

ATHERSYS, INC / NEW  
Form 10-Q  
November 08, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 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, 2012

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: 001-33876

**Athersys, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>20-4864095</b> (I.R.S. Employer Identification No.)
<b>3201 Carnegie Avenue, Cleveland, Ohio</b> (Address of principal executive offices)	<b>44115-2634</b> (Zip Code)
<b>Registrant's telephone number, including area code: (216) 431-9900</b>	
<b>Former name, former address and former fiscal year, if changed since last report: Not Applicable</b>	

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>

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 outstanding shares of the registrant's common stock, \$0.001 par value, as of November 6, 2012 was 53,058,632.

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**ATHERSYS INC.**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****Athersys, Inc.****Condensed Consolidated Balance Sheets**

(In thousands, except share and per share data)

	September 30, 2012 (Unaudited)	December 31, 2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,903	\$ 8,785
Available-for-sale securities		3,999
Accounts receivable	438	689
Prepaid clinical trial costs		629
Prepaid expenses and other	370	304
<b>Total current assets</b>	<b>8,711</b>	<b>14,406</b>
Equipment, net	1,338	1,267
Deposits and other	28	28
<b>Total assets</b>	<b>\$ 10,077</b>	<b>\$ 15,701</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,309	\$ 2,301
Accrued compensation and related benefits	669	444
Accrued clinical trial costs	598	872
Accrued expenses	979	663
Deferred revenue	759	3,140
<b>Total current liabilities</b>	<b>4,314</b>	<b>7,420</b>
Note payable	51	
Warrant liabilities	3,762	983
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2012 and December 31, 2011		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 30,052,843 and 24,487,260 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	30	24
Additional paid-in capital	232,378	226,206
Accumulated other comprehensive income		28
Accumulated deficit	(230,458)	(218,960)
<b>Total stockholders' equity</b>	<b>1,950</b>	<b>7,298</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 10,077</b>	<b>\$ 15,701</b>

*See accompanying notes to unaudited condensed consolidated financial statements.*

**Table of Contents****Athersys, Inc.****Condensed Consolidated Statements of Operations and Comprehensive Loss**

(In thousands, except share and per share data)

(Unaudited)

	Three months ended		Nine months ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
<b>Revenues</b>				
Contract revenue	\$ 623	\$ 2,071	\$ 5,356	\$ 6,712
Grant revenue	392	283	1,063	1,067
Total revenues	1,015	2,354	6,419	7,779
<b>Costs and expenses</b>				
Research and development	4,105	4,328	14,701	13,360
General and administrative	1,079	1,110	3,500	3,721
Depreciation	81	75	236	202
Total costs and expenses	5,265	5,513	18,437	17,283
Loss from operations	(4,250)	(3,159)	(12,018)	(9,504)
Interest income	6	11	21	78
Other income (expense), net	795	807	499	(68)
<b>Net loss</b>	\$ (3,449)	\$ (2,341)	\$ (11,498)	\$ (9,494)
Basic and diluted net loss per share	\$ (0.12)	\$ (0.10)	\$ (0.41)	\$ (0.41)
Weighted average shares outstanding, basic and diluted	29,800,452	23,502,932	28,256,873	22,966,047
Items included in other comprehensive income (loss):				
Proportional share of comprehensive (loss) income of equity-method investment		5	(28)	36
Unrealized gain on available-for-sale securities		(5)		(26)
Other comprehensive income (loss) items			(28)	10
<b>Comprehensive loss</b>	\$ (3,449)	\$ (2,341)	\$ (11,526)	\$ (9,484)

*See accompanying notes to unaudited condensed consolidated financial statements.*

**Table of Contents****Athersys, Inc.****Condensed Consolidated Statements of Cash Flows**

(In thousands)

(Unaudited)

	Nine months ended	
	September 30,	
	2012	2011
<b>Operating activities</b>		
Net loss	\$ (11,498)	\$ (9,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	236	202
Gain on sale of investment	(183)	(55)
Stock-based compensation	380	401
Issuance of common stock to former lenders	769	607
Change in fair value of warrant liabilities	(1,351)	(695)
Amortization of (discount) premium on available-for-sale securities	(1)	55
Changes in operating assets and liabilities:		
Accounts receivable	251	2,097
Prepaid expenses and other assets	480	(206)
Accounts payable and accrued expenses	(724)	919
Deferred revenue	(2,381)	(3,838)
Net cash used in operating activities	(14,022)	(10,007)
<b>Investing activities</b>		
Purchase of available-for-sale securities		(12,508)
Maturities of available-for-sale securities	4,237	17,672
Purchase of equipment	(307)	(565)
Net cash provided by investing activities	3,930	4,599
<b>Financing activities</b>		
Proceeds from issuance of common stock and warrants, net of offering costs	9,160	11,842
Proceeds from note payable	50	
Net cash provided by financing activities	9,210	11,842
(Decrease) increase in cash and cash equivalents	(882)	6,434
Cash and cash equivalents at beginning of the period	8,785	2,105
Cash and cash equivalents at end of the period	\$ 7,903	\$ 8,539

See accompanying notes to unaudited condensed consolidated financial statements.

