

# ATHERSYS, INC / NEW

## FORM 10-Q (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
FORM 10-Q**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2017

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

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**Athersys, Inc.**

(Exact name of registrant as specified in its charter)

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

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

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

**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

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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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes  No

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of August 4, 2017 was 113,911,309.

**ATHERSYS, INC.**  
**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

<a href="#">ITEM 1. Financial Statements</a>	3
<a href="#">ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	14
<a href="#">ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</a>	24
<a href="#">ITEM 4. Controls and Procedures</a>	24

**PART II. OTHER INFORMATION**

<a href="#">ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	24
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<b><u>SIGNATURES</u></b>	26
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<b><u>EXHIBIT INDEX</u></b>	27
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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.**

**Athersys, Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share data)

	June 30, 2017 (Unaudited)	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,594	\$ 14,753
Accounts and other receivables	608	598
Prepaid expenses and other	920	929
Total current assets	30,122	16,280
Equipment, net	2,410	2,605
Deferred tax assets	191	175
Total assets	<u>\$ 32,723</u>	<u>\$ 19,060</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,936	\$ 4,761
Accrued compensation and related benefits	726	1,190
Accrued clinical trial costs	204	389
Accrued expenses	339	535
Deferred revenue	503	—
Total current liabilities	6,708	6,875
Warrant liabilities	—	1,004
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value; 300,000,000 and 150,000,000 shares authorized at June 30, 2017 and December 31, 2016, respectively, and 113,059,889 and 86,629,302 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	113	87
Additional paid-in capital	356,189	329,373
Accumulated deficit	(330,287)	(318,279)
Total stockholders' equity	\$ 26,015	\$ 11,181
Total liabilities and stockholders' equity	<u>\$ 32,723</u>	<u>\$ 19,060</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**Athersys, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share data)  
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
<b>Revenues</b>				
Contract revenue	\$ 449	\$ 136	\$ 1,709	\$ 15,260
Grant revenue	220	459	430	793
Total revenues	669	595	2,139	16,053
<b>Costs and expenses</b>				
Research and development	4,633	5,824	10,266	12,487
General and administrative	2,207	1,985	4,278	4,001
Depreciation	167	67	331	134
Total costs and expenses	7,007	7,876	14,875	16,622
Loss from operations	(6,338)	(7,281)	(12,736)	(569)
Income (expense) from change in fair value of warrants, net	—	301	728	(1,880)
Other income, net	58	11	84	221
<b>Loss before income taxes</b>	<b>(6,280)</b>	<b>(6,969)</b>	<b>(11,924)</b>	<b>(2,228)</b>
Income tax benefit	13	13	26	22
<b>Net loss and comprehensive loss</b>	<b>\$ (6,267)</b>	<b>\$ (6,956)</b>	<b>\$ (11,898)</b>	<b>\$ (2,206)</b>
Net loss per share, basic	\$ (0.06)	\$ (0.08)	\$ (0.11)	\$ (0.03)
Weighted average shares outstanding, basic	111,819,655	84,341,401	106,960,354	84,061,257
Net loss per share, diluted	\$ (0.06)	\$ (0.08)	\$ (0.11)	\$ (0.03)
Weighted average shares outstanding, diluted	111,819,655	85,416,506	106,960,354	84,061,257

See accompanying notes to unaudited condensed consolidated financial statements.

**Athersys, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	Six months ended June 30,	
	2017	2016
<b>Operating activities</b>		
Net loss	\$(11,898)	\$ (2,206)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	331	134
Gain from forgiveness of note payable	—	(190)
Stock-based compensation	1,418	1,430
Change in fair value of warrant liabilities	(728)	1,880
Amortization of premium of available-for-sale-securities	—	16
Changes in operating assets and liabilities:		
Accounts receivable	(10)	(287)
Prepaid expenses and other assets	(7)	(580)
Accounts payable and accrued expenses	(670)	900
Deferred revenue	503	(245)
Net cash (used in) provided by operating activities	(11,061)	852
<b>Investing activities</b>		
Purchases of available-for-sale securities	—	(10,203)
Purchases of equipment	(136)	(503)
Net cash used in investing activities	(136)	(10,706)
<b>Financing activities</b>		
Proceeds from issuance of common stock, net	23,270	874
Shares retained for withholding tax payments on stock-based awards	(93)	(327)
Proceeds from exercise of warrants	1,861	117
Net cash provided by financing activities	25,038	664
Increase (decrease) in cash and cash equivalents	13,841	(9,190)
Cash and cash equivalents at beginning of the period	14,753	23,027
Cash and cash equivalents at end of the period	<u>\$ 28,594</u>	<u>\$ 13,837</u>

