

AMICUS THERAPEUTICS INC

Form 10-Q

November 09, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

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 October 29, 2010 was 27,637,495 shares.

AMICUS THERAPEUTICS, INC
Form 10-Q for the Quarterly Period Ended September 30, 2010

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We have filed applications to register certain trademarks in the United States and abroad, including AMICUS™,

AMICUS THERAPEUTICS™ (and design), AMIGAL™ and PLICERA™.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- the progress and results of our clinical trials of our drug candidates, including Amigal;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- 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;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to execute our operational and business plans including our ability to achieve development and commercialization milestone payments and sales royalties under our collaboration with GlaxoSmithKline;
- and
- our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part I Item 1A Risk Factors of the Annual Report on Form 10-K for the year ended December 31, 2009 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)**

	December 31, 2009	September 30, 2010
Assets:		
Current assets:		
Cash and cash equivalents	\$ 19,339	\$ 22,097
Investments in marketable securities	58,885	35,484
Prepaid expenses and other current assets	2,262	2,897
Total current assets	80,486	60,478
Property and equipment, less accumulated depreciation and amortization of \$6,340 and \$7,917 at December 31, 2009 and September 30, 2010, respectively	4,399	3,017
Other non-current assets	485	267
Total Assets	\$ 85,370	\$ 63,762
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,635	\$ 6,809
Current portion of secured loan	1,253	1,253
Current portion of capital lease obligations	305	86
Total current liabilities	11,193	8,148
Warrant liability		3,766
Secured loan, less current portion	2,296	1,357
Capital lease obligations, less current portion	48	
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value, 50,000,000 shares authorized, 22,672,427 shares issued and outstanding at December 31, 2009, 50,000,000 shares authorized, 27,637,718 shares issued and outstanding at September 30, 2010	287	337
Additional paid-in capital	242,259	260,747
Accumulated other comprehensive income	43	11
Deficit accumulated during the development stage	(170,756)	(210,604)
Total stockholders' equity	71,833	50,491

Total Liabilities and Stockholders' Equity	\$	85,370	\$	63,762
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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		Nine Months		Period from
					February 4,
					2002
					(inception)
					to September
	Ended September 30,	2010	Ended September 30,	2010	30,
	2009		2009		2010
Revenue:					
Research revenue	\$ 4,219	\$	\$ 12,799	\$	\$ 31,108
Collaboration revenue	694		2,083		50,000
Total revenue	\$ 4,913	\$	\$ 14,882	\$	\$ 81,108
Operating Expenses:					
Research and development	\$ 12,609	\$ 8,862	\$ 37,954	\$ 25,888	\$ 201,611
General and administrative	5,217	3,892	15,635	11,837	89,546
Restructuring charges					1,522
Impairment of leasehold improvements					1,030
Depreciation and amortization	561	511	1,585	1,577	7,997
In-process research and development					418
Total operating expenses	18,387	13,265	55,174	39,302	302,124
Loss from operations	(13,474)	(13,265)	(40,292)	(39,302)	(221,016)
Other income (expenses):					
Interest income	129	33	924	121	13,878
Interest expense	(84)	(66)	(155)	(203)	(2,127)
Change in fair value of warrant liability		(2,059)		(464)	(918)
Other expense					(1,116)
Loss before tax benefit	(13,429)	(15,357)	(39,523)	(39,848)	(211,299)
Benefit from income taxes					695
Net loss	(13,429)	(15,357)	(39,523)	(39,848)	(210,604)
Deemed dividend					(19,424)
Preferred stock accretion					(802)
Net loss attributable to common stockholders	\$ (13,429)	\$ (15,357)	\$ (39,523)	\$ (39,848)	\$ (230,830)

Net loss attributable to common stockholders per common share basic and diluted	\$	(0.59)	\$	(0.56)	\$	(1.75)	\$	(1.50)
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Weighted-average common shares outstanding basic and diluted	22,621,513	27,625,137	22,617,808	26,516,688
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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,		Period from February 4, 2002 (inception) to September 30, 2010
	2009	2010	
Operating activities			
Net loss	\$ (39,523)	\$ (39,848)	\$ (210,604)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense			525
Depreciation and amortization	1,585	1,577	7,997
Amortization of non-cash compensation			522
Stock-based compensation employees	6,039	4,702	25,575
Stock-based compensation non-employees			853
Stock-based license payments			1,220
Change in fair value of warrant liability		464	918
Loss on disposal of asset	9		239
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	(1,842)	(635)	(3,115)
Other non-current assets		218	(71)
Accounts payable and accrued expenses	3,963	(2,826)	6,808
Deferred revenue	(3,010)		
Net cash used in operating activities	(32,779)	(36,348)	(167,550)
Investing activities			
Sale and redemption of marketable securities	106,455	77,435	556,449
Purchases of marketable securities	(82,634)	(54,065)	(592,039)
Purchases of property and equipment	(1,724)	(195)	(12,280)
Net cash provided by/(used in) investing activities	22,097	23,175	(47,870)
Financing activities			
Proceeds from the issuance of preferred stock, net of issuance costs			143,022
Proceeds from the issuance of common stock and warrants, net of issuance costs		17,131	85,224
Proceeds from the issuance of convertible notes			5,000
Payments of capital lease obligations	(710)	(267)	(5,501)
Payments of secured loan agreement		(939)	(1,149)
Proceeds from exercise of stock options	48	6	1,288

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Proceeds from exercise of warrants (common and preferred)			264
Proceeds from capital asset financing arrangement			5,611
Proceeds from secured loan arrangement	3,758		3,758
Net cash provided by financing activities	3,096	15,931	237,517
Net (decrease)/ increase in cash and cash equivalents	(7,586)	2,758	22,097
Cash and cash equivalents at beginning of period	28,073	19,339	
Cash and cash equivalents at end of period	\$ 20,487	\$ 22,097	\$ 22,097

