AMICUS THERAPEUTICS INC
Form 10-Q
August 06, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2009

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)

6 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 þ 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 o 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 þ	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 þ

The number of shares outstanding of the registrant s common stock, $.01 par value per share, as of July 24, 2009 was 22,643,184 shares.

AMICUS THERAPEUTICS, INC
Form 10-Q for the Quarterly Period Ended June 30, 2009

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Exhibit 10.1
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We have filed applications to register certain trademarks in the United States and abroad, including AMICUS^{TM}, AMICUS THERAPEUTICS^{TM} (and design), AMIGAL^{TM} and PLICERA^{TM}.

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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, in may, plan, predict, project, will, would and similar expressions are intended to identify forward-looking state 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:

- our plans to develop, seek regulatory approval for and commercialize Amigal, Plicera and AT2220;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- our ability to enter into selective collaboration arrangements and obtain milestone, royalty or other payments from any such collaborators;
- the timing of and our ability to obtain agreement with regulatory agencies on the design of our Phase 3 program for Amigal;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our ability to quickly and efficiently identify and develop product candidates;
- the extent to which our scientific approach may potentially address a broad range of diseases across multiple therapeutic areas;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our belief about our ability to fund our operating expenses; and
- our eligibility to receive milestone payments under our collaboration agreement with Shire Pharmaceuticals Ireland Ltd.

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, 2008 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.

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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, 2008	June 30, 2009
Assets:		
Current assets:		
Cash and cash equivalents	$ 28,073	$ 15,760
Investments in marketable securities	93,051	84,670
Prepaid expenses and other current assets	2,463	2,653
Total current assets	123,587	103,083
Property and equipment, less accumulated depreciation and amortization of $4,260 and $5,271 at December 31, 2008 and June 30, 2009, respectively	4,919	5,326
Other non-current assets	267	267
Total Assets	$ 128,773	$ 108,676
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,796	$ 10,988
Current portion of deferred revenue	3,705	2,778
Current portion of capital lease obligations	877	603
Current portion of secured loan		868
Total current liabilities	13,378	15,237
Deferred revenue, less current portion	44,035	42,647
Capital lease obligations, less current portion	317	164
Secured loan, less current portion		1,987
Commitments and contingencies		
Stockholders equity:		
Common stock, $.01 par value, 50,000,000 shares authorized, 22,634,711 shares issued and outstanding at December 31, 2008, 50,000,000 shares authorized, 22,643,184 shares issued and outstanding at June 30, 2009	287	287
Additional paid-in capital	234,412	238,492
Accumulated other comprehensive income	533	145
Deficit accumulated during the development stage	(164,189)	(190,283)
Total stockholders equity	71,043	48,641

Total Liabilities and Stockholders Equity	$	128,773	$	108,676

See accompanying notes to consolidated financial statements

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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, 2008	Three Months Ended June 30, 2009	Six Months Ended June 30, 2008	Six Months Ended June 30, 2009	Period from February 4, 2002 (inception) to June 30, 2009
Revenue:					
Research revenue	$ 3,113	$ 4,667	$ 5,579	$ 8,580	$ 22,143
Collaboration revenue	694	694	1,389	1,389	4,576
Total revenue	$ 3,807	$ 5,361	$ 6,968	$ 9,969	$ 26,719
Operating Expenses:					
Research and development	$ 8,848	$ 13,470	$ 15,789	$ 25,345	$ 152,987
General and administrative	5,118	5,223	10,305	10,419	68,154
Impairment of leasehold improvements					1,030
Depreciation and amortization	332	519	653	1,024	5,311
In-process research and development					418
Total operating expenses	14,298	19,212	26,747	36,788	227,900
Loss from operations	(10,491)	(13,851)	(19,779)	(26,819)	(201,181)
Other income (expenses):					
Interest income	1,331	269	3,034	795	13,555
Interest expense	(59)	(41)	(129)	(71)	(1,718)
Change in fair value of warrant liability					(454)
Other expense					(1,180)
Loss before tax benefit	(9,219)	(13,623)	(16,874)	(26,095)	(190,978)
(Provision for)/benefit from income taxes	(75)		(150)		695
Net loss	(9,294)	(13,623)	(17,024)	(26,095)	(190,283)
Deemed dividend					(19,424)
Preferred stock accretion					(802)
Net loss attributable to common stockholders	$ (9,294)	$ (13,623)	$ (17,024)	$ (26,095)	$ (210,509)

Net loss attributable to common stockholders per common share basic and diluted	$ (0.41)	$ (0.60)	$ (0.76)	$ (1.15)
Weighted-average common shares outstanding basic and diluted	22,467,198	22,618,026	22,439,893	22,615,951

