

AMICUS THERAPEUTICS INC

Form 10-Q

August 06, 2009

**Table of Contents**

**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, 2009**

**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

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  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 July 24, 2009 was 22,643,184 shares.



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

	Page
<u>PART I. FINANCIAL INFORMATION</u>	4
<u>Item 1. Financial Statements (unaudited)</u>	4
<u>Consolidated Balance Sheets as of December 31, 2008 and June 30, 2009</u>	4
<u>Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2008 and 2009, and period February 4, 2002 (inception) to June 30, 2009</u>	5
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2008 and 2009, and period February 4, 2002 (inception) to June 30, 2009</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	23
<u>Item 4T. Controls and Procedures</u>	23
<u>PART II. OTHER INFORMATION</u>	23
<u>Item 1. Legal Proceedings</u>	23
<u>Item 1A. Risk Factors</u>	23
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	24
<u>Item 3. Defaults Upon Senior Securities</u>	26
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	26
<u>Item 5. Other Information</u>	26
<u>Item 6. Exhibits</u>	27
<u>SIGNATURES</u>	28
<u>INDEX TO EXHIBITS</u>	29
<u>Exhibit 10.1</u>	
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	

Edgar Filing: AMICUS THERAPEUTICS INC - Form 10-Q

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

**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, 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, 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.

**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)**

	<b>December 31, 2008</b>	<b>June 30, 2009</b>
<b>Assets:</b>		
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
<b>Total Assets</b>	<b>\$ 128,773</b>	<b>\$ 108,676</b>
<b>Liabilities and Stockholders Equity</b>		
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

<b>Total Liabilities and Stockholders Equity</b>	\$	128,773	\$	108,676
--	----	---------	----	---------

*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)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>		<b>Period from February 4, 2002 (inception) to June 30, 2009</b>
	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2009</b>	
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*

**Table of Contents**

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

	<b>Six Months Ended June 30,</b>		<b>Period from February 4, 2002 (inception) to June 30, 2009</b>
	<b>2008</b>	<b>2009</b>	
<b>Operating activities</b>			
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)
<b>Investing activities</b>			
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)
<b>Financing activities</b>			
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

Edgar Filing: AMICUS THERAPEUTICS INC - Form 10-Q

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
<b>Supplemental disclosures of cash flow information</b>				
Cash paid during the period for interest	\$ 129	\$ 71	\$	1,425
<b>Non-cash activities</b>				
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*

**Table of Contents****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.

**Table of Contents**

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.



**Table of Contents**

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.



**Table of Contents**

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

	<b>As of December 31, 2008</b>			
	<b>Cost</b>	<b>Unrealized Gain</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>
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

	<b>As of June 30, 2009</b>			
	<b>Cost</b>	<b>Unrealized Gain</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>
Cash balances	\$ 5,766	\$	\$	\$ 5,766
Money market fund	9,994			9,994
U.S. government agency securities	73,828	143		73,971
Commercial paper	7,846	3		7,849
Corporate debt securities	2,851		(1)	2,850
	\$ 100,285	\$ 146	\$ (1)	\$ 100,430
Included in cash and cash equivalents	\$ 15,760	\$	\$	\$ 15,760
Included in marketable securities	84,525	146	(1)	84,670
Total cash and available for sale securities	\$ 100,285	\$ 146	\$ (1)	\$ 100,430

All of the Company's available for sale investments as of December 31, 2008 and June 30, 2009 are due in one year or less.

Unrealized gains and losses are reported as a component of accumulated other comprehensive gain/loss in stockholders' equity. For the year ended December 31, 2008, unrealized holding gains included in accumulated other comprehensive income was \$0.1 million. For the six months ended June 30, 2009, unrealized holding losses included in accumulated other comprehensive income was \$0.4 million.

For the year ended December 31, 2008 and the six months ended June 30, 2009, there were no realized gains or losses. The cost of securities sold is based on specific identification method.

Unrealized loss positions in the available for sale securities as of December 31, 2008 and June 30, 2009 reflect temporary impairments that have not been recognized and have been in a loss position for less than twelve months. The fair value of these available for sale securities in unrealized loss positions was \$8.9 million and \$2.9 million as of

December 31, 2008 and June 30, 2009, respectively.

**Table of Contents**

The Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), which is applicable for all financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 requires fair value measurements be classified and disclosed in one of the following three categories:

*Level 1* Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

*Level 2* Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

*Level 3* Inputs that are unobservable for the asset or liability.