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

	Nine Months Ended September 30,		Period from February 4, 2002 (inception) to September 30, 2010
	2009	2010	
Supplemental disclosures of cash flow information			
Cash paid during the period for interest	\$ 155	\$ 223	\$ 1,827
Non-cash activities			
Conversion of notes payable to preferred stock	\$	\$	\$ 5,000
Conversion of preferred stock to common stock	\$	\$	\$ 148,591
Accretion of redeemable convertible preferred stock	\$	\$	\$ 802
Beneficial conversion feature related to the issuance of Series C redeemable convertible preferred stock	\$	\$	\$ 19,424

See accompanying notes to consolidated financial statements

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Note 1. Description of Business and Significant Accounting Policies

Corporate Information, Status of Operations and Management Plans

Amicus Therapeutics, Inc. (the Company) was incorporated on February 4, 2002 in Delaware for the purpose of creating a premier drug development company at the forefront of therapy for human genetic diseases initially based on intellectual property in-licensed from Mount Sinai School of Medicine. The Company is focused on the discovery, development and commercialization of orally-administered, small molecule drugs known as pharmacological chaperones. Pharmacological chaperones are a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage disorders and neurodegenerative diseases. 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.

On October 28, 2010, the Company entered into a License and Collaboration Agreement (the License and Collaboration Agreement) with Glaxo Group Limited, an affiliate of GlaxoSmithKline PLC (GSK), to develop and commercialize Amigal (migalastat HCl), currently in Phase 3 for the treatment of Fabry disease. Under the terms of the License and Collaboration Agreement, GSK will receive an exclusive worldwide license to develop, manufacture and commercialize Amigal. In consideration of the license grant, the Company will receive an upfront, license payment of \$30 million from GSK and is eligible to receive further payments of approximately \$170 million upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of Amigal. GSK and the Company will jointly fund development costs in accordance with an agreed upon development plan. This plan provides that the Company will fund 100% of the development costs for the remainder of 2010; 50% of the development costs for 2011 and 25% of the development costs in 2012 and beyond. The Company's development costs are subject to annual and aggregate caps. Additionally, GSK is purchasing approximately 6.9 million shares of the Company's common stock at a price of \$4.56 per share pursuant to a Stock Purchase Agreement (SPA). The total value of this equity investment to the Company is approximately \$31 million and represents a 19.9% ownership position in the Company.

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 were jointly developing three of the Company's pharmacological chaperone compounds for lysosomal storage disorders: Amigal (migalastat hydrochloride), Plicera (isofagomine tartrate) and AT2220 (1-deoxynojirimycin HCl). In October 2009, the Company and Shire mutually agreed to terminate the collaboration agreement. For further information, see Note 8. Development and Commercialization Agreement with Shire.

The Company had an accumulated deficit of approximately \$210.6 million at September 30, 2010 and anticipates incurring losses through the year 2010 and beyond. The Company has not yet generated commercial sales revenue and has been able to fund its operating losses to date through the sale of its common stock and redeemable convertible preferred stock, issuance of convertible notes, payments from Shire during the term of the collaboration agreement and other financing arrangements. In March 2010, the Company sold 4.95 million shares of its common stock and warrants to purchase 1.85 million shares of common stock in a registered direct offering to a select group of institutional investors for net proceeds of approximately \$17.1 million. The Company believes that its existing cash and cash equivalents and short-term investments will be sufficient to cover its cash flow requirements for 2011.

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.

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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, 2009. 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, 2009.

Revenue Recognition

The Company recognizes revenue when amounts are realized or realizable and earned. Revenue is considered realizable and earned when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collection of the amounts due are reasonably assured.

In determining the accounting for collaboration agreements, the Company determines 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. If this division is required, 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 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.

The revenue associated with reimbursements for research and development costs under collaboration agreements 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.

Fair Value Measurements

The Company records certain asset and liability balances under the fair value measurements as defined by the Financial Accounting Standards Board (FASB) guidance. Current FASB fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.

Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

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New Accounting Standards

In February 2010, the FASB issued revised guidance on the disclosure of events subsequent to the date of the financial statements but prior to issuance. The Company adopted these changes in the disclosure in the Company's Annual Report on Form 10-K for the year ended December 31, 2009. These changes in disclosure did not have an impact on the financial statements of the Company.

In January 2010, the FASB issued amendments to its fair value guidance which requires additional disclosures that include: 1) separate disclosures on significant transfers into and out of Level 3; 2) the amount of transfers between Level 1 and Level 2 and the reasons for such transfers; 3) lower level of disaggregation for fair value disclosures by class rather than by major category and 4) additional details on the valuation techniques and inputs used to determine Level 2 and Level 3 measurements. The Company has included these additional disclosures within the Form 10-Q for the period ended September 30, 2010 and they did not have a significant impact on the financial statements of the Company.

In October 2009, the FASB issued guidance on revenue recognition related to multiple-element arrangements. This new guidance requires companies to allocate revenue in multiple-element arrangements based on an element's estimated selling price if vendor-specific or other third party evidence of value is not available. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted retrospectively from the beginning of an entity's fiscal year. The Company is currently evaluating the effect that the adoption of this guidance will have on our results of operations and financial position, if any.

Note 2. Cash, Cash Equivalents and Available-For-Sale Investments

As of September 30, 2010, the Company held \$22.1 million in cash and cash equivalents and \$35.5 million of available-for-sale investment securities which 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.

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.

