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Healios Acquires Substantially All of the Assets of Athersys, Inc. Free and Clear of Liabilities, Becomes Sole Owner of MultiStem®

On January 8, 2024, Athersys, Inc. and certain of its affiliates (together, "Athersys") announced the filing of voluntary petitions for protection under Chapter 11 of the U.S. Bankruptcy Code (the "Code"). HEALIOS K.K ("Healios") entered into an agreement with Athersys to acquire substantially all of its assets under Section 363 of the Code and moved forward with the related process (the "Process"). Pursuant to the order of the U.S. Bankruptcy Court for the Northern District of Ohio (the "Court"), on April 3, 2024, Healios completed the acquisition, becoming the owner of MultiStem®*1 and other assets of Athersys.

1. Background

On January 9, 2024, Healios announced that it agreed to provide a debtor in possession loan ("DIP loan") to Athersys, thereby becoming its sole secured creditor, and at the same time agreed to act as the "stalking horse" purchaser in relation to an auction process whereby Athersys sought to sell substantially all of its assets under Section 363 of the Code ("Healios enters into Agreement to Serve as DIP Lender and Stalking Horse Purchaser to acquire substantially all of the assets of Athersys in a Section 363 Sale Process in the United States"). We guided at the time that it would take approximately 8 to 12 weeks to complete the Process, and it took place in the Court over the course of January through March, 2024.

On March 27th, 2024, the Court approved the sale order accepting the terms of the asset purchase agreement (the "APA") proposed by Healios, whereby Healios would acquire substantially all of the assets of Athersys, including specified contracts, free and clear of liabilities, for a credit bid of $2.25 million against its DIP loan. We are pleased to announce today that further to this order by the Court, on April 3, 2024, Athersys and Healios closed on the asset purchase, and Healios became the owner of MultiStem and other Athersys assets pursuant to these terms, to be further described herein.

2. Significance of asset acquisition

The acquisition of the Athersys assets is highly strategic and accretive to the business of Healios, and represents a significant capture of value for our shareholders. As most readers will be aware, Healios has been developing MultiStem for ischemic stroke*2 and Acute Respiratory Distress Syndrome (ARDS) *3 in Japan. Last year, we acquired rights to develop ARDS globally. These promising programs involved potential milestone and royalty

payments to Athersys, and as a result of the acquisition of Athersys assets Healios is no longer subject to these milestones and royalties. Instead, Healios is now the owner of a MultiStem intellectual property ("IP") portfolio that currently includes over 400 patents, and while Healios will rationalize this portfolio for optimal efficiency, the control of the MultiStem IP provides tremendous new global development and partnering opportunities for the company. 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.

3. Major assets acquired

a) MultiStem Clinical Trial Data and Expansion of Indication to Trauma[*4]

Now, in addition to advancing MultiStem for the ARDS indication globally, we are in a position to advance the product through development and partnerships for any number of geographies and indications. While our immediate efforts are focused on ARDS, we will in the near future analyze data from the phase 3 MASTERS-2 study in ischemic stroke and utilizing the approximately 200 patients worth of data from it that is now in our possession, in combination with the 206 patients worth of data from our phase 2/3 TREASURE study in Japan, we will consider the going forward path for stroke on a global basis. We have spent time with stroke clinicians in the United States recently and they continue to be enthusiastic about MultiStem as the therapeutic candidate in development globally with the highest and best hope to become a new approved product for stroke.

In addition, we are announcing for the first time that as part of the acquisition, we have taken control of a 156 patient, phase 2 clinical trial in trauma (the "MATRICS" study) currently being run at University of Texas Health Science Center at Houston ("UTH") and Memorial Hermann-Texas Medical Center, the busiest level 1 trauma center in the U.S. The study is almost entirely funded by MTEC (United States Department of Defense) and the Memorial Hermann Foundation. The trauma being treated in this study is that which results from car accidents, industrial accidents, gun shot wounds, etc., and is the leading cause of death for people under the age of 45 and the leading cause of quality-of-life years lost. The use of MultiStem in the treatment of trauma also has meaningful potential US military applicability. We look forward to working with the clinicians at UTH on advancing the program for trauma patients.

b) Securing MultiStem Clinical Product and Other Materials

Beyond eliminating royalties and gaining rights to global indications, a next key asset that we acquired is hundreds of doses of MultiStem product for use in clinical trials. The majority of this product is made with our proprietary 3D bioreactor technology, which positions us to efficiently advance the product for multiple indications using cutting-edge, 3D bioreactor produced clinical material. We also obtained large volumes of master and working cell bank and other biological materials which we will utilize to efficiently advance the technology.

c) Expand R&D into New Areas

As part of the acquisition, we have taken over an out-licensing relationship with Ardent Animal Health, a Kentucky, U.S. based animal health company, who has licensed MultiStem for use in non-human mammals with a focus on dogs, cats, and horses in the United States domestic market. This license involves meaningful potential milestone and royalty payments to Healios over time. We look forward to working with the Ardent team to advance the technology for animal health. We also acquired an out-license relationship with Bristol Myers Squib, pertaining to a non-MultiStem technology developed by Athersys called RAGE (Random Activation of Gene Expression – which allows the large scale production of therapeutic proteins), and may earn income from this agreement over time. Additionally, as a result of the acquisition we are now engaged with several universities in Europe who have received grants for the research of MultiStem in liver disease, kidney transplant, and for perinatal stress, which provides us with additional sources of useful data for the technology.

d) Frozen Cell Product Storage

Over the past few years, Athersys developed an advanced frozen cell product storage device called SIFU™ ("Secure Integrated Freezer Unit") which is a promising solution to the logistical challenges faced by the cell and gene therapy industry due to the need for extremely low temperature storage, and the precise handling and streamlined management of highly valuable frozen inventory. We have acquired this technology, including its patents, plans, and prototype units. The SIFU technology not only offers a potential method for efficient commercial distribution of MultiStem, but a platform for the broader market, and we already have numerous discussions ongoing with potential partners for the technology.

