

AMICUS THERAPEUTICS INC
Form 8-K
July 23, 2012

**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): **July 17, 2012**

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:

Edgar Filing: AMICUS THERAPEUTICS INC - Form 8-K

- 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 July 17, 2012, Amicus Therapeutics, Inc. (Amicus) entered into an Amended and Restated License and Expanded Collaboration Agreement (the Expanded Collaboration Agreement) with Glaxo Group Limited (Glaxo) pursuant to which Amicus and Glaxo will continue to develop and commercialize migalastat HCl, currently in Phase 3 development for the treatment of Fabry disease. The Expanded Collaboration Agreement amends and replaces in its entirety the License and Collaboration Agreement entered into between Amicus and Glaxo on October 28, 2010 (the Original Collaboration Agreement) for the development and commercialization of migalastat HCl. Under the terms of the Expanded Collaboration Agreement, Amicus and Glaxo will co-develop all formulations of migalastat HCl for Fabry disease, including the development of migalastat HCl co-formulated with an investigational proprietary enzyme replacement therapy (ERT) for Fabry disease (the Co-formulated Product) in collaboration with another Glaxo collaborator, JCR Pharmaceutical Co., Ltd. Amicus will commercialize all migalastat HCl products for Fabry disease in the United States while Glaxo will commercialize all such products in the rest of the world. The exclusive license granted to Glaxo under the Original Collaboration Agreement to commercialize migalastat HCl worldwide is therefore replaced under the Expanded Collaboration Agreement with two exclusive licenses: (i) an exclusive license from Glaxo to Amicus to commercialize migalastat HCl in the United States, and (ii) an exclusive license from Amicus to Glaxo to commercialize migalastat HCl in the rest of world. Glaxo and Amicus each have a license to manufacture migalastat HCl for commercialization of monotherapy and chaperone-ERT co-administration migalastat HCl products while Glaxo maintains an exclusive license to manufacture such products for development purposes (subject to limited exceptions) and to manufacture the Co-formulated Product. In the event of a change of control of Amicus during the term of the Expanded Collaboration Agreement, Glaxo has the option to purchase an exclusive license to develop, manufacture and commercialize all formulations of migalastat HCl in the United States.

Glaxo is eligible to receive U.S. regulatory approval and product launch milestones totaling \$20 million for migalastat HCl monotherapy and migalastat HCl for co-administration with ERT, and additional regulatory approval and time-based milestone payments totaling up to \$35 million within seven years following the launch of the Co-formulated Product. Amicus will also be responsible for certain pass-through milestone payments and single-digit royalties on the net U.S. sales of the Co-formulated Product that Glaxo must pay to a third party. In addition, Amicus is no longer eligible to receive any milestones or royalties it would have been eligible to receive under the Original Collaboration Agreement other than a \$3.5 million clinical development milestone achieved in the second quarter of 2012 and expected to be paid by Glaxo to Amicus in the third quarter of 2012.

Amicus and Glaxo will continue to jointly fund development costs for all formulations of migalastat HCl in accordance with agreed upon development plans pursuant to which Amicus and Glaxo will fund 25% and 75% of such costs, respectively, for the monotherapy and co-administration development of migalastat HCl for the remainder of 2012 and 40% and 60%, respectively, thereafter. Effective immediately, costs for the development of the Co-formulated Product are also split 40% and 60% between Amicus and Glaxo, respectively.

Additionally, simultaneous with entry into the Expanded Collaboration Agreement, Amicus and Glaxo entered into a Stock Purchase Agreement (the SPA) pursuant to which Glaxo will purchase approximately 2.9 million shares of Amicus common stock at a price of \$6.30 per share. The SPA provides Glaxo with customary registration rights for the shares and includes a six-month lock-up provision.

The foregoing description of the Expanded Collaboration Agreement and SPA is not complete and is qualified in its entirety by reference to the Expanded 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.

Edgar Filing: AMICUS THERAPEUTICS INC - Form 8-K

On July 17, 2012, Amicus and Glaxo entered into the SPA pursuant to which Glaxo will purchase 2,949,581 shares of unregistered Amicus common stock, par value \$0.01 per share (the Shares), at a price of \$6.30 per share. The total purchase price for the Shares is \$18,582,360; the Company will receive all proceeds from the sale of the Shares. The Shares will be 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. The sale of the Shares is expected to close on or about July 31, 2012.

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: July 23, 2012

By:	/s/ PETER M. MACALUSO
Name:	Peter M. Macaluso
Title:	Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 17, 2012

4