The Company's available for sale investment securities are classified within Level 1 or Level 2 of the fair value hierarchy. These investment securities are valued using quoted market prices, broker or dealer quotations or other observable inputs. A summary of the fair value of the Company's available for sale investment securities (allocated by Level) as of June 30, 2009 are identified in the following table (in thousands):

	<b>Level 1</b>	<b>Level 2</b>	<b>Total</b>
Cash/Money market funds	\$ 15,760	\$	\$ 15,760
U.S. government agency securities		73,971	73,971
Commercial paper		7,849	7,849
Corporate debt securities		2,850	2,850
	\$ 15,760	\$ 84,670	\$ 100,430

**Note 3. Stock-Based Compensation**

During the three and six months ended June 30, 2009, the Company recorded compensation expense of approximately \$2.0 million and \$4.0 million, respectively. The stock-based compensation expense had no impact on the Company's cash flows from operations and financing activities. As of June 30, 2009, the total unrecognized compensation cost related to non-vested stock options granted was \$13.8 million and is expected to be recognized over a weighted average period of 2.6 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, 2008</b>	<b>Six Months Ended June 30, 2008</b>	<b>Three Months Ended June 30, 2009</b>	<b>Six Months Ended June 30, 2009</b>
Expected stock price volatility	78.0%	78.2%	81.4%	80.6%
Risk free interest rate	3.5%	2.9%	2.3%	2.1%
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

**Table of Contents**

A summary of option activities related to the Company's stock options for the six months ended June 30, 2009 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, 2008	3,077.3	\$ 9.19		
Options granted	969.7	\$ 10.30		
Options exercised	(9.8)	\$ 2.34		
Options forfeited	(75.2)	\$ 9.93		
Balance at June 30, 2009	3,962.0	\$ 9.46	8.0 years	\$ 9.8
Vested and unvested expected to vest, June 30, 2009	3,734.6	\$ 9.39	7.9 years	\$ 9.6
Exercisable at June 30, 2009	1,787.3	\$ 8.05	7.0 years	\$ 7.0

**Note 4. 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*. However, because 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,	
	2008	2009	2008	2009
<b>Statement of Operations</b>				
Net loss attributable to common stockholders	\$ (9,294)	\$ (13,623)	\$ (17,024)	\$ (26,095)
Net loss attributable to common stockholders per common share - basic and diluted	\$ (0.41)	\$ (0.60)	\$ (0.76)	\$ (1.15)

**Note 5. Comprehensive Loss**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
Net loss	\$ (9,294)	\$ (13,623)	\$ (17,024)	\$ (26,095)
Change in unrealized net gain on marketable securities	(431)	(88)	90	(388)
Comprehensive loss	\$ (9,725)	\$ (13,711)	\$ (16,934)	\$ (26,483)

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

**Table of Contents**

**Note 6. Capital Structure**

***Common Stock***

As of June 30, 2009, the Company was authorized to issue 50,000,000 shares of common stock. Dividends on common stock will be paid when, and if declared by the board of directors. Each holder of common stock is entitled to vote on all matters and is entitled to one vote for each share held.

**Note 7. Development and Commercialization Agreement with Shire**

In November 2007, the Company entered into a License and Collaboration Agreement with Shire. Under the agreement, the Company and Shire will jointly develop the Company's three lead pharmacological chaperone compounds for lysosomal storage disorders: Amigal, Plicera and AT2220. The Company granted Shire the rights to commercialize these products outside the U.S. The Company retains all rights to its other programs and to develop and commercialize Amigal, Plicera and AT2220 in the U.S.

The Company received an initial, non-refundable license fee payment of \$50 million from Shire. Joint development costs toward conduct of clinical trials and pursuing global approval of the three compounds will be shared 50/50 going forward. In addition, the Company is eligible to receive, for all three drug product candidates, aggregate potential milestone payments of up to \$150 million if certain clinical and regulatory milestones are achieved for all three of the programs, and \$240 million in sales-based milestones. The Company will also be eligible to receive tiered double-digit royalties on net sales of the products which are marketed outside of the U.S.

In accordance with the guidance in EITF 00-21, the Company determined that its various deliverables due under the collaboration agreement represent a single unit of accounting for revenue recognition purposes. The initial, non-refundable upfront license fee payment of \$50 million will be recognized on a straight line basis as Collaboration Revenue over the period of the performance obligations. The Company determined that the period of performance obligations is 18 years as contractually defined.

During the three and six months ended June 30, 2009, the Company recorded \$0.7 million and \$1.4 million, respectively, in Collaboration Revenue. As of June 30, 2009, the Company recorded \$2.8 million of current deferred revenue and \$42.6 million of long-term deferred revenue related to the \$50 million upfront payment.

During the three and six months ended June 30, 2008, the Company recorded \$0.7 million and \$1.4 million, respectively, in Collaboration Revenue. As of June 30, 2008, the Company recorded \$2.8 million of current deferred revenue and \$45.4 million of long-term deferred revenue related to the \$50 million upfront payment.

During the three and six months ended June 30, 2009, the Company recorded \$4.7 million and \$8.6 million, respectively, in Research Revenue. As of June 30, 2009, the Company recorded \$0.4 million of other receivables related to amount due from Shire for reimbursable research and development costs.

During the three and six months ended June 30, 2008, the Company recorded \$3.1 million and \$5.6 million, respectively, in Research Revenue. As of June 30, 2008, the Company recorded \$0.5 million of current portion of deferred revenue related to reimbursed research and development costs.

