

ATHERSYS, INC / NEW  
Form 10-Q  
November 05, 2015  
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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, 2015

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)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-4864095**  
(I.R.S. Employer  
Identification No.)

**3201 Carnegie Avenue, Cleveland, Ohio**  
(Address of principal executive offices)

**44115-2634**  
(Zip Code)

Registrant's telephone number, including area code: (216) 431-9900

**Former name, former address and former fiscal year, if changed since last report: Not Applicable**

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  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 outstanding shares of the registrant's common stock, \$0.001 par value, as of November 1, 2015 was 83,285,747.

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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)

	<b>September 30, 2015 (Unaudited)</b>	<b>December 31, 2014</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,533	\$ 26,127
Accounts and other receivables	315	694
Prepaid expenses and other	383	427
Total current assets	29,231	27,248
Equipment, net	1,167	1,270
Deferred tax assets	195	200
Total assets	\$ 30,593	\$ 28,718
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,639	\$ 2,767
Accrued compensation and related benefits	795	1,060
Accrued clinical trial costs	179	126
Accrued expenses	475	664
Deferred revenue	10,000	75
Note payable	189	
Total current liabilities	14,277	4,692
Note payable		183
Warrant liabilities	813	2,948
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock, \$0.001 par value; 150,000,000 shares authorized, and 83,285,747 and 77,706,816 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	83	78
Additional paid-in capital	321,954	307,337
Accumulated deficit	(306,534)	(286,520)

Total stockholders' equity	<b>15,503</b>	20,895
Total liabilities and stockholders' equity	<b>\$ 30,593</b>	<b>\$ 28,718</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 September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
<b>Revenues</b>				
Contract revenue	\$ 39	\$ 75	\$ 194	\$ 155
Grant revenue	357	218	1,149	1,233
Total revenues	396	293	1,343	1,388
<b>Costs and expenses</b>				
Research and development	5,089	5,775	16,018	17,756
General and administrative	1,941	1,695	5,751	5,303
Depreciation	66	91	201	272
Total costs and expenses	7,096	7,561	21,970	23,331
Loss from operations	(6,700)	(7,268)	(20,627)	(21,943)
Other (expense) income, net	(79)	8	(31)	62
Income from change in fair value of warrants, net	255	2,540	609	6,335
Loss before taxes	(6,524)	(4,720)	(20,049)	(15,546)
Tax benefit	27	1	35	18
<b>Net loss and comprehensive loss</b>	<b>\$ (6,497)</b>	<b>\$ (4,719)</b>	<b>\$ (20,014)</b>	<b>\$ (15,528)</b>
Net loss per share - Basic	\$ (0.08)	\$ (0.06)	\$ (0.24)	\$ (0.20)
Weighted average shares outstanding - Basic	83,140,864	77,320,425	81,736,273	76,755,599
Net loss per share - Diluted	\$ (0.08)	\$ (0.08)	\$ (0.24)	\$ (0.23)
Weighted average shares outstanding - Diluted	83,425,669	78,349,840	82,572,984	78,495,281

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

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

(In thousands)

(Unaudited)

	<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>		
Net loss	<b>\$ (20,014)</b>	\$ (15,528)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	<b>201</b>	272
Stock-based compensation	<b>2,187</b>	1,894
Change in fair value of warrant liabilities	<b>(609)</b>	(6,335)
Changes in operating assets and liabilities:		
Accounts receivable	<b>379</b>	(145)
Prepaid expenses and other	<b>55</b>	(29)
Accounts payable and accrued expenses	<b>(529)</b>	295
Deferred revenue	<b>9,925</b>	(81)
Net cash used in operating activities	<b>(8,405)</b>	(19,657)
<b>Investing activities</b>		
Purchases of equipment	<b>(99)</b>	(270)
Net cash used in investing activities	<b>(99)</b>	(270)
<b>Financing activities</b>		
Proceeds from issuance of common stock and warrants, net	<b>10,371</b>	19,701
Purchase of treasury stock	<b>(437)</b>	(292)
Proceeds from exercise of warrants	<b>976</b>	938
Net cash provided by financing activities	<b>10,910</b>	20,347
Increase in cash and cash equivalents	<b>2,406</b>	420
Cash and cash equivalents at beginning of the period	<b>26,127</b>	31,948
Cash and cash equivalents at end of the period	<b>\$ 28,533</b>	\$ 32,368

