

# Athersys Licenses its Animal Health Assets to Ardent Animal Health

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CLEVELAND & LEXINGTON, Ky.--(BUSINESS WIRE)-- **Athersys, Inc. (Nasdaq: ATHX)**, a cell therapy and regenerative medicine company developing MultiStem® (invivestrocel) for critical care indications, and Multipotent Adult Progenitor Cell (MAPC®) technology for equine, canine, and feline health applications, announces the signing of a licensing agreement with Ardent Animal Health (Ardent). Ardent is a privately held veterinary biotechnology company developing regenerative medicine and cancer therapies for animals.

Under the terms of the agreement, Athersys will receive an initial fee from Ardent in exchange for an exclusive license to Athersys' Multipotent Adult Progenitor Cell (MAPC®) technology for non-human mammal applications in the United States. The agreement includes pre- and post-regulatory approval milestone payments to Athersys, including payments on conditional and full product approval for each species/indication combination. Athersys will also receive tiered, double-digit royalties on commercial sales.

Athersys has also granted Ardent rights of first refusal to be the exclusive distributor for Athersys' novel cryogenic storage system, the Secure Integrated Freezer Unit (SIFU) in the United States animal health space.

"We're excited to announce this agreement with Ardent based on their proven capabilities in developing stem cell-based treatment options for animals. This agreement recognizes the progress we've made in preclinical research and manufacturing of MAPC for animal health and provides Ardent a solid foundation to build on," stated Dan Camardo, Chief Executive Officer of Athersys.

"We look forward to this partnership with Athersys as we develop innovative and life-changing treatments for animals. Through partnerships like this and with the strong results generated to date with MAPC, we're better able

to advance stem cell therapy for joint disease and other areas of unmet need in animal health,” added Thomas Masterson, President of Ardent.

## About Ardent Animal Health

Ardent Animal Health is a veterinary biotechnology company based in Lexington, Kentucky. Founded in 2016, its mission is to improve the lives of pets and people. Ardent’s pipeline includes novel cancer and regenerative medicine treatments for veterinary patients suffering from cancer and other inflammatory diseases. Ardent is a synonym for passionate, fiery and committed, which manifests through Ardent’s worldwide referral network providing advanced care for complicated diseases. Ardent is a Breakthru Portfolio company (see [www.realbreakthru.com](http://www.realbreakthru.com)). For more information, please visit <https://ardentanimalhealth.com/>.

## About MultiStem®

MultiStem® (invimestrocel) cell therapy is a patented regenerative medicine product in clinical development that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors in response to signals of inflammation and tissue damage. MultiStem therapy’s potential for multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The therapy represents a unique "off-the-shelf" stem cell product that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon its efficacy profile, its novel mechanisms of action, and a favorable and consistent tolerability demonstrated in clinical studies, we believe that MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

## About Athersys

Athersys is a biotechnology company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Athersys is developing its MultiStem® cell therapy product, a patented, adult-derived “off-the-shelf” stem cell product, initially for disease indications in the neurological, inflammatory and immune, and other critical care indications and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and a broad network of collaborations to further advance MultiStem cell therapy toward commercialization. While development of our clinical programs for human health indications remains our priority, our wholly owned subsidiary, ReGenesys developed a cell therapy based on Athersys’ Multipotent Adult Progenitor Cell (MAPC®) technology for use in treating diseases and conditions in the animal health area. We have conducted research in preclinical canine, equine and feline models to establish safety and explore the potential for MAPC cells to reduce inflammation and

promote healing which could provide meaningful benefits to animals. Investors and others should note that we may post information about Athersys on its website at [www.athersys.com](http://www.athersys.com) and/or on its accounts on Twitter, Facebook, LinkedIn or other social media platforms. It is possible that the postings could include information deemed to be material information. Therefore, Athersys encourages investors, the media and others interested in Athersys to review the information it posts on its website at [www.athersys.com](http://www.athersys.com) and on its social media accounts. Follow Athersys on Twitter at [www.twitter.com/athersys](http://www.twitter.com/athersys). Information that Athersys may post about itself on its website and/or on its accounts on Twitter, Facebook, LinkedIn or other social media platforms may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. You should not place undue reliance on forward-looking statements contained on Athersys' website and/or on its accounts on Twitter, Facebook, LinkedIn or other social media platforms, and Athersys undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

## Forward-Looking Statements

This press release 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 product candidates, Athersys' growth strategy, and its future financial performance, including its operations, economic performance, financial condition, prospects, and other future events, and any results from the license to Ardent and any revenues to Athersys as a result of such license. Athersys has attempted to identify forward-looking statements by using such words as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "should," "suggest," "will," or other similar expressions. These forward-looking statements are only predictions and are largely based on Athersys' current expectations. 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 Athersys faces are the risk that it will be unable to raise capital to fund its operations in the near term and long term, including its ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to it or at all, and to continue as a going concern. The following risks and uncertainties may cause Athersys' 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: its ability to raise capital to fund its operations in the near term and long term, including its ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to it or at all, and to continue as a going concern; whether Athersys receives a grant from BARDA; Athersys' collaborators' ability and willingness to continue to fulfill their obligations under the terms of Athersys' collaboration agreements and generate sales related to its technologies; the possibility of unfavorable results from ongoing and additional clinical trials involving MultiStem;

the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in an early stage clinical trial may not be predictive of results in later stage or large scale clinical trials; Athersys' ability to successfully license its SIFU technology; Athersys ability to regain and maintain compliance with the Nasdaq continued listing requirements; the timing and nature of results from MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial evaluating the administration of MultiStem for the treatment of ischemic stroke; Athersys' ability to meet milestones and earn royalties under its collaboration agreements, including the success of its collaboration with Healios; the MATRICS-1 clinical trial being conducted with The University of Texas Health Science Center at Houston evaluating the treatment of patients with serious traumatic injuries; the availability of product sufficient to meet Athersys' clinical needs and potential commercial demand following any approval; the possibility of delays in, adverse results of, and excessive costs of the development process; Athersys' ability to successfully initiate and complete clinical trials of its product candidates; the possibility of delays, work stoppages or interruptions in manufacturing by third parties or Athersys, such as due to material supply constraints, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors that could negatively impact Athersys' trials and the trials of its collaborators; uncertainty regarding market acceptance of Athersys' product candidates and Athersys' ability to generate revenues, including MultiStem cell therapy for neurological, inflammatory and immune, cardiovascular and other critical care indications; changes in external market factors; changes in Athersys' industry's overall performance; changes in Athersys' business strategy; Athersys' ability to protect and defend its intellectual property and related business operations, including the successful prosecution of its patent applications and enforcement of its patent rights, and operate its business in an environment of rapid technology and intellectual property development; Athersys' possible inability to realize commercially valuable discoveries in its collaborations with pharmaceutical and other biotechnology companies; the success of our efforts to enter into new strategic partnerships and advance Athersys' programs; Athersys' possible inability to execute its strategy due to changes in its industry or the economy generally; changes in productivity and reliability of suppliers; the success of Athersys' competitors and the emergence of new competitors; and the risks mentioned elsewhere in Athersys' Annual Report on Form 10-K for the year ended December 31, 2022 under Item 1A, "Risk Factors" and its other filings with the SEC. You should not place undue reliance on forward-looking statements, and Athersys undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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