

ATHERSYS, INC / NEW  
Form 10-Q  
May 06, 2016  
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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, 2016

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 May 2, 2016 was 84,364,555.

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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/>2016</b> | <b>December 31,<br/>2015</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------------------|
| <b>Assets</b>                                                                                                                                                                                                                                                             |                           |                              |
| Current assets:                                                                                                                                                                                                                                                           |                           |                              |
| Cash and cash equivalents                                                                                                                                                                                                                                                 | \$ 30,414                 | \$ 23,027                    |
| Accounts receivables                                                                                                                                                                                                                                                      | 706                       | 361                          |
| Prepaid expenses and other                                                                                                                                                                                                                                                | 426                       | 429                          |
| Total current assets                                                                                                                                                                                                                                                      | 31,546                    | 23,817                       |
| Equipment, net                                                                                                                                                                                                                                                            | 1,253                     | 1,135                        |
| Deferred tax assets                                                                                                                                                                                                                                                       | 184                       | 177                          |
| Total assets                                                                                                                                                                                                                                                              | \$ 32,983                 | \$ 25,129                    |
| <b>Liabilities and stockholders' equity</b>                                                                                                                                                                                                                               |                           |                              |
| Current liabilities:                                                                                                                                                                                                                                                      |                           |                              |
| Accounts payable                                                                                                                                                                                                                                                          | \$ 3,274                  | \$ 2,702                     |
| Accrued compensation and related benefits                                                                                                                                                                                                                                 | 515                       | 1,024                        |
| Accrued clinical trial costs                                                                                                                                                                                                                                              | 443                       | 82                           |
| Accrued expenses                                                                                                                                                                                                                                                          | 489                       | 513                          |
| Deferred revenue                                                                                                                                                                                                                                                          |                           | 245                          |
| Note payable                                                                                                                                                                                                                                                              |                           | 190                          |
| Total current liabilities                                                                                                                                                                                                                                                 | 4,721                     | 4,756                        |
| Warrant liabilities                                                                                                                                                                                                                                                       | 2,830                     | 649                          |
| Stockholders' equity:                                                                                                                                                                                                                                                     |                           |                              |
| Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2016 and December 31, 2015                                                                                                                              |                           |                              |
| Common stock, \$0.001 par value; 150,000,000 shares authorized, and 84,114,555 and 83,720,154 shares issued at March 31, 2016 and December 31, 2015, respectively, and 84,090,729 and 83,720,154 shares outstanding at March 31, 2016 and December 31, 2015, respectively | 84                        | 84                           |
| Additional paid-in capital                                                                                                                                                                                                                                                | 323,540                   | 322,582                      |

|                                            |           |           |
|--------------------------------------------|-----------|-----------|
| Accumulated deficit                        | (298,192) | (302,942) |
| Total stockholders' equity                 | 25,432    | 19,724    |
| Total liabilities and stockholders' equity | \$ 32,983 | \$ 25,129 |

*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)

|                                                          | <b>Three months ended</b> |                    |
|----------------------------------------------------------|---------------------------|--------------------|
|                                                          | <b>March 31,</b>          |                    |
|                                                          | <b>2016</b>               | <b>2015</b>        |
| <b>Revenues</b>                                          |                           |                    |
| Contract revenue                                         | \$ 15,124                 | \$ 106             |
| Grant revenue                                            | 334                       | 625                |
| Total revenues                                           | 15,458                    | 731                |
| <b>Costs and expenses</b>                                |                           |                    |
| Research and development                                 | 6,664                     | 5,668              |
| General and administrative                               | 2,014                     | 1,886              |
| Depreciation                                             | 68                        | 70                 |
| Total costs and expenses                                 | 8,746                     | 7,624              |
| Income (loss) from operations                            | 6,712                     | (6,893)            |
| Expense from change in fair value of warrants, net       | (2,181)                   | (5,604)            |
| Other income, net                                        | 210                       | 15                 |
| <b>Income (loss) before income taxes</b>                 | <b>4,741</b>              | <b>(12,482)</b>    |
| Income tax benefit                                       | 9                         |                    |
| <b>Net income (loss) and comprehensive income (loss)</b> | <b>\$ 4,750</b>           | <b>\$ (12,482)</b> |
| Net income (loss) per share - Basic and Diluted          | \$ 0.06                   | \$ (0.16)          |
| Weighted average shares outstanding - Basic              | 83,781,114                | 79,180,697         |
| Weighted average shares outstanding - Diluted            | 83,865,607                | 79,180,697         |

