

ATHERSYS, INC / NEW  
Form 10-Q  
August 06, 2015  
Table of Contents

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 June 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 August 1, 2015 was 83,116,504.

**Table of Contents**

**ATHERSYS, INC.**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

|   |    |
|---|----|
| <b><u>ITEM 1. Financial Statements</u></b>  | 1  |
| <b><u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b> | 10 |
| <b><u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>                            | 19 |
| <b><u>ITEM 4. Controls and Procedures</u></b>   | 19 |

**PART II. OTHER INFORMATION**

|   |    |
|---|----|
| <b><u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b> | 19 |
| <b><u>ITEM 5. Other Information</u></b>   | 20 |
| <b><u>ITEM 6. Exhibits</u></b>  | 20 |
| <b><u>SIGNATURES</u></b>  | 21 |
| <b><u>EXHIBIT INDEX</u></b>   | 22 |

**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>June 30,<br/>2015<br/>(Unaudited)</b> | <b>December 31,<br/>2014</b> |
|--|--|------------------------------|
| <b>Assets</b>  |  |                              |
| Current assets:  |  |                              |
| Cash and cash equivalents  | \$ 32,346                                | \$ 26,127                    |
| Accounts and other receivables   | 2,382                                    | 694                          |
| Prepaid expenses and other   | 341                                      | 427                          |
| Total current assets   | 35,069                                   | 27,248                       |
| Equipment, net   | 1,207                                    | 1,270                        |
| Deferred tax assets  | 203                                      | 200                          |
| Total assets   | \$ 36,479                                | \$ 28,718                    |
| <b>Liabilities and stockholders equity</b>   |  |                              |
| Current liabilities:   |  |                              |
| Accounts payable   | \$ 2,255                                 | \$ 2,767                     |
| Accrued compensation and related benefits  | 723                                      | 1,060                        |
| Accrued clinical trial costs   | 165                                      | 126                          |
| Accrued expenses   | 705                                      | 664                          |
| Deferred revenue   | 10,000                                   | 75                           |
| Note payable   | 187                                      |                              |
| Total current liabilities  | 14,035                                   | 4,692                        |
| Note payable   |  | 183                          |
| Warrant liabilities  | 1,068                                    | 2,948                        |
| Stockholders equity:   |  |                              |
| Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at June 30, 2015 and December 31, 2014                                      |  |                              |
| Common stock, \$0.001 par value; 150,000,000 shares authorized, and 83,082,183 and 77,706,816 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively | 83                                       | 78                           |
| Additional paid-in capital   | 321,330                                  | 307,337                      |
| Accumulated deficit  | (300,037)                                | (286,520)                    |

|  |                  |                  |
|--|------------------|------------------|
| Total stockholders' equity                 | <b>21,376</b>    | 20,895           |
| Total liabilities and stockholders' equity | <b>\$ 36,479</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 Income (Loss)**

(In thousands, except share and per share data)

(Unaudited)

|  | Three months ended |               | Six months ended   |                    |
|--|--------------------|---------------|--------------------|--------------------|
|  | June 30,           |               | June 30,           |                    |
|  | 2015               | 2014          | 2015               | 2014               |
| <b>Revenues</b>  |                    |               |                    |                    |
| Contract revenue   | \$ 49              | \$ 36         | \$ 155             | \$ 80              |
| Grant revenue  | 167                | 352           | 792                | 1,015              |
| Total revenues   | 216                | 388           | 947                | 1,095              |
| <b>Costs and expenses</b>                                |                    |               |                    |                    |
| Research and development                                 | 5,261              | 5,754         | 10,928             | 11,981             |
| General and administrative                               | 1,924              | 1,827         | 3,810              | 3,607              |
| Depreciation   | 65                 | 93            | 136                | 182                |
| Total costs and expenses                                 | 7,250              | 7,674         | 14,874             | 15,770             |
| Loss from operations                                     | (7,034)            | (7,286)       | (13,927)           | (14,675)           |
| Other income, net  | 42                 | 42            | 56                 | 71                 |
| Income from change in fair value of warrants, net        | 5,957              | 7,919         | 354                | 3,795              |
| <b>Net (loss) income and comprehensive (loss) income</b> | <b>\$ (1,035)</b>  | <b>\$ 675</b> | <b>\$ (13,517)</b> | <b>\$ (10,809)</b> |
| Net (loss) income per share - Basic                      | \$ (0.01)          | \$ 0.01       | \$ (0.17)          | \$ (0.14)          |
| Weighted average shares outstanding, basic               | 82,843,739         | 77,077,492    | 81,022,337         | 76,468,506         |
| Net loss per share - Diluted                             | \$ (0.05)          | \$ (0.04)     | \$ (0.17)          | \$ (0.16)          |
| Weighted average shares outstanding, diluted             | 83,562,405         | 78,778,181    | 81,022,337         | 78,407,380         |