*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, 2015 and 2014

**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, 2014. 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 2014, the Financial Accounting Standards Board ( FASB ) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, the amendment provides five steps that an entity should apply when recognizing revenue. The amendment also specifies the accounting of some costs to obtain or fulfill a contract with a customer and expands the disclosure requirements around contracts with customers. An entity can either adopt this amendment retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the update recognized at the date of initial application. In August 2015, the FASB issued ASU 2015-14, which delays the effective date by one year, making the new standard effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted for annual reporting periods beginning after December 15, 2016. We are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements.



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In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which establishes management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and, if so, to provide related footnote disclosures. ASU 2014-15 provides a definition of the term "substantial doubt" and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. Management will also be required to evaluate and disclose whether it has plans to alleviate that doubt. The guidance is effective for the annual periods ending after December 15, 2016 and interim periods thereafter with early adoption permitted. We will adopt ASU 2014-15 as required.

**3. Net Loss per Share**

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. The table below reconciles the net loss and the number of shares used to calculate basic and diluted net loss per share for the three- and nine-month periods ended September 30, 2015 and 2014, in thousands.

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Numerator:</b>				
Net loss attributable to common stockholders - Basic	\$ (6,497)	\$ (4,719)	\$ (20,014)	\$ (15,528)
Less: income from change in fair value of warrants	(220)	(1,160)	(196)	(2,504)
Net loss attributable to common stockholders used to calculate diluted net loss per share	\$ (6,717)	\$ (5,879)	\$ (20,210)	\$ (18,032)
<b>Denominator:</b>				
Weighted-average shares outstanding - Basic	83,141	77,320	81,736	76,756
Potentially dilutive common shares outstanding:				
Warrants	285	1,030	837	1,739
Weighted-average shares used to calculate diluted net loss per share	83,426	78,350	82,573	78,495
Basic earnings per share	\$ (0.08)	\$ (0.06)	\$ (0.24)	\$ (0.20)
Dilutive earnings per share	\$ (0.08)	\$ (0.08)	\$ (0.24)	\$ (0.23)

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:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Stock options	7,151,392	6,261,164	7,151,392	6,261,164

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Restricted stock units	<b>1,304,493</b>	2,142,779	<b>1,304,493</b>	2,142,779
Warrants	<b>2,810,000</b>	6,310,000	<b>2,810,000</b>	6,310,000
Total	<b>11,265,885</b>	14,713,943	<b>11,265,885</b>	14,713,943

**Table of Contents****4. Fair Value of Financial Instruments***Fair Value Measurements*

We classify the inputs used to measure fair value 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, 2015 (in thousands):

Description	Fair Value Measurements at September 30, 2015 Using Quoted Prices in Active Markets for Identical Assets (Level 1) Significant Other Observable Inputs (Level 2) Significant Unobservable Inputs (Level 3)			
	Balance as of September 30, 2015	Assets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Warrant liabilities	\$ 813	\$	\$	\$ 813

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 fair value hierarchy levels. There were no reclassifications for all periods presented.

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. We use the Black-Scholes valuation model to value the warrant liabilities at fair value. The fair value is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. The following inputs were used at September 30, 2015:

	Expected Volatility	Risk-Free Interest Rate		Expected Life	
Warrants with one year or less remaining term	61.59% - 84.39%	0.01%	0.33%	0.34	0.79 year
Warrants with greater than one year remaining term	67.55%	0.33%		1.45 years	

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

	<b>Three months ended September 30, 2015</b>		<b>Nine months ended September 30, 2015</b>
<b>Balance July 1, 2015</b>	<b>\$ 1,068</b>	<b>Balance January 1, 2015</b>	<b>\$ 2,948</b>
Settlements from exercise		Settlements from exercise	(1,526)
Income for the period	(255)	Income for the period	(609)
<b>Balance September 30, 2015</b>	<b>\$ 813</b>	<b>Balance September 30, 2015</b>	<b>\$ 813</b>

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**Table of Contents****5. Collaborative Arrangements and Revenue Recognition***Chugai*

On October 20, 2015, we and Chugai Pharmaceutical Co. Ltd. ( Chugai ) agreed to terminate the License Agreement (the Agreement ), dated February 28, 2015, between the parties, as a result of an inability to reach an agreement on the modification of the financial terms of the agreement and on the development strategy of our MultiStem<sup>®</sup> cell therapy for the treatment of ischemic stroke in Japan. Pursuant to the terms of the Agreement, upon termination, we regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other, and the licenses granted to Chugai to develop and commercialize MultiStem for ischemic stroke in Japan terminate.