*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>2016</b>               | <b>2015</b> |
| <b>Operating activities</b>                                                              |                           |             |
| Net income (loss)                                                                        | \$ 4,750                  | \$ (12,482) |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: |                           |             |
| Depreciation                                                                             | 68                        | 70          |
| Income from forgiveness of note payable                                                  | (190)                     |             |
| Stock-based compensation                                                                 | 707                       | 751         |
| Change in fair value of warrant liabilities and other                                    | 2,174                     | 5,605       |
| Changes in operating assets and liabilities:                                             |                           |             |
| Accounts receivable                                                                      | (345)                     | (2,143)     |
| Prepaid expenses and other assets                                                        | 3                         | 41          |
| Accounts payable and accrued expenses                                                    | 400                       | (678)       |
| Deferred revenue                                                                         | (245)                     | 9,952       |
| Net cash provided by operating activities                                                | 7,322                     | 1,116       |
| <b>Investing activities</b>                                                              |                           |             |
| Purchases of equipment                                                                   | (186)                     | (63)        |
| Net cash used in investing activities                                                    | (186)                     | (63)        |
| <b>Financing activities</b>                                                              |                           |             |
| Proceeds from issuance of common stock, net                                              | 424                       | 7,606       |
| Purchase of treasury stock                                                               | (173)                     | (257)       |
| Proceeds from exercise of warrants                                                       |                           | 976         |
| Net cash provided by financing activities                                                | 251                       | 8,325       |
| Increase in cash and cash equivalents                                                    | 7,387                     | 9,378       |
| Cash and cash equivalents at beginning of the period                                     | 23,027                    | 26,127      |
| Cash and cash equivalents at end of the period                                           | \$ 30,414                 | \$ 35,505   |

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



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**Athersys, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

Three-Month Periods Ended March 31, 2016 and 2015

**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, 2015. 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 November 2015, the Financial Accounting Standards Board ( FASB ) issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which amends the existing guidance to require that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet and eliminates the prior guidance, which required an entity to separate deferred tax liabilities and assets into a current amount and a noncurrent amount in a classified balance sheet. The amendments in this ASU are effective for financial statements for annual periods and interim periods within those annual periods beginning after December 15, 2016, with early adoption permitted, and the new guidance can be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We have adopted this ASU in the first quarter of 2016 on a prospective basis and, therefore, the adoption did not impact prior period financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU 2014-09 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, the amendment provides five steps that an entity should apply when recognizing revenue. The amendment also specifies the accounting of some costs to obtain or fulfill a contract with a customer and expands the disclosure requirements around contracts with customers. An entity can either adopt this amendment retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the update recognized at the date of initial application. In August 2015, the FASB issued ASU 2015-14, which delays the effective date by one year, making the new standard effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted

for annual reporting periods beginning after December 15, 2016. We are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to put most leases on their balance sheets, but recognize expenses on their income statements in a manner similar to current accounting practice. Under the guidance, lessees initially recognize a lease liability for the obligation to make lease payments and a right-of-use (ROU) asset for the right to use the underlying asset for the lease term. The lease liability is measured at the present value of the lease payments over the lease term. The ROU asset is measured at the lease liability amount, adjusted for lease prepayments, lease incentives received and the lessee's initial direct costs. The guidance is effective for the annual periods beginning after December 15, 2018 and interim periods thereafter, with early adoption permitted. We are in the process of evaluating the impact the new guidance will have on our financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Under the new standard, income tax benefits and deficiencies are to be recognized as income tax expense or benefit in the income statement and the tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity should also recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Excess tax benefits should be classified along with other income tax cash flows as an operating activity. In regards to forfeitures, the entity may make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. This ASU is effective for fiscal years beginning after December 15, 2016 including interim periods within that reporting period, with early adoption permitted, provided that all amendments are adopted in the same period. We are currently evaluating the impact the adoption of ASU 2016-09 will have on its financial statements.

