

ATHERSYS, INC / NEW  
Form 10-Q  
May 08, 2014  
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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 March 31, 2014**

**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**

**20-4864095**  
**(I.R.S. Employer**

**incorporation or organization)**

**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 May 5, 2014 was 77,046,136.

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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)

(Unaudited)

|  | <b>March 31,<br/>2014</b> | <b>December 31,<br/>2013</b> |
|--|---------------------------|------------------------------|
| <b>Assets</b>  |                           |                              |
| Current assets:  |                           |                              |
| Cash and cash equivalents  | \$ 44,981                 | \$ 31,948                    |
| Accounts receivable  | 894                       | 520                          |
| Prepaid expenses and other   | 319                       | 387                          |
| Total current assets   | 46,194                    | 32,855                       |
| Equipment, net   | 1,394                     | 1,333                        |
| Total assets   | \$ 47,588                 | \$ 34,188                    |
| <b>Liabilities and stockholders equity</b>   |                           |                              |
| Current liabilities:   |                           |                              |
| Accounts payable   | \$ 2,454                  | \$ 2,243                     |
| Accrued compensation and related benefits  | 601                       | 1,067                        |
| Accrued clinical trial costs   | 96                        | 88                           |
| Accrued expenses   | 890                       | 884                          |
| Deferred revenue   | 46                        | 86                           |
| Note payable   | 178                       |                              |
| Total current liabilities  | 4,265                     | 4,368                        |
| Note payable   |                           | 176                          |
| Warrant liabilities  | 13,663                    | 9,823                        |
| Stockholders equity:   |                           |                              |
| Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2014 and December 31, 2013   |                           |                              |
| Common stock, \$0.001 par value; 150,000,000 shares authorized and 77,121,743 and 70,749,212 shares issued at March 31, 2014 and December 31, 2013, respectively, and 77,046,136 and 70,683,480 shares outstanding at March 31, 2014 and December 31, 2013, respectively |                           |                              |
|  | 77                        | 71                           |
| Additional paid-in capital   | 305,784                   | 284,323                      |
|  | (279)                     | (135)                        |

Treasury stock, at cost; 75,607 and 65,732 shares at March 31, 2014 and December 31, 2013, respectively

|  |           |           |
|--|-----------|-----------|
| Accumulated deficit                        | (275,922) | (264,438) |
| Total stockholders' equity                 | 29,660    | 19,821    |
| Total liabilities and stockholders' equity | \$ 47,588 | \$ 34,188 |

*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)

|  | <b>Three months ended</b> |                   |
|--|---------------------------|-------------------|
|  | <b>March 31,</b>          |                   |
|  | <b>2014</b>               | <b>2013</b>       |
| <b>Revenues</b>  |                           |                   |
| Contract revenue                                       | \$ 44                     | \$ 84             |
| Grant revenue  | 663                       | 242               |
| Total revenues   | 707                       | 326               |
| <b>Costs and expenses</b>                              |                           |                   |
| Research and development                               | 6,226                     | 5,576             |
| General and administrative                             | 1,781                     | 1,507             |
| Depreciation   | 89                        | 85                |
| Total costs and expenses                               | 8,096                     | 7,168             |
| Loss from operations                                   | (7,389)                   | (6,842)           |
| Other income, net                                      | 29                        | 17                |
| Expense from change in fair value of warrants, net     | (4,124)                   | (2,563)           |
| <b>Net loss and comprehensive loss</b>                 | <b>\$ (11,484)</b>        | <b>\$ (9,388)</b> |
| Basic and diluted net loss per common share            | \$ (0.15)                 | \$ (0.18)         |
| Weighted average shares outstanding, basic and diluted | 75,852,753                | 53,455,779        |

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

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

(In thousands)

