
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): February 16, 2010

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))
-

Item 2.02. Results of Operations and Financial Condition.

On February 16, 2010, Amicus Therapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2009. 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, including Exhibit 99.1, 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.

Amicus Therapeutics, Inc.

Date: February 16, 2010

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

EXHIBIT INDEX

| Exhibit No. | Description |
|-------------|---------------------------------------|
| 99.1 | Press Release dated February 16, 2010 |



**Amicus Therapeutics Announces Fourth Quarter
and Full Year 2009 Financial Results and Highlights Product Pipeline Advancements**

Company well-positioned to achieve key milestone with Amigal™ program in 2010; completion of enrollment for Phase 3 Study 011 to support approval in the U.S. expected in 2010

CRANBURY, N.J., February 16, 2009 – Amicus Therapeutics (Nasdaq: FOLD) today announced financial results for the fourth quarter and full year 2009. The Company also provided an update on advancements in its product pipeline related to its key strategic priorities for 2010. Additionally, the Company stated that it believes it is well positioned to achieve its key milestone of completing enrollment for its Phase 3 study of Amigal™ (migalastat HCl) to support approval in the U.S. (Study 011) by year end.

Fourth Quarter and Full-Year 2009 Financials Summary

Amicus announced net income attributable to common stockholders of \$1.45 per share for the three months ended December 31, 2009. For the year ended December 31, 2009, the net loss attributable to common stockholders was \$0.29 per share. As of December 31, 2009, cash, cash equivalents, and marketable securities totaled \$78.2 million.

John F. Crowley, Chairman and CEO of Amicus Therapeutics stated, “We are very pleased with the significant progress we made advancing Amigal into Phase 3 in 2009, and we expect to continue this momentum in 2010. We are confident in the likelihood of success for Amigal and are excited we have the potential to bring to market the first oral treatment to patients with Fabry disease.”

Key Strategic Priorities

The Company reaffirmed its three key strategic priorities for 2010: Phase 3 development of migalastat HCl for Fabry disease, advancing chaperone-ERT combination therapy into clinical development, and further preclinical evaluation of the use of pharmacological chaperones for the treatment of diseases of neurodegeneration. In addition, Amicus confirmed its commitment to exploring a wide range of opportunities, including potential global partnerships, to build on its financial strength and enable the Company to maximize the value of its pharmacological chaperone technology platform.

Amigal™ (migalastat HCl) for the treatment of Fabry disease

The Phase 3 study intended to support approval of migalastat HCl in the United States (Study 011) commenced in the second quarter of 2009 and treatment of the first patient began in the fourth quarter of 2009. The Company expects to complete enrollment by the end of 2010 and to have preliminary results from this study in mid-2011.

In addition, Amicus expects to commence a separate Phase 3 study (Study 012) before year end. Study 012 is intended to support approval in the European Union and 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).

In 2009, twenty-three of the original 26 subjects who completed Phase 2 studies continued to receive treatment in a voluntary extension study designed to evaluate the long-term safety and efficacy of migalastat HCl. Over the course of the initial Phase 2 and extension studies, fifteen subjects have been treated with migalastat HCl for approximately 2-3 years and eight subjects have been treated with migalastat HCl for more than 3 years. Twenty-one subjects now continue to receive treatment in the ongoing extension study.

Amicus recently announced additional preliminary data from this ongoing extension study, with a focus on renal function as evaluated by estimated glomerular filtration rate (eGFR) and proteinuria. These data indicated that eGFR remained stable out to 2-3 years for all subjects continuing in the extension study and the average annual rate of change in eGFR in subjects identified as responders to migalastat HCl, excluding hyperfiltrators, was +2.0 mL/min/1.73m². Additionally, trends of reduced proteinuria continued to be observed in subjects identified as responders to migalastat HCl.

John F. Crowley, Chairman and CEO of Amicus Therapeutics continued, "Throughout 2009 we continued to explore the versatility of our chaperone technology and made progress with our chaperone-ERT combination therapy approach as well as advancements studying chaperones for the treatment of diseases of neurodegeneration. In 2010, we plan to initiate a Phase 2 chaperone-ERT combination study for Fabry disease and to further develop our preclinical programs for Parkinson's disease and Alzheimer's disease."

