ATHERSYS, INC / NEW
Form 10-Q
November 10, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from _____ to _____.

Commission file number: 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**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

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 x 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 x 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 x
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 x

The number of outstanding shares of the registrant s common stock, $0.001 par value, as of November 1, 2014 was 77,515,339.

Table of Contents

ATHERSYS, INC.

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Athersys, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	**$ 32,368**	$ 31,948
Accounts receivable	**665**	520
Prepaid expenses and other	**416**	387
Total current assets	**33,449**	32,855
Equipment, net	**1,331**	1,333
Total assets	**$ 34,780**	$ 34,188
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 2,891**	$ 2,243
Accrued compensation and related benefits	**909**	1,067
Accrued clinical trial costs	**85**	88
Accrued expenses	**692**	884
Deferred revenue		86
Note payable	**181**	
Total current liabilities	**4,758**	4,368
Note payable		176
Warrant liabilities	**3,204**	9,823
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2014 and December 31, 2013		
Common stock, $0.001 par value; 150,000,000 shares authorized, and 77,515,339 and 70,749,212 shares issued at September 30, 2014 and December 31, 2013, respectively, and 77,515,339 and 70,683,480 shares outstanding at September 30, 2014 and December 31, 2013, respectively	**78**	71
Additional paid-in capital	**306,706**	284,323
Treasury stock, at cost; 65,732 shares at December 31, 2013		(135)

Accumulated deficit		**(279,966)**		(264,438)
Total stockholders equity		**26,818**		19,821
Total liabilities and stockholders equity	**$**	**34,780**	$	34,188

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except share and per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
Revenues				
Contract revenue	**$ 75**	$ 87	**$ 155**	$ 365
Grant revenue	**218**	534	**1,233**	1,153
Total revenues	**293**	621	**1,388**	1,518
Costs and expenses				
Research and development	**5,775**	4,689	**17,756**	15,372
General and administrative	**1,695**	1,450	**5,303**	4,512
Depreciation	**91**	86	**272**	257
Total costs and expenses	**7,561**	6,225	**23,331**	20,141
Loss from operations	**(7,268)**	(5,604)	**(21,943)**	(18,623)
Other income (expense), net	**9**	(4)	**80**	28
Income (expense) from change in fair value of warrants, net	**2,540**	(6)	**6,335**	(2,353)
Net loss and comprehensive loss	**$ (4,719)**	$ (5,614)	**$ (15,528)**	$ (20,948)
Net loss per share - Basic	**$ (0.06)**	$ (0.10)	**$ (0.20)**	$ (0.38)
Weighted average shares outstanding - Basic	**77,320,425**	57,646,306	**76,755,599**	55,722,235
Net loss per share - Diluted	**$ (0.08)**	$ (0.10)	**$ (0.23)**	$ (0.38)
Weighted average shares outstanding - Diluted	**78,349,840**	59,248,031	**78,495,281**	55,722,235

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2014	**2013**
Operating activities		
Net loss	**$ (15,528)**	$ (20,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**272**	257
Stock-based compensation	**1,894**	918
Change in fair value of warrant liabilities	**(6,335)**	2,353
Changes in operating assets and liabilities:		
Accounts receivable	**(145)**	37
Prepaid expenses and other assets	**(29)**	3
Accounts payable and accrued expenses	**295**	(890)
Deferred revenue and other	**(81)**	
Net cash used in operating activities	**(19,657)**	(18,270)
Investing activities		
Purchases of equipment	**(270)**	(331)
Net cash used in investing activities	**(270)**	(331)
Financing activities		
Proceeds from issuance of common stock and warrants, net	**19,701**	10,617
Purchase of treasury stock	**(292)**	(137)
Proceeds from exercise of warrants	**938**	402
Net cash provided by financing activities	**20,347**	10,882
Increase (decrease) in cash and cash equivalents	**420**	(7,719)
Cash and cash equivalents at beginning of the period	**31,948**	25,533
Cash and cash equivalents at end of the period	**$ 32,368**	$ 17,814

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three- and Nine-Month Periods Ended September 30, 2014 and 2013

1. Background and Basis of Presentation

We are an international biopharmaceutical company that is focused primarily on the field of regenerative medicine and operate in one business segment. Our operations consist primarily of research and product development activities.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our critical accounting policies, estimates and assumptions are described in Management s Discussion and Analysis of Financial Condition and Results of Operations, which is included below in this Quarterly Report on Form 10-Q.

