ATHERSYS, INC / NEW

FORM 10-Q
(Quarterly Report)

Filed 11/09/16 for the Period Ending 09/30/16

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Telephone	216-431-9900
CIK	0001368148
Symbol	ATHX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**20-4864095**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3201 Carnegie Avenue, Cleveland, Ohio	**44115-2634**
(Address of principal executive offices)	**(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐

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

The number of outstanding shares of the registrant's common stock, $0.001 par value, as of November 1, 2016 was 85,498,369.

ATHERSYS, INC.

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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)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	**$ 8,309**	$ 23,027
Available-for-sale-securities	**11,070**	—
Accounts receivable	**298**	361
Prepaid expenses and other	**855**	429
Total current assets	**20,532**	23,817
Equipment, net	**2,597**	1,135
Deferred tax assets	**190**	177
Total assets	**$ 23,319**	$ 25,129
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 3,603**	$ 2,702
Accrued compensation and related benefits	**912**	1,024
Accrued clinical trial costs	**98**	82
Accrued expenses	**548**	513
Deferred revenue	**—**	245
Note payable	**—**	190
Total current liabilities	**5,161**	4,756
Warrant liabilities	**2,134**	649
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized, and 85,498,369 and 83,720,154 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	**85**	84
Additional paid-in capital	**327,092**	322,582
Accumulated deficit	**(311,153)**	(302,942)
Total stockholders' equity	**16,024**	19,724
Total liabilities and stockholders' equity	**$ 23,319**	$ 25,129

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 September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenues				
Contract revenue	**$ 150**	$ 39	**$ 15,410**	$ 194
Grant revenue	**161**	357	**954**	1,149
Total revenues	**311**	396	**16,364**	1,343
Costs and expenses				
Research and development	**5,263**	5,089	**17,750**	16,018
General and administrative	**1,830**	1,941	**5,831**	5,751
Depreciation	**114**	66	**248**	201
Total costs and expenses	**7,207**	7,096	**23,829**	21,970
Gain from insurance proceeds, net	**682**	—	**682**	—
Loss from operations	**(6,214)**	(6,700)	**(6,783)**	(20,627)
Income (expense) from change in fair value of warrants, net	**191**	255	**(1,689)**	609
Other income (loss), net	**7**	(79)	**228**	(31)
Loss before income taxes	**(6,016)**	(6,524)	**(8,244)**	(20,049)
Income tax benefit	**12**	27	**34**	35
Net loss and comprehensive loss	**$ (6,004)**	$ (6,497)	**$ (8,210)**	$ (20,014)
Net loss per share, basic	**$ (0.07)**	$ (0.08)	**$ (0.10)**	$ (0.24)
Weighted average shares outstanding, basic	**84,928,198**	83,140,864	**84,352,347**	81,736,273
Net loss per share, diluted	**$ (0.07)**	$ (0.08)	**$ (0.10)**	$ (0.24)
Weighted average shares outstanding, diluted	**85,896,993**	83,425,669	**84,352,347**	82,572,984

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine months ended September 30, 2016	2015
Operating activities		
Net loss	**$ (8,210)**	$(20,014)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**248**	201
Income from forgiveness of note payable	**(190)**	—
Stock-based compensation	**2,177**	2,187
Gain from insurance proceeds, net	**(682)**	—
Change in fair value of warrant liabilities	**1,689**	(609)
Changes in operating assets and liabilities:		
Accounts receivable	**63**	379
Prepaid expenses and other	**(262)**	55
Accounts payable and accrued expenses	**765**	(529)
Deferred revenue	**(245)**	9,925
Net cash used in operating activities	**(4,647)**	(8,405)
Investing activities		
Purchase of available-for-sale-securities	**(15,903)**	—
Sales of available-for-sale-securities	**4,830**	—
Purchases of equipment	**(1,635)**	(99)
Proceeds from insurance	**507**	—
Net cash used in investing activities	**(12,201)**	(99)
Financing activities		
Proceeds from issuance of common stock, net	**2,386**	10,371
Purchase of treasury stock	**(418)**	(437)
Proceeds from exercise of warrants	**162**	976
Net cash provided by financing activities	**2,130**	10,910
(Decrease) increase in cash and cash equivalents	**(14,718)**	2,406
Cash and cash equivalents at beginning of the period	**23,027**	26,127
Cash and cash equivalents at end of the period	**$ 8,309**	$ 28,533

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
Three- and Nine-Month Periods Ended September 30, 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 Accounting Standards Update ("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 2-09 will have on our consolidated financial statements.

