

Bill Bunting – In-Site Communications

Thank you and good afternoon everyone. I'm Bill Bunting of In-Site Communications, Investor Relations for Athersys.

Thank you for joining today's call. You should have a copy of the press release issued at the close of market. If you've not received it, the release is available on the Athersys website at www.athersys.com or please call (Libby Abelt) at 212-759-5665 and it will be sent to you immediately.

Gil Van Bokkelen, Chairman and Chief Executive Officer, and BJ Lehmann, President and Chief Operating Officer of Athersys, will host today's call. The call is expected to last about 45 minutes and may be accessed through the company's Website at athersys.com.

A replay will be available after this call's completion by dialing 800-642-1687 in the US and Canada and 706-645-9291 from abroad and entering access code **59293658**.

Any remarks that Athersys may make about future expectations, plans, and prospects constitute forward looking statements for purposes of the Safe Harbor provision under the Private Securities Litigation Reform Act of 1995.

Actual results may differ materially from those indicated by these

forward looking statements as a result of various important factors including those discussed in the company's Form 10-Q, 10-K, and other public SEC filings.

Athersys anticipates that subsequent events and developments may cause its outlook to change. While the company may elect to update these forward looking statements at some point in the future the company specifically disclaims any obligation to do so.

With that I would like to turn the call over to BJ Lehmann.

BJ?

BJ Lehmann, President & Chief Operating Officer

Thanks, Bill. Good afternoon and welcome to the Athersys fourth quarter 2009 earnings call. I'm BJ Lehmann, President and Chief Operating Officer at Athersys. I will briefly review our financial results for the fourth quarter and full year ended December 31, 2009, and will then turn the call over to Gil Van Bokkelen, our Chairman and CEO, for a corporate update.

In the fourth quarter of 2009, we recorded revenues of approximately \$869,000 compared to \$259,000 for the same period in 2008. Our revenues are comprised of grant proceeds and contract revenues from our collaborations with Bristol-Myers Squibb and Pfizer. The

change is due principally to an increase in grant funded projects and contract fees in the fourth quarter of 2009 compared to 2008.

Our research and development expenses for the fourth quarter were approximately \$4.1 million compared to \$3.7 million for the same period last year. The difference relates primarily to increases in cash and stock compensation expenses, which were partially offset by decreases in clinical and preclinical costs and outsourced study costs during the period.

General and administrative expenses increased to \$1.7 million in the fourth quarter of 2009 compared to \$1.4 million in the fourth quarter of 2008, reflecting, among other things, increases in cash and stock compensation expenses.

Our net loss was \$5.0 million in the fourth quarter of 2009 compared to \$4.7 million in the fourth quarter of 2008.

For the year ended December 31, 2009, revenues declined to \$2.2 million from \$3.1 million in 2008, largely as a result of a decrease in revenues from our BMS collaboration. While we may continue to prepare and deliver validated drug targets to BMS for use in its drug discovery efforts, we anticipate that BMS's demand in the future for additional targets will be substantially reduced or cease all together. We expect some residual revenues associated with milestone achievement for targets previously delivered to BMS.

Also included in contract revenues are fees associated with our collaboration with Pfizer, which began in December 2009. Looking forward over the next few years, we expect our contract revenues related to the Pfizer collaboration to include (i) amortization of the \$6.0 million upfront license and technology access fee, (ii) research and development funding, (iii) payments for manufacturing, and (iv) possible milestone revenue.

Lastly, our revenues include grant proceeds, which remained relatively consistent for 2009 and 2008. However, the grant revenues could fluctuate during any year based on the timing of grant-related activities and the award of new grants.

Research and development expenses decreased to \$11.9 million in 2009 from \$16.5 million in 2008, resulting primarily from decreases in clinical and preclinical development costs and outsourced study costs, as partially offset by increases in cash and stock compensation expenses and sponsored research costs.

General and administrative expenses increased slightly in 2009 to \$5.6 million from \$5.5 million in 2008. The increase was a result of increases in cash and stock compensation expense that were partially offset by decreases in legal and professional costs.

Interest income decreased to \$375,000 in 2009 from \$1.1 million in 2008 due to the decline in cash and investment balances during the period. While we received an upfront payment from Pfizer in 2009,

the payment had limited impact on interest income given its receipt in late December.

Our net loss was \$15.4 million in 2009 compared to \$18.0 million in 2008.

Our cash, cash equivalents and available-for-sale securities were \$26.4 million at December 31, 2009. Based on our current operating plan and assuming no new financings or significant business transactions, we believe this will be sufficient to support our core operations through the end of 2011.