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Cash and available for sale securities consisted of the following as of December 31, 2009 and September 30, 2010:

	As of December 31, 2009			
	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash balances	\$ 19,339	\$	\$	\$ 19,339
U.S. government agency securities	45,020	44	(1)	45,063
Corporate debt securities	8,951	4	(7)	8,948
Commercial paper	4,521	3		4,524
Certificate of deposit	350			350
	\$ 78,181	\$ 51	\$ (8)	\$ 78,224
Included in cash and cash equivalents	\$ 19,339	\$	\$	\$ 19,339
Included in marketable securities	58,842	51	(8)	58,885
Total cash and available for sale securities	\$ 78,181	\$ 51	\$ (8)	\$ 78,224

	As of September 30, 2010			
	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash balances	\$ 22,097	\$	\$	\$ 22,097
Commercial paper	22,226	15		22,241
Corporate debt securities	12,897	1	(5)	12,893
Certificate of deposit	350			350
	\$ 57,570	\$ 16	\$ (5)	\$ 57,581
Included in cash and cash equivalents	\$ 22,097	\$	\$	\$ 22,097
Included in marketable securities	35,473	16	(5)	35,484
Total cash and available for sale securities	\$ 57,570	\$ 16	\$ (5)	\$ 57,581

All of the Company's available for sale investments as of December 31, 2009 and September 30, 2010 are due in one year or less.

Unrealized gains and losses are reported as a component of accumulated other comprehensive income/(loss) in stockholders' equity. For the year ended December 31, 2009, unrealized holding gains included in accumulated other comprehensive income was \$0.5 million. For the nine months ended September 30, 2010, unrealized holding gains included in accumulated other comprehensive income was less than \$0.04 million.

For the year ended December 31, 2009 and the nine months ended September 30, 2010, there were no realized gains or losses. The cost of securities sold is based on the specific identification method.

Unrealized loss positions in the available for sale securities as of December 31, 2009 and September 30, 2010 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 \$7.8 million and \$8.1 million as of December 31, 2009 and September 30, 2010, respectively.

Table of Contents**Note 3. Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share**

The Company calculates net loss per share as a measurement of the Company's performance while giving effect to all dilutive potential common shares that were outstanding during the reporting period. The Company has a net loss for all periods presented; accordingly, the inclusion of common stock options 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:

(In thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Statement of Operations				
Net loss attributable to common stockholders	\$ (13,429)	\$ (15,357)	\$ (39,523)	\$ (39,848)
Net loss attributable to common stockholders per common share – basic and diluted	\$ (0.59)	\$ (0.56)	\$ (1.75)	\$ (1.50)
Dilutive common stock equivalents would include the dilutive effect of common stock options and warrants for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 4.0 million and 7.0 million for the nine months ended September 30, 2009 and 2010, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.				

Note 4. Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Net loss	\$ (13,429)	\$ (15,357)	\$ (39,523)	\$ (39,848)
Change in unrealized net gain on marketable securities	(57)	5	(445)	(32)
Comprehensive loss	\$ (13,486)	\$ (15,352)	\$ (39,968)	\$ (39,880)

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 5. Stockholders' Equity***Common Stock and Warrants***

As of September 30, 2010, 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.

On March 2, 2010, the Company completed the sale of 4,946,524 shares of its common stock and the issuance of warrants to purchase 1,854,946 common shares in a registered direct offering to a select group of institutional investors. The warrants have a term of four years and are exercisable any time on or after the six month anniversary of the date they were issued, at an exercise price of \$4.43 per share. The Company received gross proceeds of \$18.5 million, with net cash proceeds after related expenses from this transaction of approximately \$17.1 million. Of those proceeds, the Company allocated an estimated fair value of \$3.3 million to the warrants which was determined on March 2, 2010 using the Black-Scholes model assuming a risk free interest rate of 1.78% and a volatility of 80.8%. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (Registration No. 333-158405), which was declared effective on May 27, 2009.

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On October 28, 2010, Amicus and GSK entered into the SPA pursuant to which GSK will purchase 6.9 million unregistered shares of Amicus common stock no later than November 11, 2010 at a price of \$4.56 per share. The total purchase price for the shares purchased by GSK is \$31.1 million. The Company will receive all proceeds from the sale of such shares.

Stock Option Plans

During the three and nine months ended September 30, 2010, the Company recorded compensation expense of approximately \$1.5 million and \$4.7 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, 2010, the total unrecognized compensation cost related to non-vested stock options granted was \$8.4 million and is expected to be recognized over a weighted average period of 2.2 years.

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

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2010
Expected stock price volatility	81.3%	80.6%	79.5%	80.5%
Risk free interest rate	2.8%	2.2%	1.9%	2.5%
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, 2010 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, 2009	4,818.9	\$ 8.01		
Options granted	757.4	\$ 2.92		
Options exercised	(20.7)	\$ 0.64		
Options forfeited	(408.8)	\$ 7.87		
Balance at September 30, 2010	5,146.8	\$ 7.31	7.7 years	\$ 1.0
Vested and unvested expected to vest, September 30, 2010	4,884.6	\$ 7.42	7.6 years	\$ 1.0
Exercisable at September 30, 2010	2,471.5	\$ 8.96	6.3 years	\$ 0.3

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Note 6. 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 September 30, 2010, the current and long-term amounts due under the loan agreement were \$1.3 million and \$1.4 million, respectively. The carrying amount of the Company's borrowings approximates fair value at September 30, 2010.

Note 7. Assets and Liabilities Measured at Fair Value

The Company's financial assets and liabilities are measured at fair value and classified within the fair value hierarchy which is defined as follows:

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.