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, i.e., for year-end 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 consolidated 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 our consolidated financial statements.

3. Net Loss per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. The table below reconciles the net loss and the number of shares used to calculate basic and diluted net loss per share for the three- and nine-month periods ended September 30, 2016 and 2015, in thousands, except per share data.

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Numerator:				
Net loss attributable to common stockholders - Basic	**$ (6,004)**	$ (6,497)	**$ (8,210)**	$ (20,014)
Less: income from change in fair value of warrants	**(191)**	(220)	**—**	(196)
Net loss attributable to common stockholders used to calculate diluted net loss per share	**$ (6,195)**	$ (6,717)	**$ (8,210)**	$ (20,210)
Denominator:				
Weighted-average shares outstanding - Basic	**84,928**	83,141	**84,352**	81,736
Potentially dilutive common shares outstanding:				
Warrants	**969**	285	**—**	837
Weighted-average shares used to calculate diluted net loss per share	**85,897**	83,426	**84,352**	82,573
Basic earnings per share	**$ (0.07)**	$ (0.08)	**$ (0.10)**	$ (0.24)
Dilutive earnings per share	**$ (0.07)**	$ (0.08)	**$ (0.10)**	$ (0.24)

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Stock - based awards	**10,840,306**	8,455,885	**10,840,306**	8,455,885
Warrants	**—**	2,810,000	**1,893,527**	2,810,000
Total	**10,840,306**	11,265,885	**12,733,833**	11,265,885

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 fair values of our assets and liabilities measured at fair value on a recurring basis as of September 30, 2016 (in thousands):

Description	Balance as of September 30, 2016	Fair Value Measurements at September 30, 2016 Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Available-for-sale securities:				
U.S. government-backed agency and municipal bonds	**$ 2,277**	—	$ 2,277	—
Bank certificates of deposit, FDIC-insured	**$ 8,793**	—	$ 8,793	—
Total available-for-sale securities	**$ 11,070**	**—**	**$ 11,070**	**—**
Liabilities:				
Warrant liabilities	**$ 2,134**	**—**	**—**	**$ 2,134**

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 our U.S. government-backed municipal bonds, representing a level 2 fair value measure, is based on market pricing for similar assets using third party certified pricing sources. The estimated fair value of our FDIC-insured bank certificates of deposit, representing a level 2 fair value measure, is based on third party calculated pricing, taking into consideration amortization and constant yield principles. 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 September 30, 2016:

	Expected Volatility	Risk-Free Interest Rate	Expected Life
Warrants with one year or less remaining term	**55.78%**	**0.45%**	**0.45 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 September 30, 2016		Nine months ended September 30, 2016
Balance July 1, 2016	**$ 2,369**	**Balance January 1, 2016**	**$ 649**
Settlements from exercise	(44)	Settlements from exercise	(204)
Income for the period	(191)	Expense for the period	1,689
Balance September 30, 2016	**$ 2,134**	**Balance September 30, 2016**	**$ 2,134**

The following is a summary of available-for-sale securities (in thousands) at September 30, 2016, and we had no available-for-sale securities at December 31, 2015:

	Cost or Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
September 30, 2016:				
U.S. government-backed agency and municipal bonds	$ 2,277	$ —	$ —	$ 2,277
Bank certificates of deposit, FDIC-insured	8,793	—	—	8,793
Total available-for-sale securities	**$ 11,070**	**$ —**	**$ —**	**$ 11,070**

All of our available-for-sale securities are in U.S. government-backed municipal bonds and FDIC-insured bank certificates of deposit. We had no realized gains or losses during the first nine months of 2016. Unrealized gains and losses on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity within accumulated other comprehensive income until realized. When available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used to determine any realized gain or loss. There were no net unrealized gains or losses on available-for-sale securities as of September 30, 2016.

All of our available-for-sale securities at September 30, 2016 have a contractual maturity of one year or less, and actual maturities may differ from contractual maturities because the issuers of the securities may have the right to repay the obligations without prepayment penalties.

In January 2016, a $190,000 loan, including accrued interest, related to a 2012 local grant was forgiven according to its terms based on our achievement of certain milestones, and the forgiveness was recognized as other income in the consolidated statement of operations and comprehensive loss.