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

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

(In thousands)

(Unaudited)

|   | <b>Six months ended</b> |             |
|---|-------------------------|-------------|
|   | <b>June 30,</b>         |             |
|   | <b>2015</b>             | <b>2014</b> |
| <b>Operating activities</b>   |                         |             |
| Net loss  | \$ (13,517)             | \$ (10,809) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |             |
| Depreciation  | 136                     | 182         |
| Stock-based compensation  | 1,456                   | 1,180       |
| Change in fair value of warrant liabilities                                 | (354)                   | (3,795)     |
| Changes in operating assets and liabilities:                                |                         |             |
| Accounts receivable   | (1,688)                 | (195)       |
| Prepaid expenses and other  | 87                      | 80          |
| Accounts payable and accrued expenses                                       | (769)                   | 11          |
| Deferred revenue  | 9,925                   | (62)        |
| Net cash used in operating activities                                       | (4,724)                 | (13,408)    |
| <b>Investing activities</b>   |                         |             |
| Purchases of equipment  | (73)                    | (192)       |
| Net cash used in investing activities                                       | (73)                    | (192)       |
| <b>Financing activities</b>   |                         |             |
| Proceeds from issuance of common stock and warrants, net                    | 10,371                  | 19,756      |
| Purchase of treasury stock  | (331)                   | (292)       |
| Proceeds from exercise of warrants  | 976                     | 938         |
| Net cash provided by financing activities                                   | 11,016                  | 20,402      |
| Increase in cash and cash equivalents                                       | 6,219                   | 6,802       |
| Cash and cash equivalents at beginning of the period                        | 26,127                  | 31,948      |
| Cash and cash equivalents at end of the period                              | \$ 32,346               | \$ 38,750   |

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

**Table of Contents**

**Athersys, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

Three- and Six-Month Periods Ended June 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.

**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 April 2015, FASB announced that the effective date of ASU 2014-09 will be 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.



**Table of Contents**

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 are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-15 will have on our disclosures.

**3. Net Loss per Share**

Basic and diluted net (loss) income 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) income and the number of shares used to calculate basic and diluted net (loss) income per share for the three and six month periods ended June 30, 2015 and 2014, in thousands.

|   | <b>Three months ended<br/>June 30,</b> |             | <b>Six months ended<br/>June 30,</b> |             |
|---|--|-------------|--------------------------------------|-------------|
|   | <b>2015</b>                            | <b>2014</b> | <b>2015</b>                          | <b>2014</b> |
| <b>Numerator:</b>   |  |             |                                      |             |
| Net (loss) income attributable to common stockholders                                     |  |             |                                      |             |
| - Basic   | <b>\$ (1,035)</b>                      | \$ 675      | <b>\$ (13,517)</b>                   | \$ (10,809) |
| Less: income from change in fair value of warrants  | <b>(3,074)</b>                         | (4,042)     |                                      | (1,344)     |
| Net loss attributable to common stockholders used to calculate diluted net loss per share | <b>\$ (4,109)</b>                      | \$ (3,367)  | <b>\$ (13,517)</b>                   | \$ (12,153) |
| <b>Denominator:</b>   |  |             |                                      |             |
| Weighted-average shares outstanding - Basic   | <b>82,844</b>                          | 77,077      | <b>81,022</b>                        | 76,469      |
| Potentially dilutive common shares outstanding:   |  |             |                                      |             |
| Warrants  | <b>718</b>                             | 1,472       |                                      | 1,938       |
| Stock-based awards  |  | 229         |                                      |             |
| Weighted-average shares used to calculate diluted net loss per share                      | <b>83,562</b>                          | 78,778      | <b>81,022</b>                        | 78,407      |
| Basic earnings per share  | <b>\$ (0.01)</b>                       | \$ 0.01     | <b>\$ (0.17)</b>                     | \$ (0.14)   |
| Dilutive earnings per share   | <b>\$ (0.05)</b>                       | \$ (0.04)   | <b>\$ (0.17)</b>                     | \$ (0.16)   |