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**Athersys, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

Three- and Nine-Month Periods Ended September 30, 2012 and 2011

**1. Background and Basis of Presentation**

We are an international biotechnology company that is focused primarily in the field of regenerative medicine and operate in one business segment. Our operations consist primarily of research and product development activities.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our critical accounting policies, estimates and assumptions are described in Management s Discussion and Analysis of Financial Condition and Results of Operations, which is included below in this Quarterly Report on Form 10-Q.

Certain prior year amounts have been reclassified to conform with current year presentations.

**2. Recently Issued Accounting Standards**

In May 2011, the Financial Accounting Standards Board ( FASB ) issued changes to fair value measurement. These changes clarify the concepts related to highest and best use and valuation premise, blockage factors and other premiums and discounts, the fair value measurement of financial instruments held in a portfolio and of those instruments classified as a component of shareholders equity. The guidance includes enhanced disclosure requirements about recurring Level 3 fair value measurements, the use of nonfinancial assets, and the level in the fair value hierarchy of assets and liabilities not recorded at fair value. The provisions are effective prospectively for interim and annual periods beginning on or after December 15, 2011 and became effective for us on January 1, 2012. Early adoption was prohibited. This required changes in presentation only and did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements; the option to present components of other comprehensive income as part of the statement of changes in shareholders equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. Additionally, no changes were made to the calculation and presentation of earnings per share. These changes became effective for us on January 1, 2012. We chose to present comprehensive income in a single continuous statement. Other than the change in presentation, the adoption of this pronouncement did not have an impact on our consolidated financial statements.



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Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. We have outstanding options, restricted stock units and warrants that are not used in the calculation of diluted net loss per share because to do so would be antidilutive. The following instruments were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	Three and nine months ended September 30,	
	2012	2011
Outstanding options	4,123,813	4,490,601
Restricted stock units	84,635	39,300
Outstanding warrants	5,806,853	6,435,496
	<b>10,015,301</b>	10,965,397

**4. Fair Value of Financial Instruments**

Our available-for-sale securities are typically in United States government obligations, including government-backed agencies.

The inputs used to measure fair value are classified into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.

Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the fair values of our assets and liabilities measured at fair value on a recurring basis as of September 30, 2012 (in thousands):

Description	Fair Value Measurements at September 30, 2012 Using			
	Balance as of September 30, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liabilities	\$ 3,762	\$	\$	\$ 3,762

The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently marked to market at each financial reporting date. The fair value of the warrants is estimated using the expected volatility based on the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, using the Black-Scholes pricing model. The fair value of the warrants issue in March 2012 is determined using probability weighted-average assumptions that give

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consideration to the exercise price repricing feature that is dependent upon the consummation of future qualified offerings, as defined, and requisite stockholder approval. The following inputs were used at September 30, 2012:

	Warrants Issued February 2011	Warrants Issued March 2012
Expected volatility	70.88%	80.26%
Risk-free interest rate	0.31%	0.62%
Expected life (in years)	3.33	4.45
Fair value at September 30, 2012	\$ 458,500	\$ 3,303,900

A rollforward of fair value measurements using significant unobservable inputs (Level 3) for the warrants is as follows (in thousands):

	Three months ended September 30, 2012		Nine months ended September 30, 2012
		<b>Balance January 1, 2012</b>	<b>\$ 983</b>
		Issuance of warrants March 2012	4,130
<b>Balance July 1, 2012</b>	<b>\$ 4,634</b>		
Gain included in other income for the period	(872)	Gain included in other income for the period	(1,351)
<b>Balance September 30, 2012</b>	<b>\$ 3,762</b>	<b>Balance September 30, 2012</b>	<b>\$ 3,762</b>

We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs in a fair value measurement may result in a reclassification between hierarchy levels. There were no reclassifications for all periods presented.

The following is a summary of available-for-sale securities (in thousands) at December 31, 2011, and there were no available-for-sale securities at September 30, 2012:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
December 31, 2011:				
U.S. government obligations, including government-backed agencies	\$ 3,999	\$	\$	\$ 3,999

We had no realized gains or losses during the first nine months of 2012 and 2011 on our available-for-sale securities. Unrealized gains and losses, if any, on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity within accumulated other comprehensive income until realized. When available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used to determine any realized gain or loss. There were no net unrealized gains or losses on available-for-sale securities at September 30, 2012 and December 31, 2011.

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**5. Collaborative Arrangements and Revenue Recognition**

*Pfizer Inc.*

Late in 2009, we entered into a collaboration agreement with Pfizer Inc. ( Pfizer ) to develop and commercialize our MultiStem<sup>®</sup> product candidate to treat inflammatory bowel disease ( IBD ) for the worldwide market. We received a non-refundable up-front payment from Pfizer and received research funding and support through June 2012. In addition, we are eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement had multiple deliverables that should be combined into a single unit of accounting. We recognized the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which was completed in June 2012, and measured manufacturing revenue beginning upon the culmination of the earnings process and recognized it over the performance period of the bundled unit of accounting.

*RTI Biologics, Inc.*

In 2010, we entered into an agreement with RTI Biologics, Inc. ( RTI ) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we were entitled to a \$5.0 million license fee in installments, of which \$3.0 million was received and recognized in 2010 and 2011, and \$2.0 million was contingent on future events and considered a substantive milestone at the inception of the agreement.

