chaperones used in combination with enzyme replacement therapies (ERT) for the treatment of lysosomal storage diseases.

"By focusing our resources on these three value creating centers within Amicus, we will balance the execution of our global late stage clinical program in Fabry disease with continued significant investment with the chaperone platform in diseases of neurodegeneration, which continue to yield very exciting near-term and long-term potential value for the Company. The chaperone-ERT combination approach is also one of potentially significant value for Amicus shareholders as a further extension of our technology," said John F. Crowley.

The Company also announced today a work-force reduction of approximately 20 percent, or 26 employees, as a part of a corporate restructuring with reductions occurring across all levels and organizations within the Company. In addition, Amicus is terminating its relationship with approximately 17 contractors currently working at the Company. Amicus is taking this step to reduce costs and to align its resources with its key strategic priorities. The Company estimates that it will record charges of approximately \$0.9 million during the fourth quarter of 2009 for employment termination costs payable in cash in connection with the workforce reduction.

"After extensive review of our business plan, we have made some very difficult decisions to restructure our workforce to best enable us to align the Company around the three key strategic priorities for Amicus going forward," said John F. Crowley. "Specifically, we expect that these changes will enable our current cash to last into the second half of 2011. It is exceptionally difficult to implement these employee changes as so many remarkably dedicated and talented persons, including Jim Dentzer, our Chief Financial Officer, will be leaving Amicus. All of them have contributed significantly to the Company, and I cannot thank them enough for all of their tireless efforts, passion and contributions."

"We are highly confident that with this restructuring and strategic repositioning, we are well poised to maximize shareholder value while ensuring that we deliver on our mission to provide innovative and high quality therapies to people afflicted with these diseases. We remain fully committed to the success of Amicus," concluded John F. Crowley.

Financial Guidance:

Based on current projections of net operating expense, the Company reiterates its expectation to end 2009 with approximately \$70-\$80 million in cash, cash equivalents and marketable securities. Additionally, the Company expects that its current cash, cash equivalents and marketable securities together with the fourth quarter \$5.2 million payment from Shire will be sufficient to fund operations and capital expenditure requirements into the second half of 2011.

Third Quarter 2009 Results Summary

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 \$0.59 per share (\$0.51 per share on a non-GAAP basis) for the three months ended September 30, 2009. As of September 30, 2009, cash, cash equivalents, and marketable securities totaled \$89.3 million.

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 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 began submitting the Phase 3 protocol to investigational sites worldwide in June 2009 and patient enrollment and dosing are now underway.

Furthermore, Amicus previously reported that it completed a series of discussions with the EMEA regarding the clinical study required for Amigal registration in Europe. The Company will provide an update on the timing of the initiation of this study in 2010.

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

The Company previously reported preliminary results from its Phase 2 randomized, open-label study to assess the safety, tolerability and preliminary efficacy of its investigational drug, Plicera, in treatment-naive adult patients with type 1 Gaucher disease. Two dose regimens of Plicera (225 mg three days on/four days off and seven days on/seven days off) were studied during this six month trial. While all patients enrolled experienced an increase in the level of the target enzyme (GCCase) as measured in white blood cells, clinically meaningful improvements in key measures of disease were observed in just one of the eighteen patients who completed the study. The preliminary results suggest that treatment with Plicera was generally well tolerated, with no serious adverse events (SAEs) reported. Nineteen subjects were enrolled and 18 subjects completed the study. One subject discontinued treatment because of an adverse event (conjunctivitis-related symptoms).

The Company plans to further analyze and evaluate the results of this Phase 2 study. However, Amicus no longer plans to advance Plicera into Phase 3 development.

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

Late in the third quarter, the Company announced its plans to initiate a Phase 1 study of AT2220 (1-deoxynojirimycin HCl), its investigational drug in development for the treatment of Pompe Disease. The primary objective of this study is to evaluate the pharmacokinetics of AT2220 in muscle tissue in healthy adult subjects. The FDA agreed to Amicus' proposal for the Phase 1 study and subsequently converted the clinical hold of AT2220 to a partial hold to allow the conduct of this study.