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

**Athersys, Inc.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
Three- and Six-Month Periods Ended June 30, 2017 and 2016

**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.

We incurred losses since our inception in 1995 and had an accumulated deficit of \$330 million at June 30, 2017. We will require substantial additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing. At June 30, 2017, we had available cash and cash equivalents of \$28.6 million, and we believe that these funds, used to execute our existing operating plans, are sufficient to meet our obligations as they come due for a period of at least twelve months from the date of the issuance of these unaudited condensed consolidated financial statements. In the longer term, we will make use of available cash, but will have to continue to generate additional capital to meet our needs through new and existing collaborations and related license fees and milestones, the sale of equity securities from time to time, including through our equity purchase agreement with Aspire Capital Fund LLC (“Aspire Capital”), grant-funding opportunities, deferring certain discretionary costs and staging certain development costs, as needed.

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, 2016. 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 March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-09, *Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”), 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 statement of operations 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 regard 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. We have adopted ASU 2016-09, effective on January 1, 2017. Upon adoption, we elected to change our policy and to recognize the impact of forfeitures when they occur, and we recognized a cumulative effect adjustment to accumulated deficit on a modified-retrospective basis as of January 1, 2017 of approximately \$0.1 million.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), 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 and interim periods beginning after December 15, 2018, with early adoption permitted. We have not elected to early adopt ASU 2016-02 in 2017 and are in the process of evaluating the impact the new guidance will have on our consolidated financial statements upon adoption. We currently have operating leases for two facilities that will need to be evaluated under the ASU 2016-02.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”). 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 recognition 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 of ASU 2014-09 by one year, making the new standard effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted for annual reporting periods beginning after December 15, 2016. We plan to adopt ASU 2014-09 effective January 1, 2018 under the modified retrospective approach. We have developed an implementation plan, identified our revenue streams and concluded that each of our contracts will be evaluated on a one-for-one basis to assess the impact of the new guidance on our consolidated financial statements. We are now examining each of the revenue streams from our collaboration agreements and grant awards, as well as documenting our internal controls over the adoption and implementation of the new standard. As the evaluation of our contracts is in process, we have not yet fully determined the impact that adopting ASU 2014-09 will have on our consolidated financial statements, however, we expect that the adoption of the new standard may result in increased disclosures in our financial statements and increased internal controls over the revenue evaluation process.



### 3. Net Loss per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. The table below reconciles the net loss and the number of shares used to calculate basic and diluted net loss per share for the three- and six-month periods ended June 30, 2017 and 2016, in thousands, except per share data.

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
<b>Numerator:</b>				
Net loss attributable to common stockholders, basic	\$ (6,267)	\$ (6,956)	\$ (11,898)	\$ (2,206)
Less: income from change in fair value of warrants	—	(203)	—	—
Net loss attributable to common stockholders used to calculate diluted net loss per share	\$ (6,267)	\$ (7,159)	\$ (11,898)	\$ (2,206)
<b>Denominator:</b>				
Weighted-average shares outstanding, basic	111,820	84,341	106,960	84,061
Potentially dilutive common shares outstanding related to warrants	—	1,076	—	—
Weighted-average shares used to calculate diluted net loss per share	111,820	85,417	106,960	84,061
Basic earnings per share	\$ (0.06)	\$ (0.08)	\$ (0.11)	\$ (0.03)
Dilutive earnings per share	\$ (0.06)	\$ (0.08)	\$ (0.11)	\$ (0.03)

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Stock-based awards	11,031,006	11,212,175	11,031,006	11,212,175
Warrants	—	1,500,000	—	3,438,527
Total	11,031,006	12,712,175	11,031,006	14,650,702

### 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.

At June 30, 2017, we had no financial assets or liabilities measured at fair value on a recurring basis. At December 31, 2016, we had warrant liabilities of \$1,004,000 that represented Level 3 liabilities under the hierarchy. As of March 31, 2017, these warrants were either exercised or expired, and we no longer have any outstanding warrants.