2. Recently Issued Accounting Standard

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, the amendment provides five steps that an entity should apply when recognizing revenue. The amendment also specifies the accounting of some costs to obtain or fulfill a contract with a customer and expands the disclosure requirements around contracts with customers. An entity can either adopt this amendment retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the update recognized at the date of initial application. The amendment is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. We are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements.

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 its plans alleviate that doubt. The guidance is effective for the annual periods ending after December 15, 2016 and interim periods thereafter with early adoption permitted. We are in the process of evaluating the impact the new guidance will have on our disclosures.

Table of Contents

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, 2014 and 2013, in thousands.

	Three months ended September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
Numerator:				
Net loss attributable to common stockholders - Basic	**$ (4,719)**	$ (5,614)	**$ (15,528)**	$ (20,948)
Less: income from change in fair value of warrants	**(1,160)**	(33)	**(2,504)**	
Net loss attributable to common stockholders used to calculate diluted net loss per share	**$ (5,879)**	$ (5,647)	**$ (18,032)**	$ (20,948)
Denominator:				
Weighted-average shares outstanding - Basic	**77,320**	57,646	**76,756**	55,722
Potentially dilutive common shares outstanding:				
Warrants	**1,030**	1,602	**1,739**	
Weighted-average shares used to calculate diluted net loss per share	**78,350**	59,248	**78,495**	55,722
Basic earnings per share	**$ (0.06)**	$ (0.10)	**$ (0.20)**	$ (0.38)
Dilutive earnings per share	**$ (0.08)**	$ (0.10)	**$ (0.23)**	$ (0.38)

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
Stock options	**6,261,164**	5,130,329	**6,261,164**	5,130,329
Restricted stock units	**2,142,779**	2,674,348	**2,142,779**	2,674,348
Warrants	**6,310,000**	1,459,026	**6,310,000**	5,409,027
Total	**14,713,943**	9,263,703	**14,713,943**	13,213,704

4. Fair Value of Financial Instruments

Fair Value Measurements

We classify the inputs used to measure fair value into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Adjusted 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 significant 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, 2014 (in thousands):

		Fair Value Measurements at September 30, 2014 Using		
Description	**Balance as of September 30, 2014**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Warrant liabilities	$ 3,204	$	$	$ 3,204

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 is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. The following inputs were used at September 30, 2014:

	Expected Volatility	Risk-Free Interest Rate	Expected Life
Warrants with one year or less remaining term	114.77%	0.13%	0.50 year
Warrants with greater than one year remaining term	67.59% - 78.63%	0.13% - 0.58%	1.34 - 2.46 years

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, 2014		Nine months ended September 30, 2014	
Balance July 1, 2014	**$**	**5,744**	**Balance January 1, 2014**	**$** **9,823**
Issuance of warrants			Issuance of warrants January 2014	2,012
Exercise of warrants			Exercise of warrants	(2,296)
Gain included in income from change in fair value of warrants for the period		(2,540)	Gain included in income from change in fair value of warrants for the period	(6,335)
Balance September 30, 2014	**$**	**3,204**	**Balance September 30, 2014**	**$** **3,204**

5. Collaborative Arrangements and Revenue Recognition

Pfizer

In 2009, we entered into a collaboration with Pfizer Inc. (Pfizer) to develop and commercialize our MultiStem® product candidate to treat inflammatory bowel disease (IBD) for the worldwide market on an exclusive basis. We are eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs. No significant milestone revenue has been recognized to date.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes, which is recognized in the period that the manufacturing services are performed. Pfizer has responsibility for development and regulatory, including decision-making regarding the advancement or cessation of further development under the collaboration. If the product is successfully developed, Pfizer would also have sole responsibility for commercialization. We may elect to co-develop with Pfizer, in which case, the parties would share development and commercialization expenses and profits (if any) on an agreed basis beginning at Phase 3 clinical development. Alternatively, we may elect to not co-develop with Pfizer, in which case Pfizer will pay us tiered single-digit royalties on worldwide commercial sales of MultiStem IBD products. Any royalties may be subject to certain reductions related to market exclusivity, patent claims and credits from sales milestone payments. In the event that Pfizer does not move the program forward, the development and commercialization rights would revert to us.