Cash, Money Market Funds and Marketable Securities

The Company classifies its cash and money market funds within the fair value hierarchy as Level 1 as these assets are valued using quoted prices in active market for identical assets at the measurement date. The Company considers its investments in marketable securities as available for sale and classifies these assets within the fair value hierarchy as Level 2 primarily utilizing broker quotes in a non-active market for valuation of these securities. No changes in valuation techniques or inputs occurred during the three months ended September 30, 2010. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three months ended September 30, 2010.

Secured Debt

As disclosed in Note 6, the Company has a loan and security agreement with Silicon Valley Bank. The carrying amount of the Company's borrowings approximates fair value at September 30, 2010. The Company's secured debt is classified as Level 2 and the fair value is estimated using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals.

Warrants

As disclosed in Note 5, the Company allocated \$3.3 million of proceeds from its March 2010 registered direct offering to warrants issued in connection with the offering that was classified as a liability. The valuation of the warrants is determined using the Black-Scholes model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant liability should be classified within Level 3 of the fair value hierarchy by evaluating each input for the Black Scholes model against the fair value hierarchy criteria and using the lowest level of input as the basis for the fair value classification. There are six inputs: closing price of Amicus stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Amicus' stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of Amicus stock would fall under Level 1 of the fair value hierarchy as it is a quoted price in an active market. The riskless rate of return is a Level 2 input, while the historical volatility is a Level 3 input in accordance with the fair value accounting guidance. Since the lowest level input is a Level 3, the Company determined the warrant liability is most appropriately classified within Level 3 of the

fair value hierarchy. This liability is subject to fair value mark-to-market adjustment each period. As a result, for the nine month period ended September 30, 2010, the Company recorded a change in warrant liability income of \$0.5 million. The resulting fair value of the warrant liability at September 30, 2010 was \$3.8 million.

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A summary of the fair value of the Company's assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of September 30, 2010 are identified in the following table (in thousands):

	Level 1	Level 2	Total
Assets:			
Cash/Money market funds	\$ 22,097	\$	\$ 22,097
Commercial paper		22,241	22,241
Corporate debt securities		12,893	12,893
Certificate of deposit		350	350
	\$ 22,097	\$ 35,484	\$ 57,581
Liabilities:			
Secured debt	\$	\$ 2,610	\$ 2,610
Warrants liability		3,766	3,766
	\$	\$ 2,610	\$ 6,376

Note 8. 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 were jointly developing three of the Company's 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. and retained 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 global approval of the three compounds were being shared 50/50. In addition, the Company was eligible to receive milestone payments if certain clinical and regulatory and sales-based milestones were met, as well as tiered double-digit royalties on net sales of the products marketed outside of the U.S.

As previously disclosed, on October 29, 2009, the Company and Shire agreed to mutually terminate the collaboration agreement. As a result of this termination, Amicus reacquired all global development and commercialization rights from Shire for Amigal, Plicera and AT2220 programs and now owns worldwide rights to them. Shire paid the Company \$5.2 million as full and final payment for amounts due to the Company under the collaboration agreement, and both parties are relieved of all other future obligations thereunder, financial or otherwise.

The Company had previously 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 was being recognized on a straight line basis as Collaboration Revenue over the period of the performance obligations. The Company had determined that the period of performance obligations was 18 years as contractually defined. During the three and nine months ended September 30, 2009, the Company recorded \$0.7 million and \$2.1 million, respectively, in Collaboration Revenue and \$4.2 million and \$12.8 million, respectively, in Research Revenue.

Note 9. Restructuring Charges

In October 2009, the Company announced a work-force reduction of approximately 20 percent, or 26 employees, as a part of a corporate restructuring, with reductions occurring across all levels and departments within the Company. This measure was intended to reduce costs and to align the Company's resources with its key strategic priorities. The Company recorded restructuring charges of \$0.9 million during the fourth quarter of 2009 for employment termination costs payable in cash in connection with the workforce reduction. At September 30, 2010, all of the restructuring charges related to the employment termination costs were paid.

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In December 2009, the Company initiated and completed a facilities consolidation effort, closing one of its subleased locations in Cranbury, NJ. The Company recorded a charge of \$0.7 million during the fourth quarter of 2009 for minimum lease payments of \$0.5 million and the write-down of fixed assets in the facility. At September 30, 2010, \$0.3 million of the restructuring charges related to the facilities consolidation were unpaid and classified under accrued expenses on the balance sheet.

The following table summarizes the restructuring charges and utilization for the nine months ended September 30, 2010 (in thousands):

	Balance as of December 31, 2009	Charges	Cash Payments	Adjustments	Balance as of September 30, 2010
Employment termination costs	\$ 271	\$	\$ (271)	\$	\$
Facilities consolidation	497		(172)		325
Total	\$ 768	\$	\$ (443)	\$	\$ 325

Note 10. Subsequent Events

The Company evaluated events that occurred subsequent to September 30, 2010 through the date of issuance of these financial statements. The following events are noted:

Definitive Development Agreement

On October 28, 2010, the Company entered into a License and Collaboration Agreement with GSK, to develop and commercialize Amigal (migalastat HCI), currently in Phase 3 for the treatment of Fabry disease. Under the terms of the License and Collaboration Agreement, GSK will receive an exclusive worldwide license to develop, manufacture and commercialize Amigal. GSK and Amicus also intend to advance clinical studies exploring the co-administration of migalastat HCI with enzyme replacement therapy (ERT) for the treatment of Fabry disease, as provided in the Collaboration Agreement.