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>Six months ended</b> |             |
|------------------------|---------------------------|-------------|-------------------------|-------------|
|                        | <b>June 30,</b>           |             | <b>June 30,</b>         |             |
|                        | <b>2015</b>               | <b>2014</b> | <b>2015</b>             | <b>2014</b> |
| Stock options          | <b>7,465,064</b>          | 6,075,165   | <b>7,465,064</b>        | 6,296,165   |
| Restricted stock units | <b>1,830,567</b>          | 7,578       | <b>1,830,567</b>        | 2,451,634   |
| Warrants               | <b>2,810,000</b>          | 6,310,000   | <b>4,864,893</b>        | 6,310,000   |
| Total                  | <b>12,105,631</b>         | 12,392,743  | <b>14,160,524</b>       | 15,057,799  |

**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 June 30, 2015 (in thousands):

| Description         | Fair Value Measurements at June 30, 2015 |  |   |   |
|---------------------|--|--|---|---|
|                     | Balance as of June 30, 2015              | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Observable Inputs (Level 2) | Other Significant Unobservable Inputs (Level 3) |
| Warrant liabilities | \$ 1,068                                 | \$   | \$                                      | \$ 1,068  |

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 June 30, 2015:

|  | Expected Volatility | Risk-Free Interest Rate | Expected Life     |
|--|---------------------|-------------------------|-------------------|
| Warrants with one year or less remaining term      | 69.46%              | 0.28%                   | 0.59 year         |
| Warrants with greater than one year remaining term | 67.33% - 76.72%     | 0.28% - 0.64%           | 1.04 - 1.71 years |



**Table of Contents**

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

|                              | <b>Three months<br/>ended<br/>June 30,<br/>2015</b> |                                | <b>Six months<br/>ended<br/>June 30, 2015</b> |
|------------------------------|---|--------------------------------|---|
| <b>Balance April 1, 2015</b> | <b>\$ 7,025</b>                                     | <b>Balance January 1, 2015</b> | <b>\$ 2,948</b>                               |
| Settlements from exercise    |   | Settlements from exercise      | (1,526)                                       |
| Income for the period        | (5,957)   | Income for the period          | (354)   |
| <b>Balance June 30, 2015</b> | <b>\$ 1,068</b>                                     | <b>Balance June 30, 2015</b>   | <b>\$ 1,068</b>                               |

**5. Collaborative Arrangements and Revenue Recognition***Chugai*

In February 2015, we entered into an exclusive license agreement (the Chugai Agreement) with Chugai Pharmaceutical Co., Ltd. (Chugai) to develop and commercialize MultiStem for the treatment of ischemic stroke in Japan. Chugai has the exclusive rights for the development, regulatory activities and commercialization of MultiStem for ischemic stroke in Japan and will pay us for supplying clinical and commercial product. Chugai will pay us royalties on net sales, starting in the low double digits and increasing incrementally to the high teens depending on net sales levels.

We received a non-refundable, up-front cash payment of \$10 million from Chugai, of which \$2.0 million was temporarily withheld by Japan taxing authorities. The withholdings are expected to be refunded to us in August 2015 and were recorded as a receivable at June 30, 2015. Under the terms of the Chugai Agreement, we may terminate the Chugai Agreement in the event that Chugai does not pay us a \$7 million milestone payment following its review of the interim results from our Phase 2 ischemic stroke study. In the event that Chugai does not make the \$7 million milestone payment within the required time and we terminate the Chugai Agreement, all rights would revert to us and we would retain the up-front \$10 million cash payment. Under the Chugai Agreement, the payment is due during the third quarter of 2015.