Under the agreement, we received a non-refundable, up-front cash payment of \$10 million from Chugai, of which approximately \$2.0 million was temporarily withheld by Japan taxing authorities and was refunded in September 2015. The \$10 million upfront payment from Chugai was recorded as deferred revenue at September 30, 2015 since we had concluded that the license grant did not have standalone value (as defined in ASC 605-25) at the inception of the arrangement. In connection with the termination and the parties having no further obligations under the Agreement, we will recognize the \$10 million upfront payment from Chugai as revenue in October 2015.

*Pfizer*

In 2009, we entered into a collaboration with Pfizer Inc. ( Pfizer ) to develop and commercialize our MultiStem product candidate to treat inflammatory bowel disease for the worldwide market on an exclusive basis. In addition, Pfizer conducted a Phase 2 clinical study exploring the potential of MultiStem cell therapy to treat advanced and severe ulcerative colitis, and would be responsible for any subsequent development. Overall, the study results were disappointing, even though a single administration of the cell therapy may have had some short-term beneficial effects. Taking these results into account, following an internal portfolio review, Pfizer determined that it would not invest further in this program, as would be required by the collaboration, and notified us of this decision to terminate the license agreement effective in the third quarter of 2015. In connection with the termination, all rights that Pfizer had to the program reverted to us, and intellectual property generated through the collaboration is owned by us.

*RTI Surgical, Inc.*

In 2010, we entered into an agreement with RTI Surgical, Inc. ( RTI ) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market on an exclusive basis. Under the terms of the agreement, we received a non-refundable license fee in installments and performed certain services that were concluded in 2012, and we are eligible to receive 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. No milestone revenue has been recognized to date. In addition, we began receiving in 2014 tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens. Any royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.



**Table of Contents****6. Stock-based Compensation**

We have two incentive plans that authorized an aggregate of 11,500,000 shares of common stock for awards to employees, directors and consultants. These equity 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, 2015, a total of 2,426,442 shares of common stock have been issued under our equity incentive plans.

As of September 30, 2015, a total of 617,673 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 8,455,885 shares of common stock were outstanding. For the three-month periods ended September 30, 2015 and 2014, stock-based compensation expense was approximately \$730,000 and \$714,000, respectively. At September 30, 2015, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$4.4 million, which is expected to be recognized by the end of 2019 using the straight-line method.

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

In January 2014, we completed a registered direct offering generating net proceeds of approximately \$18.8 million through the issuance of 5,000,000 shares of common stock and immediately exercisable warrants to purchase 1,500,000 shares of common stock with an exercise price of \$4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of \$4.10 per fixed combination.

During the quarter ended September 30, 2015, we did not sell any shares under the equity purchase agreement with Aspire Capital, and during the nine-month period ended September 30, 2015, we sold 4,023,719 shares of common stock at an average price of \$2.58 per share.

As of September 30, 2015, we had the following outstanding warrants to purchase shares of common stock:

<b>Number of</b>			
<b>Underlying Shares</b>	<b>Exercise Price</b>	<b>Expiration</b>	
1,310,000	\$ 3.55	February 2, 2016	
1,500,000	\$ 4.50	July 15, 2016	
2,054,893	\$ 1.01	March 14, 2017	
<b>4,864,893</b>			

**8. Warrant Liabilities**

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. The warrant liabilities are revalued at fair value at each balance sheet date subsequent to the initial issuance. Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as income (expense) from change in fair value of warrants.

The warrants we issued in the January 2014 registered direct offering contain a provision for a cash payment in the event that the shares are not delivered to the holder within two trading days. The cash payment equals \$10 per day per \$2,000 of warrant shares for each day late. The warrants issued in 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, and the exercise price was reduced in February 2013 to \$1.01 per share as a result of the October 2012 public offering.