**3. Net Income (Loss) per Share**

Basic and diluted net income (loss) per share have been computed using the weighted-average number of shares of common stock outstanding during the period. The table below reconciles the net income (loss) and the number of shares used to calculate basic and diluted net income (loss) per share for the three-month periods ended March 31, 2016 and 2015, in thousands, except share and per share data.

|                                                                           | Three months ended<br>March 31, |             |
|---------------------------------------------------------------------------|---------------------------------|-------------|
|                                                                           | 2016                            | 2015        |
| <b>Numerator:</b>                                                         |                                 |             |
| Net income (loss) attributable to common stockholders - Basic and Diluted | \$ 4,750                        | \$ (12,482) |

|                                                                               |                   |            |
|-------------------------------------------------------------------------------|-------------------|------------|
| <b>Denominator:</b>                                                           |                   |            |
| Weighted-average shares outstanding - Basic                                   | <b>83,781,114</b> | 79,180,697 |
| Potentially dilutive common shares outstanding:                               |                   |            |
| Stock-based awards                                                            | <b>84,493</b>     |            |
| Weighted-average shares used to calculate diluted net income (loss) per share | <b>83,865,607</b> | 79,180,697 |
| Basic and Diluted earnings (loss) per share                                   | \$ <b>0.06</b>    | \$ (0.16)  |

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We have outstanding stock-based awards and warrants that are not used in the calculation of diluted net income (loss) per share because to do so would be antidilutive. The following instruments were excluded from the calculation of diluted net income (loss) per share because their effects would be antidilutive:

|                    | <b>Three months ended<br/>March 31,</b> |             |
|--------------------|-----------------------------------------|-------------|
|                    | <b>2016</b>                             | <b>2015</b> |
| Stock-based awards | <b>7,593,940</b>                        | 8,014,773   |
| Warrants           | <b>3,554,893</b>                        | 8,364,893   |
| <b>Total</b>       | <b>11,148,833</b>                       | 16,379,666  |

**4. 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, 2016 (in thousands):

| <b>Fair Value Measurements at March 31, 2016<br/>Using</b> |                                         |                                                                                           |    |                                                      |
|------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------------------|----|------------------------------------------------------|
| <b>Description</b>                                         | <b>Balance as of<br/>March 31, 2016</b> | <b>Quoted Prices in Active<br/>Markets<br/>for<br/>Identical<br/>Assets<br/>(Level 1)</b> |    |                                                      |
|                                                            |                                         | <b>Significant Other<br/>Observable Inputs (Level 2)</b>                                  |    | <b>Significant Unobservable<br/>Inputs (Level 3)</b> |
| Warrant liabilities                                        | \$ 2,830                                | \$                                                                                        | \$ | \$ 2,830                                             |

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.



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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. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. The following inputs were used at March 31, 2016:

|                                               | Expected Volatility |        | Risk-Free Interest Rate |       | Expected Life |           |
|-----------------------------------------------|---------------------|--------|-------------------------|-------|---------------|-----------|
| Warrants with one year or less remaining term | 78.58%              | 95.67% | 0.21%                   | 0.59% | 0.29          | 0.95 year |

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

|                                                                | Three months ended<br>March 31, 2016 |
|----------------------------------------------------------------|--------------------------------------|
| Balance January 1, 2016                                        | \$ 649                               |
| Loss included in expense from change in fair value of warrants | 2,181                                |
| Balance March 31, 2016                                         | \$ 2,830                             |

**Financing Arrangement**

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we received \$166,000 in the form of a forgivable loan to fund certain preclinical work. Interest on the loan accrued at a fixed rate of 4.25% per annum and was added to the outstanding principal, and the loan carried an expiration date of March 31, 2016. In January 2016, the \$190,000 loan (including accrued interest) was forgiven according to its terms based on the achievement of certain milestones and the forgiveness was recognized as other income in the consolidated statement of operations and comprehensive income (loss).

**5. Collaborations and Revenue Recognition****Healios**

On January 8, 2016, we entered into a license agreement ( *Healios Agreement* ) with Healios K.K. ( *Healios* ) to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to Athersys proprietary MAPC technology for use in Healios organ bud program, initially for transplantation to treat liver disease or dysfunction. Under the Healios Agreement, Healios also obtained a right, at their option, to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include acute respiratory distress syndrome ( *ARDS* ) and another indication in the orthopedic area, and to include all indications for the organ bud program. Healios will develop and commercialize the MultiStem product in Japan, and we will provide the manufactured product to Healios.

Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of \$15 million from Healios, the majority of which was received in January 2016. If Healios exercises their option to expand the collaboration, we will be entitled to receive a cash payment of \$10 million. Healios may exercise its option to expand the collaboration prior to certain milestone dates that are expected to occur within the next two years.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones aggregating up to \$225 million. Such amounts are non-refundable and non-creditable towards future royalties or any other payment due from Healios. We will also receive tiered royalties on net product sales, starting in the low double-digits and increasing incrementally into the high teens, depending on net sales levels. Additionally, we will receive payments for product supplied to Healios for ischemic stroke.