In September 2012, RTI agreed to make the remaining \$2.0 million license fee payments by December 31, 2012, and we agreed to provide RTI with certain technical support through December 31, 2012. As of September 30, 2012, only \$1.0 million remained outstanding and will be received prior to December 31, 2012 in accordance with the amendment. The consideration associated with the amendment is being recognized over the performance period from September 2012 through December 2012.

We are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones. We evaluated the nature of the events triggering these contingent payments and concluded that these events are substantive and that revenue will be recognized in the period in which each underlying triggering event occurs. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies. No milestone or royalty revenue was recognized as of September 30, 2012.

**6. Stock-Based Compensation**

Our equity incentive plans authorize an aggregate of 5,500,000 shares of common stock for awards to employees, directors and consultants. These incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards.

As of September 30, 2012, a total of 1,282,808 shares were available for issuance under our equity incentive plans, and options and restricted stock units to purchase an aggregate of 4,208,448 shares of common stock were outstanding. For the three-month period ended September 30, 2012 and 2011, stock-based compensation expense was approximately \$111,000 and \$135,000, respectively. At

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September 30, 2012, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$819,000, which is expected to be recognized by the end of 2016 using the straight-line method.

**7. Issuance of Common Stock and Warrants**

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional \$2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination, and the warrants include price protection in the event we sell stock below the exercise price, as defined. As a result of the October 2012 public offering and in accordance with the warrant agreement, we will use commercially reasonable efforts to obtain stockholder approval as reasonably practicable to reduce the exercise price of these warrants to \$1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital Fund, LLC ( Aspire Capital ) is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. During the quarter ended September 30, 2012, we sold 500,000 shares to Aspire Capital at an average price of \$1.48 per share, and during the nine-month period ended September 30, 2012, we sold 800,000 shares to Aspire Capital at an average price of \$1.57 per share. As of September 30, 2012, we have received aggregate proceeds of approximately \$2.3 million under the equity purchase agreement since its inception. In connection with the October 2012 public offering, we agreed not to sell shares to Aspire Capital for ninety days following the pricing date of the offering.

In February 2011, we completed a registered direct offering with net proceeds of \$11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of \$3.00 per fixed combination.

In connection with our equity offerings, our former lenders were entitled to milestone payments until the remaining balance of an original \$2.25 million milestone was paid in cash and stock. We made cash and stock-based milestone payments of \$74,000 to our former lenders during the quarter ended September 30, 2012 and \$1,026,000 during the nine-month period ended September 30, 2012. Milestone payments to our former lenders are included in other income (expense), net, in the consolidated statements of operations and comprehensive loss. The remaining balance of the milestone was \$314,000 at September 30, 2012, and upon closing the October 2012 public offering, we settled this final balance, paying 75% of the milestone through the issuance of our common stock at \$1.01 per share.

**8. Note Payable**

In April 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation pursuant to which we are entitled to proceeds of up to \$500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive

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heart failure and for preparing the program for an investigational new drug application with the U.S. Food and Drug Administration. Interest on the loan accrues at a fixed rate of 4.25% per annum, and is added to the outstanding principal. The principal and interest on the loan will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of September 30, 2012, we have drawn \$50,000 of this financing, which is reflected on the balance sheet as a non-current note payable.

**9. Warrant Liability**

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as a non-current liability, which is revalued at fair value at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes valuation model to value the warrant liabilities at fair value. Changes in the fair market value of the warrant are reflected in the consolidated statements of operations and comprehensive loss as other income (expense).

The warrants we issued in both the March 2012 private placement and the February 2011 registered direct offering each contain a provision for net cash settlement in the event that there is a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to a Black Scholes value of the remaining unexercised portion of the warrant. Further, the March 2012 warrants include price protection in the event we sell stock below the exercise price, as defined. As a result of the October 2012 public offering and in accordance with the warrant agreement, we will use commercially reasonable effort to obtain stockholder approval as reasonably practicable to reduce the exercise price of these warrants to \$1.01 per share.

The warrants have been classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date. See Note 4.

As of September 30, 2012, we had the following outstanding warrants to purchase shares of common stock:

<b>Number of Underlying Shares</b>	<b>Exercise Price</b>	<b>Expiration</b>
149,026	\$ 5.00	June 8, 2014
1,310,000	\$ 3.55	February 2, 2016
4,347,827	\$ 2.07	March 14, 2017
<b>5,806,853</b>		

**10. Income Taxes**

We have net operating loss and research and development tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses. Our net operating loss carryforwards may be limited for use under Section 382 of the Internal Revenue Code as a result of our 2012 equity financings.

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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011. Operating results are not necessarily indicative of results that may occur in future periods.

#### **Overview and Recent Developments**

We are an international biotechnology company that is focused primarily on the field of regenerative medicine. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple areas. Our current clinical development programs are focused on treating inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other conditions. We are developing our lead platform product, MultiStem<sup>®</sup>, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in ongoing Phase II clinical trials. We are also applying our pharmaceutical discovery capabilities to identify and develop small molecule compounds with potential applications in indications such as obesity, related metabolic conditions and certain neurological conditions, and for the modulation of stem cells or related applications in the regenerative medicine area.