The warrants have been classified as liabilities, as opposed to equity, due to the potential adjustment to the exercise price that could result upon late delivery of the shares or potential cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date.



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**9. Income Taxes**

We have U.S. federal, state and foreign net operating loss, research and development tax credit and foreign tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. Substantially all of our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses. As a result of our October 2012 equity offering, the utilization of our net operating loss and tax credit carryforwards generated prior to October 2012 is substantially limited under Section 382 of the Internal Revenue Code. U.S. federal net operating loss carryforwards, research and development tax credits, and state and local net operating loss carryforwards generated after October 2012, as well as foreign net operating loss carryforwards and foreign tax credits, are not subject to annual limitations. We recognize refundable tax benefits related to research and development credits associated with our foreign subsidiary.

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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 unaudited 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, 2014. 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 in the field of regenerative medicine. Our MultiStem<sup>®</sup> cell therapy has been evaluated in multiple Phase 1 and Phase 2 clinical trials. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other conditions. 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.

#### *Current Programs*

To date, we have advanced several MultiStem cell therapy programs to the clinical development stage, including the following:

**Ischemic Stroke:** We are currently conducting a Phase 2 study of MultiStem treatment of subjects suffering a moderate to severe ischemic stroke, and announced in April 2015 the interim results from the clinical study. In the study, we are treating patients one to two days after a stroke. Published studies suggest that approximately 90% of ischemic stroke patients reach the hospital within 24 hours. By contrast, the current standard of care, thrombolytic tPA, must be administered within 3 to 4.5 hours after a stroke, limiting the proportion receiving such treatment to less than 10% of ischemic stroke patients.

Our double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and United Kingdom. Patients were assessed at 90 days in accordance with three well validated and commonly utilized clinical rating scales that are used to assess recovery. These include the Modified Rankin Score, or mRS, (which is a 6 point scale with a score of 0 reflecting no patient disability and 6 indicating death) assessing overall disability; the NIH Stroke Scale, or NIHSS, (a 42 point scale, with a score of 0 reflecting no disability, and 42 reflecting most disabled) assessing neurological and motor skill deficits; and the Barthel Index, or BI, (a 100 point index, with a score of 100 representing the best possible score) evaluating the patient's ability to engage in activities of daily living.

The interim results following the 90-day patient evaluation demonstrate favorable safety and tolerability for MultiStem, consistent with prior studies. With respect to the primary and component secondary endpoints for the intent-to-treat population, the MultiStem treatment did not show a meaningful difference at 90 days compared to placebo. However, MultiStem treatment was associated with lower rates of mortality and life threatening adverse events, infections and pulmonary events, and also a reduction in hospitalization. Furthermore, a higher proportion of patients receiving MultiStem achieved an Excellent Outcome, which is defined clinically as the patient achieving excellent recovery in each of the three clinical rating scales, as evidenced by patients achieving a score of mRS £1, NIHSS £1 and BI <sup>³</sup>95. Among all subjects who received MultiStem treatment, 15.4% of patients achieved an Excellent Outcome, compared to 6.6% of patients who received placebo (p=0.10).



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In addition, analyses show that patients who received MultiStem treatment earlier (24 to 36 hours post-stroke) in the study's treatment window had better recovery in comparison to placebo, and this treatment effect appeared to be more pronounced the earlier the MultiStem administration within this timeframe. For example, at 90 days post-stroke, patients who were treated with MultiStem within 24 to 36 hours of the stroke (i.e. consistent with our original study design) had much better outcomes compared to placebo patients as measured by recovery in each of the key secondary endpoints: mRS  $\leq 2$ , NIHSS  $\leq 7$  and BI  $\geq 95$ . Specifically, 41.9% of the MultiStem-treated patients achieved good or excellent recovery in all three clinical scales, compared to only 24.6% of patients receiving placebo, a difference of 17.3% ( $p = 0.08$ ).