(Unaudited)

|   | <b>Three months ended</b> |             |
|---|---------------------------|-------------|
|   | <b>March 31,</b>          |             |
|   | <b>2014</b>               | <b>2013</b> |
| <b>Operating activities</b>   |                           |             |
| Net loss  | \$ (11,484)               | \$ (9,388)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                           |             |
| Depreciation  | 89                        | 85          |
| Stock-based compensation  | 579                       | 116         |
| Change in fair value of warrant liabilities                                 | 4,124                     | 2,563       |
| Changes in operating assets and liabilities:                                |                           |             |
| Accounts receivable   | (374)                     | 17          |
| Prepaid expenses and other assets   | 68                        | (7)         |
| Accounts payable and accrued expenses                                       | (239)                     | 501         |
| Deferred revenue  | (40)                      |             |
| Net cash used in operating activities                                       | (7,277)                   | (6,113)     |
| <b>Investing activities</b>   |                           |             |
| Purchases of equipment  | (150)                     | (101)       |
| Net cash used in investing activities                                       | (150)                     | (101)       |
| <b>Financing activities</b>   |                           |             |
| Proceeds from issuance of common stock and warrants, net                    | 19,814                    | 2,026       |
| Purchase of treasury stock  | (292)                     |             |
| Proceeds from exercise of warrants  | 938                       |             |
| Net cash provided by financing activities                                   | 20,460                    | 2,026       |
| Increase (decrease) in cash and cash equivalents                            | 13,033                    | (4,188)     |
| Cash and cash equivalents at beginning of the period                        | 31,948                    | 25,533      |
| Cash and cash equivalents at end of the period                              | \$ 44,981                 | \$ 21,345   |

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

**Table of Contents****Athersys, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements**

Three-Month Periods Ended March 31, 2014 and 2013

**1. Background and Basis of Presentation**

We are an international biopharmaceutical company that is focused primarily on 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, 2013. 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.

**2. Net Loss per Share**

Basic and diluted net loss per share has 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:

|                        | <b>Three Months Ended</b> |             |
|------------------------|---------------------------|-------------|
|                        | <b>March 31,</b>          |             |
|                        | <b>2014</b>               | <b>2013</b> |
| Outstanding options    | 5,088,973                 | 4,005,601   |
| Restricted stock units | 2,224,096                 | 70,814      |
| Outstanding warrants   | 9,480,103                 | 5,806,853   |
| Total                  | 16,793,172                | 9,883,268   |



**Table of Contents****3. 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 financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2014 (in thousands):

| Description         | Fair Value Measurements at March 31, 2014 Using Quoted Prices in Active Markets for |                            |   |   |
|---------------------|---|----------------------------|---|---|
|                     | Balance as of March 31, 2014  | Identical Assets (Level 1) | Significant Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liabilities | \$ 13,663   | \$                         | \$                                      | \$ 13,663                                 |

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 warrants issued in our December 2013 offering were issued in two series, since 1,401,218 of the total 3,500,000 warrants issued are not exercisable until June 3, 2014. The following inputs were used at March 31, 2014:

|                     |                         |               |
|---------------------|-------------------------|---------------|
| Expected Volatility | Risk-Free Interest Rate | Expected Life |
|---------------------|-------------------------|---------------|

|  |                 |               |      |            |
|--|-----------------|---------------|------|------------|
| Warrants with one year or less remaining term      | 58.28% - 58.71% | 0.13%         | 0.82 | 1.00 year  |
| Warrants with greater than one year remaining term | 55.35% - 72.00% | 0.44% - 0.90% | 1.84 | 2.96 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</b> |         |
|--|---------------------------|---------|
|  | <b>March 31, 2014</b>     |         |
| Balance January 1, 2014  | \$                        | 9,823   |
| Issuance of warrants January 2014                              |                           | 2,012   |
| Settlements  |                           | (2,296) |
| Loss included in expense from change in fair value of warrants |                           | 4,124   |
| Balance March 31, 2014   | \$                        | 13,663  |

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**Table of Contents****4. Collaborations and Revenue Recognition***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 ( IBD ) for the worldwide market. 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. No significant milestone revenue has been recognized to date.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes, which is recognized in the period that the manufacturing services are performed. Pfizer would have responsibility for development, regulatory and commercialization and would 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 would share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase 3 clinical development.

*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. 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. In addition, we receive royalties on worldwide commercial sales of implants using our technologies. No milestone revenue has been recognized to date.