#### *Current Programs*

By applying our proprietary MultiStem cell therapy product, we have established therapeutic product development programs treating inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other conditions. To date, we have advanced five programs to the clinical development stage, including the following:

Inflammatory Bowel Disease: MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of Inflammatory Bowel Disease, or IBD. This study is being conducted with our partner, Pfizer Inc., or Pfizer, in ulcerative colitis patients who have an inadequate response or are refractory to current treatment, and is a double blind, placebo-controlled trial that began enrolling patients in 2011. Enrollment of the trial is ongoing and is expected to include approximately 130 patients, with initial results expected to be reported in 2013.

Ischemic Stroke: In contrast to treatment with thrombolytics, which must be administered within 3 to 4 hours after a stroke, we are treating patients one to two days after the stroke has occurred. In preclinical studies, administration of a single dose of MultiStem, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and may include sites in Europe. The study is expected to enroll approximately 136 patients. We completed the first patient cohorts, and the independent safety monitoring committee found that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment is ongoing and for the remainder of the trial, patients will be randomized to receive either high dose MultiStem or placebo.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem in a Phase I clinical study to patients that have suffered an acute myocardial infarction, or AMI. In 2010, we announced preliminary results for this study, demonstrating a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. One-year follow-up data suggested that the benefit observed was sustained over time. We have completed preliminary planning for a Phase II trial, which has been reviewed and authorized by the U.S. Food and Drug Administration, or FDA. Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

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**Hematopoietic Stem Cell Transplant / GvHD:** We have completed a Phase I clinical study of the administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell transplant. Such patients are at risk for serious complications, including graft-versus-host disease, or GvHD, an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In 2011 and in February 2012, we released data from the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing incidence and severity of GvHD, as well as providing other benefits. This program has been assigned orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval, and certain other benefits. We met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. We are currently refining our detailed clinical study plans and look forward to finalizing our design and undertaking operational planning. We intend to submit our plans to the FDA shortly and to be ready to start this study in the second half of 2013, but the initiation will depend on the progress in our clinical trials and the achievement of certain business development and financial objectives.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide limited financial support for this investigator-sponsored Phase I study and provide clinical grade product to conduct the trial. In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem in other inflammatory & immune, neurological and cardiovascular disease areas, as well as certain other indications. We conduct such work both through our own internal research efforts and through a broad network of collaborations we have established with investigators at leading research institutions across the United States and in Europe.

We are in discussions with third parties about collaborating in the development of MultiStem for our current clinical programs (outside of IBD) and preclinical programs and may, under the right terms, enter into one or more business partnership(s) to advance these programs.

We have also collaborated with RTI Biologics, Inc., or RTI, on the development of products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies. RTI's product development activities are progressing, and in September 2012, we amended our agreement with RTI and will receive milestone payments of \$2.0 million in 2012 in connection with technical support to assist RTI. We will also receive royalty revenue from product sales when they occur, as well as potential additional milestone payments.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions. Currently, we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain, the 5HT<sub>2c</sub> serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit favorable attributes, including outstanding receptor selectivity, as well as greater potency and activity than other 5HT<sub>2c</sub> agonists. We have also demonstrated our compounds are complementary with other agents and believe these compounds could achieve best in class weight loss, as well as a superior safety and tolerability profile. Furthermore, we have evaluated certain compounds that exhibit a particular type of selectivity profile in preclinical models of schizophrenia and observed that these compounds exhibit potent effects. We are in discussions with multiple companies and may elect to enter into a partnership to advance the development of our 5HT<sub>2c</sub> agonist program, either for the treatment of obesity, schizophrenia, or both indications.

*Financial*

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$230 million at September 30, 2012. Our losses have resulted principally from costs incurred in research and

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development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from equity and debt offerings, partnerships and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional \$2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination. The warrants have anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the warrant agreement, we will use commercially reasonable effort to obtain stockholder approval as reasonably practicable to reduce the exercise price of these warrants to \$1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital Fund, LLC, or Aspire Capital, is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. During the nine months ended September 30, 2012, we sold 800,000 shares to Aspire Capital at an average price of \$1.57 per share. As of September 30, 2012, we have received aggregate proceeds of approximately \$2.3 million under the Aspire Purchase Agreement since its inception. In connection with the October 2012 public offering, we agreed not to sell shares to Aspire Capital for ninety days following the pricing date of the offering.

In February 2011, we completed a registered direct offering with net proceeds of \$11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of \$3.00 per fixed combination.

In 2012, we were awarded grant funding aggregating \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem for the treatment of traumatic brain injury and further development of our cell therapy formulations and manufacturing capabilities. The sources of funding including federal, state and European organizations and are generally focused on the advancement of our preclinical MultiStem programs, as well as process development and manufacturing activities.

## **Results of Operations**

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date. Research and development expenses consist primarily of external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in



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research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

The following tables set forth our revenues and expenses for the periods indicated. The following tables are stated in thousands.