## [Table of Contents](#)

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

The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently marked to market at each financial reporting date. We use the Black-Scholes valuation model to value the warrant liabilities at fair value. The fair value was estimated using the expected volatility based on our historical volatility and is determined using probability weighted-average assumptions, when appropriate.

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

	<b>Six months ended June 30, 2017</b>
Balance January 1, 2017	<b>\$ 1,004</b>
Settlements from exercises	<b>(276)</b>
Gain included in income from change in fair value of warrants	<b>(728)</b>
Balance June 30, 2017	<b>\$ —</b>

### *Other*

In February 2016, a \$190,000 loan and accrued interest related to regionally-funded preclinical work was forgiven according to its terms based on the achievement of certain milestones, and the forgiveness was recognized as other income.

## **5. Insurance Recovery**

In May 2016, a flood caused damage to our primary facilities that required the reconstruction of certain laboratory space over several months. The damaged items included fully-depreciated leasehold improvements under an operating lease and laboratory supplies, all of which were covered by insurance and were replaced at replacement cost. Insurance recovery proceeds were recognized in the consolidated statement of operations and comprehensive loss as of June 30, 2016 to the extent of the losses recognized as of June 30, 2016. Ultimately, as of December 31, 2016, the net insurance recovery gain amounted to \$682,000. Since the majority of the damage from the flood was to fully-depreciated leasehold improvements, the amount of losses were less than the amount of the insurance proceeds received. No such insurance recoveries were recognized in the six-month period ended June 30, 2017.

## **6. Collaborative Arrangements 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.

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[Table of Contents](#)

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 its 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.

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.

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## [Table of Contents](#)

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 a 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 the 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 the analysis, we initially allocated \$15 million to the license, which represents the amount of consideration that was allocable at inception 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. As we perform manufacturing services, a portion of the revenue is allocated to the other delivered elements (e.g., additional license fee revenue). Such amounts are included in contract revenues in the consolidated statement of operations and comprehensive loss.

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 Healios 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, with any changes in estimates accounted for on a prospective basis.

In January 2017, we signed a clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan clinical study, the terms of which were consistent with the license agreement.

### *Other*

In January 2017, we received an option fee related to an agreement that was entered into in December 2016 with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an animal health area. Under the terms of the agreement, we received the payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area. The option fee is recorded as deferred revenue at June 30, 2017 since the performance obligation of granting a license has not occurred. If the option is exercised, we will include the option fee in the overall consideration for the license arrangement, to be evaluated at that time. If the option is not exercised, the option fee will be recognized as revenue at that time since there will be no more performance obligations. The evaluation of our technology for this application is currently ongoing.

Under our agreement with RTI Surgical, Inc. to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market, we are eligible to receive cash payments upon the successful achievement of certain commercial milestones. The first commercial milestone was achieved in the first quarter of 2017, with a payment in the amount of \$1.0 million, which we received in April 2017. In addition, we continue 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.

## **7. Stock-based Compensation**

As of June 30, 2017, we have an equity incentive plan that authorizes 20,035,000 shares of common stock for awards to employees, directors and consultants. The equity incentive plan authorizes 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. In June 2017, a separate incentive plan with 1,465,000 authorized shares expired according to its terms, and 1,081,471 stock options remain outstanding under that plan that survive such expiration. In the three-month period ended June 30, 2017, we granted 2,498,480 stock options and 1,054,720 restricted stock units to our employees and directors pursuant to our annual incentive programs. As of June 30, 2017, a total of 3,795,247 shares of common stock have been issued under our equity incentive plans.

As of June 30, 2017, a total of 6,400,968 shares of common stock were available for issuance under our current equity incentive plan, and stock-based awards to purchase 11,031,006 shares of common stock were outstanding under both the current and expired plans. For the three-month periods ended June 30, 2017 and 2016, stock-based compensation expense was approximately \$729,000 and \$722,000, respectively. At June 30, 2017, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$8.8 million, which is expected to be recognized by the end of 2021 using the straight-line method.

## **8. Stockholders' Equity**

### *Charter Amendment*

In June 2017, we amended our certificate of incorporation to increase the number of authorized shares of common stock to 300,000,000, upon approval at our annual stockholders' meeting. Other than the change to the number of authorized shares of common stock, there were no changes to the terms of our common stock.

