

**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 7, 2013**

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.)

1 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))

Item 2.02. Results of Operations and Financial Condition.

On August 7, 2013, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2013. 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 and the Exhibit 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.

(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.

Date: August 7, 2013

By: /s/ Peter M. Macaluso
Peter M. Macaluso
Secretary

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 7, 2013

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Amicus Therapeutics Announces Second Quarter 2013 Financial Results

Full-Year 2013 Net Cash Spend Guidance Reduced to \$47 Million to \$53 Million — Current Cash Expected to Fund Operations into 4Q14

Multiple Next-Generation Enzyme Replacement Therapies Advancing for Lysosomal Storage Diseases

CRANBURY, NJ, US, August 7, 2013 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of therapies for rare and orphan diseases, today announced financial results for the second quarter ended June 30, 2013. The Company also summarized recent and upcoming milestones and reduced full-year 2013 net cash spend guidance.

Key Program Highlights and Upcoming Milestones:

- Phase 2 chaperone-ERT co-administration study for Pompe disease expected to begin 2H13
- Fabry chaperone-ERT co-formulated product anticipated to enter clinic in 1H14
- Next-generation ERTs for Pompe disease and Mucopolysaccharidosis Type I (MPS I) advancing in preclinical studies
- 12-month (Stage 2) data from Phase 3 Study 011 of migalastat HCl monotherapy for Fabry disease anticipated 4Q13 and top-line data from Study 012 expected 2H14 - U.S. new drug application (NDA) submission expected to include data from all clinical studies

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics stated, “During the second quarter we continued to build out our CHART platform of chaperone-ERT combinations across the lysosomal storage diseases. We expect to initiate our next Phase 2 Pompe co-administration study in the second half of this year, as well as initial clinical studies of our chaperone-ERT co-formulated product for Fabry disease in 2014. Our long-term vision is to move multiple next-generation ERTs into the clinic over the next several years. We also remain committed to advancing migalastat HCl monotherapy toward a potential U.S. approval for Fabry patients who have amenable mutations.”

Financial Highlights for Second Quarter Ended June 30, 2013

- Cash, cash equivalents, and marketable securities totaled \$74.2 million at June 30, 2013 compared to \$99.1 million at December 31, 2012.
- Cash reimbursements received from GlaxoSmithKline (GSK) for shared development of migalastat HCl totaled \$1.3 million compared to \$4.3 million in the second quarter 2012.
- No revenue was reported due to a change in revenue recognition accounting under the expanded GSK collaboration. Total revenue of \$10.6 million was recognized in the second quarter 2012.
- Total operating expenses decreased to \$16.0 million from \$20.0 million in the second quarter 2012 due to lower expenses in research and development as well as general and administrative.
- Net loss was \$15.3 million, or \$0.31 per share, compared to a net loss of \$9.3 million, or \$0.20 per share, for the second quarter 2012.

2013 Financial Guidance

Amicus expects full-year 2013 net cash spend to total between \$47 million and \$53 million, compared to previous net cash spend guidance of \$52 million and \$58 million, including cash reimbursements received from GSK. Amicus and GSK are responsible for 40% and 60% of global development costs for migalastat HCl, respectively, in 2013 and beyond. The Company projects that the current cash position and anticipated Fabry program reimbursements from GSK are sufficient to fund operations into the fourth quarter of 2014.

William D. Baird, Chief Financial Officer of Amicus Therapeutics said, “We are reducing our full-year 2013 net cash spend guidance to reflect lower-than-anticipated cash spend during the first half of 2013 as well as some adjustments to our budget for the remainder of the year. We are committed to carefully managing our cash position to efficiently advance our programs.”

Program Updates

Migalastat HCl for Fabry Disease

Amicus in collaboration with GSK is developing the investigational pharmacological chaperone migalastat HCl for the treatment of Fabry disease. Amicus has commercial rights to all Fabry products in the United States and GSK has commercial rights to all of these products in the rest of world.

- **Migalastat HCl Monotherapy:** migalastat HCl monotherapy (150 mg, every-other-day) is being investigated in two ongoing randomized Phase 3 studies for Fabry disease (Study 011 and Study 012) in patients with genetic mutations identified as amenable to this pharmacological chaperone in a cell-based assay. Based on feedback from the FDA during a Type C meeting in the second quarter of 2013, Amicus expects to submit a new drug application (NDA) after data are available from both Study 011 and Study 012. The 6-month results from Study 011 have been reported, 12-month data from Study 011 are anticipated in the fourth quarter of 2013, and results from Study 012 are anticipated in the second half of 2014.
- **Migalastat HCl in Combination with ERT:** Amicus and GSK, in collaboration with JCR Pharmaceutical Co. Ltd, are currently developing intravenous migalastat HCl co-formulated with a proprietary recombinant human alpha-Gal A enzyme (JCR’s JR-051). In combination with ERT, migalastat HCl is designed to bind to and stabilize infused alpha-Gal A enzyme, independent of a patient’s genetic mutation. Amicus believes this approach has the potential to benefit all patients with Fabry disease. This chaperone-ERT co-formulated product is expected to enter the clinic in the first half of 2014.