Furthermore, we evaluated the recovery of patients who received treatment with MultiStem within 24 to 36 hours post stroke versus patients receiving placebo, excluding in both groups patients who received both tPA and mechanical reperfusion (and who were excluded in the original trial design). In this post-hoc analysis, the MultiStem group were more than two times as likely as the placebo group to achieve global recovery based on the Global Test Statistic – the primary endpoint ( $p=0.06$ ), demonstrated substantially better performance in the three component secondary endpoints, and also exhibited accelerated improvement in comparison to patients receiving placebo. These MultiStem-treated patients were also much more likely to achieve recovery in each of the key secondary endpoints, with 44.4% of these patients achieving such recovery on all three scales, compared to just 17.3% for the placebo group, a difference of 27.1% ( $p < 0.01$ ). Additionally, these MultiStem patients achieved significantly higher rates of Excellent Outcome ( $p=0.03$ ), and the MultiStem group showed improvement on the Cochran-Mantel-Haenszel shift analysis ( $p=0.03$ ), which compares performance for the patient groups across the spectrum of mRS outcomes. Hospitalization duration was significantly reduced for the MultiStem-treated patients (35% lower than the average for placebo patients) and the average intensive care unit stay was also meaningfully reduced.

Preliminary analysis of biomarker data obtained from samples of study subjects indicates that MultiStem treatment reduces post-stroke inflammation compared to placebo. Furthermore, it appears that this effect is more pronounced for subjects receiving MultiStem earlier than 36 hours post-stroke. This effect is consistent with our hypothesis regarding mechanisms of action and related preclinical data, and with the clinical data suggesting faster recovery for MultiStem-treated patients. Further analyses are being undertaken, and we are preparing for the next stage of clinical development of this program.

Acute Myocardial Infarction: We evaluated the administration of MultiStem to patients that suffered an acute myocardial infarction, or AMI, in a Phase 1 clinical study. The results of this study demonstrated a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal, and one-year follow-up data suggested that the benefit observed was sustained over time. We were awarded a grant for up to \$2.8 million to support the advancement of this clinical program, and we are in the process of launching this Phase 2 clinical study. The Phase 2 study is evaluating the safety and efficacy of MultiStem treatment in subjects who have a non-ST elevated myocardial infarction. The study is double-blind, sham-controlled and is being conducted at leading cardiovascular centers in the United States.

Acute Respiratory Distress Syndrome: We were awarded a grant for up to approximately £2.0 million to support an initial trial to treat patients suffering from acute respiratory distress syndrome, or ARDS. ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by pneumonia, sepsis, or other trauma and represents a major cause of

morbidity and mortality in the critical care setting. The medical need for a safe and effective treatment of ARDS is significant due to its high mortality rate, and it annually affects approximately 400,000 to 500,000 patients in Europe, the United States and Japan, together. The grant supporting this Phase 2a clinical trial was awarded by Innovate UK to our subsidiary, Athersys Limited in the United Kingdom, or UK, in conjunction with Catapult. We are currently preparing for the launch of this trial.

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**Hematopoietic Stem Cell Transplant / GvHD:** We completed a Phase 1 clinical study of the administration of MultiStem cells 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 significant 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. Data from the study demonstrated the safety of MultiStem cells in this indication and suggested that the therapy may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. The MultiStem product has been designated as an orphan drug for the GvHD prophylaxis indication by both the United States Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, which may provide market exclusivity and other substantial incentives and benefits. We have interacted with both the FDA and EMA to finalize the design of a single registration study. In February 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Currently, we are staging this program for future registration-directed development dependent on the achievement of certain business development and financial objectives.

**Inflammatory Bowel Disease:** MultiStem therapy has been evaluated in a Phase 2 clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of inflammatory bowel disease, or IBD. This study was conducted by our collaborative partner, Pfizer Inc., or Pfizer, and we released interim results in April 2014. The interim results obtained from the trial showed that a single administration of MultiStem to a patient population with longstanding, chronic advanced disease failed to show a meaningful clinical effect at the eight-week evaluation period. Despite not showing a significant improvement compared to placebo in the primary efficacy endpoints, the MultiStem therapy demonstrated favorable safety and tolerability in the eight weeks following treatment. Furthermore, at four weeks, patients getting MultiStem treatment had a significantly higher proportion of rectal bleeding responders than placebo patients, suggesting the possibility of a transient effect from the single MultiStem dose. Subsequent analyses suggest that MultiStem treatment is having a significant impact on relevant biomarkers shortly after treatment compared to placebo, suggesting the possibility of improved benefit from a different treatment regime. Taking these results into account, following an internal portfolio review of its IBD programs, Pfizer determined that it would not invest further in this IBD program as required by the collaboration and, in May 2015, notified us of its intent to terminate the license agreement effective in the third quarter of 2015. In connection with the termination, all rights to the program reverted to us, and we are free to use preclinical and clinical data for development in this area and in other areas, including immunology and inflammatory conditions.

