AMICUS THERAPEUTICS INC
Form 10-Q
November 04, 2008

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

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

For the transition period from __________ to __________

Commission file number 001-33497

Amicus Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	71-0869350
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

6 Cedar Brook Drive, Cranbury, NJ 08512

(Address of Principal Executive Offices and Zip Code)

Registrant s Telephone Number, Including Area Code: (609) 662-2000

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes þ No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer þ Smaller Reporting Company o

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

The number of shares outstanding of the registrant s common stock, $.01 par value per share, as of October 27, 2008 was 22,575,392 shares.

AMICUS THERAPEUTICS, INC
Form 10-Q for the Quarterly Period Ended September 30, 2008

Exhibit 32.1

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this quarterly report on Form 10-Q regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipate, believe, estimate, expect, in may, plan, predict, project, will, would and similar expressions are intended to identify forward-looking state although not all forward-looking statements contain these identifying words.

The forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

- our plans to develop, seek regulatory approval for and commercialize Amigal, Plicera and AT2220;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- our ability to enter into selective collaboration arrangements;
- 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 of the Annual Report on Form 10-K for the year ended December 31, 2007 that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this quarterly report on Form 10-Q in conjunction with the documents that we reference herein. We do not assume any obligation to update any forward-looking statements.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements (unaudited)

Amicus Therapeutics, Inc.
(a development stage company)
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	December 31, 2007	September 30, 2008
Assets:		
Current assets:		
Cash and cash equivalents	$ 44,188	$ 19,855
Investments in marketable securities	117,339	116,400
Prepaid expenses and other current assets	1,513	1,990
Total current assets	163,040	138,245
Property and equipment, less accumulated depreciation and amortization of $2,793 and $3,804 at December 31, 2007 and September 30, 2008, respectively	3,790	4,416
Other non-current assets	267	504
Total Assets	$ 167,097	$ 143,165
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,465	$ 9,804
Current portion of deferred revenue	3,801	4,043
Current portion of capital lease obligations	1,527	1,090
Total current liabilities	15,793	14,937
Deferred revenue, less current portion	46,813	44,730
Capital lease obligations, less current portion	1,194	483
Commitments and contingencies		
Stockholders equity:		
Common stock, $.01 par value, 50,000,000 shares authorized, 22,408,731 shares issued and outstanding at December 31, 2007, 50,000,000 shares authorized, 22,573,849 shares issued and outstanding at September 30, 2008	285	285
Additional paid-in capital	227,438	232,701
Accumulated other comprehensive income	408	68
Deficit accumulated during the development stage	(124,834)	(150,039)
Total stockholders equity	103,297	83,015

Total Liabilities and Stockholders Equity	$	167,097	$	143,165

See accompanying notes to consolidated financial statements

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Amicus Therapeutics, Inc.
(a development stage company)
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30, 2007	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Period from February 4, 2002 (inception) to September 30, 2008
Revenue:					
Research revenue	$	$ 2,959	$	$ 8,539	$ 9,913
Collaboration revenue		694		2,083	2,491
Total revenue		$ 3,653		$ 10,622	$ 12,404
Operating Expenses:					
Research and development	$ 7,537	$ 8,200	$ 21,404	$ 23,989	$ 113,867
General and administrative	3,954	4,371	9,994	14,676	52,745
Impairment of leasehold improvements					1,030
Depreciation and amortization	315	382	924	1,036	3,829
In-process research and development					418
Total operating expenses	11,806	12,953	32,322	39,701	171,889
Loss from operations	(11,806)	(9,300)	(32,322)	(29,079)	(159,485)
Other income (expenses):					
Interest income	1,593	1,019	3,346	4,053	11,993
Interest expense	(90)	(49)	(269)	(179)	(1,608)
Change in fair value of warrant liability			(149)		(454)
Other expense					(1,180)
Loss before tax benefit	(10,303)	(8,330)	(29,394)	(25,205)	(150,734)
Benefit from income taxes		150			695
Net loss	(10,303)	(8,180)	(29,394)	(25,205)	(150,039)
Deemed dividend					(19,424)
Preferred stock accretion			(351)		(802)
Net loss attributable to common stockholders	$ (10,303)	$ (8,180)	$ (29,745)	$ (25,205)	$ (170,265)
	$ (0.46)	$ (0.36)	$ (2.92)	$ (1.12)	

Net loss attributable to common stockholders per common share basic and diluted				
Weighted-average common shares outstanding basic and diluted	22,291,832	22,517,431	10,177,449	22,465,981