Table of Contents

RTI Surgical, Inc.

In 2010, we entered into an agreement with RTI Surgical, Inc. (RTI) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market on an exclusive basis. 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 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. Any royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

6. Stock-based Compensation

We have two incentive plans that authorized an aggregate of 11,500,000 shares of common stock for awards to employees, directors and consultants. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards. As of September 30, 2014, an aggregate of 1,342,905 shares of common stock underlying stock-based awards have been issued or exercised under our equity incentive plans. In the three-month period ended September 30, 2014, restricted stock units equivalent to 302,359 shares of common stock vested during the period.

As of September 30, 2014, a total of 1,753,152 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 8,403,943 shares of common stock were outstanding. For the three-month periods ended September 30, 2014 and 2013, stock-based compensation expense was approximately $714,000 and $606,000, respectively. At September 30, 2014, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $6,117,000, which is expected to be recognized by the end of 2018 using the straight-line method.

7. Issuance of Common Stock and Warrants

In January 2014, we completed a registered direct offering generating net proceeds of approximately $18.8 million through the issuance of 5,000,000 shares of common stock and warrants to purchase 1,500,000 shares of common stock with an exercise price of $4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of $4.10 per fixed combination.

During the quarter ended September 30, 2014, we did not sell any shares to Aspire Capital, and during the nine-month period ended September 30, 2014, we sold 250,000 shares of common stock at an average price of $3.78 per share. In accordance with the equity purchase agreement, we could elect to sell to Aspire Capital up to $23.5 million of shares of common stock.

As of September 30, 2014, we had the following outstanding warrants to purchase shares of common stock:

	Number of	Exercise Price	Expiration

Underlying Shares			
1,310,000	$	3.55	February 2, 2016
3,021,077	$	1.01	March 14, 2017
3,500,000	$	2.50	March 31, 2015
1,500,000	$	4.50	July 15, 2016
9,331,077			

8. Warrant Liabilities

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as a non-current liability. The warrant liabilities are revalued at fair value at each balance sheet date subsequent to the initial issuance. Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as income (expense) from change in fair value of warrants.

Table of Contents

The warrants we issued in the January 2014 and December 2013 registered direct offerings contain a provision for a cash payment in the event that the shares are not delivered to the holder within two trading days. The cash payment equals $10 per day per $2,000 of warrant shares for each day late. The warrants issued in the March 2012 private placement and the February 2011 registered direct offering each contain a provision for net cash settlement in the event that there is a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to a Black Scholes value of the remaining unexercised portion of the warrant. Further, the March 2012 warrants include price protection in the event we sell stock below the exercise price, as defined, and the exercise price as reduced in February 2013 to $1.01 per share as a result of the October 2012 public offering.

The warrants have been classified as liabilities, as opposed to equity, due to the potential adjustment to the exercise price that could result upon late delivery of the shares or potential cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date.

9. Income Taxes

We have net operating loss and research and development tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses. As a result of our October 2012 equity offering, our net operating loss carryforwards are significantly limited for use under Section 382 of the Internal Revenue Code.

Table of Contents

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

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

We are an international biopharmaceutical company that is focused primarily in the field of regenerative medicine. Our MultiStem® cell therapy is currently being evaluated in multiple clinical trials. Our current clinical development programs are focused on treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. We are also applying our pharmaceutical discovery capabilities to identify and develop small molecule compounds with potential applications in indications such as obesity, related metabolic conditions and certain neurological conditions.

