

AMICUS THERAPEUTICS INC  
Form 10-Q  
May 05, 2014  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2014**

**OR**

**o** **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 April 28, 2014 was 64,340,526 shares.



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We have registered or filed applications to register certain trademarks in the United States and abroad, including AMICUS , AMICUS THERAPEUTICS (and design) and CHART (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," "potential," "intend," "may," "plan," "predict," "project," "will," "should," "would" and similar expressions are used in 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 cost of manufacturing drug supply for our clinical and preclinical studies, including the significant cost of ERT cell line development and manufacturing as well as the cost of manufacturing the vIGF-2 peptide tag;
- 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-formulated and co-administered with ERT and for the treatment of lysosomal storage diseases;
- 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;
- our ability to successfully incorporate Callidus Biopharma, Inc. ( "Callidus" ) and its product candidates and technology into our business; 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 I Item 1A "Risk Factors" of the Annual Report on Form 10-K for the year ended December 31, 2013 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

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acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

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, 2013	March 31, 2014
<b>Assets:</b>		
Current assets:		
Cash and cash equivalents	\$ 43,640	\$ 27,533
Investments in marketable securities	38,360	44,121
Receivable due from GSK	759	38
Prepaid expenses and other current assets	5,519	1,758
Total current assets	88,278	73,450
Property and equipment, less accumulated depreciation and amortization of \$9,973 and \$10,385 at December 31, 2013 and March 31, 2014, respectively	4,120	3,748
In-process research & development	23,000	23,000
Goodwill	11,613	11,613
Other non-current assets	552	546
<b>Total Assets</b>	<b>\$ 127,563</b>	<b>\$ 112,357</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,162	\$ 9,167
Current portion of secured loan	299	199
Total current liabilities	10,461	9,366
Deferred reimbursements	36,677	36,677
Secured loan, less current portion	14,174	14,216
Contingent consideration payable	10,600	11,105
Deferred tax liability	9,186	9,186
Other non-current liability	714	723
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock, \$.01 par value, 125,000,000 shares authorized, 61,975,416 shares issued and outstanding at December 31, 2013, 125,000,000 shares authorized, 64,340,259 shares issued	679	703



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and outstanding at March 31, 2014

Additional paid-in capital	423,593	424,844
Accumulated other comprehensive income	1	2
Deficit accumulated during the development stage	(378,522)	(394,465)
Total stockholders' equity	45,751	31,084
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 127,563</b>	<b>\$ 112,357</b>

*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)**

	2013	Three Months Ended March 31, 2014	Period from February 4, 2002 (inception) to March 31, 2014
Revenue:			
Research revenue	\$	\$ 456	\$ 58,312
Collaboration and milestone revenue			64,382
Total revenue		456	122,694
Operating Expenses:			
Research and development	\$ 11,989	\$ 9,992	\$ 367,829
General and administrative	4,823	5,176	156,682
Changes in fair value of contingent consideration payable		505	505
Restructuring charges		(8)	3,502
Impairment of leasehold improvements			1,030
Depreciation and amortization	439	412	13,899
In-process research and development			418
Total operating expenses	17,251	16,077	543,865
Loss from operations	(17,251)	(15,621)	(421,171)
Other income (expenses):			
Interest income	65	42	14,605
Interest expense	(10)	(355)	(2,823)
Change in fair value of warrant liability	(262)		2,461
Other (expense)/ income		(9)	243
Loss before tax benefit	(17,458)	(15,943)	(406,685)
Income tax benefit			12,220
Net loss	(17,458)	(15,943)	(394,465)
Deemed dividend			(19,424)
Preferred stock accretion			(802)
Net loss attributable to common stockholders	\$ (17,458)	\$ (15,943)	\$ (414,691)
Net loss attributable to common stockholders per common share basic and diluted	\$ (0.35)	\$ (0.25)	
Weighted-average common shares outstanding basic and diluted	49,621,188	64,353,952	

*See accompanying notes to consolidated financial statements*

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**Amicus Therapeutics, Inc.**

**(a development stage company)**

**Consolidated Statements of Comprehensive Loss**

*(Unaudited)*

**(in thousands)**

	<b>Three Months Ended March 31,</b>		<b>Period from February 4, 2002 (inception) to March 31, 2014</b>
	<b>2013</b>	<b>2014</b>	
Net loss	\$ (17,458)	\$ (15,943)	\$ (394,465)
Other comprehensive income/(loss):			
Unrealized gain on available-for- sale securities	1	1	2
Other comprehensive income, before income taxes	1	1	2
Provision for income taxes related to other comprehensive income Items (a)			
Other comprehensive income	\$ 1	\$ 1	\$ 2
Comprehensive loss	\$ (17,457)	\$ (15,942)	\$ (394,463)

(a) 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)**

	2013	Three Months Ended March 31, 2014	Period from February 4, 2002 (inception) to March 31, 2014
<b>Operating activities</b>			
Net loss	\$ (17,458)	\$ (15,943)	\$ (394,465)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense		59	584
Depreciation and amortization	439	412	13,899
Amortization of non-cash compensation			522
Stock-based compensation	1,574	1,260	49,366
Non-cash charge for stock based compensation issued to consultants			853
Restructuring charges		(8)	3,502
Change in fair value of warrant liability	262		(2,461)
Non-cash changes in the fair value of contingent consideration payable		505	505
Loss on disposal of asset			