

AMICUS THERAPEUTICS INC

Form 10-Q

August 08, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2012

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-33497

Amicus Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

71-0869350
(I.R.S. Employer
Identification Number)

1 Cedar Brook Drive, Cranbury, NJ 08512

(Address of Principal Executive Offices and Zip Code)

Registrant's Telephone Number, Including Area Code: **(609) 662-2000**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller-reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller-reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

The number of shares outstanding of the registrant's common stock, \$.01 par value per share, as of August 2, 2012 was 49,339,581 shares.

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Form 10-Q for the Quarterly Period Ended June 30, 2012

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We have filed applications to register certain trademarks in the United States and abroad, including AMICUSTM and AMICUS THERAPEUTICSTM (and design).

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this quarterly report on Form 10-Q regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, will, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

- the progress and results of our clinical trials of our drug candidates, including migalastat HCl;
- the continuation of our collaboration with GlaxoSmithKline PLC and GSK's achievement of milestone payments thereunder;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-administered with ERT and for the treatment of diseases of neurodegeneration;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the emergence of competing technologies and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- the extent to which we acquire or invest in businesses, products and technologies; and
- our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part II Item 1A Risk Factors of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

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You should read this quarterly report on Form 10-Q in conjunction with the documents that we reference herein. We do not assume any obligation to update any forward-looking statements.

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements (unaudited)****Amicus Therapeutics, Inc.****(a development stage company)****Consolidated Balance Sheets***(Unaudited)***(in thousands, except share and per share amounts)**

	December 31, 2011	June 30, 2012
Assets:		
Current assets:		
Cash and cash equivalents	\$ 25,668	\$ 28,858
Investments in marketable securities	30,034	66,914
Receivable due from GSK	5,043	7,237
Prepaid expenses and other current assets	5,903	2,658
Total current assets	66,648	105,667
Property and equipment, less accumulated depreciation and amortization of \$9,507 and \$7,658 at December 31, 2011 and June 30, 2012, respectively	2,438	5,489
Other non-current assets	709	442
Total Assets	\$ 69,795	\$ 111,598
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,708	\$ 9,067
Current portion of deferred revenue	8,504	7,929
Current portion of secured loan	1,044	816
Total current liabilities	19,256	17,812
Deferred revenue, less current portion	18,999	15,679
Warrant liability	1,948	4,442
Secured loan, less current portion		498
Commitments and contingencies		
Stockholders equity:		
Common stock, \$.01 par value, 125,000,000 shares authorized, 34,654,206 shares issued and outstanding at December 31, 2011, 125,000,000 shares authorized, 46,377,897 shares issued and outstanding at June 30, 2012	407	524
Additional paid-in capital	299,285	365,210
Accumulated other comprehensive income	4	17

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Deficit accumulated during the development stage		(270,104)		(292,584)
Total stockholders' equity		29,592		73,167
Total Liabilities and Stockholders' Equity	\$	69,795	\$	111,598

See accompanying notes to consolidated financial statements

Table of Contents**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, 2012
	2011	2012	2011	2012	2012
Revenue:					
Research revenue	\$ 2,380	\$ 5,477	\$ 6,686	\$ 11,591	\$ 57,493
Collaboration and milestone revenue	1,660	5,160	3,320	6,820	64,382
Total revenue	\$ 4,040	\$ 10,637	\$ 10,006	\$ 18,411	\$ 121,875
Operating Expenses:					
Research and development	\$ 11,618	\$ 13,723	\$ 22,743	\$ 27,727	\$ 293,347
General and administrative	6,720	5,819	11,122	9,914	123,163
Restructuring charges					1,522
Impairment of leasehold improvements					1,030
Depreciation and amortization	426	442	864	862	10,925
In-process research and development					418
Total operating expenses	18,764	19,984	34,729	38,503	430,405
Loss from operations	(14,724)	(9,347)	(24,723)	(20,092)	(308,530)
Other income (expenses):					
Interest income	46	116	105	143	14,216
Interest expense	(41)	(15)	(89)	(58)	(2,391)
Change in fair value of warrant liability	2,078	(118)	(1,354)	(2,494)	(1,594)
Other income		21	70	21	252
Loss before tax benefit	(12,641)	(9,343)	(25,991)	(22,480)	(298,047)
Benefit from income taxes					5,463
Net loss	(12,641)	(9,343)	(25,991)	(22,480)	(292,584)
Deemed dividend					(19,424)
Preferred stock accretion					(802)
Net loss attributable to common stockholders	\$ (12,641)	\$ (9,343)	\$ (25,991)	\$ (22,480)	\$ (312,810)
Net loss attributable to common stockholders per common shares basic and diluted	\$ (0.37)	\$ (0.20)	\$ (0.75)	\$ (0.53)	
Weighted-average common shares outstanding basic and diluted	34,530,693	46,870,067	34,514,947	42,103,642	