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If Healios exercises the option to expand the collaboration to include ARDS and another indication in the orthopedic area, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, as well as payments for product supply related to the additional indications covered by the option.

For the organ bud product, we are entitled to receive a fractional royalty percentage on net sales of the organ bud products and will receive payments for manufactured product supplied to Healios under a manufacturing supply agreement. Additionally, we have a right of first negotiation for commercialization of an organ bud product in North America, with such right expiring on the later of (i) the date five years from the effective date of the Healios Agreement and (ii) 30 days after authorization to initiate clinical studies on an organ bud product under the first investigational new drug application or equivalent in Japan, North America or the European Union.

The Healios Agreement will expire automatically when there are no remaining intellectual property rights subject to the license. Additionally, Healios may terminate the Healios Agreement under certain circumstances, including for material breach and without cause upon advance written notice. We may terminate the Healios Agreement if there is an uncured material breach of the agreement by Healios. In the event that Healios does not move the program forward, the development and commercialization rights would revert to us.

To determine the appropriate accounting for the license agreement, we evaluated the Healios Agreement and related facts and circumstances, focusing in particular on the rights and obligations of the arrangement. We have determined that our obligations under the Healios Agreement represent multiple deliverables. 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.

Given Healios' ability to sublicense under the Healios Agreement and its ability to conduct the ongoing development efforts, we concluded that the license had stand-alone value at the inception of the arrangement and would be treated as a separate unit of accounting, noting that there was no general right of return associated with the license. Further, the preclinical and clinical manufacturing services and certain near-term regulatory advisory services that will be provided to Healios under the Healios Agreement had been determined to have stand-alone value and considered separate units of accounting.

We were unable to establish vendor-specific objective evidence of selling price or third-party evidence for either the license or the services, and thus, instead, allocated the arrangement consideration between the license and the services based on their relative selling prices using best estimate of selling price (BESP). We developed the BESP of the license using a probability weighted, discounted cash flow analysis using the income approach, taking into consideration market assumptions including the estimated development and commercialization timeline, data regarding patient population, discount rate related to our industry, and probability of success using market data for both our industry and therapeutic field. We estimated the BESP of the manufacturing services and certain near-term regulatory advisory services using actual historical experience and best estimates of the cost of obtaining these services at arm's length from a third-party provider, including an estimated mark-up. As a result of this analysis, we allocated \$15 million to the license, which represents the amount of consideration that is allocable pursuant to the relative selling price and is not contingent upon delivery of additional items under the Healios Agreement. The license was delivered and recognized as revenue in January 2016.

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Other contingent deliverables that were not accounted for at the inception of the arrangement, and will not be accounted for until the contingency is resolved, included the potential expansion of the collaboration to include additional indications, and the milestones that are not substantive since they are dependent on the activities of Healios. Further, the arrangement contemplates our providing manufacturing services for commercial product supply, the terms of which are not defined and are to be agreed upon in the future under a separate supply agreement.

Upon the removal of the contingencies associated with each of the potential contingent deliverables, including the expansion fee, milestone payments and / or commercial product supply, we will reevaluate the overall arrangement, including the estimated selling prices and the allocation of the overall consideration of the arrangement.

*Chugai*

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

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

*RTI Surgical, Inc.*

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

**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 March 31, 2016, a total of 2,983,302 shares of common stock have been issued under our equity incentive plans.



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As of March 31, 2016, a total of 339,111 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 8,177,587 shares of common stock were outstanding. For the three-month periods ended March 31, 2016 and 2015, stock-based compensation expense was approximately \$707,000 and \$751,000, respectively. At March 31, 2016, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$3.5 million, which is expected to be recognized by the end of 2020 using the straight-line method.

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

In November 2011, we entered into an equity purchase agreement with Aspire Capital Fund, LLC ( *Aspire Capital* ), which provided that Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. As of September 2013, we had sold all the remaining shares that were available under the equity facility, which was due to expire. In October 2013, we terminated the expiring 2011 equity purchase agreement and entered into a new 2013 equity purchase agreement with Aspire Capital to purchase up to an aggregate of \$25.0 million of shares of our common stock over a new two-year period. The terms of the 2013 equity facility were similar to the previous arrangement. Upon the 2013 equity facility's expiration, in December 2015, we entered into a new 2015 equity purchase agreement with Aspire Capital to purchase up to an aggregate of \$30.0 million of shares of our common stock over a new three-year period. The terms of the 2015 equity facility are similar to the previous arrangements, and we issued 250,000 shares of our common stock to Aspire Capital as a commitment fee in December 2015, which are accounted for as a cost of the offering, and filed a registration statement for the resale of 16,600,000 shares of common stock in connection with the new equity facility.

