

AMICUS THERAPEUTICS INC

Form 10-Q

August 07, 2007

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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, 2007**

**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)

20-0422823  
(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  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 July 27, 2007 was 22,283,773 shares.

AMICUS THERAPEUTICS, INC  
Form 10-Q for the Quarterly Period Ended June 30, 2007

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We have filed applications to register certain trademarks in the United States and abroad, including AMICUS™, AMICUS THERAPEUTICS™ (and design), AMIGAL™ and PLICERA™. Fabrazyme®, Cerezyme®, Myozyme®, Replagal®, and Zavesca® are the property of their respective owners.

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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 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:

our plans to develop 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;

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; and

our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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 this quarterly report on Form 10-Q, particularly in the Risk Factors in section 1A of Part II of this quarterly report on Form 10-Q, 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 and the documents that we reference herein. We do not assume any obligation to update any forward-looking statements.

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**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 per share amounts)**

	<b>December 31, 2006</b>	<b>June 30, 2007</b>
<b>Assets:</b>		
Current assets:		
Cash and cash equivalents	\$ 12,127	\$ 26,494
Investments in marketable securities	42,572	99,229
Prepaid expenses and other current assets	321	1,432
Total current assets	55,020	127,155
Property and equipment, less accumulated depreciation and amortization of \$1,557 and \$2,166 at December 31, 2006 and June 30, 2007, respectively	4,358	4,161
Other non-current assets	267	267
<b>Total Assets</b>	<b>\$ 59,645</b>	<b>\$ 131,583</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	1,195	338
Accrued expenses	7,704	5,123
Current portion of capital lease obligations	1,307	1,504
Total current liabilities	10,206	6,965
Warrant Liability	609	
Capital lease obligations, less current portion	2,256	1,953
Series A redeemable convertible preferred stock, \$.01 par value, 444,443 shares authorized, issued and outstanding at December 31, 2006 (aggregate liquidation preference \$2,500 at December 31, 2006), no shares authorized, issued, or outstanding at June 30, 2007	2,476	
Series B redeemable convertible preferred stock, \$.01 par value, 4,936,730 shares authorized, 4,877,056 shares issued and outstanding at December 31, 2006 (aggregate liquidation preference \$31,000 at December 31, 2006), no shares authorized, issued, or outstanding at June 30, 2007	30,868	
Series C redeemable convertible preferred stock, \$.01 par value, 5,820,020 shares authorized, issued and outstanding at December 31, 2006 (aggregate liquidation preferences \$54,999 at December 31, 2006), no shares authorized, issued, or outstanding at June 30, 2007	54,869	
	35,876	

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Series D redeemable convertible preferred stock, \$.01 par value, 4,930,405 shares authorized, 2,953,878 issued and outstanding at December 31, 2006 (aggregate liquidation preference \$36,000), no shares authorized, issued, or outstanding at June 30, 2007

Stockholders' (deficiency) equity:

Common stock, \$.01 par value, 21,333,333 shares authorized, 990,492 shares issued and outstanding at December 31, 2006, 50,000,000 shares authorized and 22,292,156 shares issued and outstanding at June 30, 2007

	70	283
Additional paid-in capital	6,067	225,027
Accumulated other comprehensive income	15	113
Deficit accumulated during the development stage	(83,667)	(102,758)
Total stockholders' (deficiency) equity	(77,515)	122,665
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 59,645</b>	<b>\$ 131,583</b>

*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)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>		<b>Period from February 4, 2002 (inception) to June 30, 2007</b>
	<b>2006</b>	<b>2007</b>	<b>2006</b>	<b>2007</b>	
Operating Expenses:					
Research and development	\$ 6,691	\$ 6,783	\$ 12,719	\$ 13,867	\$ 72,671
General and administrative	2,563	3,189	4,464	6,040	28,832
Impairment of leasehold Improvements					1,030
Depreciation and amortization	217	312	416	609	2,166
In-process research and development					418
Total operating expenses	9,471	10,284	17,599	20,516	105,117
Loss from operations	(9,471)	(10,284)	(17,599)	(20,516)	(105,117)
Other income (expenses):					
Interest income	450	1,060	685	1,753	4,561
Interest expense	(74)	(86)	(125)	(179)	(1,261)
Change in fair value of warrant liability	471	(86)	127	(149)	(454)
Other expense					(1,182)
Loss before tax benefit	(8,624)	(9,396)	(16,912)	(19,091)	(103,453)
Income tax benefit					695
Net loss	(8,624)	(9,396)	(16,912)	(19,091)	(102,758)
Deemed dividend	(19,424)		(19,424)		(19,424)
Preferred stock accretion	(41)	(310)	(81)	(351)	(802)
Net loss attributable to common stockholders	\$ (28,089)	\$ (9,706)	\$ (36,417)	\$ (19,442)	\$ (122,984)
Net loss attributable to common stockholders per common share basic and diluted	\$ (39.04)	\$ (1.37)	\$ (57.78)	\$ (4.80)	
Weighted-average common shares outstanding basic and diluted	719,556	7,083,748	630,230	4,051,709	