5. Insurance Recovery

In May 2016, a flood caused damage to our primary facilities that required the reconstruction of certain laboratory space over the past 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 are being replaced at replacement cost. The net insurance recovery gain of $682,000 included in the operating results of the consolidated statement of operations and comprehensive loss as of September 30, 2016 includes the losses associated with the flood damage (e.g., removal, disposal, clean-up, insurance deductible) and the insurance proceeds received. The net amount reflects a gain as of September 30, 2016 since most of the replacement cost was capitalized as leasehold improvements. Any further contingent gain on insurance proceeds that may be received in the future will be recognized when the contingency is resolved and the amount is realizable.

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.

Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of $15 million from Healios. 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.

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 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 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 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.

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.

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 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.

7. Stock-based Compensation

We have two equity incentive plans that authorize an aggregate of 21,500,000 shares of common stock for awards to employees, directors and consultants, which includes an amendment approved by our stockholders and made to the primary plan in June 2016 to increase the shares of common stock available to awards. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards. As of September 30, 2016, a total of 3,389,927 shares of common stock have been issued under our equity incentive plans as vested restricted stock units or exercised stock options.

As of September 30, 2016, a total of 7,269,767 shares of common stock were available for issuance under our equity incentive plans, and stock-based awards to purchase 10,840,306 shares of common stock were outstanding. For the three-month periods ended September 30, 2016 and 2015, stock-based compensation expense was approximately $748,000 and $722,000, respectively. At September 30, 2016, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $7.3 million, which is expected to be recognized by the end of 2020 using the straight-line method

8. Issuance of Common Stock and Warrants

Aspire Capital

We currently have in place an equity purchase agreement with Aspire Capital Fund, LLC (“Aspire Capital”) that was entered into in December 2015, and which provides that Aspire Capital is committed to purchase shares of our common stock up to an aggregate amount of $30 million over a three-year term, subject to our election to sell any such shares. We had previously entered into similar equity purchase agreements with Aspire Capital in 2011 and 2013 with purchase commitments of $20 million and $25 million, respectively.

Under the current equity facility, 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 we filed a registration statement for the resale of 16,600,000 shares of common stock in connection with the equity facility. During the third quarter of 2016, we sold 741,418 shares to Aspire Capital under the current equity purchase agreement at an average price of $2.04 per share, generating aggregate proceeds of $1,512,483, and during the nine-month period ended September 30, 2016, we sold 1,141,418 shares of common stock at an average price of $2.09 per share, generating aggregate proceeds of $2,389,483.

Warrants

As of September 30, 2016, we had 1,893,527 outstanding warrants to purchase shares of common stock at $1.01 per share, which were issued in March 2012 and expire in March 2017. During the three-month period ending September 30, 2016, warrants to purchase 45,000 shares of common stock were exercised.

9. 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 a 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). 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.

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.

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 one of our foreign subsidiaries.

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 clinical trials focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other 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 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 preparing for the next stage of clinical development of this program, both independently and with our collaborative partner, HEALIOS K.K., or Healios, and we recently made two important announcements. First, 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. The results from the Phase 3 trial entitled, "MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2," referred to as the MASTERS-2 clinical trial, together with other available clinical data, would provide the foundation of the regulatory package to be submitted for marketing approval.

  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.

  Secondly, also in September 2016, we announced the successful completion of Japan's Pharmaceutical and Medical Devices Agency, or PMDA, review of the Clinical Trial Notification, or CTN, allowing Healios to commence a confirmatory clinical trial evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan (designated by Healios as HLCM051 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 application, or IND, under the regulatory system used in the United States. 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.

Healios' planned study in Japan will be 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.

We intend to be prepared to launch our MASTERS-2 clinical trial in 2017 and will update our stockholders as we move forward with these plans. Concurrently, Healios is actively preparing for the launch of its study in Japan.

- Acute Myocardial Infarction : We have an ongoing 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. Since the rate of enrollment in this study has been below our expectations based on our historical data, we have taken steps to increase enrollment rates, including through protocol amendments, which are currently being implemented.
- 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 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 Phase 2a clinical trial is currently enrolling patients, although enrollment at this point is lower than expected, and we are taking steps to improve enrollment.
- 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.

We are also in the preparation stage for translational and clinical studies in other targeted areas, and we have supported investigator-initiated clinical activity from time-to-time, such as solid organ transplant. 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.

Importantly, as 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.

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 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 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. The Expansion Option must be exercised by the 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, which is initially focused on clinical product supply.