In the first quarter of 2016, we sold 200,000 shares to Aspire Capital Fund, LLC ( *Aspire Capital* ) under our equity purchase agreement at an average price of \$2.14 per share, generating aggregate proceeds of \$0.4 million.

*Warrants*

As of March 31, 2016, we had the following outstanding warrants to purchase shares of common stock:

**Number of**

| <b>Underlying Shares</b> | <b>Exercise Price</b> | <b>Expiration</b> |
|--------------------------|-----------------------|-------------------|
| 2,054,893                | \$ 1.01               | March 14, 2017    |
| 1,500,000                | \$ 4.50               | July 15, 2016     |

**3,554,893**

No warrants were exercised during the three months ended March 31, 2016.

**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 we issued in the March 2012 private placement 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).

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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.

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 net operating loss and research and development tax credit carryforwards, as well as state and city net operating loss carryforwards, which may be used to reduce future taxable income and tax liabilities. We also have foreign net operating loss and tax credit carryforwards, and the foreign net operating losses do not expire. Substantially all of our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

As a result of our October 2012 equity offering, the utilization of our net operating loss and tax credit carryforwards generated prior to October 2012 is substantially limited under Section 382 of the Internal Revenue Code. U.S. federal net operating loss carryforwards, research and development tax credits, and state and local net operating loss carryforwards generated after October 2012, as well as foreign net operating loss carryforwards and foreign tax credits, are not subject to annual limitations. We recognize refundable tax benefits related to research and development credits associated with our foreign subsidiary.

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

This discussion and analysis should be read in conjunction with our unaudited financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015. 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 is currently being evaluated in multiple 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 completed our Phase 2 study of MultiStem treatment of subjects suffering a moderate to severe ischemic stroke. In April 2015, we announced the interim results from the clinical study, and in February 2016, we announced the one-year follow-up data from the study. Our double blind, placebo-controlled, randomized trial was conducted at 33 leading stroke centers across the United States and the United Kingdom, or UK. In the study, we treated 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 of patients receiving such treatment to less than 10% of ischemic stroke patients. Patients were assessed at 90 days and one-year 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 scale from 0 to 6, with a score of 0 reflecting no patient disability and 6 indicating death), assessing overall disability; the NIH Stroke Scale, or NIHSS, which assesses neurological and motor skill deficit (a scale from 0 to 42, with a score of 0 reflecting no disability, and 42 reflecting maximum disability in every category) 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 tolerability and safety 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, meaning complete or nearly full recovery, 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 ≥95. Achievement of an Excellent Outcome is important because it means that a patient has substantially improved in each of the three clinical rating scales used to assess patient improvement and has regained the ability to live and function independently with a high quality of life. Among

all subjects who received MultiStem treatment, 15.4% of patients achieved an Excellent Outcome, compared to 6.6% of patients who received placebo ( $p=0.10$ ). Importantly, by one year, there was a significant difference between the groups with 23.1% of MultiStem subjects having an Excellent Outcome compared to 8.2% of placebo subjects ( $p=0.02$ ).

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In addition, analyses show that patients who received MultiStem treatment earlier (24 to 36 hours post-stroke) in the study's treatment window had better recovery in comparison to placebo. For example, at 90 days post-stroke, patients who were treated with MultiStem within 24 to 36 hours of the stroke (i.e. consistent with our original study design) had much better outcomes compared to placebo patients as measured by recovery in each of the key secondary endpoints: mRS  $\leq 2$ , NIHSS  $\leq 7$  <sup>375%</sup> and BI <sup>395%</sup>. Specifically, 41.9% of the MultiStem-treated patients achieved good or excellent recovery in all three clinical scales, compared to only 24.6% of all patients receiving placebo, a difference of 17.3% ( $p = 0.08$ ). Additionally, MultiStem subjects had a significantly lower rate of secondary infections than placebo subjects (16.1% v. 47.5%,  $p < 0.01$ ) and of average initial hospital days (6.8 v. 9.8,  $p = 0.02$ ). At one year, such early-treated MultiStem patients had a significantly higher rate of Excellent Outcome than all placebo subjects (29.0% v. 8.2%,  $p < 0.01$ ).