**Revenues**

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Contract revenue	\$ 623	\$ 2,071	\$ 5,356	\$ 6,712
Grant revenue	392	283	1,063	1,067
	<b>\$ 1,015</b>	<b>\$ 2,354</b>	<b>\$ 6,419</b>	<b>\$ 7,779</b>

**Research and development expenses**

<i>Type of expense</i>	Three months ended		Nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Personnel costs	\$ 1,263	\$ 1,111	\$ 3,886	\$ 3,503
Research supplies	368	324	1,100	983
Facilities	257	254	743	733
Clinical and preclinical development costs	1,137	1,481	5,912	4,559
Sponsored research	475	337	1,099	1,140
Patent legal fees	317	503	998	1,338
Other	242	280	841	952
Stock-based compensation	46	38	122	152
	<b>\$ 4,105</b>	<b>\$ 4,328</b>	<b>\$ 14,701</b>	<b>\$ 13,360</b>

**General and administrative expenses**

<i>Type of expense</i>	Three months ended		Nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Personnel costs	\$ 533	\$ 400	\$ 1,590	\$ 1,460
Facilities	68	73	209	207
Legal and professional fees	159	218	638	787
Other	254	322	805	1,018
Stock-based compensation	65	97	258	249
	<b>\$ 1,079</b>	<b>\$ 1,110</b>	<b>\$ 3,500</b>	<b>\$ 3,721</b>

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**Revenues.** Revenues decreased to \$1.0 million for the three months ended September 30, 2012 from \$2.4 million in the comparable period in 2011. Contract revenue decreased \$1.4 for the three months ended September 30, 2012, which reflects the impact of our arrangements with Pfizer and RTI. Our contract revenues reflect the amortization of Pfizer payments, including a \$6.0 million non-refundable up-front license fee, over the estimated performance period that ended in June 2012, as well as the amortization of a \$3.0 million guaranteed license fee from the RTI collaboration over the estimated performance period that ended in 2011. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. Our Pfizer contract revenues have declined during the period in conjunction with the end of the performance period and on an ongoing basis will primarily consist of reimbursements from Pfizer for outsourced central processing costs for the clinical product. Due to the receipt of the \$2.0 million milestone payments, our RTI contract revenues are expected to increase through the rest of 2012. Grant revenue increased \$109,000 for the three months ended September 30, 2012 compared to the comparable period in 2011 primarily due to the timing of expenditures that are reimbursed with grant proceeds. Our grant revenues may fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

**Research and Development Expenses.** Research and development expenses decreased to \$4.1 million for the three months ended September 30, 2012 from \$4.3 million in the comparable period in 2011. The decrease of \$223,000 related to a decrease in clinical and preclinical development costs of \$344,000 and a decrease in patent legal fee expense of \$186,000 for the three months ended September 30, 2012 from the comparable period in 2011, partially offset by an increase in personnel costs of \$152,000 and an increase in sponsored research costs of \$138,000 during the period. The decrease in clinical and preclinical development costs for the three months ended September 30, 2012 related to costs associated with our MultiStem clinical trials, primarily clinical manufacturing costs. The decrease in patent legal costs resulted from reduced patent prosecution costs during the period. The increase in personnel costs related primarily to an increase in the annual bonus accrual. We expect our 2012 annual research and development expenses to be higher than the 2011 expenses, based on the timing of our clinical development and process development activities. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

**General and Administrative Expenses.** General and administrative expenses remained consistent at \$1.1 million for the three months ended September 30, 2012 and 2011. We expect our general and administrative expenses for the 2012 year to be similar to the 2011 level.

**Depreciation.** Depreciation expense increased to \$81,000 for the three months ended September 30, 2012 from \$75,000 in the comparable period in 2011 due to depreciation on new capital purchases.

**Interest Income.** Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to \$6,000 for the three months ended September 30, 2012 from \$11,000 for the comparable period in 2011 due to the decline in our investment balances as they are used to fund our operations. We expect our 2012 interest income to reflect the impact of declining cash balances resulting from our ongoing and planned clinical and preclinical development, and interest earned on the net proceeds from the October 2012 public offering and any business transactions.

**Other Income (Expense), net.** Other income (expense), net, includes foreign currency gains and losses related to our activities in Europe, realized gains and losses on the sale of our assets, increases and decreases in our warrant liabilities, and cash and stock-based milestone payments to our former lenders in connection with our equity offerings. For the three months ended September 30, 2012, we recognized income of \$0.9 million from the valuation of our warrant liabilities and income of \$0.8 million for the three months ended September 30, 2011. Cash and stock-based milestone payments to our former lenders were \$74,000 and \$0 for the three months ended September 30, 2012 and 2011, respectively.

