

05 Apr 2024 | News

Healios Acquires Bankrupt Athersys, Expands Cell Therapy R&D Programs

by [Lisa Takagi](#)

Tokyo-based Healios will lead the global clinical studies for Athersys' cell therapy MultiStem for ARDS and start US Phase II trials for trauma following their long-term collaboration.

Regenerative medicine-focused Japanese biotech [Healios K.K.](#) has acquired its long-time US collaborator [Athersys, Inc.](#) in a move that will give it access to multiple assets and technologies.

The \$2.25m acquisition, completed on 4 April through a debtor in possession loan by Healios as sole creditor, took three months after the Cleveland-based biotech firm filed for bankruptcy in the US Bankruptcy Court for the Northern District of Ohio on 9 January and agreed to sell all its assets to Healios. (Also see "[Finance Watch: Clouds Still Darken Biopharma Sector Despite Sunny Forecasts](#)" - Scrip, 24 Jan, 2024.)

The "strategic acquisition" as described by Healios makes the Japanese firm the sole owner of Athersys's assets including MultiStem, a somatic stem cell regenerative medicine product the two firms had been co-developing for acute respiratory distress syndrome (ARDS) and ischemic stroke. Healios is now planning to further expand its indication to trauma while developing the product globally.

Athersys has financially struggled since MultiStem's Japanese Phase II/III study in collaboration with Healios for ischemic stroke missed its primary endpoint in 2022. (Also see "[Healios, Athersys Confident Despite Missed Japan Stroke Endpoint](#)" - Scrip, 25 May, 2022.) (Also see "[Finance Watch: Resilience Raises \\$625m, Bringing New Cash To \\$1.2bn](#)" - Scrip, 8 Jun, 2022.)

Long-Standing Collaboration

Tokyo-based Healios has maintained a tight partnership with Athersys since 2016, when the two firms signed an exclusive licensing agreement for MultiStem (previously HLCM051) for ischemic

stroke in Japan. MultiStem also also been the lead platform product for the US biotech focused on regenerative medicine.

In 2018, the collaboration for the product expanded to acute respiratory distress syndrome (ARDS) in Japan and to start clinical trials for the two targets.

Later the two firms also agreed to collaborate on MultiStem's commercialization, with the Japanese firm obtaining its manufacturing licence for both ischemic stroke and ARDS.

In 2023, Healios expanded its exclusive licence for MultiStem to develop the products globally for ARDS in return for milestones and royalties of up to \$4.5m to Athersys, which the Japanese firm will no longer need to pay after the acquisition. (Also see "[Asia Deal Watch: Maruho Licenses Rights In Japan To GI Innovation's Allergy Candidate](#)" - Scrip, 16 Oct, 2023.)

Japan's Healios Progresses Novel Cell Therapy For ARDS

By [Ian Haydock](#)

23 Apr 2019

Activity in Japan's cell and regenerative therapy space continues apace as venture starts trial with lead development asset for acute respiratory distress syndrome.

[Read the full article here](#)

MultiStem's R&D Goes On Despite Recent Disappointing Results

The \$2.25m acquisition provided Healios with MultiStem's intellectual property portfolio with over 400 patents, for which the Japanese firm foresees "new global development and partnering opportunities."

"This IP portfolio includes highly-valuable patents and know-how associated with the 3D bioreactor based manufacturing in which Athersys made extensive investments, and with which they successfully scaled manufacturing of MultiStem up to a 500L bioreactor, an achievement that is unmatched in the industry," the firm notes.

The firm notes its immediate focus is on developing the product for ARDS globally while announcing its ongoing Phase II MATRICS study for trauma in the US.

The Phase II at the University of Texas Health Science Center at Houston and Memorial Hermann-Texas Medical Center, with its large part being funded by the US Department of Defense and the Memorial Hermann Foundation treats trauma from serious events such as car accidents, industrial accidents, gun-shot wounds.

The recent results from MultiStem's clinical studies have been unsuccessful. In addition to the

Japanese Phase II/III for ischemic stroke which missed primary endpoints, the two firms announced in October 2023 its Phase III MASTER-2 study for moderate-to-severe ischemic stroke also missed its primary endpoints due to the small sample size of 300 patients.

Multiple Out-Licensing Agreements

Other than MultiStem, Healios gains several assets from Athersys, including out-licensing agreements with multiple firms, including Kentucky-based Ardent Animal Health for the use of the MultiStem platform in animals such as dogs, cats, horses in the US, and with [Bristol Myers Squibb Company](#) for an Athersys technology called Random Activation of Gene Expression (RAGE) for large-scale production of therapeutic proteins.

It also has several agreements with European universities, under which Athersys provided licensed MultiStem for use in research for liver disease, kidney transplant and perinatal stress.

The Japanese firm also obtains Athersys's frozen cell product storage device Secure Integrated Freezer Unit (SIFU), a technology which it expects to function as a supply chain solution for broader cell and gene therapy products.

“Healios was uniquely positioned to identify this value and execute on this transaction because of our close proximity to the situation and the skill set of our team,” noted company CEO Hardy Kagimoto.

“We would reiterate that this transaction represents an extraordinary capture of value for Healios shareholders, and an unusual achievement for a small cap Japanese company,” he added, noting the firm will announce its further strategy based on the acquired assets when finalized.