The Company will receive an upfront, license payment of \$30 million from GSK no later than November 11, 2010 and is eligible to receive further payments of approximately \$170 million upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of Amigal. GSK and the Company will jointly fund development costs in accordance with an agreed upon development plan. This plan provides that the Company will fund 100% of the development costs for the remainder of 2010; 50% of the development costs for 2011 and 25% of the development costs in 2012 and beyond; The Company's development costs are subject to annual and aggregate caps.

Additionally, GSK is purchasing approximately 6.9 million shares of the Company's common stock at a price of \$4.56 per share pursuant to the SPA. The total value of this equity investment to the Company is approximately \$31 million and represents a 19.9% ownership position in the Company. The SPA provides GSK with customary registration rights for the shares purchased and includes an eighteen-month standstill and lock-up provision, subject to certain exceptions. The total cash up-front to the Company from GSK for the upfront license payment and equity investment is approximately \$61 million.

Therapeutic Discovery Project

On November 1, 2010, the Company received approval from the Department of the Treasury for all six of its applications for the qualifying therapeutic discovery project under Section 48D of the Internal Revenue Code. This approval represents a grant of approximately \$0.24 million per application submitted for a total grant of approximately \$1.5 million, which will be paid prior to the end of 2010.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of orally-administered, small molecule drugs known as pharmacological chaperones. Pharmacological chaperones are a novel, first-in-class approach to treating a broad range of diseases including lysosomal storage disorders and neurodegenerative diseases. Our goal is to become a leading biopharmaceutical company in these areas. Our current strategic priorities include the following:

- the Phase 3 development of our lead product candidate, Amigal for Fabry disease;
- the preclinical and clinical development of pharmacological chaperone/enzyme replacement therapy combination therapy; and
- the preclinical evaluation of the use of pharmacological chaperones for neurodegenerative diseases.

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 within the cell, thereby increasing protein activity, improving cellular function and potentially reducing cell stress. We have also demonstrated in preclinical studies that pharmacological chaperones can further stabilize normal, or wild-type, proteins. This stabilization could lead to a higher percentage of the target proteins folding correctly and more stably, which can increase cellular levels of that target protein and improve cellular function, making chaperones potentially applicable to a wide range of diseases.

Our lead product candidate, Amigal (migalastat hydrochloride), is in Phase 3 development as a monotherapy for the treatment of Fabry disease. As discussed above, in October 2010, we entered into a License and Collaboration Agreement (the License and Collaboration Agreement) with Glaxo Group Limited, an affiliate of GlaxoSmithKline (GSK) pursuant to which we and GSK will develop and commercialize Amigal. In addition, we are conducting preclinical studies of our chaperone molecules in combination with enzyme replacement therapy for the treatment of Fabry, Gaucher, and Pompe diseases, as well as in neurodegenerative diseases, including Parkinson's and Alzheimer's disease.

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Amigal: The Phase 3 U.S. registration study (Study 011) of migalastat HCl remains the Company's number one priority. Study 011 is being conducted at approximately 40 investigational sites worldwide and the Company expects to complete enrollment during the first quarter of 2011. The Company expects to report preliminary results from this study in the second half of 2011. As previously announced, the Company expects to commence an additional Phase 3 study (Study 012) before year end. Study 012, a registration trial designed to support approval in the European Union, will be an 18-month, randomized, open-label study comparing Amigal to enzyme replacement therapy (ERT) in approximately 60 subjects. The primary outcome of efficacy will be renal function as measured by glomerular filtration rate (GFR).

Chaperone-ERT Co-administration Therapy Programs: Amicus and GSK will initiate a Phase 2 study with migalastat HCl co-administered with ERT for Fabry disease before the end of 2010. The Company will provide protocol details and timelines for the study in the coming weeks. Additionally, Amicus continues to evaluate the co-administration use of AT2220 (1-deoxynojirimycin HCl) with ERT in mouse models of Pompe disease. The Company previously reported that preclinical studies demonstrated that co-administration of AT2220 with ERT resulted in prolonged half-life of ERT in the circulation, increased enzyme activity in cells and greater substrate reduction in target tissues compared to that seen with ERT alone. Amicus has also completed promising preclinical studies of its chaperone Plicera (afegostat tartrate) co-administered with ERT for Gaucher disease. The Company continues to evaluate options for clinical development of both AT2220 and ERT for Pompe disease and afegostat tartrate and ERT for Gaucher disease.

Neurodegenerative Disease Programs: Amicus continues to advance its preclinical neurodegenerative disease programs. As previously reported, Amicus presented data from preclinical studies that evaluated the chaperone AT2101 in mouse models of Parkinson's disease. The studies demonstrated that treatment with AT2101 increased the activity of α -glucocerebrosidase (GCase), prevented accumulation of α -synuclein in the brain and improved motor function as assessed in various behavioral tests. At that time, the Company also announced that new compounds have been identified that improve on the properties of AT2101 and expand the range of doses and regimens that show motor improvement in mouse models of the disease. Amicus expects to provide details regarding its plans to advance the Parkinson's disease program early in January 2011. Amicus' second neurodegenerative disease program is for the treatment of Alzheimer's disease. As previously announced, Amicus was awarded a grant of \$0.2 million from the Alzheimer's Drug Discovery Foundation (ADDF). The grant from the ADDF is funding preclinical studies to evaluate the use of pharmacological chaperones for the treatment of Alzheimer's disease.

We have generated significant losses to date and expect to continue to generate losses as we continue the clinical development of our drug candidates, including Amigal, and conduct preclinical studies on other programs. 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, 2010, we have accumulated a deficit of \$210.6 million. As we have not yet generated commercial sales revenue from any of our product candidates, our losses will continue and are likely to be substantial over the next several years and we may need to obtain additional funds to further develop our research and development programs and product candidates.