See accompanying notes to consolidated financial statements

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

	Six Months Ended June 30, 2008	Six Months Ended June 30, 2009	Period from February 4, 2002 (inception) to June 30, 2009
Operating activities			
Net loss	$ (17,024)	$ (26,095)	$ (190,283)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense			525
Depreciation and amortization	653	1,024	5,310
Amortization of non-cash compensation			522
Stock-based compensation employees	3,203	4,069	17,154
Stock-based compensation non-employees			853
Stock-based license payments			1,220
Change in fair value of warrant liability			454
Loss on disposal of asset		9	54
Impairment of leasehold improvements			1,030
Non-cash charge for in-process research and development			418
Beneficial conversion feature related to bridge financing			135
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(158)	(189)	(2,652)
Other non-current assets			(289)
Accounts payable and accrued expenses	280	2,193	10,988
Deferred revenue	(1,894)	(2,316)	45,425
Net cash used in operating activities	(14,940)	(21,305)	(109,136)
Investing activities			
Sale and redemption of marketable securities	73,442	76,926	424,092
Purchases of marketable securities	(88,829)	(68,933)	(508,734)
Purchases of property and equipment	(1,059)	(1,440)	(11,718)
Net cash (used in)/provided by investing activities	(16,446)	6,553	(96,360)
Financing activities			
Proceeds from the issuance of preferred stock, net of issuance costs			143,022
Proceeds from the issuance of common stock, net of issuance costs			68,093
Proceeds from the issuance of convertible notes			5,000
Payments of capital lease obligations	(768)	(427)	(4,821)
Proceeds from exercise of stock options	281	11	1,232
Proceeds from exercise of warrants (common and preferred)			264

Proceeds from capital asset financing arrangement						5,611
Proceeds from secured loan arrangement				2,855		2,855
Net cash (used in)/ provided by financing activities		(487)		2,439		221,256
Net (decrease)/ increase in cash and cash equivalents		(31,873)		(12,313)		15,760
Cash and cash equivalents at beginning of period		44,188		28,073		
Cash and cash equivalents at end of period	$	12,315	$	15,760	$	15,760
Supplemental disclosures of cash flow information						
Cash paid during the period for interest	$	129	$	71	$	1,425
Non-cash activities						
Conversion of notes payable to preferred stock	$		$		$	5,000
Conversion of preferred stock to common stock	$		$		$	148,591
Accretion of redeemable convertible preferred stock			$		$	802
Beneficial conversion feature related to the issuance	$					
of Series C redeemable convertible preferred stock	$		$		$	19,424

See accompanying notes to consolidated financial statements

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Note 1. Description of Business and Significant Accounting Policies

Corporate Information, Status of Operations and Management Plans

Amicus Therapeutics, Inc. (the Company) was incorporated on February 4, 2002 in Delaware for the purpose of creating a premier drug development company at the forefront of therapy for human genetic diseases initially based on intellectual property in-licensed from Mount Sinai School of Medicine. The Company s activities since inception have consisted principally of raising capital, establishing facilities, and performing research and development, including clinical trials. Accordingly, the Company is considered to be in the development stage.

In November 2007, the Company entered into a License and Collaboration Agreement with Shire Pharmaceuticals Ireland Ltd. (Shire). Under the agreement, the Company and Shire will jointly develop the Company s three lead pharmacological chaperone compounds for lysosomal storage disorders: Amigal (migalastat hydrochloride), Plicera (afegostat tartrate) and AT2220 (1-deoxynojirimycin HCl). For further information, see Note 7. Development and Commercialization Agreement with Shire.

The Company has an accumulated deficit of approximately $190.3 million at June 30, 2009 and anticipates incurring losses through the year 2009 and beyond. The Company has not yet generated commercial sales revenues and has been able to fund its operating losses to date through the sale of its redeemable convertible preferred stock, issuance of convertible notes, net proceeds from our initial public offering (IPO), the upfront licensing payment from Shire and other financing arrangements. The Company believes that its existing cash and cash equivalents and short-term investments will be sufficient to cover its cash flow requirements for 2009.

Basis of Presentation

The Company has prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Regulations S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s interim financial information.

The accompanying unaudited consolidated financial statements and related notes should be read in conjunction with the Company s financial statements and related notes as contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2008. For a complete description of the Company s accounting policies, please refer to the Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

Revenue Recognition

The Company recognizes revenue in accordance with the Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial* Statements (SAB 101), as amended by Staff Accounting Bulletin No. 104, *Revision of Topic 13* (SAB 104).

In determining the accounting for collaboration agreements, the Company follows the provisions of Emerging Issues Task Force (EITF) Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1) and Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). EITF 07-1 and EITF 00-21 provides guidance on collaborative arrangement and whether an arrangement involves multiple revenue-generating deliverables that should be accounted for as a single unit of accounting or divided into separate units of accounting for revenue recognition purposes and, if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the arrangement represents a single unit of accounting, the revenue recognition policy and the performance obligation period must be determined (if not already contractually defined) for the entire arrangement. If the arrangement represents separate units of accounting according to the EITF separation criteria, a revenue recognition policy must be determined for each unit. Revenues for non-refundable upfront license fee payments will be recognized on a straight line basis as Collaboration Revenue over the period of the performance obligations.

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Reimbursements for research and development costs under collaboration agreements are recognized as revenue in accordance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19). The revenue associated with these reimbursable amounts is included in Research Revenue and the costs associated with these reimbursable amounts are included in research and development expenses. The Company records these reimbursements as revenue and not as a reduction of research and development expenses as the Company has the risks and rewards as the principal in the research and development activities.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method deferred income tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities and for operating losses and tax credit carryforwards, using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a portion or all of a deferred tax asset will not be realized.