**Note 8. Short-Term Borrowings and Long-Term Debt**

In May 2009, the Company entered into a loan and security agreement with Silicon Valley Bank that provides for up to \$4 million of equipment financing through October 2012. Borrowings under the loan agreement are collateralized by equipment purchased with the proceeds of the loan and bear interest at a fixed rate of approximately 9%. The loan agreement contains customary terms and conditions, including a financial covenant whereby the Company must maintain a minimum amount of liquidity measured at the end of each month equal to the greater of (i) \$30 million of unrestricted cash, cash equivalents, and marketable securities, or (ii) six months of trailing cash burn net of outstanding borrowings under the loan agreement. The Company has at all times been in compliance with this covenant during the term of the agreement.

At June 30, 2009, the current and long-term amounts due under the loan agreement were \$0.9 million and \$2.0 million, respectively. The carrying amount of the Company's borrowings approximates fair value at June 30, 2009.



**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Overview**

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule, orally-administered drugs, known as pharmacological chaperones, for the treatment of a range of human genetic diseases. Certain human diseases result from mutations in specific genes that, in many cases, lead to the production of proteins with reduced stability. Proteins with such mutations may not fold into their correct three-dimensional shape and are generally referred to as misfolded proteins. Misfolded proteins are often recognized by cells as having defects and, as a result, may be eliminated prior to reaching their intended location in the cell. The reduced biological activity of these proteins leads to impaired cellular function and ultimately to disease. Our novel approach to the treatment of human genetic diseases consists of using pharmacological chaperones that selectively bind to the target protein increasing the stability of the protein and helping it fold into the correct three-dimensional shape. This allows proper trafficking of the protein, thereby increasing protein activity, improving cellular function and potentially reducing cell stress. We continue to develop our product candidates and explore new uses for our platform pharmacological chaperone technology.

We have three compounds in clinical development: Amigal (migalastat hydrochloride) for the treatment of Fabry disease, Plicera (afegostat tartrate) for the treatment of Gaucher disease and AT2220 (1-deoxynojirimycin HCl) for the treatment of Pompe disease.

***Amigal:*** In the second quarter of 2009, Amicus announced that the Company reached agreement with the U.S. Food and Drug Administration (FDA) on the key protocol design elements of its pivotal trial, including the use of the surrogate primary endpoint of the change in the amount of kidney interstitial capillary GL-3, the substrate that accumulates in the cells of Fabry patients. In addition, the FDA is in agreement that the Company is eligible to seek Accelerated Approval for Amigal according to Subpart H regulations. Amicus has begun submitting the Phase 3 protocol to investigational sites worldwide and expects to begin the dosing of subjects in the second half of this year. As previously announced, the Phase 3 trial will evaluate the efficacy, safety and pharmacodynamics of Amigal in males and females with Fabry disease. The trial will consist of a six-month double-blind, randomized, placebo-controlled treatment stage and will enroll approximately 60 subjects who are naïve to enzyme replacement therapy (ERT) or who have not received ERT for at least six months prior to the start of treatment with Amigal. The Amigal treatment arm dose and regimen will be 150 mg every other day. The primary endpoint will be the change in the amount of kidney interstitial capillary GL-3 as measured in kidney biopsies using histology. Secondary endpoints will include safety and tolerability, kidney GL-3 as measured in urine, and an assessment of renal function (including glomerular filtration rate (GFR) and 24-hour urine protein). Additionally, the FDA and Amicus reached agreement on an improved methodology for the histological evaluation of GL-3 in the kidney biopsies. An analysis of the Phase 2 and Phase 2 extension study biopsies using the improved methodology demonstrated that all of the evaluable baseline samples had detectable interstitial capillary GL-3 and that reductions were observed in 8 of the 9 responders. It is expected that approximately 30 clinical sites worldwide will participate in this trial.

***Plicera:*** A Phase 2 clinical trial of the Company's investigational drug Plicera is ongoing. This 6-month study is designed to evaluate safety, dosing and preliminary efficacy, as measured by the standard endpoints in Gaucher disease. The Company expects to report the results early in the fourth quarter of 2009. Amicus continues to work closely with its partner, Shire HGT, to prepare for Phase 3 development of Plicera pending the results of the ongoing Phase 2 trial.



## **Table of Contents**

***AT2220:*** As previously reported, the Company suspended enrollment for the Phase 2 clinical trial of its investigational drug AT2220 for the treatment of Pompe Disease and received notice from the FDA that the trial is on clinical hold. The Company continues to work closely with the FDA to determine appropriate next steps for advancing the development of AT2220 and expects to provide guidance on this progress over the upcoming months. Additionally, Amicus continues to be encouraged with its preclinical studies with AT2220 in combination with ERT. As previously announced, the Company expects to report additional data from these activities throughout the remainder of 2009.