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**Table of Contents*****Nine Months Ended September 30, 2012 and 2011***

**Revenues.** Revenues decreased to \$6.4 million for the nine months ended September 30, 2012 from \$7.8 million in the comparable period in 2011. Contract revenue decreased \$1.4 million for the nine months ended September 30, 2012 compared to the comparable period in 2011 and reflects the impact of our arrangements with Pfizer and RTI. Our contract revenues reflect the amortization of Pfizer payments, including a \$6.0 million non-refundable up-front license fee, over the estimated performance period that ended in June 2012, as well as the amortization of a \$3.0 million guaranteed license fee from the RTI collaboration over the estimated performance period that ended in 2011. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. Our Pfizer contract revenues have declined during the period in conjunction with the end of the performance period and on an ongoing basis will primarily consist of reimbursements from Pfizer for outsourced central processing costs for the clinical product. Due to the receipt of the \$2.0 million milestone payments, our RTI contract revenues are expected to increase through the rest of 2012. Grant revenue remained consistent at \$1.1 million for the nine months ended September 30, 2012 and 2011. Our grant revenues may fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

**Research and Development Expenses.** Research and development expenses increased to \$14.7 million for the nine months ended September 30, 2012 from \$13.4 million in the comparable period in 2011. The increase of \$1.3 million related to an increase in clinical and preclinical development costs of \$1.4 million, an increase in personnel costs of \$383,000 and an increase in research supplies of \$117,000 for the nine months ended September 30, 2012 from the comparable period in 2011. These increases were partially offset by a decrease in patent legal fees of \$340,000 and a decrease in other research and development expenses of \$111,000. The increase in clinical and preclinical development costs for the nine months ended September 30, 2012 related primarily to costs associated with our MultiStem clinical trials, including contract research organization costs and clinical consulting costs. The increase in personnel costs related to an increase in the annual bonus accrual, the impact of merit increases in salaries and the impact of several 2011 new hires supporting our preclinical and clinical programs. Sponsored research costs decreased primarily due to a decrease in grant-funded programs that require collaboration with certain academic research institutions. The decrease in patent legal costs resulted from reduced patent prosecution costs during the period. We expect our 2012 annual research and development expenses to be higher than the 2011 expenses, based on the timing of our clinical development and process development activities. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

**General and Administrative Expenses.** General and administrative expenses decreased to \$3.5 million for the nine months ended September 30, 2012 from \$3.7 million in the comparable period in 2011. The \$221,000 decrease was due primarily to a decrease in legal and professional fees of \$149,000 and a decrease in other general and administrative costs of \$213,000 related to outside services, partially offset by an increase in personnel costs of \$130,000 for the nine months ended September 30, 2012 from the comparable period in 2011. We expect our general and administrative expenses for the 2012 year to be similar to the 2011 level.

**Depreciation.** Depreciation expense increased to \$236,000 for the nine months ended September 30, 2012 from \$202,000 in the comparable period in 2011 due to depreciation on new capital purchases.

**Interest Income.** Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to \$21,000 for the nine months ended September 30, 2012 from \$78,000 for the comparable period in 2011 due to the decline in our investment balances as they are used to fund our operations. We expect our 2012 interest income to reflect the impact of declining cash balances resulting from our ongoing and planned clinical and preclinical development, and interest earned on the net proceeds from the October 2012 public offering and any new business transactions.

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*Other Income (Expense), net.* Other income (expense), net, includes foreign currency gains and losses related to our activities in Europe, realized gains and losses on the sale of our assets, increases and decreases in our warrant liabilities, and cash and stock-based milestone payments to our former lenders in connection with our equity offerings. For the nine months ended September 30, 2012 and 2011, we recognized income of \$1.4 million and \$0.7 million, respectively, from the valuation of our warrant liabilities. Also, in the nine-month period ended September 30, 2012, we recognized a gain of \$183,000 related to an equity-method investment that was liquidated in the period. Cash and stock-based milestone payments to our former lenders were \$1.0 million and \$0.8 million for the nine months ended September 30, 2012 and 2011, respectively.

## **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities on hand. At September 30, 2012, we had \$7.9 million in cash and cash equivalents and no available-for-sale securities. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional \$2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination. The warrants have anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the warrant agreement, we will use commercially reasonable efforts to obtain stockholder approval as reasonably practicable to reduce the exercise price of these warrants to \$1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As of September 30, 2012, we have received aggregate proceeds of \$2.3 million under the equity purchase agreement since its inception (\$1.3 million year-to-date in 2012). In connection with the October 2012 public offering, we agreed not to sell shares to Aspire Capital for ninety days following the pricing date of the offering.

In February 2011, we completed a registered direct offering with net proceeds of \$11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of \$3.00 per fixed combination.

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In connection with our equity offerings, our former lenders were entitled to milestone payments until the remaining balance of an original \$2.25 million milestone was paid in cash and stock. We made cash and stock-based milestone payments of \$74,000 to our former lenders during the quarter ended September 30, 2012 and \$1,026,000 during the nine-month period ended September 30, 2012. The remaining balance of the milestone was \$314,000 at September 30, 2012, and upon closing the October 2012 public offering, we settled this final balance, paying 75% of the milestone through the issuance of our common stock at \$1.01 per share. The senior lenders also received in 2007 seven-year warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00. The exercise of such warrants could provide us with cash proceeds. No warrants were exercised as of September 30, 2012.

Under the terms of our agreement with Pfizer, we are eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve any milestones. No significant milestone payments have been received as of September 30, 2012. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

In November 2011, we reached an agreement with Angiotech Pharmaceuticals, Inc., or Angiotech, to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with respect to our technologies and products. In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from us equal to a percentage of cash license fee payments we receive within the first six months from a third-party related to such AMI collaboration, and is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments. The future payment, if any, will be either (i) 15% of third-party license fees if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, but before we have spent \$5.0 million on the clinical trial, and within 24 months of the termination agreement, or (ii) 10% of third-party license fees up to a maximum of \$5.0 million to Angiotech if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, and after we have spent \$5.0 million on the clinical trial, and within 36 months of the termination agreement.