### *Equity Offering*

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

### *Aspire Capital*

We currently have in place an equity purchase agreement with Aspire Capital that was entered into in December 2015 and provides that Aspire Capital is committed to purchase shares of our common stock up to an aggregate amount of \$30.0 million over a three-year term, subject to our election to sell any such shares. We filed a registration statement for the resale of 16,600,000 shares of common stock in connection with the equity facility. During the three- and six-month periods ended June 30, 2017, we sold 1,650,000 shares to Aspire Capital under the equity purchase agreement at an average price of \$1.45 per share, generating aggregate proceeds of \$2.4 million, and we sold no shares to Aspire Capital during the first quarter of 2017.

## **9. Warrant Liabilities**

As of June 30, 2017, we had no warrants outstanding. All of our previously outstanding warrants were either exercised prior to expiration or expired in March 2017. We received proceeds of \$1.9 million in the first quarter of 2017 from warrant exercises. Prior to their expiration, we accounted 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 were accounted for as liabilities and classified on the consolidated balance sheet as a non-current liability. The warrant liabilities were revalued at fair value at each balance sheet date subsequent to the initial issuance, and changes in the fair market value of the warrants were reflected in the consolidated statement of operations as income (expense) from change in fair value of warrants.

## **10. 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. We recognize refundable tax benefits related to research and development credits associated with one of our foreign subsidiary.

The utilization of net operating loss and tax credit carryforwards generated prior to October 2012 is substantially limited under Section 382 of the Internal Revenue Code of 1986, as amended, as a result of our October 2012 equity offering. We generated U.S. federal net operating loss carryforwards, research and development tax credits, and state and local net operating loss carryforwards since 2012. We will update our analysis under Section 382 prior to using these attributes.

**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, 2016. Operating results are not necessarily indicative of results that may occur in future periods.

**Overview and Recent Developments**

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem<sup>®</sup> cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in later-stage clinical development. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other conditions where the current standard of care is limited or inadequate for many patients.

*Current Programs*

By applying our proprietary MultiStem cell therapy product, we established therapeutic product development programs treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other conditions. Our programs in the clinical development stage include the following:

- **Ischemic Stroke**: We completed our Phase 2 study of MultiStem treatment of patients suffering a moderate to severe ischemic stroke and announced the one-year follow-up data and final results from the study in February 2016. We are actively engaged in advancing the next stage of clinical development of this program, both independently and with HEALIOS K.K., or Healios.

In September 2016, we announced that we received agreement from the U.S. Food and Drug Administration, or FDA, under a Special Protocol Assessment, or SPA, for the design and planned analysis of a pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke. The SPA provides agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses encompassed in Athersys’ planned Phase 3 study are acceptable to support a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients. If the trial is successful, we believe the results from our Phase 3 MASTERS-2 clinical trial, together with other available clinical data, would provide the foundation of the regulatory package to be submitted for marketing approval. In May 2017, we announced that the FDA granted us Fast Track designation for our clinical product for the treatment of ischemic stroke. Such designation for a new biologic product means that the FDA will take such actions as are appropriate to expedite the development and review of our application to approve the product, and specifically, under Fast Track designation, the program becomes eligible for rolling submission, accelerated approval and priority review of the biologics license application, facilitating a timely regulatory review. Also, in August 2017, we announced that the design of MASTERS-2 received a Final Scientific Advice positive opinion from the European Medicines Agency, or EMA, representing EMA’s opinion that successful results from the trial could result in commercialization of the MultiStem therapy. This positive opinion provides further alignment among the key regulators regarding potential commercialization of the MultiStem product upon success of this single pivotal trial.

In September 2016, we announced the successful completion of the Pharmaceutical and Medical Devices Agency, or PMDA, review of Healios' Clinical Trial Notification, or CTN, allowing Healios to commence its confirmatory clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan, which will be evaluated under the new regulatory framework for regenerative medicine therapies. In accordance with the regulatory system in Japan, a CTN is equivalent to an Investigational New Drug, or IND, application under the regulatory system used in the United States, or U.S. This clinical trial to be conducted in Japan is part of a partnership and license agreement between Healios and Athersys, focused on the development and commercialization of MultiStem in Japan for the treatment of ischemic stroke, and potentially other indications. The study design was accepted as proposed to PMDA in the CTN.

Our MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale, or mRS, scores at three months, comparing the distribution, or the "shift" between the MultiStem treatment and placebo groups. The mRS shift analyzes patient improvement across the full disability spectrum, enabling recognition of improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome (the achievement of mRS  $\leq$  1, NIHSS  $\leq$  1, and Barthel Index  $\geq$  95) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection.