New Accounting Standards

In June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*, (SFAS No. 168), which will become the source of US generally accepted accounting principles to be applied to nongovernmental entities. On the effective date, SFAS No. 168 will supersede all existing non-SEC accounting and reporting standards. SFAS No. 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Since it is not intended to change or alter existing U.S. GAAP, this pronouncement is not expected to have any impact on the Company s financial statements. Beginning after the third quarter of 2009, references to U.S. GAAP will be replaced with references to the applicable codification paragraphs in the Company s financial statements.

In June 2009, the FASB issued SFAS No. 165, *Subsequent Events*, (SFAS No. 165), which applies to the accounting for and disclosure of subsequent events. SFAS No. 165 requires application of the requirements to interim or annual financial periods ending after June 15, 2009. The adoption of this pronouncement did not have a material effect on the financial statements of the Company.

At its April 2009 Board meeting, the FASB issued the following:

FASB Staff Position No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP 115-2). FSP 115-2 provides new guidance on the recognition of an Other Than Temporary Impairment and provides new disclosure requirements. The recognition and presentation provisions apply only to debt securities classified as available for sale and held to maturity.

Proposed Staff Position No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments; An amendment of FASB Statement No. 107* (FSP 107-1). FSP 107-1 extends the disclosure requirements of FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments* (Statement No. 107), to interim financial statements of publicly traded companies. Statement No. 107 requires disclosures of the fair value of all financial instruments (recognized or unrecognized), when practicable to do so. These fair value disclosures must be presented together with the carrying amount of the financial instruments in a manner that clearly distinguishes between assets and liabilities and indicates how the carrying amounts relate to amounts reported on the balance sheet. An entity must also disclose the methods and significant assumptions used to estimate the fair value of the financial instruments.

FASB Staff Position No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity has Significantly Decreased and Identifying Transactions that are Not Orderly* (FSP 157-4). FSP 157-4 amends FASB Statement No. 157, *Fair Value Measurement*, to provide additional guidance on estimating fair value when the volume and level of activity for an asset or liability has significantly decreased in relation to normal market activity for the asset or liability.

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Each of the accounting pronouncements listed above is effective for interim and annual periods ending after June 15, 2009. The adoption of these pronouncements did not have a material effect on the financial statements of the Company and the additional disclosures required were included in the financial statements of the Company for the period ended June 30, 2009.

Subsequent Events

The Company evaluated events that occurred subsequent to June 30, 2009 through the date of issuance of these financial statements on August 5, 2009. There were no material recognized or non-recognized subsequent events during this period.

Note 2. Cash and Available for Sale Investments

As of June 30, 2009, the Company held $15.8 million in cash and cash equivalents and $84.7 million of available for sale investment securities. In accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, these investments are reported at fair value on the Company s balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income/(loss) as a separate component of stockholders equity. If a decline in the fair value of a marketable security below the Company s cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. To date, only temporary impairment adjustments have been recorded.

The recent and precipitous decline in the market value of certain securities backed by residential mortgage loans has led to a large liquidity crisis affecting the broader U.S. housing market, the financial services industry and global financial markets. Investors holding many of these and related securities have experienced substantial decreases in asset valuations and uncertain secondary market liquidity. Furthermore, credit rating authorities have, in many cases, been slow to respond to the rapid changes in the underlying value of certain securities and pervasive market illiquidity, regarding these securities.

As a result, this credit crisis may have a potential impact on the determination of the fair value of financial instruments or possibly require impairments in the future should the value of certain investments suffer a decline in value which is determined to be other than temporary.

Consistent with the Company s investment policy, the Company does not use derivative financial instruments in its investment portfolio. The Company regularly invests excess operating cash in deposits with major financial institutions, money market funds, notes issued by the U.S. government, as well as fixed income investments and U.S. bond funds both of which can be readily purchased and sold using established markets. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated as many of these securities are either government backed or of the highest credit rating.

The Company s investment portfolio has not been materially adversely impacted by the recent disruption in the credit markets. However, if there is continued and expanded disruption in the credit markets, there can be no assurance that the Company s investment portfolio will not be adversely affected in the future.

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Cash and available for sale securities consisted of the following as of December 31, 2008 and June 30, 2009:

	As of December 31, 2008			
	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash balances	$ 3,457	$	$	$ 3,457
Money market fund	24,616			24,616
Commercial paper	22,343	104		22,447
U.S. government agency securities	58,341	449		58,790
Asset-based securities	7,251		(34)	7,217
Corporate debt securities	4,583	17	(3)	4,597
	$ 120,591	$ 570	$ (37)	$ 121,124
Included in cash and cash equivalents	$ 28,073	$	$	$ 28,073
Included in marketable securities	92,518	570	(37)	93,051
Total cash and available for sale securities	$ 120,591	$ 570	$ (37)	$ 121,124

	As of June 30, 2009		
	Unrealized	Unrealized	Fair