**5. 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 March 31, 2014, a total of 762,972 shares of common stock have been issued under our equity incentive plans.

As of March 31, 2014, a total of 3,423,959 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 7,313,069 shares of common stock were outstanding. For the three-month periods ended March 31, 2014 and 2013, stock-based compensation expense was approximately \$579,000 and \$116,000, respectively. At March 31, 2014, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$5,124,000, which is expected to be recognized by the end of 2017 using the straight-line method.

**6. 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.

In the first quarter of 2014, we sold 250,000 shares to Aspire Capital Fund, LLC under our equity purchase agreement at an average price of \$3.78 per share.

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As of March 31, 2014, 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> |  |
| 149,026                  | \$ 5.00               | June 8, 2014      |  |
| 1,310,000                | \$ 3.55               | February 2, 2016  |  |
| 3,021,077                | \$ 1.01               | March 14, 2017    |  |
| 3,500,000                | \$ 2.50               | March 31, 2015    |  |
| 1,500,000                | \$ 4.50               | July 15, 2016     |  |
| 9,480,103                |                       |                   |  |

During the three months ended March 31, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants, resulting in the issuance of 928,924 shares of common stock in the aggregate.

**7. 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 and December 2013 registered direct offerings 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 as 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.

**8. 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. As a result of our October 2012 equity offering, our net operating loss carryforwards are significantly limited for use under Section 382 of the Internal Revenue Code.



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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, 2013. Operating results are not necessarily indicative of results that may occur in future periods.

**Overview and Recent Developments**

We are an international biopharmaceutical company that is focused primarily in the field of regenerative medicine. Our MultiStem<sup>®</sup> cell therapy has been evaluated in two completed Phase 1 clinical trials and is currently being evaluated in two ongoing Phase 2 clinical trials, as well as an investigator-led Phase 1 trial. Our current clinical development programs are focused on treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, 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*

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

**Ischemic Stroke:** In our ongoing Phase 2 clinical study, we are evaluating the administration of MultiStem cell therapy to patients that have suffered an 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 cells, 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 Europe. The study is expected to enroll approximately 136 patients. Enrollment completion is currently anticipated to occur around the end of the summer of 2014, and initial results are targeted for later in 2014.

**Inflammatory Bowel Disease:** MultiStem therapy is being evaluated in a Phase 2 clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, or UC, the most common form of inflammatory bowel disease, or IBD. This double blind, placebo controlled trial being conducted with our partner, Pfizer, in UC patients that have an inadequate response or are refractory to current treatment, completed enrolling patients in December 2013. The study is expected to run through 2014.

We recently reported interim results from the study, which showed that a single administration of our cell therapy candidate in this complicated patient population with chronic advanced disease failed to show a meaningful clinical effect during the eight-week evaluation period. MultiStem therapy demonstrated favorable tolerability and safety through eight weeks following treatment. However, MultiStem did not show a significant improvement compared to placebo in the primary efficacy endpoints – changes in endoscopic score from baseline as measured by modified Baron score at eight weeks and change in Mayo rectal bleeding subscore from baseline at four and eight weeks. At four weeks (but not eight weeks), the proportion of responders - as measured by a  $\geq 1$  point improvement in the Mayo rectal bleeding score - in patients treated with MultiStem was greater than placebo, and the difference was statistically

significant; however, worsening of scores in a small number of non-responders resulted in no significant difference in the mean Mayo rectal bleeding subscores for the groups through eight weeks. Additional evaluations are expected, including data about the impact from a second round of dosing for a subset of patients and longer-term secondary clinical endpoints at sixteen weeks, and biomarker analysis.



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Acute Myocardial Infarction: We have evaluated the administration of MultiStem to patients that have suffered an acute myocardial infarction, or AMI, in a Phase 1 clinical study. 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. This data was published in a leading peer reviewed scientific journal in 2012. One-year follow-up data suggested that the benefit observed was sustained over time. In 2013, we were awarded a grant for up to \$2.8 million to support funding this clinical program, and we are preparing for a Phase 2 clinical study to initiate late 2014.