Current Programs

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

Ischemic Stroke: In our ongoing Phase 2 clinical study, we are evaluating the administration of MultiStem cell therapy to patients that have suffered an ischemic stroke. In contrast to treatment with thrombolytics, which must be administered within 3 to 4 hours after a stroke, we are treating patients one to two days after the stroke has occurred. In preclinical studies, administration of a single dose of MultiStem therapy, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and Europe. The study is expected to enroll approximately 136 patients. Enrollment is nearing completion and interim safety and initial efficacy results are expected to be available and communicated following analysis of the ninety-day patient data.

Inflammatory Bowel Disease: MultiStem therapy is being evaluated in a Phase 2 clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, or UC, the most common form of inflammatory bowel disease, or IBD. This study is being conducted with our partner, Pfizer, and we released interim results in April 2014. The study is expected to run through 2014 to complete the secondary evaluations. The interim results showed that a single administration of MultiStem to a patient population with chronic advanced disease failed to show a meaningful clinical effect at the eight-week evaluation period. Despite not showing a significant improvement compared to placebo in the primary efficacy endpoints, the MultiStem therapy demonstrated favorable tolerability and safety in the eight weeks following treatment. Furthermore, at four weeks, the proportion of responders treated with MultiStem had a statistically significant improvement in their Mayo rectal bleeding score, as compared to patients treated with placebo, raising the possibility of a transient effect from a single MultiStem dose. Additional detail is being collected through the course of 2014, and further analysis of this and other data, such as biomarker information, is being undertaken by Pfizer. In the event that Pfizer does not move forward with the program, development and commercialization rights would revert to us.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem to patients that suffered an acute myocardial infarction, or AMI, in a Phase 1 clinical study. The results of this study demonstrated a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal, and one-year follow-up data suggested that the benefit observed was sustained over time. We have been awarded a grant for up to $2.8 million to support the advancement of this clinical program, and we are completing preparations for the launch of this Phase 2 clinical study.

Hematopoietic Stem Cell Transplant / GvHD: We have completed a Phase 1 clinical study of the administration of MultiStem cells to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell transplant. Such patients are at significant risk for serious complications, including graft-versus-host disease, or GvHD, an imbalance of immune system function caused by transplanted immune cells that

Table of Contents

attack various tissues and organs in the patient. Data from the study demonstrated the safety of MultiStem cells in this indication and suggested that the therapy may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. The MultiStem therapy has been designated an orphan drug by both the United States Food and Drug Administration, or FDA, and the European Medicines Agency, which may provide market exclusivity and other substantial incentives and benefits. We have interacted with the FDA and also engaged with the EMA to finalize trial design. Currently, we are staging this program for future development dependent our other clinical programs and the achievement of certain business development and financial objectives.

We are conducting or supporting clinical activity in other areas, such as solid organ transplant, which is an investigator initiated study being conducted at a leading transplant center in Europe. We are also engaged in the preparation stages for clinical studies in other targeted areas.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem therapy in other inflammatory and immune, neurological and cardiovascular disease areas, as well as certain other indications. We conduct such work both through our own internal research efforts and through a broad global network of collaborators.

We are in discussions with third parties about collaborating in the development of MultiStem therapy for certain programs and may enter into one or more business partnership(s) to advance these programs.

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

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

Financial

In January 2014, we completed a registered direct offering generating net proceeds of approximately $18.8 million through the issuance of 5,000,000 shares of common stock and warrants to purchase 1,500,000 shares of common stock with an exercise price of $4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of $4.10 per fixed combination.

Under our equity purchase agreement with Aspire Capital Fund LLC, or Aspire Capital, we sold 250,000 shares of common stock at an average price of $3.78 per share during the nine-month period ended September 30, 2014. During the nine months ended September 30, 2014, we received proceeds of approximately $938,000 from the exercise of warrants, resulting in the issuance of 928,924 shares of common stock in the aggregate.

