

ATHERSYS, INC / NEW
Form 10-Q
May 14, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

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)

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| | |
|--|--|
| Delaware (State or other jurisdiction of incorporation or organization) | 20-4864095 (I.R.S. Employer Identification No.) |
| 3201 Carnegie Avenue, Cleveland, Ohio (Address of principal executive offices) | 44115-2634 (Zip Code) |
| Registrant's telephone number, including area code: <u>(216) 431-9900</u> | |

Former name, former address and former fiscal year, if changed since last report: Not Applicable

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|--|---|
| Large accelerated filer <input type="checkbox"/> | Accelerated filer <input type="checkbox"/> |
| Non-accelerated filer <input type="checkbox"/> | Smaller reporting company <input checked="" type="checkbox"/> |

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

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of May 9, 2013 was 56,304,763.

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ATHERSYS, INC.

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Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****Athersys, Inc.****Condensed Consolidated Balance Sheets**

(In thousands, except share and per share data)

(Unaudited)

| | March 31, 2013 | December 31, 2012 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 21,345 | \$ 25,533 |
| Accounts receivable | 473 | 490 |
| Prepaid expenses and other | 293 | 286 |
| Total current assets | 22,111 | 26,309 |
| Equipment, net | 1,310 | 1,294 |
| Total assets | \$ 23,421 | \$ 27,603 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,054 | \$ 1,767 |
| Accrued compensation and related benefits | 405 | 827 |
| Accrued clinical trial costs | 547 | 950 |
| Accrued expenses | 971 | 934 |
| Total current liabilities | 4,977 | 4,478 |
| Note payable | 171 | 169 |
| Warrant liabilities | 5,272 | 2,709 |
| Stockholders' equity: | | |
| Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2013 and December 31, 2012 | | |
| Common stock, \$0.001 par value; 100,000,000 shares authorized, and 54,381,937 and 53,058,632 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively | | |
| | 54 | 53 |
| Additional paid-in capital | 256,030 | 253,889 |
| Accumulated deficit | (243,083) | (233,695) |
| Total stockholders' equity | 13,001 | 20,247 |
| Total liabilities and stockholders' equity | \$ 23,421 | \$ 27,603 |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Athersys, Inc.****Condensed Consolidated Statements of Operations and Comprehensive Loss**

(In thousands, except share and per share data)

(Unaudited)

| | Three months ended | |
|--|--------------------|-------------------|
| | 2013 | March 31, 2012 |
| Revenues | | |
| Contract revenue | \$ 84 | \$ 2,463 |
| Grant revenue | 242 | 284 |
| Total revenues | 326 | 2,747 |
| Costs and expenses | | |
| Research and development | 5,576 | 5,569 |
| General and administrative | 1,507 | 1,259 |
| Depreciation | 85 | 75 |
| Total costs and expenses | 7,168 | 6,903 |
| Loss from operations | (6,842) | (4,156) |
| Other income (expense), net | 17 | (755) |
| (Expense) income from change in fair value of warrants | (2,563) | 575 |
| Net loss | \$ (9,388) | \$ (4,336) |
| Basic and diluted net loss per common share | \$ (0.18) | \$ (0.17) |
| Weighted average shares outstanding, basic and diluted | 53,455,779 | 25,547,219 |
| Items included in other comprehensive loss: | | |
| Proportional share of comprehensive loss of equity-method investment | | (28) |
| Comprehensive loss | \$ (9,388) | \$ (4,364) |

See accompanying notes to unaudited condensed consolidated financial statements.