With that, I'd like to turn it over to Gil for a corporate update.

Gil Van Bokkelen, Chairman and Chief Executive Officer

Thanks, BJ.

Good afternoon everyone and thank you for joining our call today. I would like to begin with an update on our key development programs and briefly summarize the progress that we have made over the last several months. Let me start with our lead programs involving MultiStem[®], a patented and proprietary, allogeneic stem cell product that we are developing as a treatment for multiple disease indications. In 2009 we made significant progress on both the

business development front as well as in our own clinical and preclinical development efforts.

First, in December 2009, we entered into a collaborative agreement with Pfizer to develop and commercialize MultiStem for the treatment of inflammatory bowel disease, or IBD, for the worldwide market. Members of the Pfizer regenerative medicine team are already actively engaged in work with members of the Athersys team, and we are very pleased with the launch of the collaborative activities, and the coordinated effort by both teams, and are excited about the future direction of the partnership.

As we have described previously, under the terms of the agreement, we received an up-front cash payment of \$6 million from Pfizer and will receive research funding and additional support during the initial phase of the collaboration. In addition, we are eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones. Pfizer will have the primary responsibility for the development, regulatory approval and commercialization of the program, although the team at Athersys will be actively involved along the way, and we will be responsible for product manufacturing. In addition, we will receive tiered royalties on worldwide sales of any approved MultiStem IBD products. Alternatively, just prior to the initiation of Phase III clinical development, we may elect to co-develop MultiStem IBD products with Pfizer in which case we would share the development and commercialization expenses and profits

or losses on an agreed upon basis from Phase III forward, in addition to certain milestone payments that we may receive.

Currently we are working closely with Pfizer to complete planning and additional preparatory work prior to submitting an IND and moving the program into clinical development. One of the main reasons we mutually decided to collaborate is that both companies share a common objective and philosophy regarding how to approach the process of development, regulatory approval and commercialization of new medicines. As I have stated before, we will approach the development of MultiStem for IBD in a systematic and comprehensive manner. What that means is that our approach will be rigorous and thorough, so as to minimize the potential for unexpected delays or obstacles in the future. Again, our mutual objective is to leverage the prior work we have done in other areas, while working together with Pfizer to develop a deeper understanding of the biological and clinical profile and characteristics of MultiStem for IBD, and de-risk the overall development effort. Our work is well underway and we expect to make efficient progress with Pfizer toward our objective of advancing the program into clinical development.

Next, let me review the recent progress and status of our on-going MultiStem development programs. In 2008, we advanced two MultiStem programs into clinical development, initiating Phase I safety studies in cardiovascular disease for treating patients that have suffered an acute myocardial infarction, or AMI, and in oncology treatment support, administering MultiStem to leukemia or lymphoma

patients who are receiving a traditional bone marrow or hematopoietic stem cell transplant. The objective of this clinical program is to reduce the risk or severity of graft vs. host disease, or GvHD, while also potentially addressing other complications commonly associated with radiation conditioning regimens, such as compromised gastrointestinal function. Both of these Phase I safety studies were initiated based on extensive preclinical work in which MultiStem displayed a strong safety profile and efficacy in relevant animal models.

During the first quarter of 2010, we completed patient enrollment for our Phase I MultiStem AMI study. During the first half of 2010 we will complete both the one-month and four-month patient follow-up visits, and we expect to announce our top line results with our partner Angiotech during the middle of the year. The primary endpoint for the Phase I AMI trials is evaluating safety, although as we have described previously, we will also be monitoring secondary endpoints that involve assessment of cardiovascular function, such as ejection fraction and other measures of function. Looking forward, we plan to utilize the Phase I results combined with our extensive development efforts to design a robust Phase II program which will determine dose levels and delivery timing. Following the announcement of our Phase I results, we expect to provide some initial guidance on the prospective timing of a Phase II study.

For the Phase I study involving administration of MultiStem to cancer patients at risk for complications from a traditional bone marrow or

HSC transplant, we have two treatment arms: the first arm is a dose escalation study that involves administration of a single dose of MultiStem shortly after the initial hematopoietic stem cell transplant, and involves three separate dose levels. We have now successfully completed dosing of patients in the first two dose levels, and expect to initiate dosing of the third cohort shortly. The second arm of study involves administration of multiple doses of MultiStem, given over the first 30 days following the initial transplant in the second arm. The primary endpoint for this Phase I trial is safety, such as monitoring for acute infusional toxicity. In addition, we are evaluating multiple secondary endpoints, such as monitoring for incidence and severity of GvHD, survival and infection. I am pleased to report that we have recently received authorization from the independent safety committee to commence the multi-dose study and we are now dosing patients in this arm of the study.