In addition to the programs described above, we are also conducting or supporting clinical activity in other areas, such as solid organ transplant, which is an investigator-initiated study being conducted at a leading transplant center in Europe. We are also engaged in the preparation stages for translational and clinical studies in other targeted areas. We are also pursuing the development of novel small molecule therapies to treat obesity and other conditions, such as schizophrenia.

We are routinely in discussions with third parties about collaborating in the development of MultiStem therapy for various programs and may enter into one or more business partnerships to advance these programs over time. In October 2015, we announced that we had entered into a letter of intent with a Japanese company, accompanied by a good faith payment, to collaborate on the development and commercialization of MultiStem cell therapy for several indications in Japan, including ischemic stroke. However, there can be no assurance that we will enter into a definitive agreement with the Japanese company. We are also in ongoing discussions with several companies about collaborating on the development and commercialization of MultiStem therapy in multiple areas, including ischemic

stroke outside of Japan.

We are also partnered with RTI Surgical, Inc., or RTI, on the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market. We began recognizing royalty revenue from product sales in 2014 and may receive other payments upon the successful achievement of certain commercial milestones.

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On October 20, 2015, we and Chugai agreed to terminate the License Agreement, which we refer to as the Agreement, dated February 28, 2015, between the parties as a result of an inability to reach an agreement on the modification of the financial terms of the Agreement and on the development strategy of our MultiStem cell therapy for the treatment of ischemic stroke in Japan. We will retain the \$10 million up-front cash payment from Chugai received in 2015, which will be recognized in full in October 2015 in connection with the termination of the collaboration. Pursuant to the terms of the Agreement, upon termination, we regained all rights for developing its stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other, and the licenses granted to Chugai to develop and commercialize MultiStem for ischemic stroke in Japan terminate.

In January 2014, we completed a registered direct offering generating net proceeds of approximately \$18.8 million through the issuance of 5,000,000 shares of common stock and immediately exercisable warrants to purchase 1,500,000 shares of common stock with an exercise price of \$4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of \$4.10 per fixed combination.

We did not sell any shares under our equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, during the three-month period ended September 30, 2015. During the nine-month period ended September 30, 2015, we sold 4,023,719 shares of common stock at an average price of \$2.58 per share to Aspire Capital, generating aggregate proceeds of approximately \$10.4 million.

In February 2015, we were awarded a grant from Innovate UK, which will support a Phase 2a clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. The grant is expected to provide up to approximately £2.0 million in support over the course of the study, which will be conducted at leading clinical sites in the UK in conjunction with Catapult, a not-for-profit center focused on the development of the UK cell therapy industry.

**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, but we receive royalties on commercial sales by a licensee of products using our technologies. 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 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.

***Three Months Ended September 30, 2015 and 2014***

*Revenues.* Revenues rose slightly to \$0.4 million for the three months ended September 30, 2015 compared to \$0.3 million for the three months ended September 30, 2014 due to an increase of \$0.1 million in grant revenues. Our grant



revenues fluctuate from period to period based on the timing of grant-related activities and the award and expiration of new grants.

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*Research and Development Expenses.* Research and development expenses decreased to \$5.1 million for the three months ended September 30, 2015 from \$5.8 million in the comparable period in 2014. The \$0.7 million decrease is primarily comprised of a decrease in preclinical and clinical development costs of \$0.3 million, a decrease in sponsored research costs of \$0.1 million, a decrease in personnel costs of \$0.1 million, a decrease in research supplies of \$0.1 million and a decrease in travel costs of \$0.1 million. The decrease in our preclinical and clinical development costs is primarily due to decreased manufacturing costs, clinical study costs and regulatory costs. 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 increased to \$1.9 million for the three months ended September 30, 2015 from \$1.7 million in the comparable period in 2014. The \$0.2 million increase was due primarily to an increase in consulting costs of \$0.1 million and an increase in professional fees of \$0.1 million compared to the same period in 2014. We expect our general and administrative expenses to continue at a similar level during the remainder of the year.