Under the terms of our RTI agreement, we initially received \$3.0 million of guaranteed license fee payments and were entitled to an additional \$2.0 million in license fee payments that were contingent upon future events. In September 2012, RTI agreed to make these payments in full by December 31, 2012, and we agreed to provide RTI with certain technical support. In accordance with the partnership agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties.

In April 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we are entitled to proceeds of up to \$500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive heart

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failure and for preparing the program for an investigational new drug application, or IND with the FDA. Interest on the loan accrues at a fixed rate of 4.25% per annum, and is added to the outstanding principal. The loan will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of September 30, 2012, we had drawn \$50,000 of this financing.

In February 2012, we were awarded grant funding aggregating \$3.6 million to further advance our MultiStem product programs and cell therapy platform. Specifically, we were awarded a Small Business Innovation Research Fast-Track grant of up to \$1.9 million from the National Institute of Neurological Disorders and Stroke to develop MultiStem for the treatment of traumatic brain injury. In addition, our subsidiary based in Belgium was awarded a \$1.2 million ( 0.9 million) grant from Belgium's Agency for Innovation by Science and Technology to further develop cell therapy formulations and manufacturing capabilities, as well as the aforementioned \$0.5 million in funding from the Global Cardiovascular Innovation Center to work in other areas, such as using MultiStem to treat chronic cardiovascular disease.

In 2011, we entered into an alliance with Fast Forward, a nonprofit subsidiary of the National Multiple Sclerosis Society, pursuant to which Fast Forward will fund the development of MultiStem for the treatment of multiple sclerosis through the filing of an IND. Fast Forward will commit up to \$640,000 to fund the advancement of the program to clinical development stage. In return, upon successful achievement of certain development and commercialization milestones, we would remit certain milestone payments to Fast Forward.

When we hold investments, our available-for-sale securities typically include United States government obligations and corporate debt securities. We have been investing conservatively due to the ongoing economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments and have held our investments until maturity. All available-for-sale securities had matured as of September 30, 2012. Also, although the unfavorable market and economic conditions have resulted in a decrease to our market capitalization, there has been no impairment to the value of our assets. Our fixed assets are used for internal research and development and, therefore, are not impacted by these external factors.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates. At September 30, 2012, we had available cash and cash equivalents of \$7.9 million. Early in the fourth quarter, we completed a public offering of common stock, generating net proceeds of approximately \$21.1 million. As a result, we intend to meet our short-term liquidity needs with available cash. Over the longer term, we will make use of available cash, but will have to generate additional funding to meet our needs. We are actively exploring business development opportunities for certain of our MultiStem programs and our small molecule obesity program, as well as grant-funding opportunities. Additionally, after the ninety-day lock-up expires in January 2013, we may raise capital from time to time through the equity purchase agreement with Aspire Capital, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and stage certain development costs to extend our operational runway, as needed. Over time, we may consider the sale of additional equity securities, or possibly borrowing from financing institutions.

Our capital requirements over time depend on a number of factors, including progress in our clinical development programs, our clinical and preclinical pipeline of additional opportunities and their stage of development, additional external costs such as payments to contract research organizations and contract manufacturing organizations, additional personnel costs, and the costs in filing and prosecuting patent applications and enforcing patent claims. The availability of funds impacts our ability to advance multiple clinical programs concurrently, and any shortfall in funding could result in our having to delay or curtail research and development efforts. Further, these requirements may change at any time due to technological advances, business development activity or competition from other companies. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms.

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We expect to continue to incur substantial losses through at least the next several years and may incur losses in subsequent periods. The amount and timing of our future losses are highly uncertain. Our ability to achieve and thereafter sustain profitability will be dependent upon, among other things, successfully developing, commercializing and obtaining regulatory approval or clearances for our technologies and products resulting from these technologies.

### *Cash Flow Analysis*

Net cash used in operating activities was \$14.0 million for the nine months ended September 30, 2012 and \$10.0 million for the nine months ended September 30, 2011, and represented the use of cash in funding preclinical and clinical product development activities. Net cash used in operating activities has fluctuated significantly over the past few years primarily due to the receipt of milestone payments and specific clinical trial costs. Taking into account working capital fluctuations, which reflect the receipt of milestone payments and timing of certain payments related to clinical activities, the increase in cash used in operating activities in recent quarters reflects predominantly an increase in clinical development costs during the periods. Such increases include the impact of the Phase II stroke trial and the timing of payments for manufacturing clinical product for the Phase II IBD trial and reimbursements from Pfizer. We anticipate that net cash used in operating activities will continue to fluctuate from quarter to quarter in connection with the fluctuations and changes in activity associated with the MultiStem clinical trials, the timing of clinical manufacturing, and the receipt of potential milestone payments.

Net cash provided by investing activities was \$3.9 million for the nine months ended September 30, 2012, and net cash used in investing activities was \$4.6 million for the nine months ended September 30, 2011. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$307,000 and \$565,000 for the nine months ended September 30, 2012 and 2011, respectively. We anticipate that our overall capital equipment expenditures will be similar in 2012 compared to 2011.