*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)**

	<b>Six Months Ended June</b>		<b>Period from</b>
	<b>30,</b>		<b>February 4,</b>
	<b>2006</b>	<b>2007</b>	<b>2002</b>
			<b>(inception) to</b>
			<b>June 30, 2007</b>
<b>Operating activities</b>			
Net loss	\$ (16,912)	\$ (19,091)	\$ (102,758)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense			525
Depreciation and amortization	416	609	2,166
Amortization of non-cash compensation			522
Stock-based compensation employees	1,106	1,632	4,448
Stock-based compensation non-employees	228	134	824
Stock-based license payments			1,220
Change in fair value of warrant liability	(127)	149	454
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	298	(1,111)	(1,434)
Other non-current assets	(833)		(290)
Accounts payable and accrued expenses	763	(3,438)	5,460
Net cash used in operating activities	(15,061)	(21,116)	(87,280)
<b>Investing activities</b>			
Sale and redemption of marketable securities	20,226	42,936	85,632
Purchases of marketable securities	(10,154)	(99,495)	(184,866)
Purchases of property and equipment	(1,008)	(412)	(7,351)
Net cash provided by (used in) investing activities	9,064	(56,971)	(106,585)
<b>Financing activities</b>			
Proceeds from the issuance of preferred stock, net of issuance costs	27,500	24,053	143,022
Proceeds from the issuance of common stock, net of issuance costs		68,146	68,146
Proceeds from the issuance of convertible notes			5,000
Payments of capital lease obligations	(382)	(652)	(2,130)
Proceeds from exercise of stock options	129	263	446
Proceeds from exercise of warrants (common and preferred)	76	98	264
Proceeds from capital asset financing arrangement	2,008	546	5,611

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Net cash provided by financing activities	29,331	92,454	220,359
Net increase in cash and cash equivalents	23,334	14,367	26,494
Cash and cash equivalents at beginning of period	6,449	12,127	
Cash and cash equivalents at end of period	\$ 29,783	\$ 26,494	\$ 26,494
<b>Supplemental disclosures of cash flow information</b>			
Cash paid during the period for interest	\$ 125	\$ 179	\$ 967
<b>Non-cash activities</b>			
Warrant issued with convertible notes	\$	\$	\$ 8
Warrant issued with series B redeemable convertible preferred stock	\$	\$	\$ 50
Conversion of notes payable to series B redeemable convertible preferred stock	\$	\$	\$ 5,000
Conversion of preferred stock to common stock	\$	\$ 148,591	\$ 148,591
Accretion of redeemable convertible preferred stock	\$ 81	\$ 351	\$ 802
Beneficial conversion feature related to issuance of the second tranche of Series C redeemable convertible preferred stock	\$ 19,424	\$	\$ 19,424

*See accompanying notes to consolidated financial statements*

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**Amicus Therapeutics, Inc.  
(a development stage company)**

**Notes to Unaudited Consolidated Financial Statements**

**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.

The Company has an accumulated deficit of approximately \$102.8 million at June 30, 2007 and anticipates incurring losses through the year 2007 and beyond. The Company has not yet generated revenues and has been able to fund its operating losses to date through its initial public offering of common stock, its issuance of redeemable convertible preferred stock, its issuance of convertible notes, and other financing arrangements. The Company expects to continue to incur losses for at least the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure, and until that time, the Company will have to continue to raise additional debt or equity financing. If adequate funds are not available, the Company may have to substantially reduce or eliminate expenditures relating to the development of its product candidates or cease operations.

Management believes that the Company's current cash position is sufficient to cover its cash flow requirements until at least June 30, 2008.

***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 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 notes thereto should be read in conjunction with the audited financial statements for the year ended December 31, 2006 included in the Company's Registration Statement on Form S-1 (as amended), which was declared effective by the Securities and Exchange Commission (the SEC) on May 30, 2007.

***Initial Public Offering***

In June 2007, the Company closed its initial public offering of 5,000,000 shares of its common stock at a public offering price of \$15.00 per share. Net proceeds to the Company were approximately \$68.1 million, after deducting underwriting discounts, commissions and offering expenses totaling approximately \$6.9 million.

In connection with the initial public offering, the outstanding shares of series A redeemable convertible preferred stock were converted into 444,443 shares of common stock, the outstanding shares of series B redeemable convertible preferred stock were converted into 4,877,056 shares of common stock, the outstanding shares of series C redeemable convertible preferred stock were converted into 5,820,020 shares of common stock and the outstanding shares of series D redeemable convertible preferred stock were converted into 4,930,405 shares of common stock. In connection with the initial public offering, the outstanding warrants to purchase series B redeemable convertible preferred stock were automatically exercised and the shares of series B redeemable convertible preferred stock automatically converted into 40,797 shares of the common stock. As a result, the Company no longer recognizes accretion expense for preferred stock or non-operating income or expense for changes in the fair value of the warrant liability.