CHART™ Programs for Pompe Disease and Mucopolysaccharidosis Type I (MPS I)

Outside the collaboration agreement with GSK, Amicus owns exclusive rights to the rest of its pipeline and applications of its chaperone-advanced replacement therapy (CHART™) platform technology. In each CHART program, a unique pharmacological chaperone is designed to bind to and stabilize a specific therapeutic enzyme in its properly folded and active form. These next-generation therapies have the potential to allow for enhanced tissue uptake of active enzyme, greater lysosomal activity, more reduction of substrate, and lower immunogenicity compared to current standard of care ERTs.

- **AT2220-IV Co-Administered with Marketed ERTs for Pompe Disease:** Amicus plans to conduct a Phase 2 repeat-dose clinical study to evaluate a novel intravenous formulation of AT2220 (AT2220-IV) co-administered with currently marketed recombinant human GAA (Myozyme/Lumizyme) in Pompe patients. The study is designed to build upon positive results from a single-dose Phase 2 co-administration study (Study 010). Amicus expects to initiate the repeat-dose study in the second half of 2013 and to report initial results in the first half of 2014.
- **Next-Generation ERTs for Pompe Disease and Mucopolysaccharidosis Type I (MPS I):** Amicus is currently conducting preclinical studies to evaluate IV and subcutaneous administration of a proprietary recombinant human GAA enzyme co-formulated with AT2220 as a next-generation therapy for Pompe disease. In addition, a proprietary recombinant human alpha-L-iduronidase (rhIDUA) enzyme co-formulated with a novel pharmacological chaperone is in preclinical development for MPS I. In support of its development of a proprietary rhIDUA enzyme, Amicus has received a grant of up to \$250,000 from a private U.S.-based donor.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, August 7, 2013 at 5:00 p.m. ET to review financial results and provide a corporate update. Interested participants and investors may access the conference call at 5:00 p.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at <http://www.amicusrx.com>, and will be archived for 30 days. 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. A telephonic replay of the call will be available for seven days beginning at 8:00 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 26879608.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq:FOLD) is a biopharmaceutical company at the forefront of therapies for rare and orphan diseases. The Company is developing novel, first-in-class treatments for a broad range of human genetic diseases, with a focus on delivering new benefits to individuals with lysosomal storage diseases. Amicus' lead programs include the small molecule pharmacological chaperones migalastat HCl as a monotherapy and in combination with enzyme replacement therapy (ERT) for Fabry disease; and AT2220 (duvoglustat HCl) in combination with ERT for Pompe disease.

About Chaperone-Advanced Replacement Therapy (CHART)

The Chaperone-Advanced Replacement Therapy (CHART™) platform combines unique pharmacological chaperones with enzyme replacement therapies (ERTs) for lysosomal storage diseases (LSDs). In a chaperone-advanced replacement therapy, a unique pharmacological chaperone is designed to bind to and stabilize a specific therapeutic enzyme in its properly folded and active form. This proposed CHART mechanism may allow for enhanced tissue uptake of active enzyme, greater lysosomal activity, more reduction of substrate, and lower immunogenicity compared to ERT alone. Improvements in enzyme stability may also enable more convenient delivery of next-generation therapies. Amicus is leveraging the CHART platform to develop pharmacological chaperones co-administered with currently marketed ERTs as well as proprietary next-generation therapies that consist of lysosomal enzymes co-formulated with pharmacological chaperones.

Current CHART programs in development include the pharmacological chaperone AT2220 co-administered with currently marketed ERTs in Phase 2 for Pompe disease, as well as preclinical-stage next-generation ERTs for Pompe disease and Mucopolysaccharidosis Type I (MPS I).

About Migalastat HCl for Fabry Disease

Migalastat HCl is an investigational pharmacological chaperone in development as a monotherapy and in combination with enzyme replacement therapy (ERT) for the treatment of Fabry disease. As a monotherapy, migalastat HCl is designed to bind to and stabilize, or "chaperone" a patient's own alpha-galactosidase A (alpha-Gal A) enzyme in those with genetic mutations that are amenable to this chaperone in a cell-based assay. For patients currently receiving ERT for Fabry disease, migalastat HCl in combination with ERT may improve ERT outcomes by keeping the infused alpha-Gal A enzyme in its properly folded and active form.

