Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
biosenic@ibcomms.agency

BioSenic provides third quarter 2023 Business Update

Following the in-principle agreement reached with its main creditors in the context of ongoing equity raise process, the focus of BioSenic is now to proceed with fundraising, allowing to start its phase 3 international clinical trial with oral arsenic trioxide (ATO) in the first-line treatment of chronic Graft-versus-Host-Disease (cGvHD).

Mont-Saint-Guibert, Belgium, October 25, 2023 – BIOSENIC (Euronext Brussels and Paris: BIOS), the innovative company addressing unmet medical needs in the areas of innate immunity, inflammation and organ/function repair, today provides its business update for the third quarter, ended September 30, 2023.

Key highlights

- In July 2023, BioSenic obtained an agreement with Monument and Patronale for a standstill, postponing until Q4 any payment to these creditors.
- In September 2023, new binding term sheets have been signed for the replacement of the Monument and Patronale bonds and loans, by new unsecured convertible bonds. New potential terms, subject to formal approval by the European Investment Bank, have also been formulated for the long-term extension of the existing loan financing with the European Investment Bank in the context of ongoing equity raise process. Implementation of the terms agreed with all three lenders is subject to the completion of an equity investment in the Company.
- In August 2023, BioSenic announced the allowance of a new patent entitled 'Use of metal ions to potentiate the therapeutic effects of arsenic' by the China National Intellectual Property Administration (CNIPA). This patent (ZL202080040613.1) covers the use of its ATO platform in combination with metal ions like copper, allowing further further potential upon the use of arsenic to improve the treatment of autoimmune diseases, starting with cGvHD (the European Patent Office had granted a parallel wide patent protection in eight countries in Europe - EP3972613 - in April 2023).
- In September 2023, BioSenic published data in a peer-reviewed international journal 'Arthritis Research & Therapy', providing additional indications of its lead API (Active Pharmaceutical Ingredient) arsenic trioxide (ATO) to treat systemic sclerosis (SSc). These results give ground to the proposed clinical relevance of ATO treatment in SSc, and more generally in autoimmune related pathologies.
- In September 2023, BioSenic announced the completion of a post-hoc analysis of its phase 2 clinical trial of ATO, finding the most adapted scheme for administration of an efficient treatment for chronic Graft-versus-Host-Disease (cGvHD). As a result, BioSenic will further use this two-cycle treatment in its forthcoming phase 3 clinical trial. This involves the administration of a double four-week course, separated by a rest period, resulting in the use of two to four times more doses of ATO.

Financial highlights

- Net cash at the end of September 2023 amounted to EUR 0.39 million [(1)].
- Upon receipt of the two final instalments of EUR 300,000 under the existing convertible bonds program with GTO15, BioSenic anticipates having sufficient cash to carry out its business objectives until the end of January 2024. BioSenic will continue to require additional financing over the last 2023 Quarter and therefore actively evaluates various options, including a significant fundraising operation.

Outlook for the remainder of 2023

- BioSenic is involved in preliminary discussions with Pregene, and other potential partners, to reach an agreement for the global development and commercialization of proprietary ALLOB cells, derived from mesenchymal stem cells.
- Since BioSenic has obtained new statistical analysis results from the past Bone Therapeutics JTA-004 Phase 3 clinical trial data, the therapeutic profile of JTA-004 has significantly changed. The results allow to specifically target patients severely affected by osteoarthritis, suggesting to proceed to a new, optimized phase 3 clinical study in this pathologyand possibly other indications.

BioSenic is actively working on new intellectual property rules and new patent submissions related to a better use of the JTA-004 technology and improved versions.

- The Medsenic (BioSenic's subsidiary) phase 2 clinical study with ATO in the first-line treatment of cGvHD has provided additional positive results, with new data related to the optimal duration of the treatment. The phase 3 study with oral ATO in the first-line treatment of cGvHD, for which Medsenic received positive pre-IND response from the FDA, is indeed anticipated to start in 2024. A previous phase 2a clinical trial for systemic lupus erythematosus (SLE) had established safety for the patient and efficacy on the development of the autoimmune disease. Positive studies on preclinical models further give good grounds for a phase 2 clinical trial on systemic sclerosis (SSc). Phase 2b clinical trials for SLE and SSc are in the planning stage with the synopsis for both studies ready.
- In 2024 BioSenic expects to use the proceeds of anticipated future fundraisings in priority for progressing the phase 3 clinical trial in cGvHD. As a result, it will only be possible to start the SLE and SSc phase 2b clinical trials if the BioSenic Group succeeds in concluding a strong partnership with a biopharmaceutical company or if it manages to successfully out-license some of its technology. The start of SLE and SSc phase 2 clinical trials is therefore not envisioned before 2025.

(1) Unaudited numbers

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i) the arsenic trioxide (ATO) platform (with key target indications including Graft-versus-Host Disease (GvHD), systemic lupus erythematosus (SLE) and systemic sclerosis (SSc)) and (ii), the development of innovative products to meet unmet needs in orthopedics.

Following a reverse merger in October 2022, BioSenic combined a strategic positionings and strengths to use, separately and combined, an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral ATO (OATO) with its innovative cell therapy platform and strong IP for tissue repair protection.

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 ATO platform, which has been successfully developed, has immunomodulatory properties with fundamental effects on the activated cells of the immune system. The first effect is the increase of the cell oxidative stress in activated B, T and 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 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. cGvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-HSCT). cGvHD is primarily mediated by the transplanted immune cells that can lead to severe multiorgan damage. BioSenic has been successful in a phase 2 trial with its intravenous formulation, which has orphan drug designation status by FDA and EMA. The Company is heading towards an international phase 3 confirmatory study, with its new, IP-protected, OATO formulation. Another selected target is moderate-to-severe forms of systemic lupus erythematosus (SLE), using the same oral formulation. ATO has shown good safety and significant clinical efficacy on several affected organs (skin, mucosae and the gastrointestinal tract) in an early phase 2a study. Systemic sclerosis is also part of the clinical pipeline of BioSenic. This serious chronic disease badly affects skin, lungs or vascularization, and has no actual current effective treatment. Preclinical studies on pertinent animal models are positive, giving good grounds to launch a phase 2 clinical protocol.
2. The allogeneic cell and gene therapy platform developed by BioSenic, with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs), which can be stored at the point of use in hospitals. ALLOB represents a unique and 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. ALLOB has recently been evaluated in a randomized, double-blind, placebo-controlled phase 2b 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. However, in June 2023, BioSenic decided to suspend its interventional trial on fracture healing using ALLOB, following negative results obtained for the primary endpoint in this exploratory phase 2b clinical trial, interpreted as a failure of a too early cell injection, just after fracture. BioSenic is now focusing on determining the best time to optimise the efficacy of ALLOB (choice between early or late treatment).

Note: Biosenic has reevaluated a previous important and years-long clinical development program. In March 2023, after the clinical identification of distinct OA subtypes, BioSenic delivered a new post-hoc analysis of its phase 3 JTA-004 trial on knee OA, demonstrating positive action on the most severely affected patient subpopulation. This new post-hoc analysis drastically changes the therapeutic profile of the combined components and allows for better patient targeting in future clinical developments. This leads to a next generation of JTA, off-the-shelf enhanced viscosupplement to treat 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 are intended to provide effective lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic (OA) pain and inflammation.
The company, will nevertheless focus its present R&D and clinical activities on a selective, accelerated development of its autoimmune (ATO/OATO) platform.