In June 2007, we completed our initial public offering (IPO) of 5,000,000 shares of common stock at a public offering price of \$15.00 per share. Net cash proceeds from the initial public offering were approximately \$68.1 million after deducting underwriting discounts, commissions and offering expenses payable by us. In connection with the closing of the IPO, all of Amicus' shares of redeemable convertible preferred stock outstanding at the time of the offering were automatically converted into 16,112,721 shares of common stock.

In March 2010, we sold 4.95 million shares of our common stock and warrants to purchase 1.85 million shares of common stock in a registered direct offering to a select group of institutional investors. The shares of common stock and warrants were sold in units consisting of one share of common stock and one warrant to purchase 0.375 shares of common stock at a price of \$3.74 per unit. The warrants have a term of four years and are exercisable any time on or after the six month anniversary of the date they were issued, at an exercise price of \$4.43 per share. The net proceeds of the offering were approximately \$17.1 million after deducting the placement agency fee and all other estimated offering expenses.

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In October 2010, we entered into the License and Collaboration Agreement with GSK and in connection therewith will receive and upfront license payment of \$30 million and are eligible to receive further payments of approximately \$170 million upon the successful achievement of development and commercialization milestones, as well as tiered double-digit royalties on global sales of Amigal. We will jointly fund development costs with GSK in accordance with an agreed upon development plan. This plan provides that we will fund 100% of the development costs for the remainder of 2010; 50% of the development costs for 2011 and 25% of the development costs in 2012 and beyond. Our development costs are subject to annual and aggregate caps. In addition, GSK is purchasing approximately 6.9 million shares of the Company's common stock at a price of \$4.56 per share for a total purchase price of approximately \$31 million. The total cash up-front to us from GSK for the upfront license payment and equity investment is approximately \$61 million.

Financial Operations Overview

Revenue

We have not generated any commercial sales revenue since our inception.

On November 7, 2007, we entered into a license and collaboration agreement with Shire. Under the agreement, Amicus and Shire were jointly developing three of our pharmacological chaperone compounds for lysosomal storage disorders: Amigal, Plicera and AT2220. In connection with this agreement, Shire paid us an initial, non-refundable license fee of \$50 million and reimbursed us for certain research and development costs associated with these clinical development programs. The license fee was classified as deferred revenue and was being recognized as Collaboration Revenue on a straight line basis over the period of the performance obligations. We also recognized any reimbursed research and development costs as Research Revenue. In October 2009, we mutually terminated our collaboration agreement with Shire and received a cash payment of \$5.2 million as full and final settlement of all amounts due under the collaboration agreement. This final payment was recorded as Research Revenue net of a cost sharing receivable. As a result of the termination of the agreement and as there were no further obligations under the original agreement, we recognized all previously deferred revenue as Collaboration Revenue in the fourth quarter of 2009. The Company is currently evaluating the accounting for revenue from the GSK collaboration and any other new collaboration agreements it may enter into from time to time in the future under the guidance on revenue recognition related to multiple-element arrangements issued by the FASB that is effective for collaboration agreements entered into after June 15, 2010.

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. However, we will share future research and development costs related to Amigal with GSK in accordance with the License and Collaboration Agreement.

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.

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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, 2010, we have incurred research and development expense in the aggregate of \$201.6 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).

Projects	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		February 4,
	2009	2010	2009	2010	(inception) to
					September 30,
					2010
Third party direct project expenses					
Amigal (Fabry Disease Phase 3)	\$ 3,096	\$ 3,020	\$ 6,854	\$ 8,140	\$ 42,214
Plicera (Gaucher Disease Phase 2*)	1,098	100	5,693	434	26,299
AT2220 (Pompe Disease Phase 1)	266	23	1,528	334	13,232
Neurodegenerative Diseases (Preclinical)	1,038	82	2,592	488	6,103
Total third party direct project expenses	5,498	3,225	16,667	9,396	87,848
Other project costs ⁽¹⁾					
Personnel costs	4,830	3,983	14,758	12,166	69,932
Other costs ⁽²⁾	2,281	1,654	6,529	4,326	43,831
Total other project costs	7,111	5,637	21,287	16,492	113,763
Total research and development costs	\$ 12,609	\$ 8,862	\$ 37,954	\$ 25,888	\$ 201,611

(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.

- * We do not plan
to advance
Plicera into
Phase 3
development at
this time.

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, including Amigal 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.

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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, legal, 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 September 30, 2010, we spent \$89.5 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.

Restructuring Charges

In October 2009, the Company implemented a work-force reduction plan to reduce costs and align the Company's resources with its key strategic priorities. The restructuring charges include employee termination costs, facilities consolidation costs related to minimum lease payments of a subleased location that was closed and the write-down of fixed assets in this subleased location.

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, 2010 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, 2009, 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 when amounts are realized or realizable and earned. Revenue is considered realizable and earned when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collection of the amounts due are reasonably assured.

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The Company is currently evaluating the accounting for revenue from the GSK collaboration and any other new collaboration agreements it may enter into from time to time in the future under the guidance on revenue recognition related to multiple-element arrangements issued by the FASB that is effective for collaboration agreements entered into after June 15, 2010.

The revenue associated with reimbursements for research and development costs under collaboration agreements 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

We adopted the fair value method of measuring stock-based compensation, which requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based upon the grant-date fair value of the award. 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 vesting period of the related awards.