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

(In thousands)

(Unaudited)

| | Three months ended | |
|---|---------------------------|-------------|
| | March 31, | |
| | 2013 | 2012 |
| Operating activities | | |
| Net loss | \$ (9,388) | \$ (4,336) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 85 | 75 |
| Gain on sale of investment | | (183) |
| Stock-based compensation | 116 | 136 |
| Issuance of common stock to former lenders | | 703 |
| Change in fair value of warrant liability | 2,563 | (575) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 17 | 290 |
| Prepaid expenses and other assets | (7) | 57 |
| Accounts payable and accrued expenses | 501 | (233) |
| Deferred revenue | | (1,351) |
| Net cash used in operating activities | (6,113) | (5,417) |
| Investing activities | | |
| Maturities of available-for-sale securities | | 3,237 |
| Purchases of equipment | (101) | (206) |
| Net cash (used in) provided by investing activities | (101) | 3,031 |
| Financing activities | | |
| Proceeds from issuance of common stock and warrants, net | 2,026 | 8,376 |
| Net cash provided by financing activities | 2,026 | 8,376 |
| (Decrease) increase in cash and cash equivalents | (4,188) | 5,990 |
| Cash and cash equivalents at beginning of the period | 25,533 | 8,785 |
| Cash and cash equivalents at end of the period | \$ 21,345 | \$ 14,775 |

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Athersys, Inc.****Notes to Unaudited Condensed Consolidated Financial Statements**

Three-Month Periods Ended March 31, 2013 and 2012

1. Background and Basis of Presentation

We are an international biotechnology 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, 2012. 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.

Certain prior year amounts have been reclassified to conform with current year presentations.

2. 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. 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 | |
|------------------------|---------------------------|-------------|
| | March 31, | |
| | 2013 | 2012 |
| Outstanding options | 4,005,601 | 4,519,601 |
| Restricted stock units | 70,814 | 39,300 |
| Outstanding warrants | 5,806,853 | 10,783,323 |
| Total | 9,883,268 | 15,342,224 |

Table of Contents**3. Financial Instruments***Fair Value Measurements*

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

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

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.

Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2013 (in thousands):

| Description | Fair Value Measurements at March 31, 2013 Using Significant | | | |
|---------------------|---|--|--------------------------------|--|
| | Balance as of March 31, 2013 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liabilities | \$ 5,272 | \$ | \$ | \$ 5,272 |

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. The fair value of the warrants is estimated using a Black-Scholes pricing model using the expected volatility based on the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants issued in March 2012 is determined using probability weighted-average assumptions that give consideration to the exercise price repricing feature that is dependent upon the consummation of future qualified offerings, as defined, and requisite stockholder approval. The following inputs were used at March 31, 2013:

| | Warrants Issued February 2011 | Warrants Issued March 2012 |
|---|----------------------------------|-------------------------------|
| Expected volatility | 71.5% | 71.6% |
| Risk-free interest rate | 0.36% | 0.36% |
| Expected life (in years) | 2.83 years | 3.95 years |
| Fair value at March 31, 2013 (in thousands) | \$576 | \$4,696 |

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

| | Three months ended March 31, 2013 |
|---|--|
| Balance January 1, 2013 | \$ 2,709 |
| Loss included in expense from change in fair value of warrants for the period | 2,563 |
| Balance March 31, 2013 | \$ 5,272 |

4. Collaborations 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. Under the terms of the agreement, we received a non-refundable up-front payment from Pfizer and research funding and support through June 2012. In addition, 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. In concluding that each milestone is substantive, we considered factors such as whether the associated consideration fairly represents either the level of effort required to reach the milestone or the value added to the product based on the achievement of such milestone. No significant milestone revenue has been recognized to date.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement had multiple deliverables that should be combined into a single unit of accounting. We recognized the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which was completed mid-2012, and measured manufacturing revenue beginning upon the culmination of the earnings process and recognized it over the performance period of the bundled unit of accounting.

RTI Biologics, Inc.

In 2010, we entered into an agreement with RTI Biologics, Inc. (RTI) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we received a \$5.0 million license fee in installments, of which \$3.0 million was guaranteed and received in 2010 and 2011, and \$2.0 million was contingent upon future events and considered a substantive milestone at the inception of the agreement. We evaluated the facts and circumstances and determined the RTI agreement had obligations constituting deliverables and concluded that it has multiple deliverables, including deliverables relating to the grant of a license to our technology and performance of research and development services, and concluded that these deliverables should be combined into a single unit of accounting. We recognized the \$3.0 million guaranteed license fee ratably on a straight-line basis over the estimated performance period, which was completed in 2011.