***Research:*** Amicus continues to invest in research to assess the potential for applying its versatile chaperone technology platform to the treatment of a broad range of human genetic diseases. As part of this effort, Amicus continues to conduct preclinical studies in Parkinson's disease and is investing in new research aimed at evaluating disease targets for other neurodegenerative and genetic disorders.

Costs associated with the clinical development of Amigal, Plicera and AT2220 and research conducted on other programs have caused us to generate significant losses to date, which we expect to continue. These activities are budgeted to expand over time and will require further resources if we are to be successful. From our inception in February 2002 through June 30, 2009, we have accumulated a deficit of \$190.3 million. As we have not yet generated commercial sales revenue from any of our product candidates, our operating losses will continue and are likely to be substantial over the next several years. Although Shire will be responsible for a portion of the costs associated with the clinical development of Amigal, Plicera and AT2220 as discussed below, we may need to obtain additional funds to further develop our research and development programs and product candidates.

### ***Collaboration with Shire***

On November 7, 2007, we entered into a license and collaboration agreement with Shire. Under the agreement, Amicus and Shire will jointly develop Amicus' three lead pharmacological chaperone compounds for lysosomal storage disorders: Amigal, Plicera and AT2220. We granted Shire the rights to commercialize these products outside the United States (U.S.). We will retain all rights to our other programs and to develop and commercialize Amigal, Plicera and AT2220 in the U.S.

We received an initial, non-refundable license fee payment of \$50 million from Shire. Joint development costs associated with clinical development and pursuing global approval of the three compounds will be shared on a 50/50 basis going forward. In addition, we are eligible to receive, for all three drug product candidates, aggregate potential milestone payments of up to \$150 million if certain clinical and regulatory milestones are achieved and \$240 million in sales-based milestones. We are also eligible to receive tiered double-digit royalties on net sales of these products when marketed outside of the U.S.

### **Financial Operations Overview**

#### ***Revenue***

In connection with our collaboration agreement with Shire, Shire paid us an initial, non-refundable license fee of \$50 million and reimburses us for certain research and development costs associated with our lead clinical development programs.

For the three and six months ended June 30, 2009, we recognized approximately \$0.7 million and \$1.4 million, respectively, of the license fee in Collaboration Revenue and \$4.7 million and \$8.6 million, respectively, of Research Revenue for reimbursed research and development costs.

For the three and six months ended June 30, 2008, we recognized approximately \$0.7 million and \$1.4 million, respectively, of the license fee in Collaboration Revenue and \$3.1 million and \$5.6 million, respectively, of Research Revenue for reimbursed research and development costs.

The license fee will be recognized as Collaboration Revenue over the 18 year performance obligation period. We have not generated any commercial sales revenue since our inception.

**Table of Contents****Research and Development Expenses**

We expect our research and development expense to increase as we continue to develop our product candidates and explore new uses for our pharmacological chaperone technology. Research and development expense consists of:

- internal costs associated with our research and clinical development activities;
- payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants;
- technology license costs;
- manufacturing development costs;
- personnel related expenses, including salaries, benefits, travel, and related costs for the personnel involved in drug discovery and development;
- activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies.

We have multiple research and development projects ongoing at any one time. We utilize our internal resources, employees and infrastructure across multiple projects. We record and maintain information regarding external, out-of-pocket research and development expenses on a project specific basis.

We expense research and development costs as incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates. From our inception in February 2002 through June 30, 2009, we have incurred research and development expense in the aggregate of \$153.0 million.

The following table summarizes our principal product development programs, including the related stages of development for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate (in thousands).

Product Candidate	Three Months Ended		Six Months Ended		Period from February 4, 2002 (inception) to June 30, 2009
	2008	2009	2008	2009	
Third party direct project expenses					
Amigal (Fabry Disease Phase 2)	\$ 1,547	\$ 2,297	\$ 2,250	\$ 3,758	\$ 29,198
Plicera (Gaucher Disease Phase 2)	539	2,606	1,025	4,595	23,499
AT2220 (Pompe Disease Phase 2)	459	657	944	1,262	12,286
Total third party direct project expenses	2,545	5,560	4,219	9,615	64,983
Other project costs <sup>(1)</sup>					
Personnel costs	3,588	4,948	6,969	9,929	48,895
Other costs <sup>(2)</sup>	2,715	2,962	4,601	5,801	39,109
Total other project costs	6,303	7,910	11,570	15,730	88,004
	\$ 8,848	\$ 13,470	\$ 15,789	\$ 25,345	\$ 152,987

Total research and development costs

- (1) Other project costs are leveraged across multiple projects.
- (2) Other costs include facility, supply, overhead, and licensing costs that support multiple clinical and preclinical projects.

## **Table of Contents**

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our product candidates. As a result, we are not able to reasonably estimate the period, if any, in which material net cash inflows may commence from our product candidates, Amigal, Plicera, AT2220 or any of our other preclinical product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the conduct, duration and cost of clinical trials, which vary significantly over the life of a project as a result of evolving events during clinical development, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the results of our clinical trials; and
- any mandate by the FDA or other regulatory authority to conduct clinical trials beyond those currently anticipated.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of the foregoing variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development, regulatory approval and commercialization of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those which we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug development may take several years and millions of dollars in development costs.