Healios' TREASURE study in Japan is a randomized, double-blind, placebo-controlled clinical trial conducted at hospitals in Japan that have extensive experience at providing care for stroke victims. Based on the experience from our B01-02 study, subjects enrolled in the trial will receive either a single dose of MultiStem or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to standard of care. The study will evaluate patient recovery through approximately 90 days following initial treatment based on Excellent Outcome and other neurological, functional and clinical endpoints. The TREASURE study has been initiated, though interruption in media supply at our contract manufacturer, Lonza, affected manufacturing of the MultiStem product and has slowed the launch of the study.

We intend to be prepared to launch our MASTERS-2 clinical trial later in 2017 and will provide updates as we move forward with these plans. Currently, we are pursuing business development or other financial initiatives to provide adequate funding for this pivotal trial and intend to commence the study as soon as possible once such funding is received and trial preparations are complete. We then look forward to using the accelerated pathway afforded to us by the regulators in the U.S., Europe and Japan upon study completion.

- Acute Myocardial Infarction: We are conducting an ongoing Phase 2 clinical study in the U.S. for the administration of MultiStem cell therapy to patients that have suffered an acute myocardial infarction, or AMI. In a Phase 1 clinical study, we previously evaluated the administration of MultiStem to patients that suffered an AMI. 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 in 2013 a grant for up to \$2.8 million in funding to support the advancement of this clinical program, and we launched a double-blind, sham-controlled 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 currently enrolling patients and is being conducted at leading cardiovascular centers in the U.S.



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## [Table of Contents](#)

- **Acute Respiratory Distress Syndrome** : We have also initiated a clinical study for the treatment of acute respiratory distress syndrome, or ARDS, in the United Kingdom and in the U.S. We were awarded a grant from Innovate UK for up to approximately £2.0 million as partial support of a Phase 1/2 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 that severely compromises pulmonary function, requiring patients to be placed on a ventilator. 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 Phase 1/2 clinical trial is ongoing.
- **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-vs-host disease, or GvHD. Data from the study 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 EMA for MultiStem treatment in the prevention of GvHD, and 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 SA procedure, as well as a SPA designation from the FDA. Currently, this program is staged for future registration-directed development dependent on the achievement of certain business development and financial objectives and the development and success of alternative therapies for treating the underlying conditions leading to transplant.

MultiStem therapy has been evaluated in other disease areas, such as inflammatory bowel disease with a collaborator, solid organ transplant in an investigator-sponsored study, and a limited number of compassionate use cases.

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our wholly-owned subsidiary, we are also evaluating our cell therapy for use in treating diseases and conditions in the animal health segment. We have demonstrated in preclinical animal health models that our cell therapy can promote tissue repair and healing that could provide meaningful benefits to animal patients, including those suffering from conditions with unmet medical need. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area. We received a payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area. The evaluation of our technology for this application is currently ongoing.

We are engaged in preclinical development and evaluation of MultiStem therapy in other indications, focusing on the neurological, cardiovascular and inflammatory and immune disease areas, and 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.

While the MultiStem product platform continues to advance, we are engaged in process development initiatives intended to increase manufacturing scale, reduce production costs, and enhance process controls and product quality, among other things. These initiatives are being conducted both internally and outsourced to select contractors, and the related investments are meant to enable us to meet potential commercial demand in the event of eventual regulatory approval. Until such time as we are able to manufacture products ourselves in accordance with good manufacturing practices, we will continue to rely on third party manufacturers to make our MultiStem product for clinical trials and eventual commercial sales. These third parties may not deliver sufficient quantities of our MultiStem product, manufacture MultiStem product in accordance with specifications, or comply with applicable government regulations. From time to time, such third party manufacturers, or their material suppliers, may experience production delays, stoppages or interruptions in supply, which may affect the initiation, execution and timing of completion of clinical trials or commercial activities. In the first half of 2017, our contract manufacturer, Lonza, experienced interruptions to its media supply, which affected manufacturing of the MultiStem product and slowed the launch of Healios' TREASURE study in Japan.

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## [Table of Contents](#)

In January 2016, we entered into a license agreement with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to our proprietary technologies 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 is working toward the development and commercialization of the MultiStem product in Japan, and we are providing the manufactured product to Healios for its clinical studies.