To determine the appropriate accounting for the Chugai Agreement, we evaluated its terms, considering our specific facts and circumstances, to assess the rights and obligations and determined that our obligations under the Chugai Agreement represent multiple deliverables. In the period prior to Chugai's decision to continue the collaboration and make the \$7 million payment to us, the deliverables include the license grant and access to our technology, and importantly, the interim results of our stroke Phase 2 clinical study. For deliverables with standalone value, our policy is to account for these as separate units of accounting. We allocate the overall consideration of the arrangement that is fixed and determinable, excluding consideration that is contingent upon future deliverables, to the separate units of accounting based on estimated selling prices (as defined in ASC 605-25) of each deliverable.

We considered the deliverables and concluded that the license grant, for example, did not have standalone value (as defined in ASC 605-25) at the inception of the arrangement. At the time, the Phase 2 ischemic stroke study results were not yet available to Chugai and, once available, Chugai has several months to review the results before making the \$7 million milestone payment required for it to retain its license. Thus, the effective use of the license by Chugai

would not take place until after Chugai makes the \$7 million payment to us. Accordingly, we have recorded the \$10 million up-front payment as deferred revenue at June 30, 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 ( IBD ) for the worldwide market on an exclusive basis. Under the terms of the agreement, we received a \$6 million non-refundable, up-front payment from Pfizer and research funding and support, totaling \$6.25 million, through June 2012. 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 effects. Taking these results into account, following an internal portfolio review, Pfizer determined that it would not invest further in this program targeting IBD, as would be required by the collaboration, and in May 2015, notified us of this decision and its intent 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 revert to us, and intellectual property generated through the collaboration will be owned by us. Pfizer will transfer to us all preclinical and clinical data relating to the program in its possession, all reports, records and other information relating to preclinical and clinical development, and ownership of all investigator brochures, regulatory filings and approvals related to the program. We will be free to use such information, data, filings and approvals for subsequent analyses and development in this area, and such research findings to support development in other areas, including immunology and inflammatory conditions.

## **Table of Contents**

### *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. 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.

## **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 June 30, 2015, a total of 2,143,332 shares of common stock have been issued under our equity incentive plans.

In the three-month period ended June 30, 2015, we granted 1,187,296 stock options and 455,776 restricted stock units to our employees and directors pursuant to our annual incentive programs. As of June 30, 2015, a total of 61,037 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 9,295,631 shares of common stock were outstanding. For the three-month periods ended June 30, 2015 and 2014, stock-based compensation expense was approximately \$705,000 and \$601,000, respectively. At June 30, 2015, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$5.8 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.

**Table of Contents**

In the second quarter of 2015, we sold 974,959 shares to Aspire Capital Fund, LLC ( Aspire Capital ) under our equity purchase agreement at an average price of \$2.84 per share, generating aggregate proceeds of \$2.8 million.

As of June 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>         |                       |                   |  |

In January 2015, we amended the warrants we issued in December 2013 to purchase 3,500,000 shares of common stock to increase the exercise price from \$2.50 to \$2.75 per share and to extend the expiration date from March 31, 2015 to May 31, 2015. Any outstanding warrants expired unexercised on May 31, 2015.

**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 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.

**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. In 2014, we recognized a refundable tax benefit related to research and development credits associated with our foreign subsidiary.

---

## **Table of Contents**

### **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® 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>395</sup>. 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).

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  $\geq 75\%$  and BI  $\geq 95$ . **Specifically, 41.9% of the MultiStem-treated patients achieved good or better recovery as measured using 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.

## Table of Contents

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.

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.

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 revert to us, and we will be free to use preclinical and clinical data for development in this area and in other areas, including immunology and inflammatory conditions.

## **Table of Contents**

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.

We 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.