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)

	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Period from February 4, 2002 (inception) to September 30, 2008
Operating activities			
Net loss	$ (29,394)	$ (25,205)	$ (150,039)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense			525
Depreciation and amortization	924	1,036	3,828
Amortization of non-cash compensation			522
Stock-based compensation employees	2,712	4,819	11,457
Stock-based compensation non-employees	162		853
Stock-based license payments			1,220
Change in fair value of warrant liability	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	(924)	(477)	(1,990)
Other non-current assets		(236)	(525)
Accounts payable and accrued expenses	(849)	(661)	9,804
Deferred revenue		(1,841)	48,773
Net cash used in operating activities	(27,220)	(22,565)	(73,535)
Investing activities			
Sale and redemption of marketable securities	70,404	125,925	294,991
Purchases of marketable securities	(127,101)	(125,326)	(411,440)
Purchases of property and equipment	(479)	(1,663)	(9,274)
Net cash used in investing activities	(57,176)	(1,064)	(125,723)
Financing activities			
Proceeds from the issuance of preferred stock, net of issuance costs	24,053		143,022
Proceeds from the issuance of common stock, net of issuance costs	68,146		68,093
Proceeds from the issuance of convertible notes			5,000
Payments of capital lease obligations	(1,016)	(1,148)	(4,013)
Proceeds from exercise of stock options	375	444	1,136
Proceeds from exercise of warrants (common and preferred)	98		264
Proceeds from capital asset financing arrangement	546		5,611

Net cash provided by/(used in) financing activities		92,202		(704)		219,113
Net increase/(decrease) in cash and cash equivalents		7,806		(24,333)		19,855
Cash and cash equivalents at beginning of period		12,127		44,188		
Cash and cash equivalents at end of period	$	19,933	$	19,855	$	19,855
Supplemental disclosures of cash flow information						
Cash paid during the period for interest	$	268	$	179	$	1,315
Non-cash activities						
Conversion of notes payable to preferred stock	$		$		$	5,000
Conversion of preferred stock to common stock	$	148,591	$		$	148,591
Accretion of redeemable convertible preferred stock	$	351	$		$	802
Beneficial conversion feature related to the issuance of Series C redeemable convertible preferred stock	$		$		$	19,424

See accompanying notes to consolidated financial statements

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Note 1. Description of Business and Significant Accounting Policies

Corporate Information, Status of Operations and Management Plans

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

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

The Company has an accumulated deficit of approximately $150.0 million at September 30, 2008 and anticipates incurring losses through the year 2008 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 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 (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, 2007. 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, 2007.

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 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). EITF 00-21 provides guidance on 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.

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 May 2008, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162), which identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS No. 162 is effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles . The Company does not expect this will have a significant impact on the financial statements of the Company.

In May 2008, the FASB issued FASB Staff Position (FSP) No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*, which specifies that issuers of these instruments should separately account for the liability and equity components in a manner that reflects the entity s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP No. 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. FSP No. 14-1 is also to be applied retrospectively to all periods presented except if these instruments were not outstanding during any of the periods that are presented in the annual financial statements for the period of adoption but were outstanding during an earlier period. The Company does not expect this will have a significant impact on the financial statements of the Company.

In March 2008, the FASB issued SFAS No. 161, *Disclosures About Derivative Instruments and Hedging Activities* (SFAS No. 161), which requires enhanced disclosures about an entity s derivative and hedging activities in order to improve the transparency of financial reporting. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company does not expect this will have a significant impact on the financial statements of the Company.

Note 2. Investments in Marketable Securities

The Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), effective January 1, 2008. SFAS No. 157 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.

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As of September 30, 2008, the Company held $116.4 million of available for sale investment securities and in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, 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 (deficiency) 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 charges 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 minimal.

The Company s investment portfolio has not been adversely materially 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.