Net cash provided from financing activities was \$9.2 million for the nine months ended September 30, 2012 and \$11.8 million for the nine months ended September 30, 2011 primarily as a result of our equity offerings during each of those periods, and will increase in the fourth quarter of 2012 reflecting the impact of the October 2012 public offering.

Investors in our March 2012 private placement received five-year warrants to purchase an aggregate of 4,347,827 shares of common stock with an exercise price of \$2.07 per share, with anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the warrant agreement, we will use commercially reasonable efforts to obtain stockholder approval as reasonably practicable to reduce the exercise price of these warrants to \$1.01 per share. Also, investors in our February 2011 registered direct offering received five-year warrants to purchase an aggregate of 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at September 30, 2012.

We have no off-balance sheet arrangements.

### **Critical Accounting Policies and Management Estimates**

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of

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assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. A description of these accounting policies and estimates is included in Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2011. There have been no material changes in our accounting policies and estimates as described in our Annual Report. For additional information regarding our accounting policies, see Note B to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2011.

### **Recently Issued Accounting Standards**

In May 2011, the Financial Accounting Standards Board, or FASB, issued changes to fair value measurement. These changes clarify the concepts related to highest and best use and valuation premise, blockage factors and other premiums and discounts, the fair value measurement of financial instruments held in a portfolio and of those instruments classified as a component of shareholders' equity. The guidance includes enhanced disclosure requirements about recurring Level 3 fair value measurements, the use of nonfinancial assets, and the level in the fair value hierarchy of assets and liabilities not recorded at fair value. The provisions are effective prospectively for interim and annual periods beginning on or after December 15, 2011 and became effective for us on January 1, 2012. Early adoption was prohibited. This required changes in presentation only and did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements; the option to present components of other comprehensive income as part of the statement of changes in shareholders' equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. Additionally, no changes were made to the calculation and presentation of earnings per share. These changes became effective for us on January 1, 2012. We chose to present comprehensive income in a single continuous statement. Other than the change in presentation, the adoption of this pronouncement did not have an impact on our consolidated financial statements.

### **Cautionary Note on Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as anticipates, believes, can, continue, could, estimates, expects, intends, may, plans, potential, should, will, or shall. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this quarterly report on Form 10-Q.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. These risks may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements.



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Other important factors to consider in evaluating our forward-looking statements include:

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of IBD, acute myocardial infarction, stroke and other disease indications, and the prevention of graft-versus-host disease;

our ability to raise capital to fund our operations;

final results from our MultiStem clinical trials;

the possibility of delays in, adverse results of, and excessive costs of the development process;

our ability to successfully initiate and complete clinical trials and obtain all necessary regulatory approvals to commercialize our product candidates;

changes in external market factors;

changes in our industry's overall performance;

changes in our business strategy;

our ability to protect our intellectual property portfolio;

our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;

our ability to meet milestones under our collaboration agreements;

our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreement;

our possible inability to execute our strategy due to changes in our industry or the economy generally;

changes in productivity and reliability of suppliers; and

the success of our competitors and the emergence of new competitors.

Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the United States government and its agencies, and corporate debt securities. As of September 30, 2012, we had no investments. We have been investing conservatively due to the current economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At September 30, 2012, we had no borrowings outstanding other than a forgivable note payable associated with local grant funding bearing fixed, forgivable interest of 4.25% per annum.

**Item 4. Controls and Procedures.**

**Disclosure controls and procedures**

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Vice President of Finance, has evaluated the effectiveness of our disclosure controls and procedures,

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as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this quarterly report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Vice President of Finance have concluded that, as of the end of the period covered by this quarterly report on Form 10-Q, our disclosure controls and procedures were effective.

**Changes in internal control over financial reporting**

During the third quarter of 2012, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****PART II. OTHER INFORMATION****Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On each of September 25, 2012, September 6, 2012, August 8, 2012, July 18, 2012 and July 9, 2012, we sold an additional 100,000 shares of common stock, or 500,000 shares in the aggregate, to Aspire Capital at purchase prices of \$147,670, \$148,000, \$149,000, \$151,000 and \$145,000, respectively. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, in each case Aspire Capital had the necessary investment intent.

On each of September 25, 2012, September 6, 2012, August 8, 2012, July 18, 2012 and July 9, 2012, we issued 7,500 shares of our common stock to our former lenders pursuant to a 2004 loan agreement. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because the issuance by us did not involve a public offering. The offerings were not public offerings due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, the lenders acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions, and the lenders had the necessary investment intent since they agreed to and received share certificates bearing a legend stating that such securities are restricted. We did not receive any proceeds from these issuances.

**Item 6. Exhibits.**

Exhibit	
No.	Description
31.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Laura K. Campbell, Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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**SIGNATURES**

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

ATHERSYS, INC.

Date: November 8, 2012

/s/ Gil Van Bokkelen  
Gil Van Bokkelen  
Chairman and Chief Executive Officer  
(principal executive officer authorized to sign on behalf of the registrant)

/s/ Laura K. Campbell  
Laura K. Campbell  
Vice President of Finance  
(principal financial and accounting officer authorized to sign on behalf of the registrant)

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