Furthermore, we evaluated the recovery at 90 days of patients who received treatment with MultiStem within 24 to 36 hours post stroke versus all 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, patients in 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 patients in 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. One-year follow-up data demonstrates that MultiStem-treated subjects, on average, continued to improve relative to placebo with significant differences in Excellent Outcome (29.6% v. 5.8%,  $p < 0.01$ ), the shift analysis ( $p = 0.04$ ) and Barthel Index (67.7% v. 38.5%,  $p = 0.02$ ).

Analysis of biomarker data obtained from samples of study subjects indicated that MultiStem treatment reduces post-stroke inflammation compared to placebo, and it appears that this effect is more pronounced for subjects receiving MultiStem within 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.

If the MultiStem therapy is proven effective in a registrational study, this would represent a substantial increase in the time window for treatment for ischemic stroke victims, which currently is limited to several hours. Further analyses are being undertaken, and we are actively preparing for the next stage of clinical development of this program and are engaged in discussions with the Pharmaceuticals and Medical Devices Agency in Japan in conjunction with our development partner Healios, as well as with the U.S. Food and Drug Administration, or FDA, and other regulators.

**Acute Myocardial Infarction:** We recently initiated a Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered an acute myocardial infarction, or AMI. We previously evaluated the administration of MultiStem to patients that suffered an 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 in funding to support the advancement of this clinical program, and we are currently enrolling patients in our Phase 2 clinical study, 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.

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Acute Respiratory Distress Syndrome: We have also initiated a clinical study for the treatment of acute respiratory distress syndrome, or ARDS, in the UK and in the United States. In 2015, we were awarded a grant from Innovate UK for up to approximately £2.0 million in support of a Phase 2a clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. 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 Phase 2a clinical trial is currently enrolling patients.

Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase 1 clinical study of the administration of MultiStem cell therapy 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 cells that trigger an attack against various tissues and organs in the patient. Data from the study demonstrated the safety of MultiStem cell therapy in this indication and suggested that the treatment may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. We were granted orphan drug designation by the FDA and the European Medicines Agency, or EMA, for MultiStem treatment in the prevention of GvHD. In February 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, in December 2015, the proposed registration study received Special Protocol Assessment designation from the FDA, meaning that the trial is adequately designed to support a biologics license application, or BLA, submission for registration if it is successful. 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, or UC, the most common form of inflammatory bowel disease, or IBD, which was conducted by a collaborative partner, Pfizer Inc. Overall, the study results released in 2014 were disappointing, in 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 has an 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 and following an internal portfolio review of its IBD programs, Pfizer determined that it would not invest further in this program as required by the collaboration and notified us of its decision to terminate the license agreement effective in the third quarter of 2015. In connection with the termination, all rights to the program reverted to us, and we are free to use preclinical and clinical data for development in this area and in other areas, including immunology and inflammatory conditions.



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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 actively engaged in multiple process development initiatives intended to enable increased manufacturing scale, reduce production costs, and enhance process controls and product quality, among other things. These initiatives and investment are meant to improve our ability to meet potential commercial demand in the event of eventual regulatory approval.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem therapy in other neurological, cardiovascular and inflammatory and immune disease areas, as well as certain other indications. We conduct such work both through our own internal research efforts and through a broad global network of collaborators. We are routinely in discussions with third parties about collaborating in the development of MultiStem therapy for various programs and may enter into one or more business partnerships to advance these programs over time.

In January 2016, we entered into a license agreement with Healios K.K., or Healios, to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to our proprietary MAPC, for use in Healios proprietary organ bud program, initially for transplantation to treat liver disease or dysfunction. Under the agreement, Healios also obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include ARDS and another indication in the orthopedic area, as well as all indications for the organ bud program. Healios will develop and commercialize the MultiStem product in Japan, and we will provide the manufactured product to Healios.

We had entered into a similar arrangement with Chugai Pharmaceuticals Co., Ltd., or Chugai, early in 2015 for the development and commercialization of MultiStem therapy for stroke in Japan, but we terminated the license agreement in October 2015 when the parties were unable to reach an agreement on a potential modification of the financial terms of the agreement and on the development strategy in Japan as proposed by Chugai following the initial results from our Phase 2 clinical study.

We also have a collaboration with RTI Surgical, Inc., or RTI, for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, we have been earning royalty revenue from product sales since 2014 and may receive other payments upon the successful achievement of certain commercial milestones.

