

BioSenic provides financial update and financial calendar 2023

Mont-Saint-Guibert, Belgium, March 31, 2023 - BIOSENIC (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in severe autoimmune/inflammatory diseases and cellular repair, provides today a financial update and publishes its financial calendar for the year 2023.

Financial Update

As a result of cost management efforts made and payments received (mainly from Pregene) in Q1 2023, BioSenic Group now anticipates having sufficient cash to carry out its business objectives until May 2023.

This updated cash forecast is based on the currently available cash and assumes negotiation of a revised RCA repayment schedule for turnover-independent reimbursements to be made under the recoverable cash advances (RCA) previously received by BioSenic.

Financial Calendar 2023

- 27 April – Full Year Results & Annual Report 2022
- 25 May – Q1 2023 Business and Financial Highlights
- 8 June – Annual General Meeting 2023
- 7 September – Half Year Results 2023
- 26 October – Q3 2023 Business and Financial Highlights

The financial calendar is communicated on an indicative basis and may be subject to change.

About BioSenic

BioSenic is a biotech company focused on (i) the development of innovative products to address high unmet needs in orthopedics and (ii) exploiting the possibilities offered by the therapeutic use of arsenic salts (mainly arsenic trioxide (ATO) for patients with autoimmune diseases. Key target indications for the platforms include Graft versus Host Disease (GvHD), Systemic lupus erythematosus (SLE), Systemic Sclerosis (SSc) and high-risk tibial fractures and other orthopedics indications, such as osteoarthritis, by combining new and tested, IP protected, techniques.

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

1. 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 after a single local injection. These cells are produced via a BioSenic's scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, BioSenic has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb 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 should allow BioSenic to get the main results of this trial much earlier than anticipated in the original protocol, since they are expected by mid-2023.

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. 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 transplantation (allo-SCT). GvHD is primarily mediated by the transplanted immune system that can lead to severe multiorgan damage. Medsenic had been successful in a Phase II trial with its intravenous formulation, allowing arsenic trioxide to be granted an orphan drug designation status by FDA and EMA and is heading towards an international Phase III confirmatory study, with a 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 a Phase IIa study.

Systemic Sclerosis is, in addition, 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 for this serious disease that badly affects skin, lungs or vascularization, and with no actual current effective treatment.

In addition, BioSenic is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, consisting of a unique combination of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic. JTA-004 intends 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 identification of new OA subtypes, BioSenic delivered a new post-hoc analysis of its Phase III JTA-004 trial on knee OA with positive action on the most severely affected patient population. This new post-hoc analysis changes the therapeutic profile of the molecule and potentially allows for the possibility of stratifying patients for a new, optimized Phase III clinical study. BioSenic, which does not intend to allocate R&D resources to support the clinical development of JTA-004 and will continue to focus its R&D activities on the development of its autoimmune (ATO) and cell therapy (ALLOB) platforms, is now seeking to collaborate with existing and potential partners to explore options for the future development of JTA-004 based on this new post-hoc analysis.