AMICUS THERAPEUTICS INC Form 10-Q November 12, 2013 Table of Contents

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 September 30, 2013

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 x No o

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 x No o

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 o

Accelerated filer o

Non-accelerated filer x

Smaller Reporting Company o

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

The number of shares outstanding of the registrant s common stock, \$.01 par value per share, as of October 31, 2013 was 49,631,672 shares.

Table of Contents

AMICUS THERAPEUTICS, INC

Form 10-Q for the Quarterly Period Ended September 30, 2013

PART I. FINANCIAL INFORMATION		Page 4
Item 1.	Financial Statements (unaudited)	4
	Consolidated Balance Sheets as of December 31, 2012 and September 30, 2013	4
	Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2013, and period February 4, 2002 (inception) to September 30, 2013	5
	Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2012 and 2013, and period February 4, 2002 (inception) to September 30, 2013	6
	Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2013, and period February 4, 2002 (inception) to September 30, 2013	7
	Notes to Consolidated Financial Statements	9
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	35
Item 4.	Controls and Procedures	36
PART II. OTHER INFORMATION		37
Item 1.	<u>Legal Proceedings</u>	37
Item 1A.	Risk Factors	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 3.	<u>Defaults Upon Senior Securities</u>	38
Item 4.	Mine Safety Disclosures	38
Item 5.	Other Information	38
Item 6.	Exhibits	39
<u>SIGNATURES</u>		40
INDEX TO EXHIBITS		41

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).

Table of Contents

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, should, would and similar expressions are intended to id 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 (GSK) and GSK s achievement of milestone payment 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-formulated and co-administered with enzyme replacement therapy (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 I Item 1A Risk Factors of the Annual Report on Form 10-K for the year ended December 31, 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.

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, 2012		September 30, 2013	
Assets:				
Current assets:				
Cash and cash equivalents	\$,	\$ 30,047	
Investments in marketable securities		65,151	30,448	
Receivable due from GSK		3,225	2,121	
Prepaid expenses and other current assets		2,270	1,692	
Total current assets		104,617	64,308	
Property and equipment, less accumulated depreciation and amortization of \$8,501 and				
\$9,751 at December 31, 2012 and September 30, 2013, respectively		5,029	4,356	
Other non-current assets		442	442	
Total Assets	\$	110,088	\$ 69,106	
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	8,845	\$ 8,166	
Current portion of secured loan		398	398	
Warrant liability			34	
Total current liabilities		9,243	8,598	
Deferred reimbursements		30,418	34,019	
Warrant liability, non-current		908	31,019	
Secured loan, less current portion		299		
Commitments and contingencies				
Stockholders equity:				
Common stock, \$.01 par value, 125,000,000 shares authorized, 49,631,672 shares issued and outstanding at December 31, 2012, 125,000,000 shares authorized, 49,631,672				
shares issued and outstanding at September 30, 2013		556	556	
Additional paid-in capital		387,539	392,213	
• •		387,339	592,213	
Accumulated other comprehensive income		14	3	

Deficit accumulated during the development stage	(318,889)	(366,285)
Total stockholders equity	69,220	26,489
Total Liabilities and Stockholders Equity	\$ 110,088 \$	69,106

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)

					Period from
					February 4,
					2002
	Three M	Three Months Ended September 30,		Nine Months Ended September 30,	
	Ended Septe				
	2012	2013	2012	2013	2013
Revenue:					

Research revenue

\$