Fabry disease is an inherited lysosomal storage disorder caused by deficiency of the alpha-Gal A enzyme. The role of alpha-Gal A within the body is to break down specific lipids in lysosomes, including globotriaosylceramide (GL-3, also known as Gb3). Lipids that can be degraded by the action of alpha-Gal A are called "substrates" of the enzyme. Reduced or absent levels of alpha-Gal A activity leads to the accumulation of GL-3 in the affected tissues, including the kidneys, heart, central nervous system, and skin. This accumulation of GL-3 is believed to cause the various manifestations of Fabry disease, including pain, kidney failure, and increased risk of heart attack and stroke. It is currently estimated that Fabry disease affects approximately 5,000 to 10,000 people worldwide. However, several literature reports suggest that Fabry disease may be significantly under-diagnosed, and the prevalence of the disease may be much higher.

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 trials 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," "potential," "plan," "targets," "likely," "may," "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 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 regulatory authorities may not grant or may delay approval for our product candidates; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we will need additional funding to complete all of our studies 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. 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. In addition, all forward looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2012. 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:

Investors/Media:
Sara Pellegrino
spellegrino@amicusrx.com
(609) 662-5044

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, 2013
	2012	2013	2012	2013	
Revenue:					
Research revenue	\$ 5,477	\$ —	\$ 11,591	\$ —	\$ 57,493
Collaboration and milestone revenue	5,160	—	6,820	—	64,382
Total revenue	<u>10,637</u>	<u>\$ —</u>	<u>18,411</u>	<u>\$ —</u>	<u>121,875</u>
Operating Expenses:					
Research and development	13,723	10,725	27,727	22,714	338,607
General and administrative	5,819	4,830	9,914	9,653	142,226
Restructuring charges	—	—	—	—	1,522
Impairment of leasehold improvements	—	—	—	—	1,030
Depreciation and amortization	442	450	862	889	12,657
In-process research and development	—	—	—	—	418
Total operating expenses	<u>19,984</u>	<u>16,005</u>	<u>38,503</u>	<u>33,256</u>	<u>496,500</u>
Loss from operations	(9,347)	(16,005)	(20,092)	(33,256)	(374,625)
Other income (expenses):					
Interest income	116	46	143	111	14,500
Interest expense	(15)	(9)	(58)	(19)	(2,441)
Change in fair value of warrant liability	(118)	619	(2,494)	357	1,910
Other income	21	—	21	—	252
Loss before tax benefit	<u>(9,343)</u>	<u>(15,349)</u>	<u>(22,480)</u>	<u>(32,807)</u>	<u>(360,404)</u>
Income tax benefit	—	—	—	—	8,708
Net loss	(9,343)	(15,349)	(22,480)	(32,807)	(351,696)
Deemed dividend	—	—	—	—	(19,424)
Preferred stock accretion	—	—	—	—	(802)
Net loss attributable to common stockholders	<u>\$ (9,343)</u>	<u>\$ (15,349)</u>	<u>\$ (22,480)</u>	<u>\$ (32,807)</u>	<u>\$ (371,922)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.31)</u>	<u>\$ (0.53)</u>	<u>\$ (0.66)</u>	
Weighted-average common shares outstanding — basic and diluted	<u>46,870,067</u>	<u>49,621,188</u>	<u>42,103,642</u>	<u>49,621,188</u>	

Table 2

Amicus Therapeutics, Inc.

(a development stage company)
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	December 31, 2012	June 30, 2013
Assets:		
Current assets:		
Cash and cash equivalents	\$ 33,971	\$ 23,476
Investments in marketable securities	65,151	50,700
Receivable due from GSK	3,225	1,024
Prepaid expenses and other current assets	2,270	1,978
Total current assets	<u>104,617</u>	<u>77,178</u>
Property and equipment, less accumulated depreciation and amortization of \$8,501 and \$9,321 at December 31, 2012 and June 30, 2013, respectively	5,029	4,715
Other non-current assets	442	442
Total Assets	<u>\$ 110,088</u>	<u>\$ 82,335</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,845	\$ 9,018
Current portion of secured loan	398	398
Warrant liability	—	551
Total current liabilities	<u>9,243</u>	<u>9,967</u>
Deferred reimbursements	30,418	32,709
Warrant liability, non-current	908	—
Secured loan, less current portion	299	100
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value, 125,000,000 shares authorized, 49,631,672 shares issued and outstanding at December 31, 2012, 49,631,672 shares issued and outstanding at June 30, 2013	556	556
Additional paid-in capital	387,539	390,696
Accumulated other comprehensive income	14	3
Deficit accumulated during the development stage	(318,889)	(351,696)
Total stockholders' equity	<u>69,220</u>	<u>39,559</u>
Total Liabilities and Stockholders' Equity	<u>\$ 110,088</u>	<u>\$ 82,335</u>

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