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, and we continue to receive royalty revenue from product sales and may receive other payments, from time to time, upon the successful achievement of certain commercial milestones. The first commercial milestone was achieved in the first quarter of 2017, with a payment in the amount of \$1.0 million.

### *Financial*

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

In connection with our January 2016 license agreement with Healios, we received a non-refundable 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, which we refer to as the Expansion Option. Healios may exercise its option to expand the collaboration after receipt of the initial results from our ongoing ARDS clinical trial.

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 product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement.

If Healios exercises the Expansion 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. We are also entitled to receive a fractional royalty percentage on net sales of the "organ bud" products. 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 license 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.

In 2016, a flood caused damage to our primary facilities that required the reconstruction of certain laboratory space over several months. The damaged items included fully-depreciated leasehold improvements under an operating lease and laboratory supplies, all of which were covered by insurance and were replaced at replacement cost. Insurance recovery proceeds were recognized in the consolidated statement of operations and comprehensive loss as of June 30, 2016 to the extent of the losses recognized as of June 30, 2016. Ultimately, as of December 31, 2016, the net insurance recovery gain amounted to \$682,000. Since the majority of the damage from the flood was to fully-depreciated leasehold improvements, the amount of losses were less than the amount of the insurance proceeds received. No such insurance recoveries were recognized in the six-month period ended June 30, 2017.

## Results of Operations

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date, but we receive royalties on commercial sales by a licensee of products using our technologies. Research and development expenses consist primarily of external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

### *Three Months Ended June 30, 2017 and 2016*

*Revenues*. Revenues increased to \$0.7 million for the three months ended June 30, 2017 from \$0.6 million in the comparable period in 2016 due to an increase of \$0.3 million in contract revenues from our collaboration with Healios, partially offset by a \$0.2 million decrease in grant revenue. Grant revenue often fluctuates from period to period based on the timing of grant-related activities and the award and expiration of new grants.

*Research and Development Expenses*. Research and development expenses decreased to \$4.6 million for the three months ended June 30, 2017 from \$5.8 million for the comparable period in 2016. The \$1.2 million decrease is primarily associated with decreased clinical and preclinical development costs of \$0.9 million, decreased sponsored research costs of \$0.2 million and decreased internal research supplies of \$0.2 million, partially offset by a \$0.1 million increase in legal and professional fees. The decrease in our clinical and preclinical costs is primarily due to the timing of process development activities to support large-scale manufacturing, as well as the timing of clinical product manufacturing costs. Based on our planned clinical development, manufacturing and process development activities, we expect our 2017 annual research and development expenses to be similar to 2016, and such costs will vary over time based on clinical manufacturing campaigns, the timing and stage of clinical trials underway, and manufacturing 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 increased to \$2.2 million for the three months ended June 30, 2017 compared to \$2.0 million in 2016. The \$0.2 million increase was primarily due to increased legal and professional fees, salaries and benefits, and other contracted services. We expect our general and administrative expenses to continue at similar levels in 2017 as compared to 2016.

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[Table of Contents](#)

*Depreciation* . Depreciation expense increased to \$0.2 million for the three months ended June 30, 2017 and \$0.1 million in the comparable period in 2016. The increase related to assets placed in service in the latter half of 2016 as a result of flood repairs, and equipment purchased for use in manufacturing process development activities. As a result of these additions, we expect our depreciation to increase in 2017 as compared to 2016.

*Income (expense) from Change in Fair Value of Warrants, net*. We had no income recognized during the three months ended June 30, 2017 for the market value change in our warrant liabilities, since as of March 31, 2017, all of our warrants were either exercised or expired. For the comparable period of 2016, we had \$0.3 million of income 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.

*Income Tax Benefit*. The income tax benefit in 2017 and 2016 represents refundable foreign tax credits.

***Six Months Ended June 30, 2017 and 2016***

*Revenues* . Revenues decreased to \$2.1 million for the six months ended June 30, 2017 from \$16.1 million in the comparable period in 2016, reflecting the upfront license fee of \$15 million from our Healos collaboration in the first quarter of 2016, partially offset by a milestone payment from RTI of \$1.0 million in 2017.