Results of Operations

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date, but we receive royalties on commercial sales by a licensee of products using our technologies. Research and development expenses consist primarily of external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from

intellectual property prosecution processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

Table of Contents

Three Months Ended September 30, 2014 and 2013

Revenues. Revenues decreased to $0.3 million for the three months ended September 30, 2014 from $0.6 million in the comparable period in 2013, reflecting a $0.3 million decrease in our grant revenues. Our grant revenues fluctuate from period to period based on the timing of grant-related activities and the award and expiration of new grants. Contract revenue remained consistent at $0.1 million for each of the three months ended September 31, 2014 and 2013. Absent any new collaborations, we expect our contract revenues to continue at similar levels for the remainder of the year and to be comprised of royalty payments from RTI and potential license and milestone payments from Bristol-Myers Squibb.

Research and Development Expenses. Research and development expenses increased to $5.8 million for the three months ended September 30, 2014 from $4.7 million in the comparable period in 2013. The $1.1 million increase is primarily comprised of an increase in preclinical and clinical development costs of $0.4 million, an increase in research supplies of $0.4 million, an increase in personnel costs of $0.2 million and an increase in stock-based compensation of $0.1 million. The increase in our preclinical and clinical development costs is primarily due to increased manufacturing costs, clinical study costs and regulatory costs. The increase in research supplies was due to an increase in internal process development activities. The increase in personnel costs related to selective personnel additions and annual compensation increases. We expect our 2014 annual research and development expenses to be higher than the 2013 expenses based on our planned clinical development and manufacturing process development activities, and such costs will vary over time based on clinical manufacturing and clinical trial activity during any given period. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to $1.7 million for the three months ended September 30, 2014 from $1.5 million in the comparable period in 2013. The increase was due primarily to an increase in personnel costs of $0.1 million and an increase in legal and professional costs of $0.1 million compared to the same period in 2013. The increase in personnel costs related primarily to annual compensation increases, and legal and professional costs primarily due to increased professional services. We expect our 2014 quarterly general and administrative expenses to continue at similar levels during the remainder of the year.

Depreciation. Depreciation expense of $0.1 million remained consistent during each of the three-month periods ended September 30, 2014 and 2013.

Other Income (Expense), net. Other income (expense), net, for the three-month period ended September 30, 2014 and 2013 remained relatively consistent during the periods, and was comprised of interest income and expense and foreign currency gains and losses.

Income (Expense) from Change in Fair Value of Warrants, net. Income of $2.5 million was recognized during the three months ended September 30, 2014 for the market value change in our warrant liabilities, compared to $6,000 of expense in the comparable period in 2013. The fluctuation is related to the impact of new warrant issuances and changes in warrant value as affected by the exercise prices, our stock price and the remaining lives of the issued warrants.

Nine Months Ended September 30, 2014 and 2013

Revenues. Revenues decreased to $1.4 million for the nine months ended September 30, 2014 from $1.5 million in the comparable period in 2013 reflecting a $0.2 million decrease in our contract revenues, partially offset by a $0.1 million dollar increase in our grant revenue. Our grant revenues fluctuate from period to period based on the timing of

grant-related activities and the award of new grants. Absent any new collaborations, we expect our contract revenues to continue at similar levels for the remainder of the year and to be comprised of RTI royalty payments and potential license and milestone payments from Bristol-Myers Squibb.

Research and Development Expenses. Research and development expenses increased to $17.8 million for the nine months ended September 30, 2014 from $15.4 million in the comparable period in 2013. The increase of $2.4 million related primarily to an increase in personnel costs of $0.8 million, an increase in stock-based compensation of $0.5 million, an increase in sponsored research costs of $0.2 million, an increase in research supplies of $0.5 million, an increase in legal and professional fees of $0.2 million and an increase