## *Financial*

In connection with our January 2016 license agreement with Healios, we received an up-front cash payment of \$15 million from Healios, and the collaboration can be expanded at Healios election. If Healios expands the collaboration, we will be entitled to receive an additional cash payment of \$10 million. Healios may exercise its option to expand the collaboration prior to certain milestone dates that are expected to occur within the next two years.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones aggregating up to \$225 million. We will also receive tiered royalties on net product sales, starting in the low double digits and increasing incrementally into the high teens, depending on net sales levels. Additionally, we will receive payments for product supplied to Healios under a manufacturing supply agreement.

If Healios exercises the option to expand the collaboration to include ARDS and another indication in the orthopedic area, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, and payments for product supply for the additional indications, as well as a fractional royalty percentage on net sales of the organ bud products.

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In October 2015, we and Chugai agreed to terminate our 2015 license agreement as a result of an inability to reach an agreement on the modification of the financial terms of the agreement and on the development strategy of our MultiStem cell therapy for the treatment of ischemic stroke in Japan. We retained the \$10 million up-front cash payment from Chugai that we received in 2015, which was recognized in full in October 2015 in connection with the termination of the collaboration. We regained all rights for developing its stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other.

We have in place an equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, which provides us the ability to sell shares to Aspire Capital from time-to-time, as appropriate. Under our facility that was renewed in December 2015, we can elect to sell to Aspire Capital up to an additional \$30 million of shares of common stock under the agreement. During the quarter ended March 31, 2016, 200,000 shares were sold under the Aspire equity purchase agreement at an average price of \$2.14.

In February 2015, we were awarded a grant from Innovate UK in support of 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 March 31, 2016 and 2015***

**Revenues.** Revenues increased to \$15.5 million for the three months ended March 31, 2016 from \$731,000 in the comparable period in 2015. We received an upfront license fee from our Healios collaboration, which resulted in the recognition of \$15.0 million of contract revenue during the quarter ended March 31, 2016. 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 \$6.7 million for the three months ended March 31, 2016 from \$5.7 million for the comparable period in 2015. The \$1.0 million increase is primarily associated with increased clinical and preclinical development costs of \$858,000, increased legal and professional fees of \$173,000 and an increase in research supplies of \$154,000. These increases were partially offset by a decrease in sponsored research costs of \$75,000 and a decrease in stock-based compensation of \$83,000. The increase in our clinical and preclinical costs is primarily due to increased product manufacturing costs and increased

clinical trial costs during the three-month period. The increase in legal fees resulted from additional expenses associated with patent prosecution, national filings, and interparty proceedings and related filings.

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The increase in research supplies was due to an increase in internal process development activities. We expect our research and development expenses to increase in 2016 as compared to 2015 related to our clinical and process development activities. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

*General and Administrative Expenses.* General and administrative expenses were relatively consistent at \$2.0 million for the three months ended March 31, 2016 and \$1.9 million in the comparable period in 2015. We expect our general and administrative expenses to remain relatively consistent in 2016 as compared to 2015.

*Depreciation.* Depreciation expense was relatively consistent at \$68,000 for the three months ended March 31, 2016 and \$70,000 in the comparable period in 2015. We expect our depreciation to increase in 2016 as compared to 2015 related to planned equipment purchases for our process development activities.

*Expense from Change in Fair Value of Warrants.* Expense of \$2.2 million was recognized during the three months ended March 31, 2016 for the market value change in our warrant liabilities, compared to \$5.6 million in the comparable period in 2015, reflecting primarily changes in our stock price.

*Other Income, net.* Other income, net, generally includes net foreign currency gains and losses, and net interest income and expense. However, in the three-month period ended March 31, 2016, we recognized other income of \$190,000 from a loan (including interest) that was forgiven.

*Income Tax Benefit.* The income tax benefit in 2016 represents refundable foreign tax credits.

## **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities. At March 31, 2016, we had \$30.4 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 incurred losses since inception of operations in 1995 and had an accumulated deficit of \$298 million at March 31, 2016. 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 \$30.0 million of shares of our common stock over a three-year period ending in January 2019, 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 three-month period ended March 31, 2016, we generated net proceeds aggregating \$424,000 from sales of our common stock to Aspire Capital at an average price per share of \$2.14.