*Research and Development Expenses*. Research and development expenses decreased to \$10.3 million for the six months ended June 30, 2017 from \$12.5 million in the comparable period in 2016. The decrease of \$2.2 million related primarily to a decrease in clinical and preclinical costs of \$1.2 million, a decrease in research supplies of \$0.5 million, a decrease in license fees of \$0.3 million and a decrease of \$0.3 million in sponsored research costs. These decreases were partially offset by an increase in legal and professional fees of \$0.1 million. The decrease in our clinical and preclinical costs was primarily due to the timing of process development activities to support large-scale manufacturing, and the timing of clinical product manufacturing costs. The decrease in research supplies was due to the completion of certain internal 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 increased to \$4.3 million for the six months ended June 30, 2017 from \$4.0 million in the comparable period in 2016. The \$0.3 million increase was due primarily to an increase in salary and benefits and other contracted services compared to the same period in 2016.

*Depreciation* . Depreciation expense increased to \$0.3 million for the six-month period ended June 30, 2017 versus \$0.1 million for the comparative period ended June 30, 2016. The increase related primarily to assets placed in service in the latter half of 2016 as a result of flood repairs, and equipment purchased for use in manufacturing process development activities. As a result of these additions, we expect our depreciation to increase in 2017 as compared to 2016.

*Income (expense) from Change in Fair Value of Warrants, net* . Income of \$0.7 million was recognized during the six months ended June 30, 2017, compared to \$1.9 million of expense in the comparable period in 2016. All remaining warrants were either exercised or expired as of March 31, 2017, resulting in the variance from period-to-period.

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[Table of Contents](#)

*Other Income, net.* Other income, net, was \$0.1 million for the six-month period ended June 30, 2017 and \$0.2 million for the comparable 2016 period, and is typically comprised of interest income and expense, and foreign currency gains and losses. However, we recognized other income of \$190,000 from a loan that was forgiven in the first quarter of 2016.

*Income Tax Benefit.* The income tax benefit in 2017 and 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 June 30, 2017, we had \$28.6 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 \$330 million at June 30, 2017. 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.

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

We have an equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, whereby Aspire Capital is committed to purchase up to an aggregate of \$30 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 June 30, 2017, we generated net proceeds aggregating \$2.4 million from sales of our common stock to Aspire Capital at an average price per share of \$1.45 per share.

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 after the receipt of the initial results from Athersys' ongoing ARDS clinical trial. For the ischemic stroke indication, we may also receive additional success-based development and regulatory approval milestones potential sales milestones from Healios aggregating up to \$225 million. We will also receive tiered royalties on product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement; provided, that, if we determine that we are not able to supply product at a defined price or a price otherwise agreeable to Healios after using commercially reasonable efforts, we may notify Healios and grant Healios a license to make the product solely for use in the licensed field in Japan. In January 2017, we signed a clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan clinical study, the terms of which were consistent with the license agreement.

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[Table of Contents](#)

If Healios exercises the option to expand the 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.

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. The first commercial milestone was achieved in the first quarter of 2017 in the amount of \$1.0 million, which we received in April 2017. However, there can be no assurance that additional milestones will be achieved. In addition, we continue 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.

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 June 30, 2017, 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 connection with our expanding intellectual property portfolio, we periodically enter into other academic license agreements, which are typically specific to patents in a specific field.

In 2015, we and another company were awarded a grant from Innovate UK as partial support of our Phase 1/2 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 (of which £0.75 million is our portion) over the course of the study, which is currently enrolling patients.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates and manufacturing process development. At June 30, 2017, we had available cash and cash equivalents and investments of \$28.6 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. 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.

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[Table of Contents](#)

*Cash Flow Analysis*

Net cash used in operating activities was \$11.1 million for the six months ended June 30, 2017 compared to cash provided by of \$0.9 million for the six months ended June 30, 2016, reflecting the approximately \$15 million of cash received from Healios in January 2016, the \$1.0 million commercial milestone received from RTI in April 2017, other contract and deferred revenues received in the first half of 2017, and the variation in the use of cash to fund preclinical and clinical development activities. Net cash used in operating activities may fluctuate significantly on a quarter-to-quarter basis, as it has over the past several years, primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs and manufacturing process development projects.

Net cash used by investing activities was \$0.1 million and \$10.7 million for the six months ended June 30, 2017 and 2016, respectively. The fluctuations from period-to-period were due to the purchase of \$10.2 million of available-for-sale securities in the first six months of 2016 and the purchase of equipment primarily for our manufacturing process development activities. Purchases of equipment were \$0.1 million and \$0.5 million for the first six months of 2017 and 2016, respectively. We expect that our capital equipment expenditures will decrease overall in 2017 compared to 2016.