Table of Contents

in other research and development costs of $0.2 million. Personnel costs rose due to selective personnel additions and annual compensation increases. Stock-based compensation increased primarily due to additional months of ratable expense from restricted stock units granted in June 2013. Sponsored research costs increased primarily due to an increase in grant-funded programs involving collaboration with certain academic research institutions. The increase in research supplies was due to an increase in internal process development activities. The increase in legal fees resulted from increased patent expenses associated with patent prosecution, national filings, and interparty proceedings and related filings. The increase in our clinical and preclinical costs is primarily due to increased manufacturing costs, increased clinical study costs and increased process development costs. We expect our 2014 annual research and development expenses to be higher than the 2013 expenses based on our planned clinical development and manufacturing process development activities, and such costs will vary over time based on clinical manufacturing and clinical trial activity during any given period. 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 $5.3 million for the nine months ended September 30, 2014 from $4.5 million in the comparable period in 2013. The $0.8 million increase was due primarily to an increase in personnel costs of $0.3 million and an increase in stock based compensation of $0.5 million compared to the same period in 2013. The increase in personnel costs related primarily to annual compensation increases, and stock-based compensation increased primarily due to the impact of vesting of restricted stock units granted in June 2013. We expect our 2014 quarterly general and administrative expenses to continue at similar levels during the remainder of the year.

Depreciation. Depreciation expense of $0.3 million remained consistent during each of the nine-month periods ended September 30, 2014 and 2013.

Other Income (Expense), net. Other income (expense), net, for the nine-month period ended September 30, 2014 and 2013 remained relatively consistent during the periods, and was comprised of interest income and expense and foreign currency gains and losses.

Income (Expense) from Change in Fair Value of Warrants, net. Income of $6.3 million was recognized during the nine months ended September 30, 2014 for the market value change in our warrant liabilities, and expense of $2.4 million was recognized during the nine months ended September 30, 2013. The fluctuation is related to the impact of new warrant issuances and changes in warrant value as affected by the exercise prices, our stock price and the remaining lives of the issued warrants.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and any available-for-sale securities on hand. At September 30, 2014, we had $32.4 million in cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company.

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of $280 million at September 30, 2014. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

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

We have an equity purchase agreement with Aspire Capital, whereby Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over a two-year period ending in 2015, subject to our election to sell any such shares. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price.

Table of Contents

During the quarter ended September 30, 2014, we did not sell any shares to Aspire Capital, and during the nine-month period ended September 30, 2014, we sold 250,000 shares of common stock at an average price of $3.78 per share. In accordance with the equity purchase agreement, we could elect to sell to Aspire Capital up to $23.5 million of shares of common stock.

During the nine months ended September 30, 2014, we received proceeds of approximately $938,000 from the exercise of warrants, resulting in the issuance of 928,924 shares of common stock in the aggregate.

Under the terms of our agreement with Pfizer, we are eligible to receive milestone payments of up to $105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve any milestones. No significant milestone payments have been received as of September 30, 2014. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development and regulatory, including decision-making regarding the advancement or cessation of further development under the collaboration. If the product is successfully developed, Pfizer would also have sole responsibility for commercialization. We may elect to co-develop with Pfizer, in which case, the parties would share development and commercialization expenses and profits (if any) on an agreed basis beginning at Phase 3 clinical development. Alternatively, we may elect to not co-develop with Pfizer, in which case Pfizer will pay us tiered single-digit royalties on worldwide commercial sales of MultiStem IBD products. Any royalties may be subject to certain reductions related to market exclusivity, patent claims and credits from sales milestone payments. In the event that Pfizer does not move the program forward, the development and commercialization rights would revert to us.

Under the terms of our RTI agreement, we are eligible to receive cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no milestone payments have been received as of September 30, 2014. 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. 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.

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties.

We are obligated to pay the University of Minnesota a royalty based on worldwide commercial sales of licensed products if covered by a valid licensed patent. The low single-digit royalty rate may be reduced if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we are entitled to proceeds of up to $500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive heart failure and for preparing the program for an investigational new drug application, or IND, with the FDA. Interest on the loan accrues at a fixed rate of 4.25% per annum and is added to the outstanding principal. The loan is forgivable based on the achievement of a certain milestone within three to four years. As of September 30, 2014, we had drawn $166,000 of this financing, which is recorded as a current liability of $181,000 (including accrued interest) since the note is due in the first quarter of 2015 if the forgiveness conditions are not met.