In connection with our January 2016 license agreement with Healios, we received an up-front cash payment of \$15 million from Healios, and the collaboration can be expanded at Healios' election. If Healios expands the collaboration, we will be entitled to receive an additional cash payment of \$10 million.

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Healios may exercise its option to expand the collaboration prior to certain milestone dates that are expected to occur within the next two years. For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones aggregating up to \$225 million. We will also receive tiered royalties on net product sales, starting in the low double digits and increasing incrementally into the high teens, depending on net sales levels. Additionally, we will receive payments for product supplied to Healios under a manufacturing supply agreement.

If Healios exercises the option to expand to collaboration, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, and payments for product supply for the additional indications, as well as a fractional royalty percentage on net sales of the organ bud products.

In connection with our license agreement with Chugai that was terminated in October 2015, we received an up-front cash payment of \$10 million in 2015 and were entitled to receive a potential near-term payment of \$7 million tied to the results of our ongoing Phase 2 clinical trial in ischemic stroke. We terminated the license agreement when the parties were unable to reach an agreement on the potential modification of the financial terms of the agreement and on the development strategy in Japan. We retained the \$10 million up-front cash payment from Chugai and regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other.

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 March 31, 2016. 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 are obligated to pay the University of Minnesota a sublicense fee or 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. As of March 31, 2016, we have paid no royalties to the University of Minnesota and have paid sublicense fees from time-to-time in connection with our collaborations.

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we were entitled to proceeds of up to \$500,000 in the form of a forgivable loan to fund certain preclinical work. Interest on the loan accrued at a fixed rate of 4.25% per annum and was added to the outstanding principal, and the loan carried an expiration date of March 31, 2016. In January 2016, the loan and accrued interest, which amounted to approximately \$190,000 at January 28, 2016, was forgiven according to its terms based on the achievement of certain milestones.

In 2015, we were awarded a grant from Innovate UK in support of 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 \$2.9 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 March 31, 2016, we had available cash and cash equivalents of \$30.4 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, achievement of milestones under our collaborations, and grant-funding opportunities.

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Additionally, we may raise capital from time to time through our 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.

### *Cash Flow Analysis*

Net cash provided by operating activities was \$7.3 million for the three months ended March 31, 2016, and \$1.1 million for the three months ended March 31, 2015, reflecting the \$14.8 million of cash received from Healios in January 2016 (noting that \$245,000 was received from Healios in December 2015 in connection with a letter of intent) and the \$10 million of cash received from Chugai in the first quarter of 2015, and the use of cash in funding preclinical and clinical development activities. 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. We expect the cash use for operating activities to increase in 2016 as compared to 2015 due to our planned clinical and process development activities.

Net cash used by investing activities was \$186,000 and \$63,000 for the three months ended March 31, 2016 and 2015, respectively, representing purchases of equipment supporting our operations. We expect our 2016 annual capital equipment expenditures to be higher than 2015 in support of our manufacturing process development activities.

Financing activities provided cash of \$251,000 for the three months ended March 31, 2016 related primarily to equity sales to Aspire Capital. Financing activities provided cash of \$8.3 million for the three months ended March 31, 2015 related primarily to equity sales to Aspire Capital and the exercise of common stock warrants.

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 3.6 million shares remain outstanding at March 31, 2016 with a weighted average exercise price of \$2.48 per share. The exercise of warrants could provide us with cash proceeds.

We have no off-balance sheet arrangements.



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**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, 2015. 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, 2015.

**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 treatment of stroke, AMI, and ARDS, and the prevention of GvHD 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 and earn royalties under our collaboration agreements, including in connection with our collaboration with Healios;

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.

**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, 2016, 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 March 31, 2016, we had no borrowings outstanding.

**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 Senior 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 Senior 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 2016, 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, 2016, we sold an aggregate of 200,000 shares of common stock to Aspire Capital at an average purchase price of \$2.14 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                                                                                                                                                                                                                         |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.1*       | License Agreement by and between ABT Holding Company and Healios K.K., dated as of January 8, 2016.                                                                                                                                 |
| 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, Senior 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, Senior 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                                                                                                                                                                              |

\* Confidential treatment requested as to certain portions, which portions have been filed separately with the SEC.



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**SIGNATURES**

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

ATHERSYS, INC.

Date: May 5, 2016

/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

Senior 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                                                                                                                                                                                                                           |
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| 101.INS     | XBRL Instance Document                                                                                                                                                                                                                |
| 101.SCH     | XBRL Taxonomy Extension Schema Document                                                                                                                                                                                               |
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