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, or HSC, 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. In 2011 and in 2012, we released data from the study, which demonstrated the safety of MultiStem cells in this indication and suggested that the MultiStem therapy may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. The MultiStem therapy has been designated an orphan drug by both the United States Food and Drug Administration, or FDA and the European Medicines Agency, which may provide market exclusivity and other substantial potential incentives and benefits. We have had several interactions with the FDA and international agencies regarding study design and the potential to accelerate the path to product approval. Based on current plans, we intend to be ready to start this study in 2014, but study initiation will depend on the progress in our other 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 initiated a small institutional sponsored clinical trial exploring the administration of MultiStem cells in patients following a liver transplant. We are providing the clinical product and some financial support to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem therapy in other inflammatory and 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 therapy for certain programs and may enter into one or more business partnership(s) to advance these programs.

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

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions, such as schizophrenia. We may elect to enter into a partnership to advance the development of our 5HT2c agonist program, either for the treatment of obesity, schizophrenia, or both indications, as well as for certain programs involving MultiStem.

## *Financial*

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.

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Under our equity purchase agreement with Aspire Capital, we sold 250,000 shares of common stock at an average price of \$3.78 per share during the quarter ended March 31, 2014. During the three months ended March 31, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants, resulting in the issuance of 928,924 shares of common stock in the aggregate.

**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 March 31, 2014 and 2013***

*Revenues.* Revenues increased to \$707,000 for the three months ended March 31, 2014 from \$326,000 in the comparable period in 2013, reflecting a \$421,000 increase in our grant revenues. Grant revenue may fluctuate from period to period based on the timing of grant-related activities and the award and expiration of new grants.

*Research and Development Expenses.* Research and development expenses increased to \$6.2 million for the three months ended March 31, 2014 from \$5.6 million for the comparable period in 2013. The \$650,000 increase is primarily comprised of an increase in personnel costs of \$269,000, an increase in stock based compensation of \$209,000, an increase in legal and professional fees of \$199,000 and an increase in sponsored research costs of \$100,000. These increases were partially offset by a decrease in clinical and preclinical development costs of \$314,000. The increase in personnel costs related to selective personnel additions and annual compensation increases. The increase in stock-based compensation related primarily to restricted stock units granted in June 2013 to our named executive officers in exchange for the termination of an old incentive agreement, which vest over a three-year period. The increase in legal fees resulted from increased patent expenses associated with patent prosecution, national filings, and interparty proceedings and related filings. The decrease in our clinical and preclinical costs is primarily due to the timing of our ongoing clinical studies, net of increased manufacturing process development costs. We expect our 2014 annual research and development expenses to be higher than the 2013 expenses based on our planned clinical development and manufacturing process development activities, and such costs will vary over time based on clinical manufacturing campaigns and the timing and stage of clinical trials underway. 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 \$1.8 million for the three months ended March 31, 2014 from \$1.5 million in the comparable period in 2013. The increase was due primarily to an increase in personnel costs of \$129,000 and an increase in stock based compensation of \$254,000 compared to the same period in 2013. These increases were partially offset by



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a decrease of \$113,000 in legal and professional fees. The increase in personnel costs related to selective personnel additions and annual compensation increases. The increase in stock-based compensation related primarily to restricted stock units granted to our named executive officers in June 2013 in exchange for the termination of an old incentive agreement, which vest over a three-year period. We expect our 2014 quarterly general and administrative expenses to continue at similar levels during the remainder of the year.

*Depreciation.* Depreciation expense increased to \$89,000 for the three months ended March 31, 2014 from \$85,000 in the comparable period in 2013, due to depreciation on new capital purchases.

*Other Income, net.* Other income, net, includes foreign currency gains and losses, interest income and interest expense and was \$29,000 for the three months ended March 31, 2014 and \$17,000 in the comparable period in 2013.

*Expense from Change in Fair Value of Warrants.* Expense of \$4.1 million was recognized during the three months ended March 31, 2014 for the market value change in our warrant liabilities, compared to expense of \$2.6 million in the comparable period in 2013.