### ***General and Administrative Expense***

General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance, accounting, information technology and human resource functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services, including patent-related expense, and accounting services. From our inception in February 2002 through June 30, 2009, we spent \$68.2 million on general and administrative expense.

### ***Interest Income and Interest Expense***

Interest income consists of interest earned on our cash and cash equivalents and marketable securities. Interest expense consists of interest incurred on our capital lease facility and our equipment financing agreement.

### ***Critical Accounting Policies and Significant Judgments and Estimates***

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While there were no significant changes during the quarter ended June 30, 2009 to the items that we disclosed as our significant accounting policies and estimates described in Note 2 to the Company's financial statements as contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.



**Table of Contents*****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.

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.

***Accrued Expenses***

When we are required to estimate accrued expenses because we have not yet been invoiced or otherwise notified of actual cost, we identify services that have been performed on our behalf and estimate the level of service performed and the associated cost incurred. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. Examples of estimated accrued expenses include:

- fees owed to contract research organizations in connection with preclinical and toxicology studies and clinical trials;
- fees owed to investigative sites in connection with clinical trials;
- fees owed to contract manufacturers in connection with the production of clinical trial materials;
- fees owed for professional services, and
- unpaid salaries, wages and benefits.

***Stock-Based Compensation***

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, using the fair value method, which requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. Our financial statements as of the three and six months ended June 30, 2008 and 2009 reflect the impact of SFAS No. 123(R). We chose the straight-line attribution method for allocating compensation costs and recognized the fair value of each stock option on a straight-line basis over the requisite service period of the last separately vesting portion of each award. Expected volatility was calculated based on a blended weighted average of historical information of our stock and the weighted average of historical information of similar public entities for which historical information was available. The average expected life was determined using the SEC shortcut approach as described in Staff Accounting Bulletin No. 107, which is the mid-point between the vesting date and the end of the contractual term. The risk-free interest rate is based on U.S. Treasury, zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant.

**Table of Contents**

We account for equity instruments issued to non-employees in accordance with the provisions of Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The equity instruments, consisting of stock options, are valued using the Black-Scholes-Merton valuation model. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

**Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share**

We calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. However, because we operate at a loss, and losses are not allocated to the redeemable convertible preferred stock, the two-class method does not affect our calculation of earnings per share. We had 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.

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss attributable to common stockholders per common share and pro forma net loss attributable to common stockholders per common share:

(In thousands, except per share amount)	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2009	2008	2009
<b>Historical</b>				
Numerator:				
Net loss attributable to common stockholders	\$ (9,294)	\$ (13,623)	\$ (17,024)	\$ (26,095)
Denominator:				
Weighted average common shares outstanding basic and diluted	22,467,198	22,618,026	22,439,893	22,615,951

Dilutive common stock equivalents would include the dilutive effect of common stock options for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 3.0 million and 4.0 million for the six months ended June 30, 2008 and 2009, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.

**Results of Operations****Three Months Ended June 30, 2009 Compared to Three Months Ended June 30, 2008**

*Research and Development Expense.* Research and development expense was \$13.5 million for the three months ended June 30, 2009 representing an increase of approximately \$4.7 million or 53% from \$8.8 million for the three months ended June 30, 2008. The variance was primarily attributable to higher personnel costs associated with headcount growth, an increase in manufacturing costs due to the timing of batch production and an increase in contract research related to clinical trials. We expect research and development expense to continue to increase in 2009 as we move forward with clinical trials relating to our lead clinical development compounds and expand our discovery research activities.

*General and Administrative Expense.* General and administrative expense was \$5.2 million for the three months ended June 30, 2009, representing an increase of \$0.1 million or 2% from \$5.1 million for the three months ended June 30, 2008. The variance was primarily attributable higher personnel costs associated with headcount growth.

*Interest Income and Interest Expense.* Interest income was \$0.3 million for the three months ended June 30, 2009, compared to \$1.3 million for the three months ended June 30, 2008. The decrease of \$1.0 million or 77% was due to lower interest rates and decreased cash and cash equivalents balances. Interest expense was approximately \$0.1 million for the three months ended June 30, 2009 and 2008.





**Table of Contents****Six Months Ended June 30, 2009 Compared to Six Months Ended June 30, 2008**

**Research and Development Expense.** Research and development expense was \$25.3 million for the six months ended June 30, 2009 representing an increase of approximately \$9.5 million or 62% from \$15.8 million for the six months ended June 30, 2008. The variance was primarily attributable to higher personnel costs associated with headcount growth, an increase in manufacturing costs due to the timing of batch production and an increase in contract research related to clinical trials. We expect research and development expense to continue to increase in 2009 as we move forward with clinical trials relating to our lead clinical development compounds and expand our discovery research activities.