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, 2014, we had available cash and cash equivalents of $32.4 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 opportunities, as well as grant-funding opportunities. Additionally, we are raising capital from time to time through the equity purchase agreement with Aspire Capital, subject to its 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.

Table of Contents

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 $19.7 million for the nine months ended September 30, 2014 and $18.3 million for the nine months ended September 30, 2013, representing the use of cash to fund operations, clinical trials, and preclinical and process development activities. We expect that net cash used in operating activities will be higher in total in 2014 compared to 2013 in connection with increased clinical development activities for our MultiStem product candidates and platform. Net cash used in operating activities has fluctuated significantly on a quarter-to-quarter basis over the past few years primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs, and manufacturing process development projects.

Net cash used in investing activities was $0.3 million for each of the nine months ended September 30, 2014 and 2013 related to the purchase of equipment supporting our operations. We anticipate that our overall capital equipment expenditures will be similar in 2014 as compared to 2013.

Financing activities provided cash of $20.3 million for the nine months ended September 30, 2014 related to the January 2014 registered direct offering, the exercise of common stock warrants, and equity sales to Aspire Capital, net of treasury stock purchases. Financing activities provided cash of $10.9 million for the nine months ended September 30, 2013 as a result of equity sales to Aspire Capital and the exercise of common stock warrants during the period.

Investors in certain of our equity offerings have received warrants to purchase shares of our common stock, of which warrants to purchase an aggregate of 9.3 million shares remain outstanding at September 30, 2014 with a weighted average exercise price of $2.49 per share. The exercise of warrants could provide us with cash proceeds. During the three months ended September 30, 2014, no warrants were exercised.

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management s view, important to the portrayal of our financial condition and results of operations and demanding of management s judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been

prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. A description of these accounting policies and estimates is included in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2013. There have been no material changes in our accounting policies and estimates as described in our Annual Report. For additional information regarding our accounting policies, see Note B to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2013.

Table of Contents

Cautionary Note on Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as anticipates, believes, can, continue, could, estimates, expects, intends, may, plans, potential, should, suggest, will, expressions. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this Quarterly Report on Form 10-Q.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. These risks may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements.

Other important factors to consider in evaluating our forward-looking statements include:

- our ability to raise capital to fund our operations;
- the timing and nature of results from our MultiStem clinical trials;
- the possibility of delays in, adverse results of, and excessive costs of the development process;
- our ability to successfully initiate and complete clinical trials of our product candidates;
- uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the prevention of GvHD and the treatment of IBD, AMI, stroke and other disease indications;
- changes in external market factors;
- changes in our industry s overall performance;
- changes in our business strategy;

our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development;

our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;

our ability to meet milestones under our collaboration agreements;

our collaborators ability to continue to fulfill their obligations under the terms of our collaboration agreement;

the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in Japan;

our possible inability to execute our strategy due to changes in our industry or the economy generally;

changes in productivity and reliability of suppliers; and

the success of our competitors and the emergence of new competitors.

Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. When appropriate based on interest rates, we invest our excess cash primarily in debt instruments of the United States government and its agencies and corporate debt securities, and as of September 30, 2014, we had no investments. Over the past several years, we have been investing conservatively due to economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At September 30, 2014, we had no borrowings outstanding other than a potentially forgivable note payable associated with local grant funding bearing fixed, forgivable interest of 4.25% per annum.

Item 4. Controls and Procedures.

Disclosure controls and procedures

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Vice President of Finance, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as of the end of the period covered by this quarterly report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Vice President of Finance have concluded that, as of the end of the period covered by this quarterly report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

During the third quarter of 2014, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 6. Exhibits.

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

Table of Contents

SIGNATURES

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

ATHERSYS, INC.

Date: November 10, 2014

/s/ Gil Van Bokkelen
Gil Van Bokkelen
Chairman and Chief Executive Officer
(principal executive officer authorized to sign on behalf of the registrant)

/s/ Laura K. Campbell
Laura K. Campbell
Vice President of Finance
(principal financial and accounting officer authorized to sign on behalf of the registrant)

Table of Contents

EXHIBIT INDEX

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