Chaperone-ERT Combination Therapy

In 2009, Amicus advanced its programs evaluating the use of pharmacological chaperones in combination with ERT as an expansion of the chaperone technology platform. The Company reported preclinical data at several scientific conferences demonstrating that the addition of a pharmacological chaperone to ERT has the potential to address key limitations of ERT.

Amicus recently presented new data from preclinical studies that evaluated the combination of migalastat HCl and ERT and AT2220 and ERT in mouse models of Fabry and Pompe disease, respectively. Studies of both combinations demonstrated that co-administration of the chaperone with ERT resulted in prolonged half-life of ERT in the circulation, increased enzyme activity in cells and greater substrate reduction in target tissues compared to that seen with ERT alone.

As previously announced, the Company plans to initiate a Phase 2 study with migalastat HCl in combination with ERT for Fabry disease before the end of 2010. Additionally, the Company is evaluating options to advance chaperone-ERT combination therapy programs for Pompe disease and Gaucher disease.

Diseases of Neurodegeneration

As previously reported, the Company has established initial proof-of-concept for the use of its pharmacological chaperones in animal models of Parkinson's disease and continues to advance this preclinical program.

Amicus recently presented data from preclinical studies that evaluated the chaperone AT2101 in mouse models of Parkinson's disease. The studies demonstrated that treatment with AT2101 increased the activity of β -glucocerebrosidase (GCase), prevented accumulation of α -synuclein in the brain and improved motor function as assessed in various behavioral tests. The Company also reported that new compounds have been identified that improve on the properties of AT2101 and expand the range of doses and regimens that show motor improvement in mouse models of the disease.

Additionally, Amicus previously announced that its second lead preclinical program using the pharmacological chaperone approach for diseases of neurodegeneration is for the treatment of Alzheimer's disease. The Company expects to complete initial proof-of-concept studies during 2010 and report data in the second half of 2010.

2010 Financial Guidance

As previously reported, the Company expects to spend a total of \$40 to \$50 million on 2010 operating expenses. The current cash position is expected to be sufficient to fund operations and capital expenditure requirements into the second half of 2011.

Additional Financial Results & Notes

Net income attributable to common stockholders for the three months ended December 31, 2009, was \$33.0 million as compared to a net loss of \$14.2 million for the same period in 2008.

Amicus recorded revenue during the fourth quarter of 2009 representing two different revenue streams from the Shire collaboration agreement. Upon signing the agreement, Amicus received an upfront payment of \$50 million that was being recognized as revenue on a straight-line basis over 18 years from the date of the agreement. In connection with the mutual termination of the Shire collaboration agreement in the fourth quarter of 2009, Amicus recognized \$44.7 million of previously deferred revenue on the upfront payment from Shire. Additionally, Amicus received a \$5.2 million termination payment from Shire as full and fair settlement of all development cost sharing obligations. Approximately \$4.7 million of this payment was recognized as research revenue during the fourth quarter and \$0.5 million was applied to a receivable for reimbursable research and development costs incurred during the prior quarter.

In line with prior estimates, Amicus recorded \$0.9 million of employment termination costs associated with its 20%, or 26 employee, workforce reduction in the fourth quarter. Additionally, Amicus completed a facility consolidation that resulted in a charge of \$0.7 million.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and webcast today, Tuesday, February 16, 2010, at 5:00 P.M. EST to review financial results and provide a corporate update. Interested participants and investors may access the conference call at 5 p.m. EST by dialing 888-791-4315 (U.S./Canada) or 913-312-0641 (international).

An audio webcast and archive can also be accessed via the investor section of the Amicus Therapeutics 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 webcast replay will remain available in the Investors section of the Amicus Therapeutics Web site for 30 days.

A telephonic replay of the call will be available for seven days beginning at 8 p.m. EST. Access numbers for this replay are 888-203-1112 (U.S./Canada) and 719-457-0820 (international); participant code 9348622.