If Healios exercises the Expansion Option, 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 May 2016, a flood caused damage to our primary facilities that required the reconstruction of certain laboratory space. The damaged items included fully-depreciated leasehold improvements under an operating lease and laboratory supplies, all of which were covered by insurance and are being replaced at replacement cost. To date, we have only recognized insurance proceeds to the extent of the losses for the period, netting to $682,000 at September 30, 2016. Any further contingent gain on insurance proceeds that may be received in the future will be recognized when the contingency is resolved and the amount is realizable, which is expected by the end of 2016.

Results of Operations

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

Three Months Ended September 30, 2016 and 2015

Revenues . Revenues decreased slightly to $0.3 million for the three months ended September 30, 2016 compared to $0.4 million for the three months ended September 30, 2015 due to a decrease of $0.2 million in grant revenues which was partially offset by an increase in contract revenues of $0.1 million. Our grant revenues 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 $5.3 million for the three months ended September 30, 2016 from $5.1 million in the comparable period in 2015. The $0.2 million increase is primarily comprised of a increases in personnel costs, sponsored research, research supplies and professional fees, partially offset by a decrease in preclinical and clinical development costs of $0.3 million. Our preclinical and clinical development costs vary from time-to-time and include, among other things, the costs to conduct our clinical studies and manufacture clinical product, as well as process development costs to support large-scale manufacturing. 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 decreased to $1.8 million for the three months ended September 30, 2016 from $1.9 million in the comparable period in 2015. The $0.1 million decrease was due primarily to a decrease in professional and consulting fees compared to the same period in 2015.

Depreciation . Depreciation expense of $0.1 million remained consistent during each of the three-month periods ended September 30, 2016 and 2015.

Gain from Insurance Proceeds, net . The net insurance recovery gain of $0.7 million during the three months ended September 30, 2016 included the cumulative losses associated with May 2016 flood damage (e.g., removal, disposal, clean-up, insurance deductible) and the cumulative insurance proceeds received. The net amount reflects a gain as of September 30, 2016 since most of the replacement cost was capitalized as leasehold improvements.

Income (expense) from Change in Fair Value of Warrants, net . Income of $0.2 million was recognized during the three months ended September 30, 2016 for the market value change in our warrant liabilities, compared to income of $0.3 million during the comparable period in 2015. The fluctuation is primarily affected by the exercise prices of the warrants, our stock price and the remaining lives of the issued warrants.

Other Income, net. Other income, net, for the three-month period ended September 30, 2016 and 2015 remained relatively consistent during the periods, and is typically comprised of net interest income and expense and net foreign currency gains and losses.

Income Tax Benefit. The income tax benefit in 2016 and 2015 represents refundable foreign tax credits.

Nine Months Ended September 30, 2016 and 2015

Revenues . Revenues increased to $16.3 million for the nine months ended September 30, 2016 from $1.3 million in the comparable period in 2015, reflecting the upfront license fee of $15.0 million from our Healios collaboration in the first quarter of 2016.

Research and Development Expenses. Research and development expenses increased to $17.7 million for the nine months ended September 30, 2016 from $16.0 million in the comparable period in 2015. The increase of $1.7 million related primarily to an increase of $1.2 million in preclinical and clinical development costs, an increase in research supplies of $0.3 million, and increases in sponsored research and personnel costs. The increase in our clinical and preclinical costs is primarily due to increased product manufacturing costs and other costs related to our clinical trials. The increase in research supplies was due to an increase in 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 stayed consistent at $5.8 million for the nine months ended September 30, 2016 and September 30, 2015. We expect our general and administrative expenses to continue at a similar level during the remainder of the year.

Depreciation . Depreciation expense remained consistent at $0.2 million for the nine months ended September 30, 2016 and September 30, 2015.

Gain from Insurance Proceeds, net . The net insurance recovery gain of $0.7 million during the nine months ended September 30, 2016 included the cumulative losses associated with May 2016 flood damage (e.g., removal, disposal, clean-up, insurance deductible) and the cumulative insurance proceeds received. The net amount reflects a gain as of September 30, 2016 since most of the replacement cost was capitalized as leasehold improvements. As of June 30, 2016, such net insurance gain was zero, since the insurance proceeds were not yet in excess of the cumulative losses at that time.

Income (expense) from Change in Fair Value of Warrants, net . Expense of $1.7 million was recognized during the nine months ended September 30, 2016 for the market value change in our warrant liabilities, and $0.6 million of income was recognized during the nine months ended September 30, 2015. The fluctuation is primarily affected by the exercise prices of the warrants, our stock price and the remaining lives of the issued warrants.