4. Potential for future business

Tadahisa Kagimoto, MD, Chairman and CEO of Healios, made the following comment: "Athersys spent more than $650 million over time on the development of its technology. We have attempted to describe herein some of the value we have been able to obtain for $2.25 million. 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. 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. Not only have we eliminated our largest future potential liabilities, but we have increased our addressable market by many fold due to the global scope of our rights that now exist across all indications, we have made moving the technology forward more efficient by the attainment of a large volume of investigational product and materials, and we have obtained valuable other assets, contracts and data. We will announce our strategy based on this asset acquisition when our policy is finalized."

5. Future outlook

As announced on January 9, Healios has recorded $2.25 million as the amount of the DIP loan financing to obtain the APA and related preferential rights. The assets were acquired for the same amount as the DIP loan. The $2.25 million cost for this transaction will be recorded

as an expense in the 2nd quarter of the fiscal year ending December 31, 2024. We will promptly announce any matters that should be disclosed in the future.

*1 MultiStem®
MultiStem® (HLCM051) is a somatic stem cell regenerative medicine product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. MultiStem has been shown to exhibit powerful anti-inflammatory and immunomodulatory properties with applicability in a range of disease states, has been tested in hundreds of patients in late stage clinical trials, is manufactured consistently at scale in 3D bioreactors, and has demonstrated both safety and suggested efficacy in hundreds of patients across multiple indications. MultiStem is a proprietary technology wholly owned by Healios.

Healios has a long history developing MultiStem. It originally added MultiStem to its pipeline in 2016 through an exclusive license to develop and distribute the product to treat ischemic stroke in Japan. Further, in 2018 Healios expanded its license to include development and distribution to treat ARDS in Japan, and in 2023 it expanded its ARDS license to include global territories. Having acquired the full technology platform in April 2024, Healios is seeking to advance MultiStem on a global basis for ischemic stroke, ARDS, and trauma.

*2 Ischemic Stroke
Ischemic stroke is a condition in which a blockade in blood vessels in the brain precludes the delivery of oxygen and nutrients beyond the blockade, causing necrosis of nerve cells over time. Currently, ischemic stroke is treated with t-PA (a thrombolytic agent) that dissolves clots lodged in a blood vessel in the brain, mechanical reperfusion therapy, or other treatment options; however, there is a need for a new drug that can be used during a longer period of time after the onset of ischemic stroke. Healios conducted a randomized, double-blind, placebo-controlled Phase 2/3 trial (TREASURE study) designed to confirm the efficacy and safety of MultiStem in treating patients with ischemic stroke. Patients received a single intravenous infusion of MultiStem or placebo within 18-36 hours of stroke onset and a total of 220 patients were enrolled. The product has also been tested in two additional ischemic stroke clinical studies, the MASTERS-1 and MASTERS-2 trials, which collectively enrolled over 300 patients.

*3 Acute Respiratory Distress Syndrome (ARDS)
ARDS is a general term for respiratory failure that occurs suddenly in a variety of critically ill patients. Although there are many causes of ARDS, approximately one-third of ARDS cases are caused by pneumonia, and it has been confirmed that ARDS also occurs in critically ill patients with COVID-19. There is currently no approved drug therapy that can directly improve the prognosis of patients with ARDS, and respiratory failure is treated with mechanical ventilation. The mortality rate after the onset of ARDS is 30~58%*a, and there is a need for new therapies that can improve the prognosis of patients with ARDS. Currently, the number of patients in Japan is estimated to be approximately 28,000*b per year, and ARDS is designated as a rare disease. However, it is estimated that between 213,000 and

262,000*c patients in the United States, 133,000*d patients in Europe, 670,000 patients in China*e and more than 1.1 million patients worldwide are affected.
(Source)
*a ARDS Diagnostic Guidelines 2016
*b Healios Estimates Based on the Incidence Rate of Epidemiological Data and the Total Population of Japan by Demography
*c Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: Estimates for our company based on 28613773 Data and US Population Based on the Ministry of Foreign Affairs Basic Data
*d Community Research and Development Information Service (CORDIS) 2020 7-9.
*e song-et-al-2014-acute-respiratory-distress-syndrome-emergingresearch-in-china

*4 Trauma
Trauma involves severe injury to tissues or organs caused by mechanical, physical, or chemical forces external to the body, causing damage to bones, muscles and tendons, nerves, blood vessels, etc., as well as ruptured internal organs. Despite heterogeneity of the origin of traumatic injury, a high percentage of patients experience hyperinflammatory activity including Systemic Inflammatory Response Syndrome (SIRS) which leads to complications such as acute kidney injury (AKI), acute lung injury, ARDS, multiple organ failure, secondary infection, sepsis, venous thromboembolism (VTE), and other secondary injury (e.g., cerebral edema). Approximately two-thirds of trauma patients will experience SIRS, and new treatments are needed to modulate the inflammatory system to reduce its associated risk, which may lead to further complications and organ injury. In the United States alone, trauma accounts for over 150,000 deaths and over 3 million non-fatal injuries per year and is the leading cause of death for people under the age of 45. The economic cost of trauma amounts to an estimated $671 billion every year, including health care and work loss for those suffering from both fatal and non-fatal injuries.