As we reported in our prior earnings call, initial efforts to enroll patients in this study were slower than expected. However, last fall, we took steps to address this issue, through the addition of clinical sites, and through proposing protocol amendments that were subsequently authorized by the FDA and the Institutional Review Boards of the participating clinical sites. Protocol amendments included increasing the age limit for patients eligible to participate in the study, as well as enabling enrollment of patients receiving a bone marrow or HSC transplant or after previously experiencing a first remission, as opposed to limiting the study to inclusion of second remission patients. These modifications appear to have had a

positive impact on our enrollment rates, as we had hoped. Our goals for the program this year are to complete enrollment for the single dose administration arm, and to make substantial progress in the multi-dose arm.

In addition to these studies, we have been granted authorization by the FDA to initiate a third clinical study, administering MultiStem to patients for the treatment of ischemic stroke, a leading cause of death and disability. In contrast to single agent therapeutics, our preclinical data suggest that MultiStem can provide multiple therapeutic benefits in the context of a stroke or other neurological injury, and that the treatment window is potentially substantially greater than conventional therapies. The Phase I safety study authorized by the FDA is a double-blind, placebo-controlled study that allows for administration of MultiStem to patients 48 – 60 hours after an ischemic stroke has occurred. This treatment window would represent a meaningful increase over the current standard of care, which involves administration of the thrombolytic TPA within three hours of the occurrence of the stroke. As a result of this narrow treatment window, the vast majority of stroke patients do not receive treatment with TPA. Furthermore, we believe this IND is the first for a double-blind, placebo controlled clinical study in ischemic stroke patients using a stem cell therapy that may be produced at scale, administered “off the shelf”, and that offers multiple potential mechanisms of therapeutic benefit and a consistent safety profile.

In 2009 we took a cautious approach to initiating this clinical study, in

light of the volatile and uncertain capital markets. However, while we continued our preparations to initiate the study, we have also continued our research efforts designed to deepen our understanding of the ways in which MultiStem can promote healing and repair in the wake of an ischemic stroke or other types of neurological injury. Earlier today, members of Athersys and collaborators of the company presented research at the 8th Annual World Congress on Trauma, Shock, Inflammation and Sepsis (in Munich) that further demonstrates how MultiStem, when administered in various neurological injury models, including ischemic stroke, neonatal hypoxic ischemia, or spinal cord injury, can dramatically modulate gene expression and dynamically regulate multiple cell types and biological pathways that play a fundamental role in controlling damage and inflammation following neurological injury. As a result of this and the substantial prior work we and our growing network of collaborators have completed, we believe MultiStem will have broad application in the neurological area.

If MultiStem is demonstrated to be both safe and effective in appropriately designed, well-controlled studies, we believe that it would have a substantial effect on the standard of care for ischemic stroke, and could improve the quality of life for many patients in need, while also creating substantial value for the company and our shareholders. We are committed to advancing our stroke clinical program, as well as other programs in the neurological area.

We are excited about the progress we have made with MultiStem and

look forward to the further advancement of our trials. We believe that MultiStem has the potential to offer advancement in treatment to patients suffering from a range of diseases, including autoimmune diseases and other conditions that involve the immune system, and certain neurological conditions, especially those in which inflammation plays a role. As we have discussed publicly, we recognize that we are not in a position to pursue each potential opportunity relying solely on our current resources or internal operational capabilities. Accordingly over the past several years, we undertook two parallel efforts to address this. First, we have engaged in a network of collaborations with outstanding investigators across various disciplines and disease areas in work that is being conducted at leading institutions both here in the United States and Europe. We are excited by the progress being made in many of these collaborations, and look forward to publications, presentations and announcements by and with our collaborators to highlight the progress.

Second, we began to actively evaluate possible partnering opportunities with companies that understand the potential of stem cell therapy and its long term potential impact across multiple clinical areas. The collaborative agreement with Pfizer I discussed earlier is a result of these efforts, and it complements our previously established partnership in the cardiovascular area with Angiotech. We continue to pursue discussions with others, and we are encouraged by the growing evidence of interest in and commitment to the area among companies that possess complementary capabilities,

significant resources, and a dedication to developing therapies with best-in-class potential.