In September 2012, RTI agreed to make the remaining \$2.0 million license fee payments by December 31, 2012, and we agreed to provide RTI with certain technical support through December 31, 2012. The \$2.0 million consideration associated with the amendment was recognized over the performance period from September 2012 through December 2012.

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We are also 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. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies. No milestone or royalty revenue has been recognized to date.

5. Stock-based Compensation

We have two incentive plans that authorized an aggregate of 5,500,000 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 to qualified employees, directors and consultants.

As of March 31, 2013, a total of 1,414,841 shares were available for issuance under our equity compensations plans and stock-based awards to purchase 4,076,415 shares of common stock were outstanding. For the three-month periods ended March 31, 2013 and 2012, stock-based compensation expense was approximately \$116,000 and \$136,000, respectively. At March 31, 2013, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$524,000, which is expected to be recognized by the end of 2017 using the straight-line method.

6. Issuance of Common Stock and Warrants

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional \$2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination, and the warrants include price protection in the event we sell stock below the exercise price, as defined. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to \$1.01 per share. In connection with this private placement, our former lenders were entitled to a milestone payment in the amount of \$900,000, of which 75% was settled through the issuance of our common stock at \$1.94 per share to the former lenders at our election.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital Fund, LLC (Aspire Capital) is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. 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. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of 666,667 shares of our common stock at \$1.50 per share in 2011, and received 266,667 additional shares as compensation for its commitment. In 2012, we sold an additional 800,000 shares to Aspire Capital at an average price of \$1.57 per share. In the first quarter 2013, we sold an additional 1,323,305 shares to Aspire Capital at an average price of \$1.54 per share. From its inception through May 9, 2013, we have issued 4,364,972 shares and received aggregate gross proceeds of approximately \$7.3 million under the equity purchase agreement.

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As of March 31, 2013, we had the following outstanding warrants to purchase shares of common stock:

| Number of Underlying Shares | Exercise Price | Expiration |
|--|-----------------------|-------------------|
| 149,026 | \$ 5.00 | June 8, 2014 |
| 1,310,000 | \$ 3.55 | February 2, 2016 |
| 4,347,827 | \$ 1.01 | March 14, 2017 |
| 5,806,853 | | |

As of March 31, 2013, no warrants had been exercised. Subsequent to March 31, 2013, we have received proceeds of approximately \$350,000 from the exercise of March 2012 warrants aggregating 347,826 shares of common stock.

7. Warrant Liability

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, which is revalued at fair value at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes valuation model to value the warrant liability at its fair value. 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 both 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 was 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 cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date.

8. 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 most recent equity offerings, all of the net operating loss and credit carryforwards have been significantly limited for use under Section 382 of the Internal Revenue Code.

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

This discussion and analysis should be read in conjunction with our unaudited financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2012. 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 on the field of regenerative medicine. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem[®], a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in two ongoing Phase II 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. These represent major areas of clinical need, as well as substantial commercial opportunities.

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. To date, we have advanced five programs to the clinical development stage, including the following:

Inflammatory Bowel Disease: MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis (UC), the most common form of IBD. This study is being conducted with our partner, Pfizer, in UC patients who have an inadequate response or are refractory to current treatment, and is a double blind, placebo controlled trial that began enrolling patients in 2011. Enrollment of the trial is ongoing and designed to include up to 126 patients, with initial results expected to be reported in the second half of 2013.