**General and Administrative Expense.** General and administrative expense was \$10.4 million for the six months ended June 30, 2009, representing an increase of \$0.1 million or 1% from \$10.3 million for the six months ended June 30, 2008. The variance was primarily attributable higher personnel costs associated with headcount growth.

**Interest Income and Interest Expense.** Interest income was \$0.8 million for the six months ended June 30, 2009, compared to \$3.0 million for the six months ended June 30, 2008. The decrease of \$2.2 million or 73% was due to lower interest rates and decreased cash and cash equivalents balances. Interest expense was approximately \$0.1 million for the six months ended June 30, 2009 and 2008.

**Liquidity and Capital Resources****Source of Liquidity**

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since our inception in 2002. We have funded our operations principally with \$148.7 million of proceeds from redeemable convertible preferred stock offerings, \$75.0 million of gross proceeds from our initial public offering in June 2007 and \$50.0 million from the non-refundable license fee from the Shire collaboration agreement in November 2007. The following table summarizes our significant funding sources as of June 30, 2009:

<b>Funding</b>	<b>Year</b>	<b>No. Shares</b>	<b>Approximate Amount <sup>(1)</sup> (in thousands)</b>
Series A Redeemable Convertible Preferred Stock	2002	444,443	\$ 2,500
Series B Redeemable Convertible Preferred Stock	2004, 2005, 2006, 2007	4,917,853	31,189
Series C Redeemable Convertible Preferred Stock	2005, 2006	5,820,020	54,999
Series D Redeemable Convertible Preferred Stock	2006, 2007	4,930,405	60,000
Common Stock	2007	5,000,000	75,000
Upfront License Fee from Shire	2007		50,000
		21,112,721	\$ 273,688

(1) Represents gross proceeds

In addition, in conjunction with the Shire collaboration agreement, we have received reimbursement of research and development expenditures from the date of the agreement (November 7, 2007) through June 30, 2009 of \$21.7 million.

In May 2009, the Company entered into a loan and security agreement with Silicon Valley Bank that provides for up to \$4 million of equipment financing through October 2012. At June 30, 2009, the total amount due under the loan agreement was \$2.9 million.



**Table of Contents**

As of June 30, 2009, we had cash, cash equivalents and marketable securities of \$100.4 million. We invest cash in excess of our immediate requirements with regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such cash balances.

***Net Cash Used in Operating Activities***

Net cash used in operations for the six months ended June 30, 2008 of \$14.9 million primarily consisted of the net loss for the six months ended June 30, 2008 of \$17.0 million and a reduction in deferred revenue of \$1.9 million.

Net cash used in operations for the six months ended June 30, 2009 of \$21.3 million was comprised of the net loss for the six months ended June 30, 2009 of \$26.1 million and a reduction in deferred revenue of \$2.3 million, partially offset by the change in other operating assets and liabilities of \$2.0 million.

***Net Cash (Used in)/Provided By Investing Activities***

Net cash used in investing activities for the six months ended June 30, 2008 was \$16.4 million. Net cash used in investing activities reflects \$88.8 million for the purchase of marketable securities and \$1.1 million for the acquisition of property and equipment, partially offset by \$73.4 million for the sale and redemption of marketable securities.

Net cash provided by investing activities for the six months ended June 30, 2009 was \$6.6 million. Net cash provided by investing activities reflects \$76.9 million for the sale and redemption of marketable securities, partially offset by \$68.9 million for the purchase of marketable securities and \$1.4 million for the acquisition of property and equipment.

***Net Cash (Used in)/Provided By Financing Activities***

Net cash used in financing activities for the six months ended June 30, 2008 was \$0.5 million and primarily consisted of \$0.8 million of payments of capital lease obligations partially offset by \$0.3 million of proceeds from exercise of stock options.

Net cash provided by financing activities for the six months ended June 30, 2009 was \$2.4 million and reflected the proceeds from our secured loan agreement of \$2.9 million, partially offset by the payments of our capital lease obligations of \$0.4 million.

***Funding Requirements***

We expect to incur losses from operations for the foreseeable future primarily due to increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials, and greater general and administrative expenses resulting from expanding our finance and administrative staff, adding infrastructure, and incurring additional costs related to being a public company. Our future capital requirements will depend on a number of factors, including:

- the progress and results of our clinical trials of Amigal, Plicera and AT2220;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- our achievement of milestone payments under our collaboration agreement with Shire;
- 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;

**Table of Contents**

the costs of preparing, filing and prosecuting patent application 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 do not anticipate that we will generate revenue from commercial sales for at least the next several years, if at all. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years. However, we believe that our existing cash and cash equivalents and short-term investments, together with the expected reimbursement of research and development expenses and research milestones from our collaboration with Shire, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least until 2011.