Financing activities provided cash of \$25.0 million for the six months ended June 30, 2017, including \$20.9 million of net proceeds from the February 2017 stock offering, equity sales to Aspire Capital and the exercise of common stock warrants, net of shares retained for withholding tax payments on stock-based awards. Financing activities provided cash of \$0.7 million for the six months ended June 30, 2016 related primarily to equity sales to Aspire Capital and the exercise of common stock warrants, net of shares retained for withholding tax payments on stock-based awards.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

**Critical Accounting Policies and Management Estimates**

The Securities and Exchange Commission, or SEC, defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations is 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, 2016. 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, 2016.

### 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,” or other similar 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, including the MASTERS-2 Phase 3 clinical trial and the Healios TREASURE clinical trial in Japan;
- 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;
- the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints or regulatory issues;
- 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;
- 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 the success of our collaboration with Healios;
- our collaborators’ ability to continue to fulfill their obligations under the terms of our collaboration agreements;
- the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in the United States, Europe and Japan;
- our possible inability to execute our strategy due to changes in our industry or the economy generally;
- changes in productivity and reliability of suppliers; and
- the success of our competitors and the emergence of new competitors.



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[Table of Contents](#)

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**

We invest our cash from time to time in conservative portfolios. We had no investments at June 30, 2017.

We enter into loan arrangements with financial institutions when needed and when available to us, and we had no borrowings outstanding at June 30, 2017.

**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.

**Changes in internal control over financial reporting**

During the last fiscal quarter covered by this Quarterly Report on Form 10-Q, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

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

During the quarter ended June 30, 2017, we sold an aggregate of 1,650,000 shares of common stock to Aspire Capital at an average purchase price of \$1.45 per share, generating aggregate proceeds of \$2,393,000. 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.

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[Table of Contents](#)

**Item 6. Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
3.1	Certificate of Amendment of Certificate of Incorporation of Athersys, Inc.
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 of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

**SIGNATURES**

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

Date: August 9, 2017

ATHERSYS, INC.

/s/ Gil Van Bokkelen

Gil Van Bokkelen

Chairman and Chief Executive Officer

(principal executive officer authorized to sign on behalf of the registrant)

/s/ Laura K. Campbell

Laura K. Campbell

Senior Vice President of Finance

(principal financial and accounting officer authorized to sign on behalf of the registrant)

**EXHIBIT INDEX**

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**CERTIFICATE OF AMENDMENT  
OF  
CERTIFICATE OF INCORPORATION  
OF  
ATHERSYS, INC.**

Athersys, Inc., a corporation duly organized and existing under the General Corporation Law of the State of Delaware (the “*Corporation*”), does hereby certify that:

1. The Certificate of Incorporation of the Corporation is hereby amended by deleting the provisions of “Section 1. Authorization of Shares” thereof and inserting the following in lieu thereof:

“The total number of shares that the Corporation shall have authority to issue is 310,000,000 shares, consisting of 300,000,000 shares of common stock, having a par value of \$.001 per share (“Common Stock”), and 10,000,000 shares of preferred stock, having a par value of \$.001 per share (“Preferred Stock”).”

2. The foregoing amendment was duly adopted in accordance with the provisions of Sections 242 and 216 of the General Corporation Law of the State of Delaware.

*[signature to follow]*

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IN WITNESS WHEREOF, the Corporation has caused this Certificate to be executed by Gil Van Bokkelen, its Chief Executive Officer, on this 7th day of June, 2017.

**ATHERSYS, INC.**

By: /s/ Gil Van Bokkelen

Name: Gil Van Bokkelen

Title: Chief Executive Officer

## CERTIFICATIONS

I, Gil Van Bokkelen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 9, 2017

/s/ Gil Van Bokkelen

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Gil Van Bokkelen  
Chief Executive Officer and Chairman of the Board of Directors

## CERTIFICATIONS

I, Laura K. Campbell, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 9, 2017

/s/ Laura K. Campbell

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Laura K. Campbell

Senior Vice President of Finance



**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Athersys, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: August 9, 2017

/s/ Gil Van Bokkelen

Name: Gil Van Bokkelen

Title: Chairman and Chief Executive Officer

/s/ Laura K. Campbell

Name: Laura K. Campbell

Title: Senior Vice President of Finance

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.