Ischemic Stroke: In an ongoing Phase II clinical study, we are evaluating the administration of MultiStem to patients who 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, 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 may include sites in Europe. The study is expected to enroll approximately 136 patients. We completed the first patient cohorts, and the independent safety monitoring committee found in 2012 that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment is ongoing and for the remainder of the trial, patients are being randomized to receive either high dose MultiStem or placebo. We anticipate announcing initial results for the study in the first half of 2014.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem in a Phase I clinical study to patients who have suffered an acute myocardial infarction (AMI). In 2010, we announced preliminary results for this study, demonstrating 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 in 2012. One-year follow-up data suggested that the benefit observed was sustained over time. We completed preliminary planning for a Phase II trial, and a 150 patient study has been authorized by the United States Food and Drug Administration (FDA). Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

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Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase I clinical study of the administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell (HSC) transplant. Such patients are at significant risk for serious complications, including graft-versus-host disease (GvHD), an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In 2011 and in 2012, we released data from the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. This program has been assigned orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval and certain other benefits. We met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the initiation will depend on the progress in our other clinical trials and the achievement of certain business development and financial objectives.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide some financial support for this investigator-sponsored Phase I study and provide the product to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem 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 network of collaborations we have established with investigators at leading research institutions across the United States and in Europe.

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

We have also collaborated with RTI on the development of products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies, and have received \$5.0 million in license fees. We will also receive royalty revenue from product sales should they occur, as well as potential additional milestone payments.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions, such as schizophrenia. Currently, we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain, the 5HT_{2c} serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit favorable attributes, including outstanding receptor selectivity, as well as greater potency and activity than other 5HT_{2c} agonists. We have also demonstrated our compounds are complementary with other agents and believe these compounds could achieve best in class weight loss, as well as a superior safety and tolerability profile. Furthermore, we have evaluated certain compounds in preclinical models of schizophrenia that exhibit an attractive selectivity profile and also observed that these compounds exhibit potent effects. We are in discussions with interested companies and may elect to enter into a partnership to advance the development of our 5HT_{2c} agonist program, either for the treatment of obesity, schizophrenia, or both indications.

Financial

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$243 million at March 31, 2013. 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.

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In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. 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. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of 666,667 shares of our common stock at \$1.50 per share in 2011, and received 266,667 additional shares as compensation for its commitment. In 2012, we sold an additional 800,000 shares to Aspire Capital at an average price of \$1.57 per share. In the first quarter 2013, we sold an additional 1,323,305 shares to Aspire Capital at an average price of \$1.54 per share. From its inception through May 9, 2013, we have issued 4,364,972 shares and received aggregate proceeds of approximately \$7.3 million under the equity purchase agreement.

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. 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.

The following table sets forth our revenues and expenses for the periods indicated. The following tables are stated in thousands.

| | Three months ended March 31, | |
|--|---|-------------|
| | 2013 | 2012 |
| Revenues | | |
| Contract revenue | \$ 84 | \$ 2,463 |
| Grant revenue | 242 | 284 |
| | \$ 326 | \$ 2,747 |
| | | |
| | Three months ended March 31, | |
| | 2013 | 2012 |
| Research and development expenses | | |
| <i>Type of expense</i> | | |
| Personnel costs | \$ 1,311 | \$ 1,343 |
| Research supplies | 547 | 398 |
| Facilities | 274 | 255 |
| Clinical and preclinical development costs | 2,457 | 2,540 |
| Sponsored research | 277 | 297 |
| Patent legal fees | 418 | 389 |
| Other | 252 | 305 |
| Stock-based compensation | 40 | 42 |
| | \$ 5,576 | \$ 5,569 |

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| | Three months ended March 31, | |
|--|---------------------------------|----------|
| | 2013 | 2012 |
| General and administrative expenses | | |
| <i>Type of expense</i> | | |
| Personnel costs | \$ 576 | \$ 540 |
| Facilities | 60 | 66 |
| Legal and professional fees | 413 | 287 |
| Other | 382 | 272 |
| Stock-based compensation | 76 | 94 |
| | \$ 1,507 | \$ 1,259 |