***Financial Uncertainties Related to Potential Future Payments***

***Milestone Payments***

We have acquired rights to develop and commercialize our product candidates through licenses granted by various parties. While our license agreements for Amigal and AT2220 do not contain milestone payment obligations, two of our agreements related to Plicera do require us to make such payments if certain specified pre-commercialization events occur. Upon the satisfaction of these milestones and assuming successful development of Plicera, we may be obligated, under the agreements that we have in place, to make future milestone payments aggregating up to approximately \$7.9 million. However, such potential milestone payments are subject to many uncertain variables that would cause such payments, if any, to vary in size.

The events that trigger these payments include:

- commencement of Phase 3 clinical trials;
- submission of a new drug application to the FDA or foreign equivalents; and
- receipt of marketing approval from the FDA or foreign equivalents.

***Royalties***

Under our license agreements, if we owe royalties on net sales for one of our products to more than one licensor, then we have the right to reduce the royalties owed to one licensor for royalties paid to another. The amount of royalties to be offset is generally limited in each license and can vary under each agreement. For Amigal and AT2220, we will owe royalties only to Mt. Sinai School of Medicine (MSSM). We expect to pay royalties to all three licensors with respect to Plicera. To date, we have not made any royalty payments on sales of our products and believe we are several years away from selling any products that would require us to make any such royalty payments.

On October 31, 2008, the Company amended and restated its license agreement with MSSM. The amended and restated agreement consolidated previous amendments into a single agreement, clarified the portion of royalties and milestone payments the Company receives from Shire that are payable to MSSM, and provided the Company with the sole right to control the prosecution of patent rights described in the amended and restated license agreement. Under the terms of the amended and restated license agreement, the Company agreed to pay MSSM \$2.6 million in connection with the \$50 million upfront payment that the Company received in November 2007 and an additional \$2.6 million for the sole right to and control over the prosecution of patent rights.

Whether we will be obligated to make other milestone or royalty payments in the future is subject to the success of our product development efforts and, accordingly, is inherently uncertain.

**Table of Contents**

**ITEM 3. Quantitative and Qualitative Disclosures about Market Risk**

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 our investment policy, we do not use derivative financial instruments in our investment portfolio. We regularly invest 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. We believe that the market risk arising from our holdings of these financial instruments is minimal. We currently do not believe that any change in the market value of fixed income investments in our portfolio is material, nor does it warrant a determination that there was any other than temporary impairment.

We do not have exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. Although we do not believe we have any material exposure to market risks associated with interest rates, we may experience reinvestment risk as fixed income securities mature and are reinvested in securities bearing lower interest rates.

**ITEM 4T. CONTROLS AND PROCEDURES**

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation of the effectiveness of our disclosure controls and procedures (pursuant to Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) was carried out under the supervision of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer), with the participation of our management. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. During the fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**ITEM 1A. RISK FACTORS**

Except for the risk factor set forth below, there have been no material changes with respect to the Risk Factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

**Table of Contents**

**We may expand our clinical pipeline through the acquisition of additional product candidates, technologies or scientific capabilities. Opportunities for such acquisitions may not be available to us on favorable terms or could require us to incur debt, issue additional equity or assume contingent liabilities and expenses. In addition, the acquired product candidates may ultimately not result in a successful commercial product.**

Amicus is evaluating business development opportunities that would enable it to facilitate further development of clinical development programs. These opportunities include potential in-licensing transactions, collaborations, including further collaboration with Amicus' current partner, Shire Pharmaceuticals Ireland Ltd., and acquisitions of businesses with products and technologies that would complement Amicus' strategies.

We may face substantial competition for such opportunities from companies focused on developing therapies for our target indications, many of which have greater resources than we do. Opportunities to acquire additional product candidates, technologies or scientific capabilities may not be available to us, or if available, the terms may not be favorable. We may also need to license additional technologies in order to continue to develop our clinical pipeline with the acquired product candidates, technologies or scientific capabilities.

All transactions such as those described above involve risks, but if we acquire additional product candidates, technologies or scientific capabilities through the acquisition of a business we may be exposed to additional risks related to:

- the integration of our business with the business acquired;
- our expectations and business judgments concerning the value, strengths and weaknesses of the combined businesses;
- our expectations regarding the costs resulting from acquiring the business including the costs associated with the incurrence of debt, contingent liabilities, interest expense, amortization expense or periodic impairment charges related to goodwill and other intangible assets as well as significant charges relating to integration costs; and
- increased research and development costs that could affect our cash flows and cash on-hand.

In addition to the risks related to the acquisition and integration of additional product candidates, technologies or scientific capabilities, we cannot guarantee the successful commercialization of any product candidates.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**Recent Sales of Unregistered Securities**

None.

**Use of Proceeds**

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-141700) that was declared effective by the Securities and Exchange Commission on May 30, 2007, which registered an aggregate of 5,750,000 shares of our common stock. On June 5, 2007, at the closing of the offering, 5,000,000 shares of common stock were sold on our behalf at an initial public offering price of \$15.00 per share, for aggregate offering proceeds of \$75.0 million. The initial public offering was underwritten and managed by Morgan Stanley, Merrill Lynch & Co., JPMorgan, Lazard Capital Markets and Pacific Growth Equities, LLC. Following the sale of the 5,000,000 shares, the public offering terminated.