In addition to our MultiStem programs, we are developing pharmaceuticals for the treatment of obesity and certain neurological conditions affecting attention, cognition and wakefulness. In the obesity area, we are developing compounds that selectively stimulate the 5HT_{2c} serotonin receptor in the brain, which is known to play an important role in regulating appetite. These compounds, known as 5HT_{2c} agonists, are designed to reduce appetite and food intake, in order to achieve meaningful weight loss over time. The mechanism of action is extensively validated in humans through drugs such as fenfluramine and dexfenfluramine, and more recently through clinical experience with a novel 5HT_{2c} agonist, Lorcaserin. Unfortunately, fenfluramine and dexfenfluramine activated the 5HT_{2b} receptor which is now known to cause cardiovascular toxicity. Based on extensive clinical studies, Lorcaserin appears free to be free of these cardiovascular liabilities, as we and others had predicted. However, limited selectivity at the 5HT_{2a} receptor results in undesirable CNS related side effects when the drug is administered at higher dose levels, thereby limiting dosing and efficacy. This receptor is known to be the biological target of action for LSD and other hallucinogens.

The evidence in this area now clearly demonstrates that while potency for the 5HT_{2c} receptor offers the potential to achieve meaningful weight loss, compound selectivity at both the 5HT_{2b} and 5HT_{2a} receptors is necessary to achieve safety and tolerability, as

well as maximize efficacy. I am happy to report that we have successfully achieved a major objective, and have developed a high quality portfolio of potent compounds which are potent at the 5HT2c receptor, yet exhibit no agonist activity at either the 5HT2b or 5HT2a receptors at any physiologically relevant concentration. We believe this represents a substantial achievement, and that these compounds have the potential to be best-in-class clinical candidates. We are actively evaluating which compounds we want to move forward in our further development efforts, while we also evaluate potential partnering opportunities.

In addition to our 5HT2c agonist program, we are also independently developing novel orally active pharmaceutical products for the treatment of certain central nervous system disorders, including disorders affecting cognition, attention or wakefulness. This includes a range of indications, such as narcolepsy, excessive daytime sleepiness, or chronic fatigue associated with certain other disease conditions. It also includes potential indications such as attention deficit hyperactivity disorder, and cognitive disorders such as schizophrenia or certain diseases affecting memory. These programs are focused on the development of potent, selective histamine H3 receptor antagonist or inverse agonist compounds that act by elevating levels of neurotransmitters in the sleep and cognitive centers of the brain and stimulating neurological tone. This results in an enhanced state of wakefulness and cognition, without causing hyperactivity, excessive “rebound” sleepiness or addiction.

At Athersys we have developed a portfolio of highly potent, selective Histamine H3 antagonists and inverse agonists with properties that we believe create the potential for establishing best-in-class therapeutics. Specifically, we have been committed to developing compounds that exhibit outstanding potency and selectivity, half lives suitable for once per day dosing, and a strong safety profile that is free of toxicological properties that could be problematic for competing programs established at other companies. We are happy to report that we have successfully achieved that goal, and have established a portfolio of compounds that we believe have an outstanding competitive profile. Our histamine H3 program leads have demonstrated high potency and selectivity, excellent pharmacokinetic profile, are well tolerated and efficacious in animal models. In 2010, our goal is to select a clinical candidate for further development, whether developed alone or in the context of a partnership.

In addition to the development and collaboration efforts I have discussed today, I also want to briefly highlight some recent intellectual property achievements. In February, we were awarded two broad patents, one in the U.S. and the other in Europe, for non-embryonic pluripotent stem cells. These patents are especially important to Athersys as they extend the coverage of composition, isolation, differentiation and scalable manufacturing of non-embryonic stem cells that are at the core of our technology and product portfolio. Today, Athersys has a broad IP portfolio including 14 granted patents and more than 120 global patent applications surrounding our stem

cell technology and MultiStem product platform. We intend to further grow this intellectual property estate over time.

In closing I would like to state that we are encouraged by the results we have achieved and look forward to the continued progress of our trials and business development efforts. We believe that each program we are pursuing offers the opportunity to develop best-in-class therapeutic products with the potential to establish safer and more effective therapies to treat patients suffering from a broad range of diseases. We are committed to achieving that goal, and believe that in doing so we will be able to create substantial value for our shareholders. Finally our balance sheet is strong with \$26.4 million in cash at year end and provides us with adequate resources to prudently manage our development programs through 2011.

With that, we'd be happy to take a few questions.