# **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 28, 2010

# AMICUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-33497	71-0869350
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
6 Cedar Brook Drive, Cranbury, NJ		08512
(Address of Principal Executive Offices)		(Zip Code)
Registrant's telephone number, including area code: <b>(609) 662-2000</b> (Former name or former address if changed since last report.)		
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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:		
o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)		
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)		
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))		
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240 13e-4(c))		

#### Item 1.01. Entry into a Material Definitive Agreement.

On October 28, 2010, Amicus Therapeutics, Inc. ("Amicus") entered into a License and Collaboration Agreement (the "Collaboration Agreement") with Glaxo Group Limited ("Glaxo") to develop and commercialize Amigal ™ (migalastat HCI), currently in Phase 3 for the treatment of Fabry disease, a rare inherited disorder. Under the terms of the Collaboration Agreement, GSK will receive an exclusive worldwide license to develop, manufacture and commercialize migalastat HCI. GSK and Amicus also intend to advance clinical studies exploring the co-administration of migalastat HCI with enzyme replacement therapy (ERT) for the treatment of Fabry disease, as provided in the Collaboration Agreement.

Amicus will receive an upfront, license payment of \$30 million from Glaxo and is eligible to receive further payments of approximately \$170M upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of migalastat HCl. Glaxo and Amicus will jointly fund development costs in accordance with an agreed upon development plan.

Additionally, simultaneous with entry into the Collaboration Agreement, Amicus and Glaxo entered into a Stock Purchase Agreement (the "SPA") pursuant to which Glaxo will purchase approximately 6.9 million shares of Amicus common stock at a price of \$4.56 per share. The SPA provides Glaxo with customary registration rights for the shares purchased and includes an eighteen-month standstill and lock-up provision, subject to certain exceptions.

The foregoing description of the Collaboration Agreement and SPA is not complete and is qualified in its entirety by reference to the Collaboration Agreement and SPA to be filed at a later date with the United States Securities and Exchange Commission ("SEC"). A copy of the press release announcing the collaboration between Amicus and Glaxo is attached hereto as Exhibit 99.1 and incorporated herein by reference.

#### Item 3.02. Unregistered Sales of Equity Securities.

On October 28, 2010, Amicus and Glaxo entered into the SPA pursuant to which Glaxo will purchase 6,866,244 shares of unregistered Amicus common stock, par value \$0.01 per share (the "Shares"), at a price of \$4.56 per share. The total purchase price for the Shares is \$31,284,583; the Company will receive all proceeds from the sale of the Shares. The Shares were sold by Amicus to Glaxo in accordance with SEC Rule 506 and pursuant to Glaxo's qualification as an "accredited investor" under SEC Rule 501.

### 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: November 2, 2010

Name:

<u>/s/ GEOFFREY P. GILMORE</u> Geoffrey P. Gilmore Senior Vice President and General Counsel Title:

# **EXHIBIT INDEX**

Exhibit No. 99.1

Description
Press Release dated October 29, 2010



GSK and Amicus Therapeutics Enter Exclusive Worldwide Agreement to Develop and Commercialize Amigal™ for Fabry Disease

-Amicus to receive \$60M in upfront license payment and equity investment and eligible for approximately \$170M million in future potential milestone payments-

LONDON, UK & CRANBURY, NJ, US, October 29, 2010 —GlaxoSmithKline PLC (GSK) and Amicus Therapeutics (Nasdaq: FOLD) today announced a definitive agreement to develop and commercialize Amigal<sup>TM</sup> (migalastat HCl), currently in Phase 3 for the treatment of Fabry disease, a rare inherited disorder. Under the terms of the agreement, GSK will receive an exclusive worldwide license to develop, manufacture and commercialize migalastat HCl. Additionally, as part of the agreement GSK and Amicus also intend to advance clinical studies exploring the co-administration of migalastat HCl with enzyme replacement therapy (ERT) for the treatment of Fabry disease.

Under the terms of the Agreement, Amicus will receive an upfront, license payment of \$30M from GSK and is eligible to receive further payments of approximately \$170M upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of migalastat HCl. GSK and Amicus will jointly fund development costs in accordance with an agreed upon development plan. Additionally, as part of the collaboration, GSK is purchasing 6.9 million shares of Amicus common stock at a price of \$4.56 per share. The total value of this equity investment to Amicus is \$31 million and represents a 19.9% ownership position for GSK in the Company. The total cash up-front to Amicus from GSK for the upfront license payment and equity investment is approximately \$60 million.