Other Income, net. Other income, net, is typically comprised of net interest income and expense and net foreign currency gains and losses. However, we recognized other income of $0.2 million from a loan that was forgiven in the first quarter of 2016.

Income Tax Benefit. The income tax benefit in 2016 and 2015 represents refundable foreign tax credits.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and any available-for-sale securities. At September 30, 2016, we had $19.4 million in investments and cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

We have incurred losses since inception of our operations in 1995 and had an accumulated deficit of $311 million at September 30, 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 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 September 30, 2016, we generated proceeds aggregating $1.5 million from sales of our common stock to Aspire Capital at an average price per share of $2.04 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 with an additional cash payment of $10 million. Healios may exercise its option to expand the collaboration by the later of (i) December 31, 2016 and (ii) the 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 will receive payments for product supplied to Healios under a manufacturing supply agreement.

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. 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.

Under the terms of our RTI agreement, we are eligible to receive cash payments aggregating up to $35.5 million upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no milestone payments have been received as of September 30, 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 September 30, 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 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 January 2016, a $190,000 loan, including accrued interest, related to a 2012 local grant was forgiven according to its terms based on our achievement of certain milestones

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates and manufacturing process development. At September 30, 2016, we had available investments and cash and cash equivalents of $19.4 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. 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 used in operating activities was $4.6 million for the nine months ended September 30, 2016 and $8.4 million for the nine months ended September 30, 2015, reflecting the approximately $15.0 million of cash received from Healios in January 2016 and $10.0 million of cash received from Chugai Pharmaceuticals in the first nine months of 2015, and the use of cash in funding our preclinical and clinical development operating activities. Net cash used in operating activities has fluctuated significantly on a quarter-to-quarter basis 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. We expect the annual cash used for operating activities to increase in 2016 compared to 2015 due to our planned clinical and process development activities.

Net cash used in investing activities was $12.2 million and $0.1 million for the nine months ended September 30, 2016 and 2015, respectively. The increase in the 2016 period related to net $11.1 million of investment purchases, with the remainder of the increase related to purchases of equipment primarily for our process development projects and as replacements for assets damaged in the 2016 flood damage. Purchases of equipment, net of insurance proceeds received, were $1.1 million for the nine-month period ended September 30, 2016, compared to $0.1 million for the comparable prior year period.

Financing activities provided cash of $2.1 million and $10.9 million for the nine months ended September 30, 2016 and 2015, respectively, related to equity sales to Aspire Capital and the exercise of common stock warrants, net of treasury stock purchases.

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

The Securities and Exchange Commission, or SEC, defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. A description of these accounting policies and estimates is included in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 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," 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:

- the timing and nature of results from our MultiStem cell therapy clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios clinical trial in Japan;
- our ability to successfully initiate and complete clinical trials of our product candidates within an expected timeframe or at all
- the possibility of delays in, adverse results of, and excessive costs of the development process;

- the productivity, reliability and availability of suppliers, including contract research and contract manufacturing organizations;
- 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 other disease indications, including GvHD;
- our ability to raise capital to fund our operations;
- the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs;
- the success of our collaboration with Healios and others, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments;
- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;
- our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements;
- 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;
- changes in our business strategy;
- changes in external economic and market factors;
- changes in our industry's overall performance; 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. We invest our excess cash primarily in debt instruments of the United States government, municipal government-backed bonds and FDIC-insured bank certificates of deposit. As of September 30, 2016, all of our investments were in municipal government-backed bonds and FDIC-insured bank certificates of deposit. 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 have entered into loan arrangements with financial institutions when needed and when available to us. At September 30, 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.

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 September 30, 2016, we sold an aggregate of 741,418 shares of common stock to Aspire Capital at an average purchase price of $2.04 per share. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, in each case Aspire Capital had the necessary investment intent.

Item 6. Exhibits.

Exhibit No.	Description
31.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Laura K. Campbell, 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

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: November 9, 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)

EXHIBIT INDEX

Exhibit No.	Description
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EXHIBIT 31.1

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.

November 9, 2016

/s/ Gil Van Bokkelen

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

EXHIBIT 31.2

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.

November 9, 2016

/s/ Laura K. Campbell

Laura K. Campbell
Senior Vice President of Finance

EXHIBIT 32.1

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 September 30, 2016, 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: November 9, 2016

/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.