### *Financial*

In February 2015, we entered into an exclusive license agreement with Chugai, or the Chugai Agreement, to develop and commercialize MultiStem for the treatment of ischemic stroke in Japan. Under the terms of the Chugai Agreement, we received a non-refundable up-front cash payment of \$10 million. We are also entitled to receive a potential near-term milestone payment of \$7 million for Chugai to retain its license following its review of the results of our Phase 2 clinical trial in ischemic stroke. We may also receive additional success-based development and regulatory milestones aggregating up to \$38 million, as well as potential sales milestones of up to 17.5 billion yen (approximately \$140 million based on the current exchange rate). We are also eligible for royalties on net sales, starting in the low double digits and increasing incrementally to the high teens depending on net sales levels. Additionally, we would receive payments for product supplied to Chugai.

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.

Under our equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, we sold 974,959 shares of common stock during the quarter ended June 30, 2015 at an average price of \$2.84 per share, generating aggregate proceeds of \$2.8 million.

---

**Table of Contents**

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 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 June 30, 2015 and 2014***

*Revenues.* Revenues decreased to \$0.2 million for the three months ended June 30, 2015 from \$0.4 million in the comparable period in 2014, reflecting a \$0.2 million decrease in our grant revenues. Revenue associated with our recent Chugai collaboration is deferred at June 30, 2015, until Chugai elects whether to make the \$7 million milestone payment required by the Chugai Agreement for it to retain its license. Our grant revenues 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 decreased to \$5.3 million for the three months ended June 30, 2015 from \$5.8 million in the comparable period in 2014. The \$0.5 million decrease is primarily comprised of reduced clinical and preclinical developments costs of \$0.4 million and reduced sponsored research costs of \$0.2 million, partially offset by a \$0.1 million increase in legal and professional fees. The decrease in our clinical and preclinical costs is primarily due to reduced product manufacturing and clinical study costs, partially offset by an increase in clinical consulting costs during the three-month periods. Sponsored research costs decreased primarily due to the timing of costs incurred by certain academic research institutions under our grant-funded programs. The increase in legal fees is due to the timing of certain patent legal expenses. 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 were relatively consistent at \$1.9 million for the three months ended June 30, 2015 and \$1.8 million in the comparable period in 2014.

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

---

**Table of Contents**

*Other Income, net.* Other income, net, of \$42,000 remained consistent during the three-month periods ended June 30, 2015 and 2014.

*Income from Change in Fair Value of Warrants, net.* Income of \$6.0 million was recognized during the three months ended June 30, 2015 for the market value change in our warrant liabilities, compared to income of \$7.9 million in the comparable period in 2014. The decrease is primarily due to changes in our stock price.

***Six Months Ended June 30, 2015 and 2014***

*Revenues.* Revenues decreased to \$0.9 million for the six months ended June 30, 2015 from \$1.1 million in the comparable period in 2014, reflecting, in part, a \$0.2 million decrease in our grant revenues. Revenue associated with our recent Chugai collaboration is deferred at June 30, 2015, until Chugai elects whether to make the \$7 million milestone payment required by the Chugai Agreement for it to retain its license. The decrease in grant revenues for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 was due to the timing of grant-related activities.

*Research and Development Expenses.* Research and development expenses decreased to \$10.9 million for the six months ended June 30, 2015 from \$12.0 million in the comparable period in 2014. The decrease of \$1.1 million related primarily to a decrease in clinical and preclinical costs of \$0.9 million, a decrease in sponsored research costs of \$0.4 million and a decrease in legal and professional fees of \$0.2 million. These decreases were partially offset by increases in stock-based compensation fees of \$0.2 million and license fees of \$0.2 million. The decrease in our clinical and preclinical costs is primarily due to reduced product manufacturing costs, central processing costs and clinical consulting costs. Sponsored research costs decreased primarily due to the timing of costs incurred by certain academic research institutions under our grant-funded programs. The decrease in legal fees resulted from decreased patent expenses associated with patent prosecution, national filings, interparty proceedings and related filings. Stock-based compensation increased primarily due to the layering effect of annual stock-based awards that are granted each June. 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.

*General and Administrative Expenses.* General and administrative expenses increased to \$3.8 million for the six months ended June 30, 2015 from \$3.6 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 stock based compensation of \$0.1 million compared to the same period in 2014.