*Depreciation.* Depreciation expense of \$0.1 million remained consistent during each of the three-month periods ended September 30, 2015 and 2014.

*Other (Expense) Income, net.* Other (expense) income, net, for the three-month period ended September 30, 2015 and 2014 remained relatively consistent during the periods, and was comprised of interest income, interest expense and foreign currency gains and losses.

*Income from Change in Fair Value of Warrants, net.* Income of \$0.3 million was recognized during the three months ended September 30, 2015 for the market value change in our warrant liabilities, compared to income of \$2.5 million during the comparable period in 2014. The fluctuation is primarily affected by the exercise prices of the warrants, our stock price and the remaining lives of the issued warrants.

*Tax Benefit.* The tax benefit relates to refundable tax credits from a foreign subsidiary.

***Nine Months Ended September 30, 2015 and 2014***

*Revenues.* Revenues decreased to \$1.3 million for the nine months ended September 30, 2015 from \$1.4 million in the comparable period in 2014 reflecting a \$0.1 million decrease in our grant revenues. Our grant revenues 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 \$16.0 million for the nine months ended September 30, 2015 from \$17.8 million in the comparable period in 2014. The decrease of \$1.8 million related primarily to a decrease of \$1.2 million in preclinical and clinical development costs, a decrease in sponsored research costs of \$0.5 million, a decrease in legal and professional fees of \$0.2 million, and a decrease in travel costs of \$0.1 million. These decreases were partially offset by an increase in license fees of \$0.2 million. The decrease in our clinical and preclinical costs is primarily due to reduced product manufacturing costs, clinical trial costs and clinical consulting costs. Sponsored research costs decreased primarily due to a decrease in grant-funded programs involving collaboration with certain academic research institutions. The decrease in legal fees resulted from decreased patent expenses associated with patent prosecution, national filings, and interparty proceedings and related filings. The increase in license fees was related to a royalty payment due in regard to the licensing agreement with Chugai. 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.



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*General and Administrative Expenses.* General and administrative expenses increased to \$5.8 million for the nine months ended September 30, 2015 from \$5.3 million in the comparable period in 2014. The \$0.5 million increase was due primarily to an increase in consulting fees of \$0.2 million, an increase in stock based compensation of \$0.2 million and an increase in legal and professional fees of \$0.1 million compared to the same period in 2014. We expect our general and administrative expenses to continue at a similar level during the remainder of the year.

*Depreciation.* Depreciation expense of \$0.2 million for the nine months ended September 30, 2015 was down slightly from the expense of \$0.3 million for the comparable nine-month period ended September 30, 2014.

*Other (Expense) Income, net.* Other (expense) income, net, for the nine-month period ended September 30, 2015 and 2014 remained relatively consistent during the periods, and was comprised of interest income, interest expense and foreign currency gains and losses.

*Income from Change in Fair Value of Warrants, net.* Income of \$0.6 million was recognized during the nine months ended September 30, 2015 for the market value change in our warrant liabilities, and \$6.3 million of income was recognized during the nine months ended September 30, 2014. The fluctuation is primarily affected by the exercise prices of the warrants, our stock price and the remaining lives of the issued warrants.

*Tax Benefit.* The tax benefit relates to refundable tax credits from a foreign subsidiary.

## **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities. At September 30, 2015, we had \$28.5 million in cash and cash equivalents. 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.

We have incurred losses since inception of our operations in 1995 and had an accumulated deficit of \$307 million at September 30, 2015. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs and general and administrative costs associated with our operations. We used the financing proceeds from equity and debt offerings 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.

We have an equity purchase agreement with Aspire Capital, whereby Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock over a two-year period ending in November 2015, 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-month period ended September 30, 2015, we generated proceeds aggregating \$10.4 million from sales of our common stock to Aspire Capital.

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During the nine months ended September 30, 2015, we received proceeds of approximately \$976,000 from the exercise of warrants, resulting in the issuance of 966,184 shares of common stock in the aggregate.

On October 20, 2015, we and Chugai agreed to terminate the Agreement as a result of an inability to reach an agreement on the modification of the financial terms of the Agreement and on the development strategy of our MultiStem cell therapy for the treatment of ischemic stroke in Japan. We will retain the \$10 million up-front cash payment from Chugai received in 2015. Neither we nor Chugai have any further obligations to each other.