See accompanying notes to consolidated financial statements

Table of Contents**Amicus Therapeutics, Inc.****(a development stage company)****Consolidated Statements of Comprehensive Loss***(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, 2012
	2011	2012	2011	2012	
Net loss	\$ (12,641)	\$ (9,343)	\$ (25,991)	\$ (22,480)	\$ (292,584)
Other comprehensive income/(loss):					
Unrealized gain (loss) on available-for-sale securities	29	(20)	29	13	17
Other comprehensive income/(loss), before income taxes	29	(20)	29	13	17
Provision for income taxes related to other comprehensive income/(loss) items (Note 1)					
Other comprehensive income/(loss)	\$ 29	\$ (20)	\$ 29	\$ 13	\$ 17
Comprehensive loss	\$ (12,612)	\$ (9,363)	\$ (25,962)	\$ (22,467)	\$ (292,567)

Note 1 Taxes have not been accrued on unrealized gain on securities as the Company is in a loss position for all periods presented.

See accompanying notes to consolidated financial statements

Table of Contents**Amicus Therapeutics, Inc.****(a development stage company)****Consolidated Statements of Cash Flows***(Unaudited)***(in thousands)**

	2011	Six Months Ended June 30, 2012	2012	Period from February 4, 2002 (inception) to June 30, 2012
Operating activities				
Net loss	\$ (25,991)		\$ (22,480)	\$ (292,584)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash interest expense				525
Depreciation and amortization	864		862	10,925
Amortization of non-cash compensation				522
Stock-based compensation - employees	5,302		3,145	38,883
Stock-based compensation - non-employees				853
Stock-based license payments				1,220
Change in fair value of warrant liability	1,354		2,494	1,594
Loss on disposal of asset			27	387
Impairment of leasehold improvements				1,030
Non-cash charge for in-process research and development				418
Debt instrument convertible beneficial conversion feature				135
Changes in operating assets and liabilities:				
Receivable due from GSK	(1,977)		(2,194)	(7,237)
Prepaid expenses and other current assets	(840)		3,245	(2,658)
Other non-current assets			267	(463)
Accounts payable and accrued expenses	(1,271)		(641)	9,067
Deferred revenue	(1,354)		(3,895)	23,608
Net cash used in operating activities	(23,913)		(19,170)	(213,775)
Investing activities				
Sale and redemption of marketable securities	57,224		34,839	706,927
Purchases of marketable securities	(36,594)		(71,706)	(773,942)
Purchases of property and equipment	(182)		(3,939)	(17,829)
Net cash provided by/(used in) investing activities	20,448		(40,806)	(84,844)
Financing activities				
Proceeds from the issuance of preferred stock, net of issuance costs				143,022
Proceeds from the issuance of common stock and warrants, net of issuance costs			62,057	175,303
Proceeds from the issuance of convertible notes				5,000
Payments of capital lease obligations	(40)			(5,587)
Payments of secured loan agreement	(626)		(726)	(3,440)
Proceeds from exercise of stock options	348		840	2,551
Proceeds from exercise of warrants (common and preferred)				264
Proceeds from capital asset financing arrangement				5,611
Proceeds from secured loan agreement			995	4,753

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Net cash (used in) /provided by financing activities	(318)	63,166	327,477
Net (decrease) increase in cash and cash equivalents	(3,783)	3,190	28,858
Cash and cash equivalents at beginning of period	29,572	25,668	
Cash and cash equivalents at end of period	\$ 25,789	\$ 28,858	\$ 28,858

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Amicus Therapeutics, Inc.

(a development stage company)

Consolidated Statements of Cash Flows (continued)

(Unaudited)

(in thousands)

	2011	Six Months Ended June 30, 2012	Period from February 4, 2002 (inception) to June 30, 2012
Supplemental disclosures of cash flow information			