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. The fair value measurements of the Company s available for sale investment securities are identified in the following table (in thousands):

		Fair Value Measurements at Reporting Date using		
	September 30, 2008	**Quoted Prices In Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Commercial paper	$ 61,318	$	$ 61,318	$
Asset-backed securities	8,092		8,092	
U.S. government agency securities	40,685		40,685	
Corporate debt securities	6,305		6,305	
Money market fund (cash equivalents)	17,146	17,146		
	$ 133,546	$ 17,146	$ 116,400	$

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Note 3. Stock-Based Compensation

During the three and nine months ended September 30, 2008, the Company recorded compensation expense of approximately $1.6 million and $4.8 million, respectively. The stock-based compensation expense had no impact on the Company s cash flows from operations and financing activities. As of September 30, 2008, the total unrecognized compensation cost related to non-vested stock options granted was $12.6 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:

	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2007	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
Expected stock price volatility	78.9%	78.2%	78.0%	78.2%
Risk free interest rate	4.7%	4.6%	3.6%	3.0%
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

A summary of option activities related to the Company s stock options for the nine months ended September 30, 2008 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, 2007	2,443.2	$ 8.08		
Options granted	916.0	$ 10.54		
Options exercised	(163.6)	$ 2.85		
Options forfeited	(100.0)	$ 9.64		
Balance at September 30, 2008	3,095.6	$ 9.02	8.1 years	$ 19.0
Vested and unvested expected to vest, September 30, 2008	2,899.8	$ 8.92	8.0 years	$ 17.7
Exercisable at September 30, 2008	1,152.0	$ 7.00	7.2 years	$ 9.4

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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*. The Company has determined that its series A, B, C, and D redeemable convertible preferred stock represented participating securities in accordance with EITF 03-6, *Participating Securities and the Two Class Method under FASB Statement No. 128*. 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	**2007**	**2008**	**2007**	**2008**
Statement of Operations				
Net loss attributable to common stockholders	$ (10,303)	$ (8,180)	$ (29,745)	$ (25,205)
Net loss attributable to common stockholders per common share basic and diluted	$ (0.46)	$ (0.36)	$ (2.92)	$ (1.12)

Note 5. Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	**2008**	**2007**	**2008**
Net loss	$ (10,303)	$ (8,180)	$ (29,394)	$ (25,205)
Change in unrealized net gain/(loss) on marketable securities	107	(250)	205	(340)
Comprehensive loss	$ (10,196)	$ (8,430)	$ (29,189)	$ (25,545)

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.

Note 6. Capital Structure

Common Stock

As of September 30, 2008, 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.

Redeemable Convertible Preferred Stock

In March 2007, the Company issued 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 IPO.

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.

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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 as 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 nine months ended September 30, 2008, the Company recorded $0.7 million and $2.1 million, respectively, in Collaboration Revenue. As of September 30, 2008, the Company recorded $2.8 million of current deferred revenue and $44.7 million of long-term deferred revenue related to the $50 million upfront payment.

During the three and nine months ended September 30, 2008, the Company recorded $3.0 million and $8.5 million, respectively, in Research Revenue. As of September 30, 2008, the Company recorded $1.2 million of current portion of deferred revenue related to reimbursed research and development costs.

Note 8. Subsequent Event

On October 31, 2008, the Company amended and restated its license agreement with Mount Sinai School of Medicine (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, which was already accrued for at year-end 2007, and an additional $2.6 million for the sole right to and control over the prosecution of patent rights.

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 are researching the applicability of our platform pharmacological chaperone technology to treating various diseases in our discovery program and developing the use of our lead compounds in our clinical development program.

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We have three compounds in clinical development: Amigal (migalastat hydrochloride) for Fabry disease, Plicera (isofagomine tartrate) for Gaucher disease and AT2220 for Pompe disease.

Amigal: As previously disclosed, Amicus completed an End of Phase 2 meeting for Amigal with the U.S. Food and Drug Administration (FDA). Along with our partner Shire Human Genetic Therapies, Inc. (Shire), we are engaged in ongoing discussions with FDA and the European Medicines Agency (EMEA) regarding plans for a global Phase 3 clinical development program for Amigal. We expect to complete these interactions and initiate Phase 3 development of Amigal in the first half of 2009. In parallel with the regulatory process, 23 of the original 26 patients who participated in the Phase 2 clinical trial of Amigal continue to be treated with Amigal in the voluntary Phase 2 extension study to monitor long term safety and efficacy and evaluate additional doses and dose regimens. Data from this extension study are expected to be available in Q1 2009 prior to finalization of the Phase 3 protocol. In addition, we expect to conduct clinical pharmacology studies to support the Phase 3 program.

Plicera: We are continuing the protocol for the ongoing 6-month Phase 2 clinical trial of Plicera in patients naive to ERT and we expect the results of this study to be available in 2009. In addition, we expect to initiate a pharmacokinetics study in Gaucher patients and expect the results to be available in the first half of 2009.