Three Months Ended March 31, 2013 and 2012

Revenues. Revenues decreased to \$326,000 for the three months ended March 31, 2013 from \$2.7 million in the comparable period in 2012, reflecting a \$2.4 million decrease in our Pfizer contract revenues. Our 2012 contract revenues included the amortization of Pfizer payments, including a \$6.0 million non-refundable up-front license fee, research and development funding, and payments for manufacturing services over the estimated performance period that ended in June 2012. Absent any new collaborations, we expect our contract revenues to continue in 2013 at a reduced level from 2012, and to be comprised of reimbursements from Pfizer for outsourced central processing costs for the clinical product, potential RTI royalty payments, and potential license and milestone payments from Bristol-Myers Squibb. Grant revenue remained relatively consistent for the periods presented and may fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

Research and Development Expenses. Research and development expenses were \$5.6 million for the three months ended March 31, 2013, which is level with the same period in 2012. The two largest components of research and development were also consistent, with clinical and preclinical development costs at \$2.5 million and personnel costs at \$1.3 million. Other minor variances for the three month periods ended March 31, 2013 and 2012 include an increase in research supply costs of \$149,000 and a decrease in other costs of \$53,000. Our annual research and development expenses are not expected to increase significantly through 2013 as compared to 2012 unless we receive proceeds from additional financing or business development activities to fund advancement of additional clinical programs. 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 \$1.5 million for the three months ended March 31, 2013 from \$1.3 million in the comparable period in 2012. The increase was due primarily to an increase in legal and professional fees of \$126,000 and an increase in other general and administrative costs of \$110,000 related to outside services for the three months ended March 31, 2013 compared to the same period in 2012. We expect our general and administrative expenses to continue at similar levels during 2013.

Depreciation. Depreciation expense increased to \$85,000 for the three months ended March 31, 2013 from \$75,000 in the comparable period in 2012, due to depreciation on new capital purchases.

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Other Income (Expense), net. Other income (expense), net, includes foreign currency gains and losses and any realized gains and losses on the sale of our assets. During the three-month period ended March 31, 2012, we recognized a gain of \$182,000 related to an equity-method investment that was liquidated. Also included in other expense for the three months ended March 31, 2012 are cash and stock-based milestone payments of \$937,000 paid to our former lenders in connection with our equity offerings.

(Expense) Income from Change in Fair Value of Warrants. Expense of \$2.6 million was recognized during the three months ended March 31, 2013 for the market value change in our warrant liabilities, and income of \$575,000 was recognized during the three months ended March 31, 2012.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and available-for-sale securities. At March 31, 2013, we had \$21.3 million in cash and cash equivalents. We have primarily financed our operations through equity financings, business collaborations and grant funding. 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 entered into an equity purchase agreement in 2011, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. 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. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of 666,667 shares of our common stock at \$1.50 per share in 2011, and received 266,667 additional shares as compensation for its commitment. In 2012, we sold an additional 800,000 shares to Aspire Capital at an average price of \$1.57 per share. In the first quarter 2013, we sold an additional 1,323,305 shares to Aspire Capital at an average price of \$1.54 per share. From its inception through May 9, 2013, we have issued 4,364,972 shares and received aggregate proceeds of approximately \$7.3 million under the equity purchase agreement.

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional \$2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination. The warrants have anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to \$1.01 per share. As of March 31, 2013, no warrants had been exercised. Subsequent to March 31, 2013, we have received proceeds of approximately \$350,000 from the exercise of March 2012 warrants aggregating 347,826 shares of common stock.

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In connection with our equity offerings, our former lenders were entitled to milestone payments until the remaining balance of an original \$2.25 million milestone was paid in cash and stock. We made cash and stock-based milestone payments of \$1.3 million to our former lenders during the year ended December 31, 2012, which settled the final balance of this contingent obligation, paying 75% of the milestone through the issuance of our common stock. The former lenders also received in 2007 seven-year warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00. The exercise of such warrants could provide us with cash proceeds. None of these warrants were exercised as of March 31, 2013.