This open label, single dose Phase 1 study was initiated in early October and the Company expects to announce results from the trial in the first half of 2010.

Additionally, Amicus continues to be encouraged by the results of preclinical studies designed to evaluate the use of AT2220 in combination with enzyme replacement therapy (ERT). The Company expects to report additional data from these studies at scientific conferences in 2010.

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.

Additional Financial Results & Notes

On a reported basis, the net loss attributable to common stockholders for the three months ended September 30, 2009, was \$13.4 million as compared to \$8.2 million for the same period in 2008. On a non-GAAP basis, the net loss for the three months ended September 30, 2009, was \$11.5 million as compared to \$6.6 million in the same period in 2008.

Amicus recorded revenue during the third quarter of 2009 representing two different revenue streams from the Shire collaboration agreement. Upon signing the collaboration agreement, Amicus received an upfront payment of \$50 million that had been recognized as revenue on a straight-line basis over 18 years from the date of the agreement. In the third quarter of 2009, Amicus recognized \$0.7 million of the Shire upfront payment and \$4.2 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.

Conference Call and Webcast

Amicus will host a conference call to discuss financial and operational results for the third quarter 2009, today, October 29, 2009 at 5:30 p.m. EDT. Interested participants and investors may access the conference call by dialing 877-440-5807 (U.S./Canada) or 719-325-4915 (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 6603470.

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 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.

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 projected cash position for the Company. 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 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, actual results may differ based on market factors and the Company’s ability to execute its operational and budget plans. 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		Nine Months		Period from February 4, 2002 (inception) to September 30, 2009
	Ended September 30,		Ended September 30,		
	2008	2009	2008	2009	2009
Revenue:					
Research revenue	\$ 2,959	\$ 4,219	\$ 8,539	\$ 12,799	\$ 26,362
Collaboration revenue	694	694	2,083	2,083	5,270
Total revenue	<u>3,653</u>	<u>4,913</u>	<u>10,622</u>	<u>14,882</u>	<u>31,632</u>
Operating Expenses:					
Research and development	8,200	12,609	23,989	37,954	165,596
General and administrative	4,371	5,217	14,676	15,635	73,371
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	382	561	1,036	1,585	5,872
In-process research and development	—	—	—	—	418
Total operating expenses	<u>12,953</u>	<u>18,387</u>	<u>39,701</u>	<u>55,174</u>	<u>246,287</u>
Loss from operations	(9,300)	(13,474)	(29,079)	(40,292)	(214,655)
Other income (expenses):					
Interest income	1,019	129	4,053	924	13,684
Interest expense	(49)	(84)	(179)	(155)	(1,802)
Change in fair value of warrant liability	—	—	—	—	(454)
Other expense	—	—	—	—	(1,180)
Loss before tax benefit	(8,330)	(13,429)	(25,205)	(39,523)	(204,407)
Benefit from income taxes	150	—	—	—	695
Net loss	(8,180)	(13,429)	(25,205)	(39,523)	(203,712)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (8,180)</u>	<u>\$ (13,429)</u>	<u>\$ (25,205)</u>	<u>\$ (39,523)</u>	<u>\$ (223,938)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.59)</u>	<u>\$ (1.12)</u>	<u>\$ (1.75)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>22,517,431</u>	<u>22,621,513</u>	<u>22,465,981</u>	<u>22,617,808</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, 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	\$ 4,913		\$ 4,913
Research and development	(11,780)	\$ (829)	(12,609)
General and administrative	(4,075)	(1,142)	(5,217)
Depreciation and amortization	(561)		(561)
Interest income	129		129
Interest expense	(84)		(84)
Summary:			
Net loss:	<u>\$ (11,458)</u>	<u>\$ (1,971)</u>	<u>\$ (13,429)</u>
Net loss per share — basic and diluted:	<u>\$ (0.51)</u>	<u>\$ (0.09)</u>	<u>\$ (0.59)</u>
Weighted average number of shares outstanding:	<u>22,621,513</u>		<u>22,621,513</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, 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	\$ 3,653		\$ 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>
Summary:			
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>

Source: FOLD -G