Amicus' press releases are available at www.amicustherapeutics.com

About Amicus Therapeutics

Amicus Therapeutics 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 diseases of neurodegeneration. Amicus' lead program is in Phase 3 for the treatment of Fabry disease.

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, the projected cash position for the Company, and business development and other transactional activities that seek to strengthen the Company's financial position. 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 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. Additionally, with respect to statements relating to potential business development opportunities and other transactions that seek to strengthen our financial position, we may not be successful in identifying suitable collaborators, establishing and implementing such collaborations or completing other transactions that could improve our financial position. 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, 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.

CONTACTS:

Investors/Media:
Jenene Thomas
Director, Investor Relations
Amicus Therapeutics
Jthomas@amicustherapeutics.com
609-662-5084

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 December 31, | | Twelve Months Ended December 31, | | Period from February 4, 2002 (inception) to December 31, |
|---|------------------------------------|-------------------|-------------------------------------|-------------------|--|
| | 2008 | 2009 | 2008 | 2009 | 2009 |
| Revenue: | | | | | |
| Research revenue | \$ 3,650 | \$ 4,746 | \$ 12,189 | \$ 17,545 | \$ 31,108 |
| Collaboration revenue | 695 | 44,730 | 2,778 | 46,813 | 50,000 |
| Total revenue | <u>4,345</u> | <u>49,476</u> | <u>14,967</u> | <u>64,358</u> | <u>81,108</u> |
| Operating Expenses: | | | | | |
| Research and development | 13,775 | 10,126 | 37,764 | 48,081 | 175,722 |
| General and administrative | 4,990 | 4,338 | 19,666 | 19,973 | 77,709 |
| Restructuring charges | — | 1,522 | — | 1,522 | 1,522 |
| Impairment of leasehold improvements | — | — | — | — | 1,030 |
| Depreciation and amortization | 457 | 548 | 1,493 | 2,132 | 6,420 |
| In-process research and development | — | — | — | — | 418 |
| Total operating expenses | <u>19,222</u> | <u>16,534</u> | <u>58,923</u> | <u>71,708</u> | <u>262,821</u> |
| Loss from operations | (14,877) | 32,942 | (43,956) | (7,350) | (181,713) |
| Other income (expenses): | | | | | |
| Interest income | 766 | 73 | 4,819 | 997 | 13,757 |
| Interest expense | (39) | (123) | (218) | (278) | (1,925) |
| Change in fair value of warrant liability | — | — | — | — | (454) |
| Other income/(expense) | — | 64 | — | 64 | (1,116) |
| Loss before tax benefit | (14,150) | 32,956 | (39,355) | (6,567) | (171,451) |
| Income tax benefit | — | — | — | — | 695 |
| Net (loss)/income | (14,150) | 32,956 | (39,355) | (6,567) | (170,756) |
| Deemed dividend | — | — | — | — | (19,424) |
| Preferred stock accretion | — | — | — | — | (802) |
| Net (loss)/income attributable to common stockholders | <u>\$ (14,150)</u> | <u>\$ 32,956</u> | <u>\$ (39,355)</u> | <u>\$ (6,567)</u> | <u>\$ (190,982)</u> |
| Net (loss)/income attributable to common stockholders per common share – basic | | | | | |
| | <u>\$ (0.63)</u> | <u>\$ 1.46</u> | <u>\$ (1.75)</u> | <u>\$ (0.29)</u> | |
| – diluted | <u>\$ (0.63)</u> | <u>\$ 1.45</u> | <u>\$ (1.75)</u> | <u>\$ (0.29)</u> | |
| Weighted-average common shares outstanding – basic | | | | | |
| | <u>22,576,561</u> | <u>22,643,507</u> | <u>22,493,803</u> | <u>22,624,134</u> | |
| – diluted | <u>22,576,561</u> | <u>22,781,090</u> | <u>22,493,803</u> | <u>22,624,134</u> | |

See accompanying notes to consolidated financial statements

Source: FOLD –G