We paid underwriting discounts totaling approximately \$5.3 million and incurred additional costs of approximately \$1.6 million in connection with the offering, for total expenses of approximately \$6.9 million. After deducting underwriting discounts and offering expenses, the net offering proceeds to us were approximately \$68.1 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

**Table of Contents**

As of August 1, 2009, we had invested the \$68.1 million in net proceeds from the offering in money market funds and in investment-grade, interest bearing instruments, pending their use. Through August 1, 2009, we have not used the net proceeds from the offering. We intend to use the proceeds for clinical development of our drug candidates, for research and development activities relating to additional preclinical programs and to fund working capital and other general corporate purposes, which may include the acquisition or licensing of complementary technologies, products or businesses.

**Issuer Purchases of Equity Securities**

The following table sets forth purchases of our common stock for the three months ended June 30, 2009:

<b>Period</b>	<b>(a) Total number of shares purchased</b>	<b>(b) Average Price Paid per Share</b>	<b>(c) Total number of shares purchased as part of publicly announced plans or programs</b>	<b>(d) Maximum number of shares that may yet be purchased under the plans or programs</b>
April 1, 2009 - April 30, 2009	220	\$ 9.13		3,975
May 1, 2009 - May 31, 2009	220	\$ 8.95		3,755
June 1, 2009 - June 30, 2009	220	\$ 6.64		3,535
<b>Total</b>	<b>660</b>			

Pursuant to a restricted stock award dated October 2, 2006 between Amicus Therapeutics and James E. Dentzer, Chief Financial Officer, Mr. Dentzer was granted 40,000 restricted shares, 25% of which vested on October 2, 2007. The remaining shares vest in a series of thirty-six successive equal monthly installments commencing on November 1, 2007 and ending on November 1, 2010, subject generally to Mr. Dentzer's continued employment with the Company. In order to comply with the minimum statutory federal tax withholding rate of 25% plus 1.45% for Medicare, Mr. Dentzer surrenders to us a portion of his vested shares on each vesting date, representing 26.45% of the total value of the shares then vested.

**Table of Contents****ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

(a) The Company's Annual Meeting of Stockholders was held on Wednesday, June 10, 2009.

(b) The results of votes of security holders for the election of Class II directors are as follows:

<b>Election of Directors</b>	<b>For</b>	<b>Withheld</b>
Sol J. Barer, Ph.D.	18,265,693	158,901
Donald J. Hayden, Jr.	18,388,721	35,873
James N. Topper, M.D., Ph.D.	18,265,042	159,552
John F. Crowley, Alexander E. Barkas, Ph.D., Michael G. Raab, Glenn P. Sblendorio and P. Sherrill Neff continued as directors after the annual meeting.		

(c) The results of votes of security holders for the ratification of the appointment of Ernst &amp; Young LLP as our independent registered public accounting firm are as follows:

<b>For</b>	<b>Against</b>	<b>Abstain</b>	<b>Broker Non-Votes</b>
18,422,775	1,808	10	

**ITEM 5. OTHER INFORMATION**

On July 31, 2009, James Barrett, Ph.D., was elected to the Board of Directors of Amicus Therapeutics, Inc. (the Company). Dr. Barrett fills the existing vacancy on the Board of Directors and will join the Board of Directors as an independent director. Dr. Barrett has not yet been appointed to any Board committees.

There is no arrangement or understanding between Dr. Barrett and any other person pursuant to which Dr. Barrett was elected as director of the Company. There are no relationships or transactions in which Dr. Barrett has or will have an interest, or was or is a party, requiring disclosure under Item 404(a) of Regulation S-K.



**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1(1)	Restated Certificate of Incorporation
3.2(2)	Amended and Restated By-laws
10.1	First Amendment to Lease dated June 11, 2009
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to Exhibit 3.2 to our Registration Statement on Form S-1

(2) Incorporated by reference to Exhibit 3.4 to our Registration Statement on Form S-1

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act

of 1934 and are not to be incorporated by reference into any filing of Amicus Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

- 27 -

---

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMICUS THERAPEUTICS, INC.

Date: August 5, 2009

By: /s/ JOHN F. CROWLEY  
John F. Crowley  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 5, 2009

By: /s/ JAMES E. DENTZER  
James E. Dentzer  
Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

- 28 -

---

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
3.1(1)	Restated Certificate of Incorporation
3.2(2)	Amended and Restated By-laws
10.1	First Amendment to Lease dated June 11, 2009
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to Exhibit 3.2 to our Registration Statement on Form S-1

(2) Incorporated by reference to Exhibit 3.4 to our Registration Statement on Form S-1

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act

of 1934 and are not to be incorporated by reference into any filing of Amicus Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

- 29 -