*Depreciation.* Depreciation expense was \$0.1 million in the six-month period ended June 30, 2015 compared to \$0.2 million during the six-month period ended June 30, 2014, as a result of equipment becoming fully depreciated.

*Other Income, net.* Other income, net, was \$56,000 for the six-month period ended June 30, 2015 and \$71,000 for the comparable 2014 period, and was comprised of interest income and expense, foreign currency gains and losses, and tax credits.

*Income from Change in Fair Value of Warrants, net.* Income of \$0.4 million was recognized during the six months ended June 30, 2015 for the market value change in our warrant liabilities, compared to income of \$3.8 million in the comparable period in 2014. This decrease is primarily due to changes in our stock price and the exercise of warrants during the periods.





## Table of Contents

### **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities. At June 30, 2015, we had \$32.3 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 \$300 million at June 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 six-month period ended June 30, 2015, we generated proceeds aggregating \$10.4 million from sales of our common stock to Aspire Capital. In accordance with the equity purchase agreement, we could elect to sell to Aspire Capital up to an additional \$13.2 million of shares of common stock.

During the six months ended June 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.

Pursuant to the Chugai Agreement, we received an up-front cash payment of \$10 million. Chugai is required to pay us a \$7 million milestone payment to retain its license after its several month review period of the interim results from our Phase 2 ischemic stroke study. In the event that Chugai does not make the \$7 million payment, which is due in the third quarter of 2015 under the Chugai Agreement, we can terminate the Chugai Agreement and all rights would revert to us and we would retain the up-front \$10 million cash payment. We may also receive additional success-based development and regulatory milestones aggregating up to \$38 million, as well as potential sales milestones of up to 17.5 billion yen (approximately \$140 million based on the current exchange rate). We are also eligible for royalties on net sales, starting in the low double digits and increasing incrementally to the high teens depending on net sales levels. Additionally, we would receive payments for product supplied to Chugai.

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 June 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.



## **Table of Contents**

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. As of June 30, 2015, we had drawn \$166,000 of this financing (\$187,000 including accrued interest), which is recorded as a current liability at June 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 June 30, 2015, we had available cash and cash equivalents of \$32.3 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 raise capital from time to time through the equity purchase agreement with Aspire Capital, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and 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.

## **Table of Contents**

### *Cash Flow Analysis*

Net cash used in operating activities was \$4.7 million for the six months ended June 30, 2015 and \$13.4 million for the six months ended June 30, 2014, representing the use of cash in funding preclinical and clinical development activities being partially offset by the \$8.0 million of cash received from Chugai (\$10 million up-front payment less the \$2 million that was temporarily withheld by Japanese taxing authorities). 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 \$0.2 million for the six months ended June 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 six months ended June 30, 2015 related to equity sales to Aspire Capital and the exercise of common stock warrants. Financing activities provided cash of \$20.4 million for the six months ended June 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 June 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 June 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.

### **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.

**Table of Contents**

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;

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, including Chugai's decision to retain its license under the Chugai Agreement by making the \$7 million milestone payment;

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.

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.



**Table of Contents**

**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 June 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 June 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 second 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.

**PART II. OTHER INFORMATION**

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

During the quarter ended June 30, 2015, we sold an aggregate of 974,959 shares of common stock to Aspire Capital at an average purchase price of \$2.84 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.



**Table of Contents****Item 5. Other Information.**

On July 31, 2015, Dr. Robert Deans notified us that he was resigning as the Company's Executive Vice President of Regenerative Medicine, effective August 31, 2015, to focus on earlier stage technology development opportunities. Dr. Deans will become an advisor to us upon his departure under a consulting agreement, whereby he will be paid \$25,000 annually for one year, renewable upon mutual agreement. Furthermore, in connection with Dr. Deans' resignation, the Board of Directors, upon recommendation of the Compensation Committee and management, has agreed to amend Dr. Deans' existing stock option awards to extend the exercise period for his vested awards from three months to twelve months immediately following the date he terminates employment with us as an employee.

**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   |

Table of Contents

**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: August 6, 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)

---

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

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