"This strategic collaboration is another significant milestone in delivering our vision for GSK Rare Diseases. Amicus' scientific and clinical expertise in human genetic diseases is among the best in the industry, and we are pleased to be collaborators and investors in this exceptional company" said Marc Dunoyer, Global Head of GSK Rare Diseases and a member of the GSK Corporate Executive Team. "Our focus now is to continue to advance Amigal for Fabry disease and it is our hope to deliver a first-in-class, oral medicine to the thousands of people worldwide living with this devastating rare disease."

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics said, "The completion of this agreement with GSK is a transformational event for Amicus. It provides a strong validation of the potential for Amigal to become an important new treatment option for people living with Fabry disease and for our pharmacological chaperone technology broadly. GSK has extremely impressive global clinical, regulatory and commercial expertise and a strong commitment to the development of treatments for rare diseases. We look forward to working in close partnership with them." Crowley continued, "With this key strategic alliance with GSK and the added financial strength it provides, Amicus is now uniquely positioned to build shareholder value through our expertise in rare disease drug development."

## About Amigal<sup>TM</sup> (migalastat HCI) for the Treatment of Fabry Disease

Migalastat HCl is an investigational treatment for Fabry disease and has the potential to be the first in a new class of oral, small molecule medicines called pharmacological chaperones. It is designed to selectively bind to and stabilize the target enzyme a-galactosidase A (a-Gal A), which facilitates proper trafficking of the enzyme to the lysosomes, where it is needed to break down the target substrate globotriaosylceramide (GL-3).

Results from Phase 2 studies of migalastat HCl, which has orphan designation in both the US and EU, demonstrated that in subjects identified as responders to migalastat HCl treatment resulted in increased levels of a-Gal A, reduced levels of GL-3 as measured in renal interstitial capillary cells from kidney biopsies and in urine, and a potential positive impact on renal function. Treatment with migalastat HCl has been generally well-tolerated, with no drug-related serious adverse events. The most common adverse events were headache, arthralgia and diarrhea.

A Phase 3 study (Study 011) commenced in the second quarter of 2009 and treatment of the first patient began in the fourth quarter of 2009. This ongoing study is a 6-month, randomized, double-blind trial comparing migalastat HCl to placebo in 60 subjects in approximately 40 investigational sites worldwide. The surrogate primary endpoint is the change in the amount of kidney interstitial capillary GL-3. Subjects being enrolled are Fabry patients who have never received enzyme replacement therapy (ERT), or who have not received ERT for at least 6 months, and who have a mutation responsive to migalastat HCl.

GSK and Amicus today provided an update to the enrollment timeline for Study 011. Enrollment is now expected to be completed in the first quarter of 2011 and preliminary results are expected to be announced in the second half of 2011.

Furthermore, a separate Phase 3 study (Study 012) is expected to commence before year end. The study will be an 18-month, randomized, open-label study comparing migalastat HCl to ERT in approximately 60 subjects. The primary outcome of efficacy will be renal function as measured by glomerular filtration rate (GFR).

#### About Fabry Disease

Fabry disease is an inherited lysosomal storage disorder caused by deficiency of an enzyme called a-galactosidase A (a-Gal A). The role of a-Gal A within the body is to break down a complex lipid called globotriaosylceramide (GL-3). Reduced or absent levels of a-Gal A activity leads to the accumulation of GL-3 in the affected tissues, including the central nervous system, heart, kidneys, and skin. This accumulation of GL-3 is believed to cause the various symptoms 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.

**GlaxoSmithKline** — one of the world's leading research-based pharmaceutical and healthcare companies — is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit <a href="https://www.gsk.com">www.gsk.com</a>

### **Amicus Therapeutics**

Amicus Therapeutics is a biopharmaceutical company focused on developing treatments for rare diseases. The Company is developing orally-administered, small molecule drugs called pharmacological chaperones, a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage disorders and CNS diseases. Amicus' lead program is in Phase 3 for the treatment of Fabry disease. For further information, please visit www.amicustherapeutics.com.

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#### **Amicus 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, including achievement of development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline. 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 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, including achievement of development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline . 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, 2009. 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.

# GSK's cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2009.

Registered in England & Wales: No. 3888792

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