AT2220: We are continuing the protocol for the ongoing Phase 2 clinical trial of AT2220 (1-deoxynojirimycin HCl) in adult Pompe patients. In addition, we are conducting preclinical animal studies to evaluate the effects of administering AT2220 in combination with enzyme replacement therapy. Based on these results, we will consider initiating a clinical trial of the AT2220-ERT combination treatment in Pompe patients in 2009.

Research: Amicus continues to invest in research and development to assess the potential for using pharmacological chaperones to treat a broader range of human genetic diseases beyond lysosomal storage 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 genetically-based metabolic disorders. In September 2008, the Company entered into a lease for laboratory space for a small scale research facility in San Diego, CA. The facility will be used to support ongoing research into new applications of the Company s platform technology.

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 September 30, 2008, we have accumulated a deficit of $150.0 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.

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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 reimbursed us for certain research and development costs associated with our lead clinical development programs. For the three and nine months ended September 30, 2008, we recognized approximately $0.7 million and $2.1 million, respectively, of the license fee in Collaboration Revenue and $3.0 million and $8.5 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.

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 September 30, 2008, we have incurred research and development expense in the aggregate of $113.9 million.

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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 September 30, 2007	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Period from February 4, 2002 (inception) to September 30, 2008
Third party direct project expenses					
Amigal (Fabry Disease Phase 2)	$ 1,667	$ 906	$ 4,073	$ 3,156	$ 24,186
Plicera (Gaucher Disease Phase 2)	978	547	3,548	1,572	17,680
AT2220 (Pompe Disease Phase 2)	932	764	2,565	1,708	9,896
Total third party direct project expenses	3,577	2,217	10,186	6,436	51,762
Other project costs (1)					
Personnel costs	2,409	3,454	7,009	10,423	34,854
Other costs (2)	1,551	2,529	4,209	7,130	27,251
Total other project costs	3,960	5,983	11,218	17,553	62,105
Total research and development costs	$ 7,537	$ 8,200	$ 21,404	$ 23,989	$ 113,867

(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.

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; and
- 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. We expect that our general and administrative expenses will increase as we add personnel, in part to meet the reporting obligations applicable to public companies. From our inception in February 2002 through September 30, 2008, we spent $52.7 million on general and administrative expense.

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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.

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 September 30, 2008 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, 2007, 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.

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 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). EITF 00-21 provides guidance on 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.

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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 and for the three and nine months ended September 30, 2007 and 2008 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, *Disclosure about Fair Value of Financial Instruments*, 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.

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*. We have determined that the Series A, B, C, and D redeemable convertible preferred stock represented participating securities in accordance with EITF 03-6, *Participating Securities and the Two Class Method under FASB Statement No. 128*. 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.

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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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amount)	2007	2008	2007	2008
Historical				
Numerator:				
Net loss	$ (10,303)	$ (8,180)	$ (29,394)	$ (25,205)
Deemed dividend				
Accretion of redeemable convertible preferred stock			(351)	
Net loss attributable to common stockholders	$ (10,303)	$ (8,180)	$ (29,745)	$ (25,205)
Denominator:				
Weighted average common shares outstanding basic and diluted	22,291,832	22,517,431	10,177,449	22,465,981

Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options and warrants for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 24.8 million and 25.7 million for the nine months ended September 30, 2007 and 2008, 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 September 30, 2008 Compared to Three Months Ended September 30, 2007

Research and Development Expense. Research and development expense was $8.2 million for the three months ended September 30, 2008 representing an increase of $0.7 million or 9% from $7.5 million for the three months ended September 30, 2007. The variance was primarily attributable to higher personnel costs associated with headcount growth and an increase in consulting and lab supplies due to the continued progress of existing programs, partially offset by decreases in contract research and manufacturing costs due to the timing of batch production. We expect research and development expense to increase in the fourth quarter of 2008 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 $4.4 million for the three months ended September 30, 2008, an increase of $0.4 million or 10% from $4.0 million from the three months ended September 30, 2007. The variance was primarily attributable to higher personnel costs associated with headcount growth, partially offset by a decrease in third party legal fees.

Interest Income and Interest Expense. Interest income was $1.0 million for the three months ended September 30, 2008, compared to $1.6 million for the three months ended September 30, 2007. The decrease of $0.6 million or 38% was due to overall lower average interest rates. Interest expense was $0.1 million for the three months ended September 30, 2008 and 2007.

Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

Research and Development Expense. Research and development expense was $24.0 million for the nine months ended September 30, 2008 representing an increase of $2.6 million or 12% from $21.4 million for the nine months ended September 30, 2007. The variance was primarily attributable to higher personnel costs associated with headcount growth and an increase in lab supplies due to the continued progress of existing programs, partially offset by lower contract manufacturing costs due to the timing of batch production. We expect research and development expense to increase in the fourth quarter of 2008 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 $14.7 million for the nine months ended September 30, 2008, an increase of $4.7 million or 47% from $10.0 million from the nine months ended September 30, 2007. The variance was primarily attributable to higher personnel costs associated with headcount growth and increased administrative costs associated with being a public company.

Interest Income and Interest Expense. Interest income was $4.1 million for the nine months ended September 30, 2008, compared to $3.3 million for the nine months ended September 30, 2007. The increase of $0.8 million or 24% was due to higher cash balances as a result of the receipt of the $50 million upfront licensing payment from Shire, partially offset by lower interest rates. Interest expense was $0.2 million for the nine months ended September 30, 2008, compared to $0.3 million for the nine months ended September 30, 2007. The decrease in interest expense is attributable to a decrease in capital lease borrowings.

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 IPO 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 September 30, 2008:

Funding	Year	No. Shares	Approximate Amount (1) (in thousands)
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 September 30, 2008 of $11.2 million.

As of September 30, 2008, we had cash, cash equivalents and marketable securities of $136.3 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 nine months ended September 30, 2007 was $27.2 million due to the net loss for the nine months ended September 30, 2007 of $29.4 million and the change in operating assets and liabilities of $1.7 million, offset primarily by non-cash charges for depreciation and amortization of $0.9 million, stock-based compensation of $2.9 million and the change in fair value of warrant liability of $0.1 million.

Net cash used in operations for the nine months ended September 30, 2008 was $22.6 million due to the net loss for the nine months ended September 30, 2008 of $25.2 million, a reduction in deferred revenue of $1.8 million and the change in other operating assets and liabilities of $1.4 million, partially offset by non-cash charges for depreciation and amortization of $1.0 million and stock-based compensation of $4.8 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2007 was $57.2 million. Net cash used in investing activities reflects $127.1 million for the purchase of marketable securities and $0.5 million for the acquisition of property and equipment, partially offset by $70.4 million for the sale and redemption of marketable securities.

Net cash used in investing activities for the nine months ended September 30, 2008 was $1.1 million. Net cash used in investing activities reflects $125.3 million for the purchase of marketable securities and $1.7 million for the acquisition of property and equipment, partially offset by $125.9 million for the sale and redemption of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2007 was $92.2 million, consisting primarily of $24.1 million from the issuance of series D redeemable convertible preferred stock, $68.1 million from the issuance of common stock, $0.5 million from asset financing arrangements, and $0.5 million proceeds from exercise of stock options and warrants offset by payments of equipment debt financing obligations of $1.0 million.

Net cash used in financing activities for the nine months ended September 30, 2008 was $0.7 million, consisting primarily of $1.1 million of payments of capital lease obligations partially offset by $0.4 million of proceeds from exercise of stock options.

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 continued progress of our research and development of products,
- the progress, results, duration and cost of discovery, preclinical development, laboratory testing and clinical trials for our product candidates,
- the timing and outcome of regulatory review of our product candidates,
- the number and development requirements of other product candidates that we pursue,
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights,
- the availability of financing,
- our success in developing markets for our product candidates,
- the costs of commercialization activities, including product marketing sales and distribution,

the acquisition of licenses to new products or compounds, and

the status of competitive products.

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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.

The events that trigger these payments include:

- completion of Phase 2 clinical trials;
- commencement of Phase 3 clinical trials;
- submission of an NDA to the FDA or foreign equivalents; and
- receipt of marketing approval from the FDA or foreign equivalents.

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.

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, which was already accrued for at year-end 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.

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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 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

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, 2007.

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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.

As of October 31, 2008, 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 October 31, 2008, 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 September 30, 2008:

Period	(a) Total number of shares purchased	(b) Average Price Paid per Share	(c) Total number of shares purchased as part of publicly announced plans or programs	(d) Maximum number of shares that may yet be purchased under the plans or programs
July 1, 2008 July 31, 2008	220	$ 10.81		5,955
August 1, 2008 August 31, 2008	220	$ 15.61		5,735
September 1, 2008 September 30, 2008	220	$ 13.86		5,515
Total	660			

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.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

On October 31, 2008, the Company amended and restated its license agreement with Mount Sinai School of Medicine (MSSM). The amended and restat