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**Amicus Therapeutics, Inc.**  
**(a development stage company)**  
**Notes to Unaudited Consolidated Financial Statements**

**Income Taxes**

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statements amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change.

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (an Interpretation of FASB Statement No. 109 (FIN 48)) to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, and classification of amounts relating to uncertain tax positions, accounting for and disclosure of interest and penalties, accounting in interim periods, disclosures and transition relating to the adoption of the new accounting standard. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 as of January 1, 2007, as required and determined that the adoption of FIN 48 did not have a material impact on the Company's financial position and results of operations. The Company did not recognize interest or penalties related to income tax during the three and six months ended June 30, 2006 or 2007 and did not accrue for interest or penalties as of June 30, 2007 or December 31, 2006. The Company does not have an accrual for uncertain tax positions as of June 30, 2007 or December 31, 2006. Tax returns for all years 2002 and thereafter are subject to future examination by tax authorities.

**Investment in Marketable Securities**

Marketable securities consist of fixed income investments with a maturity of greater than three months and other highly liquid investments that can be readily purchased or sold using established markets. In accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115), these investments are classified as available-for-sale and 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/(deficiency). 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. No other than temporary impairment charges have been recorded.

**2. Stock-Based Compensation**

During the three and six months ended June 30, 2007, the Company recorded compensation expense of approximately \$0.9 million and \$1.7 million, respectively. The compensation expense had no impact on the Company's cash flows from operations and financing activities. As of June 30, 2007, the total unrecognized compensation cost related to non-vested stock options granted was \$13.0 million and is expected to be recognized over a weighted average period of 2.2 years.

The fair value of the options granted is estimated on the date of grant using a Black-Scholes-Merton option pricing model with the following weighted-average assumptions:

	<b>Three Months Ended June 30, 2006</b>	<b>Six Months Ended June 30, 2006</b>	<b>Three Months Ended June 30, 2007</b>	<b>Six Months Ended June 30, 2007</b>
Expected stock price volatility	72.7%	73.5%	78.2%	78.2%

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Risk free interest rate	4.6%	4.7%	4.6%	4.6%
Expected life of options (years)	6.25	6.25	6.25	6.25
Expected annual dividend per share	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00

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**Amicus Therapeutics, Inc.**  
**(a development stage company)**

**Notes to Unaudited Consolidated Financial Statements**

A summary of option activities related to the Company's stock options for the six months ended June 30, 2007 is as follows:

	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in millions)
Balance at December 31, 2006	1,868.5	\$ 4.27		
Options granted	891.1	\$ 13.36		
Options exercised	(189.0)	\$ 1.46		
Options forfeited	(108.5)	\$ 8.58		
Balance at June 30, 2007	2,462.1	\$ 7.58	8.9 years	\$ 9.7
Vested and unvested expected to vest, June 30, 2007	2,220.1	\$ 7.25	8.8 years	\$ 9.5
Exercisable at June 30, 2007	633.2	\$ 4.24	8.3 years	\$ 4.6

### 3. Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share

The Company calculates net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. The Company has determined that its series A, B, C, and D redeemable convertible preferred stock represent participating securities in accordance with Emerging Issue Task Force ( EITF ) 03-6 *Participating Securities and the Two Class Method under FASB Statement No. 128*. However, since the Company operates at a loss, and losses are not allocated to the redeemable convertible preferred stock, the two class method does not affect the Company's calculation of earnings per share. The Company has a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2007	2006	2007
<b>Statement of Operations</b>				
Net loss attributable to common stockholders	\$ (28,089)	\$ (9,706)	\$ (36,417)	\$ (19,442)
Net loss attributable to common stockholders per common share — basic and diluted	\$ (39.04)	\$ (1.37)	\$ (57.78)	\$ (4.80)

### 4. Comprehensive Loss

The components of comprehensive loss are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2007	2006	2007
Net loss	\$ (8,624)	\$ (9,396)	\$ (16,912)	\$ (19,091)
Change in unrealized net gain on marketable securities	11	96	22	98

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Comprehensive loss	\$ (8,613)	\$ (9,300)	\$ (16,890)	\$ (18,993)
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**Amicus Therapeutics, Inc.**  
**(a development stage company)**

**Notes to Unaudited Consolidated Financial Statements**

Accumulated other comprehensive loss equals the unrealized net losses on marketable securities which are the only components of other comprehensive loss included in the Company's financial statements.

**5. Capital Structure*****Redeemable Convertible Preferred Stock***

In March 2007, the Company issued an additional 1,976,527 shares of its series D redeemable convertible preferred stock for gross proceeds of \$24.1 million.

On June 5, 2007, all outstanding shares of the Company's series A redeemable convertible preferred stock, series B redeemable convertible preferred stock, series C redeemable convertible preferred stock, and series D redeemable convertible preferred stock were automatically converted into shares of common stock at the closing of the Company's initial public offering.

Series A		Series B		Series C		Series D	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
	(in thousands)		(in thousands)				