



PRESS RELEASE - INSIDE INFORMATION

10/07/2023

BioSenic provides further update on negotiations with its main creditors

Agreement with the main creditors of BioSenic for a standstill running until October 2023

Mont-Saint-Guibert, Belgium, July 10th, 2023, 7.00 am CEST – <u>BIOSENIC</u> (Euronext Brussels and Paris: BIOS), the innovative company addressing unmet medical needs in the areas of innate immunity, inflammation and organ/function repair, today announces a further update on its financial arrangements with its main historical creditors, Patronale, Monument and the European Investment Bank. BioSenic aims at renegotiating its main financial debts, inherited from Bone Therapeutics. This is required for BioSenic to successfully launch a new fundraising, in the form of a private placement in Q 3-4 2023.

For the debt renegotiation, our mediator, Yves Brulard, has achieved a standstill agreement from the main historical creditors for a period of 3 to 4 months. BioSenic will therefore be able to keep a good pace to develop its lead projects, while negotiating a long-term solution to access to the levels of financing required for all its preclinical and clinical programs.

Given this agreement with the main creditors and the one obtained on 30 June 2023 with Global Tech Opportunities 15 to secure short-term financing on the basis of the existing convertible bond program, BioSenic anticipates having sufficient cash to carry out its business objectives until October 2023.

Prof. François Rieger, CEO of BioSenic and President of the Board said: "BioSenic inherited significant debts from Bone Therapeutics prior to the reverse merger with Medsenic. Over the first semester of 2023, BioSenic has invested significant corporate resources in balancing and developing its programs along the lines set out in last year's merger terms. A necessary process for a restructuration of the main debts is now underway and we make sure that all our financial partners can gather together and contribute to the best conditions of future success of the company on its present lead programs".

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i), the allogeneic cell therapy platform ALLOB and (ii) the Arsenic TriOxide (ATO) platform. Key target indications for the platforms include Graft versus Host Disease (GvHD), Systemic lupus erythematosus (SLE), Systemic Sclerosis (SSc) and high-risk tibial fractures.

Following the merger in October 2022, BioSenic combined the strategic positionings and strengths of Medsenic and Bone Therapeutics. The merger enables Biosenic to add to its innovative cell therapy platform and strong IP for tissue repair protection, an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/OATO (oral ATO)...

BioSenic is based in the Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available at http://www.biosenic.com.

About BioSenic technology platforms

BioSenic's technology is based on two main platforms:

- The allogeneic cell and gene therapy platform, developed by BioSenic with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs), that can be stored at the point of use in hospitals. Its current investigational medicinal product, ALLOB, represents a unique, proprietary approach to organ repair and specifically to bone regeneration, by turning undifferentiated stromal cells from healthy donors into bone-forming cells on the site of injury. These cells are produced via a BioSenic's scalable manufacturing process. Following the CTA (Clinical Trial Application) approval by regulatory authorities in Europe, BioSenic had initiated patient recruitment for the Phase Ilb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB has been evaluated in a randomized, double-blind, placebo-controlled Phase Ilb study in patients with high-risk tibial fractures, using its optimized production process, after a successful first safety and efficacy study (Phase 1/2a) on fractured long bones, with late delayed union. The patient recruitment has been halted late February 2023 with 57 patients and the new rules permitted for statistical analysis allowed BioSenic to get the main results of this trial much earlier than anticipated in the original protocol. In June 2023, BioSenic decided to suspend its interventional trial on fracture healing using ALLOB, following negative results obtained for the primary endpoint in the exploratory Phase Ilb clinical trial with ALLOB, focused on safety and treatment timing efficacy (choice between early or late treatment).
- 2) The Arsenic TriOxide (ATO) platform developed by Medsenic. The immunomodulatory properties of ATO have demonstrated a double basic effect on cells of the immune system. The first effect is the increase of the cell oxidative stress in activated B, T or other cells of the innate/adaptative immune system to the point they will enter a cell death program (apoptosis) and be eliminated. The second effect is potent immunomodulatory properties on several pro-inflammatory cytokines involved in inflammatory or autoimmune cell pathways, with return to homeostasis. One direct application is its use in onco-immunology to treat GvHD (Graft-versus-Host Disease) in its chronic, established stage. GvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell





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transplantation (allo-HSCT). GvHD is primarily mediated by the transplanted immune cells that can lead to severe multiorgan damage. Medsenic has been successful in a Phase II trial with its intravenous formulation, with orphan drug designation status by FDA and EMA. The company is heading towards an international Phase III confirmatory study, with its new, IP protected, oral (OATO) formulation. Moderate to severe forms of Systemic Lupus erythematosus (SLE) is another selected target, using the same oral formulation. ATO has shown good safety and significant clinical efficacy on several affected organs (skin, mucosae and the gastro-intestinal tract) in an early Phase II a study. Systemic Sclerosis is also part of the clinical pipeline of BioSenic. Preclinical studies on pertinent animal models are positive. This gives good grounds to launch a Phase II clinical protocol. This serious chronic disease badly affects skin, lungs or vascularization, and has no actual current effective treatment.

In addition, BioSenic is working on a next-generation, off-the-shelf, enhanced viscosupplement, JTA, for knee osteoarthritis (OA), made of a unique combination of mammalian plasma proteins, derivatives of hyaluronic acid (a natural component of synovial fluid in the knee) and a third active component. JTA or some derivatives intend to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain (OA) and inflammation. In March 2023, after the clinical identification of distinct OA subtypes, BioSenic delivered a new post-hoc analysis of its Phase III JTA-004 trial on knee OA, demonstrating positive action on the most severely affected patient sub-population. This new post-hoc analysis drastically changes the therapeutic profile of the combined components and allows for better patient targeting in future clinical developments. The company, which does not intend to allocate R&D resources to support the clinical development of JTA-004, will focus its R&D and clinical activities on an accelerated development of its autoimmune (ATO/OATO) platform.

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