Under the terms of our RTI agreement, we are eligible to receive cash payments aggregating up to \$35.5 million upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no milestone payments have been received as of September 30, 2015. In addition, we are entitled to receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens, and we began receiving royalty payments in 2014.

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.

We are obligated to pay the University of Minnesota a royalty based on worldwide commercial sales of licensed products if covered by a valid licensed patent. The low single-digit royalty rate may be reduced if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center, or GCIC, 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 preclinical work. Interest on the loan accrues at a fixed rate of 4.25% per annum and is added to the outstanding principal. The loan is forgivable based on the achievement of a manufacturing-related milestone within three to four years. GCIC has agreed to the four-year term, with an expiration date of March 31, 2016. We had drawn \$166,000 of this financing (\$189,000 including accrued interest), which is recorded as a current liability at September 30, 2015.

In 2015, we were awarded a grant from Innovate UK, which will support a Phase 2a clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. The grant is expected to provide up to approximately £2.0 million (approximately \$3.1 million based on the current exchange rate) in support over the course of the study, which will be conducted at leading clinical sites in the UK in conjunction with Catapult, a not-for-profit center focused on the development of the UK cell therapy industry.

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 and manufacturing process development. At September 30, 2015, we had available cash and cash equivalents of \$28.5 million, and 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 continue to generate additional funding to meet our needs, through business development and grant-funding opportunities. Additionally, we may raise capital from time to time through an equity purchase agreement with Aspire Capital, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and staging 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.



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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.

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 \$8.4 million for the nine months ended September 30, 2015 and \$19.7 million for the nine months ended September 30, 2014, representing the use of cash in funding preclinical and clinical development activities being partially offset by the \$10 million of cash received from Chugai. Net cash used in operating activities has fluctuated significantly on a quarter-to-quarter basis over the past few years primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs and manufacturing process development projects.

Net cash used in investing activities was \$0.1 million and \$0.3 million for the nine months ended September 30, 2015 and 2014, respectively. The fluctuations from period-to-period were due to purchases of equipment supporting our operations.

Financing activities provided cash of \$11.0 million for the nine months ended September 30, 2015 related to equity sales to Aspire Capital and the exercise of common stock warrants, net of treasury stock purchases. Financing activities provided cash of \$20.3 million for the nine months ended September 30, 2014 related to the January 2014 registered direct offering, the exercise of common stock warrants, and equity sales to Aspire Capital, net of treasury stock purchases.

Investors in certain of our equity offerings have received warrants to purchase shares of our common stock, of which warrants to purchase an aggregate of 4.9 million shares remain outstanding at September 30, 2015 with a weighted average exercise price of \$2.77 per share. The exercise of warrants could provide us with cash proceeds. During the three months ended September 30, 2015, no warrants were exercised.

We have no off-balance sheet arrangements.

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

The Securities and Exchange Commission, or 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. 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 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, 2014. 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, 2014.



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### **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, suggest, will, expressions. 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.

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

our ability to raise capital to fund our operations;

the timing and nature of 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 of our product candidates;

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the prevention of GvHD and the treatment of stroke, AMI, IBD, ARDS and other disease indications;

our ability to reach a definitive agreement with a Japanese company to collaborate on the development and commercialization of MultiStem cell therapy for several indications in Japan;

changes in external market factors;

changes in our industry's overall performance;

changes in our business strategy;

our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development;

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;

the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in the United States, Europe and Japan;

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.

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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. When appropriate based on interest rates, we invest our excess cash primarily in debt instruments of the United States government and its agencies and corporate debt securities, and as of September 30, 2015, 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 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, 2015, we had no borrowings outstanding other than a potentially 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, as defined in Rules 13a-15(f) and 15d-15(f) 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 2015, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**Table of Contents****PART II. OTHER INFORMATION****Item 6. Exhibits.**

Exhibit No.	Description
10.1	Consulting Agreement, dated as of September 1, 2015, by and between ABT Holding Company and Robert Deans.
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, 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.

Date: November 5, 2015

ATHERSYS, INC.

/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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**Table of Contents****EXHIBIT INDEX**

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