AMICUS THERAPEUTICS INC
Form 10-Q
August 07, 2017
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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 June 30, 2017

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	**71-0869350**
(State or Other Jurisdiction of Incorporation or Organization)	(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, smaller reporting company, or an emerging growth company. See definition of large accelerated filer, accelerated filer , smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
(Do not check if a smaller reporting company)	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. 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 o

The number of shares outstanding of the registrant s common stock, $0.01 par value per share, as of July 25, 2017 was 164,566,069 shares.

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AMICUS THERAPEUTICS, INC.

Form 10-Q for the Quarterly Period Ended June 30, 2017

We have filed applications to register certain trademarks in the U.S. and abroad, including Amicus Therapeutics® and designs, At the forefront of therapies for rare and orphan diseases , Zorblisa , and Galafold .

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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 i 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;
- the cost of manufacturing drug supply for our clinical and preclinical studies, including the significant cost of new Fabry enzyme replacement therapy (ERT) cell line development and manufacturing as well as the cost of manufacturing Pompe ERT;
- 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 disorders;
- the future results of on-going or subsequent clinical trials for SD-101, including our ability to obtain regulatory approvals and commercialize SD-101 and obtain market acceptance of SD-101;
- the future results of on-going preclinical research and subsequent clinical trials for cyclin-dependent kinase-like 5 (CDKL5), including our ability to obtain regulatory approvals and commercialize CDKL5 and obtain market acceptance for CDKL5;
- 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;
- our ability to obtain reimbursement for migalastat HCI;
- our ability to obtain market acceptance of migalastat HCl in the European Union;
- 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 integrate our acquisition of Scioderm, Inc. and its products and technologies into our business, including the possibility that the expected benefits of the transactions will not be fully realized by us or may take longer to realize than expected; 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, as amended, for the year ended December 31, 2016, 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 document that we reference herein. We do not assume any obligation to update any forward-looking statements.

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PART I. **FINANCIAL INFORMATION**

Item 1. **Financial Statements (unaudited)**

Amicus Therapeutics, Inc.

Consolidated Balance Sheets *(Unaudited)*

(in thousands, except share and per share amounts)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 37,394	$ 187,026
Investments in marketable securities	189,838	143,325
Accounts receivable	3,786	1,304
Inventories	3,948	3,416
Prepaid expenses and other current assets	6,023	4,993
Total current assets	240,989	340,064
Property and equipment, less accumulated depreciation of $13,951 and $12,495 at June 30, 2017 and December 31, 2016, respectively	10,471	9,816
In-process research & development	486,700	486,700
Goodwill	197,797	197,797
Other non-current assets	3,009	2,468
Total Assets	$ 938,966	$ 1,036,845
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other current liabilities	$ 35,645	$ 41,008
Deferred reimbursements, current portion	18,850	13,850
Contingent consideration payable, current portion	46,188	56,101
Total current liabilities	100,683	110,959
Deferred reimbursements	16,906	21,906
Convertible notes	159,171	154,464
Contingent consideration payable	219,162	213,621
Deferred income taxes	173,869	173,771
Other non-current liability	2,283	1,973
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.01 par value, 250,000,000 shares authorized, 143,371,243 and 142,691,986 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1,485	1,480
Additional paid-in capital	1,132,229	1,120,156
Accumulated other comprehensive loss:		
Foreign currency translation adjustment, less tax expense of $1,293 at June 30, 2017 and December 31, 2016	(192)	1,945
Unrealized gain on available-for securities	31	102

Warrants		16,076		16,076
Accumulated deficit		(882,737)		(779,608)
Total stockholders equity		266,892		360,151
Total Liabilities and Stockholders Equity	$	938,966	$	1,036,845

See accompanying notes to consolidated financial statements

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Amicus Therapeutics, Inc.

Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue:				