## **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities. At March 31, 2014, we had \$45.0 million in cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct our operations through our subsidiary, ABT Holding Company.

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$276 million at March 31, 2014. 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 have 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.

In January 2014, we generated net proceeds of approximately \$18.8 million in a registered direct offering. Also, in December 2013, we completed a registered direct offering generating net proceeds of approximately \$18.4 million.

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 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. In the first quarter of 2014, we sold 250,000 shares to Aspire Capital at an average price of \$3.78 per share. We have \$23.5 million of shares of common stock remaining to sell to Aspire Capital under the equity purchase agreement, if we elect to do so.

During the three months ended March 31, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants aggregating in issuances of 928,924 shares of common stock.

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 March 31, 2014. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and would pay us tiered royalties on

worldwide commercial sales of

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MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties would share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase 3 clinical development.

Under the terms of our RTI agreement, we are eligible to receive cash payments 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 March 31, 2014. In addition, we receive royalties on worldwide commercial sales of implants using our technologies, which commenced in the first quarter of 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.

In 2011, we reached an agreement with Angiotech Pharmaceuticals, Inc., or Angiotech, to terminate the collaboration agreement and license between the parties, and we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications. As part of the termination agreement, if we enter into a new AMI collaboration before November 14, 2014 and at the time of the collaboration, we have made certain progress in development, Angiotech could be eligible for 10% of any third-party license fees up to a maximum of \$5.0 million. Angiotech is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments.

In 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 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 is forgivable based on the achievement of a certain milestone within three to four years. As of March 31, 2014, we had drawn \$166,000 of this financing, which is recorded as a current liability of \$178,000 (including accrued interest) since the note is due in the first quarter of 2015 if the forgiveness conditions are not met.

In 2011, we entered into an alliance with Fast Forward, a nonprofit subsidiary of the National Multiple Sclerosis Society, pursuant to which Fast Forward is funding the development of MultiStem for the treatment of multiple sclerosis through the filing of an IND. 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. Over the past few years, we have been investing conservatively due to the ongoing macro-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. We had no available-for-sale securities at March 31, 2014. 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 and manufacturing process development. At March 31, 2014, we had available cash and cash equivalents of \$45.0 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 opportunities, as well as grant-funding opportunities. Additionally, we are raising capital from time to time through the equity purchase

agreement with Aspire Capital, subject to its



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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.

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 \$7.3 million for the three months ended March 31, 2014 and \$6.1 million for the three months ended March 31, 2013, and represented the use of cash in funding preclinical and clinical development activities. We expect that net cash used in operating activities will be higher in 2014 compared to 2013 in connection with increased clinical development activities for our MultiStem product candidates and platform. 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 by investing activities was \$150,000 and \$101,000 for the three months ended March 31, 2014 and 2013, respectively. The fluctuations from period-to-period were due to purchases of equipment supporting our operations. We anticipate that our overall capital equipment expenditures will be similar in 2014 as compared to 2013.

Financing activities provided cash of \$20.5 million for the three months ended March 31, 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. Financing activities provided cash of \$2.0 million for the three months ended March 31, 2013 as a result of equity sales to Aspire Capital during the period.

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 9.5 million shares remain outstanding at March 31, 2014 with a weighted average exercise price of \$2.53 per share. The exercise of warrants could provide us with cash proceeds, and during the three months ended March 31, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants aggregating in issuances of 928,924 shares of common stock.

We have no off-balance sheet arrangements.



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### **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 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, 2013. 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, 2013.

### **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 IBD, AMI, stroke and other disease indications;

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;

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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 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.

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 March 31, 2014, we had no investments. Over the past several years, we have been investing conservatively due to 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 March 31, 2014, 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.

**Table of Contents****Changes in internal control over financial reporting**

During the first quarter of 2014, 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.

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

During the quarter ended March 31, 2014, we sold an aggregate of 250,000 shares of common stock to Aspire Capital at an average purchase price of \$3.78 per share. 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.

**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, 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: May 8, 2014

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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