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 March 31, 2013. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

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 March 31, 2013. In addition, we will receive tiered royalties on any worldwide commercial sales of implants using our technologies.

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.

In April 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 will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of March 31, 2013, we had drawn \$166,000 of this financing.

When we hold investments, our available-for-sale securities typically include United States government obligations and corporate debt securities. We have been investing conservatively due to the ongoing 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 and have held our investments until maturity. All available-for-sale securities had matured as of December 31, 2012. Our fixed assets are used for internal research and development and, therefore, are not impacted by these external factors.

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. At March 31, 2013, we had available cash and cash equivalents of \$21.3 million. As a result, 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 generate additional funding to meet our needs. We are actively exploring business development opportunities for certain of our MultiStem programs and our small molecule 5HT2c program, 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.

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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 \$6.1 million for the three months ended March 31, 2013 and \$5.4 million for the three months ended March 31, 2012. Net cash used in operating activities has fluctuated significantly over the past several quarters primarily due to the receipt of milestone payments, timing of certain clinical trial costs, and the recent decline in contract revenues. Taking into account working capital fluctuations, the increase for the three months ended March 31, 2013 reflects predominantly the decrease in contract revenues during the period. We anticipate that net cash used in operating activities will fluctuate in the remaining quarters of 2013 in connection with the fluctuations and changes in activity associated with the MultiStem clinical trials, the timing of clinical manufacturing, and the receipt of potential milestone payments.

Net cash used by investing activities was \$101,000 for the three months ended March 31, 2013 and net cash provided by investing activities was \$3.0 million for the three months ended March 31, 2012. The fluctuations from period-to-period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$101,000 and \$206,000 in the first quarter of 2013 and 2012, respectively. We anticipate that our overall capital equipment expenditures will be similar in 2013 as compared to 2012.

Net cash provided by financing activities was \$2.0 million for the three months ended March 31, 2013 and \$8.4 million for the three months ended March 31, 2012, as a result of our equity offerings and equity sales to Aspire Capital during each of those periods.

Investors in our March 2012 private placement received five-year warrants to purchase an aggregate of 4,347,827 shares of common stock with an exercise price of \$2.07 per share, with anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to \$1.01 per share. Also, investors in our February 2011 registered direct offering received five-year warrants to purchase an aggregate of 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The exercise of such warrants could provide us with cash proceeds. No warrants had been exercised at March 31, 2013. Subsequent to March 31, 2013, we have received proceeds of approximately \$350,000 from the exercise of March 2012 warrants aggregating 347,826 shares of common stock.

We have no off-balance sheet arrangements.

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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, 2012. 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, 2012.

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, 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:

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of IBD, AML, stroke and other disease indications, and the prevention of GvHD;

our ability to raise capital to fund our operations;

final 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 and obtain all necessary regulatory approvals to commercialize our product candidates;

changes in external market factors;

changes in our industry's overall performance;

changes in our business strategy;

our ability to protect our intellectual property portfolio;

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

our ability to meet milestones 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;

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

changes in productivity and reliability of suppliers; and
the success of our competitors and the emergence of new competitors.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the United States government and its agencies and corporate debt securities, and as of March 31, 2013, we had no investments. We have been investing conservatively due to the current economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we 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 March 31, 2013, we had no borrowings outstanding other than a 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 first quarter of 2013, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds**

During the quarter ended March 31, 2013, we sold an aggregate of 1,323,305 shares of common stock to Aspire Capital at an average price of \$1.54. 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, Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Vice President, Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

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SIGNATURES

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

Date: May 14, 2013

ATHERSYS, INC.

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

of the registrant)

/s/ Laura K. Campbell

Laura K. Campbell
Vice President of Finance
(principal financial and accounting officer authorized to

sign on behalf of the registrant)

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