January 9, 2024

Company Name: HEALIOS K.K.
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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

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 "Filing") in the U.S. Bankruptcy Court for the Northern District of Ohio (the "Court"). Concurrent with the Filing, HEALIOS K.K ("Healios") has agreed to provide Athersys with $2.25 million in debtor-in-possession financing (the "DIP loan")[*1], payable in stages upon the achievement of certain milestones. Following Court approval, this new financing, combined with cash on hand, will be used by Athersys to fund a process involving the sale of substantially all of the assets of Athersys under section 363 of the Bankruptcy Code (the "Process"). Healios has also agreed, subject to Court approval, to serve as the "stalking horse" purchaser for these assets. The Process will be subject to compliance with Court-approved bidding procedures and is expected to take approximately eight to twelve weeks to complete.

1. Relationship between Healios and Athersys

In 2016, Healios entered into an exclusive license agreement with Athersys for the development and marketing of its stem cell product MultiStem® (HLCM051)[*2] for ischemic stroke in Japan, and in 2018, Healios obtained a license to develop and market the product for acute respiratory distress syndrome (ARDS)[*3] in Japan and started clinical trials for both indications. In 2021, Healios entered into a comprehensive agreement with Athersys to expand its collaboration for commercialization, and in 2022, obtained licensing rights for the manufacturing of HLCM051 for ischemic stroke and ARDS, and subsequently performed a manufacturing technology transfer. In addition, in 2023, Healios agreed to expand its License Agreement for ARDS to cover global territories, dramatically increasing the number of ARDS patients for which Healios has the opportunity to treat with this therapy. Healios completed clinical trials in Japan to investigate the safety and efficacy of HLCM051 for ischemic stroke and ARDS. Building on two successful prior trials utilizing HLCM051, Healios is currently preparing to launch a clinical trial in Japan towards the goal of obtaining approval of the therapy for ARDS in the Japanese market and Healios is continuing to consult with regulatory authorities regarding the development path for ischemic stroke.

2. Impact of the corporate reorganization proceedings of Athersys on Healios

It has been agreed that our rights under the agreement with Athersys will be protected under federal law and will be properly managed in this proceeding to ensure that our business is not affected. Please refer to the "SEC Filings 8K, Jan. 08, 2024" in the Athersys website for more information on this matter.

3. Healios' future actions

Healios has been developing HLCM051 for ischemic stroke and ARDS mainly in Japan. Continuing these efforts, Healios will proceed to enter into an agreement with Athersys to purchase its assets under the Process in connection with the Filing and provide a DIP loan to obtain priority rights related to such assets, in order to acquire intellectual property, research data and other assets held by Athersys for business expansion into overseas development for the same disease and research for other indications. The amount of the DIP loan will be US$2.25 million under the criteria of the Process. When the Court approves the DIP loan and we become the sole secured creditor of Athersys, all of its assets will be held as collateral for the DIP loan. In parallel, bidding procedures under the Filing will be conducted, and it is expected that the Court's decision to approve the commencement of such bidding procedures and the approval of the DIP loan will be made within 30 days of the filing of these procedures, and the decision to approve the asset purchase agreement within 70 days of the filing of these procedures. In addition, in the event that there is a third party other than Healios who offers to purchase the assets in accordance with such bidding procedures, an auction will be held. If a third party offers an amount higher than the DIP loan amount and we win the bid for a higher amount, we may have to pay more than the DIP loan amount, but we will take appropriate action in accordance with the provisions of the U.S. Bankruptcy Code. We will announce further developments as appropriate.

Should the Court approve the Process, Healios would become the sole secured creditor of Athersys, and all the assets of Athersys would be held as collateral against the DIP loan. As the stalking horse purchaser, Healios would seek to acquire the assets free and clear of liabilities, and should the acquisition be completed it would be accretive to the business of Healios in a number of ways. For example, Healios programs utilizing HLCM051 as the lead candidate, including its development for ARDS globally, would no longer be subject to milestones and royalties. Instead, Healios would take ownership of a patent portfolio that includes over 400 global patents, thereby eliminating future economics that would have otherwise been payable. The acquisition would also provide substantial new global development and partnering opportunities for additional indications.

Healios looks forward to working constructively with Athersys' stakeholders including service providers to smoothly conclude the Process, and to efficiently advance HLCM051 for patients worldwide with severe unmet medical needs.

4. Future outlook

This matter has no impact on our consolidated financial results at this time. We will promptly announce any matters that should be disclosed in the future.

*1 DIP (Debtor in Possession) loan
A loan to provide necessary funds to companies with excessive debts that are undergoing restructuring, such as during bankruptcy proceedings in a Chapter 11 process under the U.S. Bankruptcy Code, which generally take the form of senior, secured loans.

*2 HLCM051
HLCM051 is a somatic stem cell regenerative medicine product. Healios added it to its pipeline by signing an exclusive licensing agreement with the United States based Athersys, Inc. ("Athersys") in January 2016, whereby Healios acquired rights to develop and distribute Athersys' proprietary stem cell product MultiStem® (HLCM051) to treat ischemic stroke in Japan. Further, in June 2018 Healios and Athersys expanded their collaboration broadly, and as part of this expansion Healios acquired the development and distribution licenses to use HLCM051 to treat ARDS in Japan. Two studies have been run utilizing HLCM051 in ARDS, the ONE-BRIDGE study in Japan and the MUST-ARDS study in the United States and United Kingdom, with both producing consistent, promising efficacy data. In October 2023, supported by the data, we agreed to expand our license for ARDS to cover all territories globally. In December 2023, Healios, its wholly-owned subsidiary Procellcure Inc., and Nobelpharma Co., Ltd. ("Nobel") entered into a letter of intent in relation to the development and distribution of HLCM051 for ARDS in Japan, which adds Nobel's substantial experience and capabilities developing and distributing orphan drugs in Japan, where they have achieved 16 drug approvals, and provides for Healios to generate revenue in the Japan geography from both margin on product supply as well as a projected 25 billion yen from up front, approval, and sales milestones over time. Healios is leading the development of HLCM051 for ARDS towards global approval and is preparing to launch a global registrational trial.

*3 Acute Respiratory Distress Syndrome (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 and 133,000[*d] patients in Europe are affected annually.
(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.