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We use the Black-Scholes option pricing model when estimating the value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. 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. We will continue to use a blended weighted average approach using our own historical volatility and other similar public entity volatility information until our historical volatility is relevant to measure expected volatility for future option grants. The average expected life was determined using 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. Forfeitures are estimated based on voluntary termination behavior, as well as a historical analysis of actual option forfeitures. The weighted average assumptions used in the Black-Scholes option pricing model are as follows:

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2010
Expected stock price volatility	81.3%	80.6%	79.5%	80.5%
Risk free interest rate	2.8%	2.2%	1.9%	2.5%
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

Warrants

The warrants issued in connection with the March 2010 registered direct offering are classified as a liability. The fair value of the warrants liability is evaluated at each balance sheet date using the Black-Scholes valuation model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. Any changes in the fair value of the warrants liability is recognized in the consolidated statement of operations. The weighted average assumptions used in the Black-Scholes valuation model for the warrants at inception, at March 31, 2010, at June 30, 2010, and September 30, 2010 are as follows:

	March 2, 2010	March 31, 2010	June 30, 2010	Sept. 30, 2010
Expected stock price volatility	80.8%	80.9%	79.4%	79.6%
Risk free interest rate	1.8%	2.0%	1.3%	0.9%
Expected life of warrants (years)	4.00	3.92	3.67	3.42
Expected annual dividend per share	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00

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

We calculated net loss per share as a measurement of the Company's performance while giving effect to all dilutive potential common shares that were outstanding during the reporting period. 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:

(In thousands, except per share amount)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2010	2009	2010
Historical				
Numerator:				
Net loss attributable to common stockholders	\$ (13,429)	\$ (15,357)	\$ (39,523)	\$ (39,848)
Denominator:				
Weighted average common shares outstanding basic and diluted	22,621,513	27,625,137	22,617,808	26,516,688

Dilutive common stock equivalents would include the dilutive effect of common stock options and warrants for common stock equivalents. Potentially dilutive common stock equivalents totaled approximately 4.0 million and 7.0 million for the nine months ended September 30, 2009 and 2010, 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, 2010 Compared to Three Months Ended September 30, 2009***

Research and Development Expense. Research and development expense was \$8.9 million for the three months ended September 30, 2010 representing a decrease of approximately \$3.7 million or 29% from \$12.6 million for the three months ended September 30, 2009. The variance was primarily attributable to lower personnel costs associated with the workforce reduction completed in the fourth quarter of 2009, a decrease in consulting costs and a decrease in contract research costs due to the reduced activity within the Gaucher program.

General and Administrative Expense. General and administrative expense was \$3.9 million for the three months ended September 30, 2010, representing a decrease of \$1.3 million or 25% from \$5.2 million for the three months ended September 30, 2009. The variance was primarily due to lower personnel costs associated with the workforce reduction completed in the fourth quarter of 2009 and a decrease in third party legal and consulting fees.

Interest Income and Interest Expense. Interest income was \$0.03 million for the three months ended September 30, 2010, compared to \$0.13 million for the three months ended September 30, 2009. The decrease of \$0.1 million or 77% was to lower effective interest rates and decreased cash and cash equivalents balances. Interest expense was approximately \$0.06 million for the three months ended September 30, 2010 compared to \$0.08 million for the three months ended September 30, 2009. The decrease of \$0.02 million was due to lower overall loan balances. Interest expense was incurred on the secured loan obtained in June 2009.

Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

Research and Development Expense. Research and development expense was \$25.9 million for the nine months ended September 30, 2010 representing a decrease of approximately \$12.1 million or 32% from \$38.0 million for the nine months ended September 30, 2009. The variance was primarily attributable to lower personnel costs associated with the workforce reduction completed in the fourth quarter of 2009, a decrease in consulting costs and a decrease in contract research and manufacturing costs due to the reduced activity within the Gaucher program.

General and Administrative Expense. General and administrative expense was \$11.8 million for the nine months ended September 30, 2010, representing a decrease of \$3.8 million or 24% from \$15.6 million for the nine months ended September 30, 2009. The variance was primarily due to lower personnel costs associated with the workforce reduction completed in the fourth quarter of 2009 and a decrease in third party legal and consulting fees.

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Interest Income and Interest Expense. Interest income was \$0.1 million for the nine months ended September 30, 2010, compared to \$0.9 million for the nine months ended September 30, 2009. The decrease of \$0.8 million or 88% was due to lower effective interest rates and decreased cash and cash equivalents balances. Interest expense was approximately \$0.2 million for the nine months ended September 30, 2010 and 2009. Interest expense was incurred on the secured loan obtained in June 2009.

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, \$50.0 million from the non-refundable license fee from the Shire collaboration agreement in November 2007 and \$18.5 million of gross proceeds from the registered direct offering in March 2010. The following table summarizes our significant funding sources as of September 30, 2010:

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
Registered Direct Offering	2010	4,946,524	18,500
		26,059,245	\$ 292,188

(1) Represents
gross proceeds

In addition, in conjunction with the Shire collaboration agreement, we received reimbursement of research and development expenditures from the date of the agreement (November 7, 2007) through year-end 2009 of \$31.1 million. However, we will not receive any further reimbursement payments from Shire following the mutual termination of our collaboration agreement in October 2009.

As of September 30, 2010, we had cash, cash equivalents and marketable securities of \$57.6 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, 2009 of \$32.8 million was comprised of the net loss for the nine months ended September 30, 2009 of \$39.5 million and a reduction in deferred revenue of \$3.0 million, partially offset by the change in other operating assets and liabilities of \$2.1 million.

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Net cash used in operations for the nine months ended September 30, 2010 of \$36.3 million was primarily comprised of the net loss for the nine months ended September 30, 2010 of \$39.8 million and the change in other operating assets and liabilities of \$3.2 million.

Net Cash Provided By Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2009 was \$22.1 million. Net cash provided by investing activities reflects \$106.4 million for the sale and redemption of marketable securities, partially offset by \$82.6 million for the purchase of marketable securities and \$1.7 million for the acquisition of property and equipment.

Net cash provided by investing activities for the nine months ended September 30, 2010 was \$23.2 million. Net cash provided by investing activities reflects \$77.4 million for the sale and redemption of marketable securities, partially offset by \$54.1 million for the purchase of marketable securities and \$0.2 million for the acquisition of property and equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2009 was \$3.1 million and reflected the proceeds from our secured loan agreement of \$3.7 million, partially offset by the payments of our capital lease obligations of \$0.7 million.

Net cash provided by financing activities for the nine months ended September 30, 2010 was \$15.9 million, consisting of \$17.1 million from the issuance of common stock primarily offset by the payments of our secured loan agreement and capital lease obligations of \$0.9 million and \$0.3 million, respectively.

Funding Requirements

We expect to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Our future capital requirements will depend on a number of factors, including:

- the progress and results of our clinical trials of our drug candidates, including Amigal;
- our ability to achieve development and commercialization milestone payments and sales royalties under our collaboration with GSK;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- 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;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to execute our operational and business plans and realize reductions in our expenses in line with our restructuring plan; 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 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for 2011.

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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 these agreements related to Plicera do require us to make such payments if certain specified pre-commercialization events occur. Upon the satisfaction of certain 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 would expect to pay royalties to all three licensors with respect to Plicera should we advance Plicera to commercialization. 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.

In accordance with our license agreement with MSSM, we expect to pay \$3 million of the \$30 million upfront payment to be received from GSK pursuant to the License and Collaboration Agreement to MSSM in the fourth quarter of 2010. We will also be obligated to pay MSSM royalties on worldwide net sales of Amigal.

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and marketable securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than one year, which we believe are subject to limited interest rate and credit risk. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and, due to the short-term nature, are subject to minimal interest rate risk. We currently do not hedge interest rate exposure and consistent with our investment policy, we do not use derivative financial instruments in our investment portfolio. At September 30, 2010, we held \$57.6 million in cash, cash equivalents and available for sale securities and due to the short-term maturities of our investments, we do not believe that a 10% change in average interest rates would have a significant impact on our interest income. As September 30, 2010, our cash, cash equivalents and available for sale securities were all due on demand or within one year. Our outstanding debt has a fixed interest rate and therefore, we have no exposure to interest rate fluctuations.

We have operated primarily in the U.S., although we do conduct some clinical activities outside the U.S. While most expenses are paid in U.S. dollars, there are minimal payments made in local foreign currency. If exchange rates undergo a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

ITEM 4. 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) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) was carried out under the supervision of our Principal Executive Officer and Principal Financial Officer, with the participation of our management. Based on that evaluation, the Principal Executive Officer and the Principal 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 Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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During the fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rule 13a-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

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, 2009.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Initial Public Offering

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 (SEC) on May 30, 2007. We 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.

After deducting expenses of approximately \$6.9 million, we received net offering proceeds of approximately \$68.1 million from our initial public offering. As of September 30, 2010, approximately \$18.4 million of the net proceeds from our initial public offering were maintained in money market funds and in investment-grade, interest bearing instruments, pending their use. We have used the remaining proceeds of approximately \$49.7 million for clinical development of our projects, research and development activities relating to additional preclinical projects and to fund working capital and other general corporate purposes.

March 2010 Registered Direct Offering

In March 2010, we sold 4,946,524 million shares of our common stock and warrants to purchase 1,854,946 million shares of common stock in a registered direct offering to a select group of institutional investors through a Registration Statement on Form S-3 (File No. 333-158405) that was declared effective by the SEC on May 27, 2009. The shares of common stock and warrants were sold in units consisting of one share of common stock and one warrant to purchase 0.375 shares of common stock at a price of \$3.74 per unit. The warrants have a term of four years and are exercisable any time on or after the six month anniversary of the date they were issued, at an exercise price of \$4.43 per share. The aggregate offering proceeds were \$18.5 million. Leerink Swann LLC served as sole placement agent for the offering. Following the sale of the common stock and warrants, the public offering terminated.

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We paid Leerink Swann a placement agency fee equal to 5.7% of the aggregate offering proceeds, approximately \$1.05 million. The net proceeds of the offering were approximately \$17.1 million after deducting the placement agency fee and all other estimated offering expenses. 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 September 30, 2010, we had invested the \$17.1 million in net proceeds from our registered direct offering in money market funds and in investment-grade, interest bearing instruments, pending their use. Through September 30, 2010, we have not used the net proceeds from this offering. We intend to use the proceeds from this offering to further advance the development of our lead product candidate, Amigal, including the initiation of the Phase 3 study to support registration in the European Union and the completion of certain activities required for the submission of a license application globally, as well as for general corporate matters.

The foregoing represents our best estimate of our use of proceeds for the period indicated.

Issuer Purchases of Equity Securities

The following table sets forth purchases of our common stock for the three months ended September 30, 2010:

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, 2010 July 31, 2010	220	\$ 2.24		675
August 1, 2010 August 31, 2010	220	\$ 2.53		455
September 1, 2010 September 30, 2010	220	\$ 3.28		235
Total	660			

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description
3.1(1)	Restated Certificate of Incorporation
3.2(2)	Amended and Restated By-laws
31.1*	Certification of Principal 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 Principal 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 Principal Executive Officer and Principal 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.

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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: November 8, 2010

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

Date: November 8, 2010

By: /s/ MOHAN GANESAN
Mohan Ganesan
Senior Director, Finance
(Principal Financial Officer)

Date: November 8, 2010

By: /s/ DAPHNE QUIMI
Daphne Quimi
Corporate Controller
(Principal Accounting Officer)

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