BioSenic provides First Quarter 2024 Business Update

Mont-Saint-Guibert, Belgium, May 24, 2024, 17.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, today announces its business update for the first quarter, ended 31 March 2024.

Key highlights

- In January 2024, BioSenic signed a new subscription agreement for a maximum EUR 1.2 million convertible bonds facility, arranged by ABO Securities through its affiliated entity Global Tech Opportunities 15.
- In January 2024, Dr Carole Nicco has been promoted to Chief Operating Officer (COO) in addition to her position as Chief Scientific Officer (CSO).
- In January 2024, BioSenic's subsidiary, Medsenic SAS, signed a binding term sheet with Phebra PTY Ltd. related to an adaptation of the License Agreement and the MDA signed in May 2021.
- In January 2024, BioSenic filed for a U.S. patent for JTA-004, a viscosupplement in clinical development, following new evidence of its efficacy in a recently defined subtype of osteoarthritis (OA).
- In January 2024, BioSenic has been granted a patent by the Canadian Intellectual Property Office to expand protection of the arsenic trioxide (ATO) platform. The patent, titled “Use of metal ions to potentiate the therapeutic effects of arsenic”, covers the use of ATO platform in combination with metal ions such as copper.
- In February 2024, BioSenic raised EUR 500,000 via a private placement.
- In March 2024, BioSenic published an open-access article describing an optimized schedule for administration of oral arsenic trioxide (OATO) treatment for chronic graft-versus-host disease (cGvHD), based on an earlier post-hoc analysis of Phase II data.
- In April 2024, BioSenic submitted a global restructuring plan covering the years 2024-2030 to the enterprise Court of Nivelles.

Financial highlights

- Net cash at the end of March 2024 amounted to EUR 0.38 million (1).
- The operating cash burn for the full year 2024 is in the range of EUR 4.50-5.50 million and a financing cash burn of approximately EUR 0.80 million. BioSenic anticipates having sufficient cash to carry out its business objectives until Q3 2024, assuming (amongst other) a debt restructuration in line with the plan submitted to the enterprise Court of Nivelles.

Outlook for the remainder of 2024

- The detailed analysis of the Medsenic Phase 2 clinical study with arsenic trioxide in the first-line treatment of cGvHD has been completed and provides new valuable details for the next trial. These results will help justify clinically relevant choices for our forthcoming Phase 3 study with oral arsenic trioxide as a first-line treatment of cGvHD, for which Medsenic received earlier positive pre-IND responses from the FDA. A Phase 2a clinical trial for systemic lupus erythematosus (SLE) had previously established safety for the autoimmune patient and efficacy on the course of an autoimmune disease. Recent positive preclinical work gives 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 protocols for both studies being ready.
- BioSenic is currently preparing a fundraising composed of convertible debt and equity. BioSenic Group expects for end 2024 to use the proceeds of this forthcoming fundraising in order to actively get into the Phase 3 clinical trial in cGvHD. Consequently, it will be possible to begin Phase 2b clinical trials on SLE and SSc provided that the BioSenic

group succeeds in concluding a solid partnership with a biopharmaceutical company or if it manages to successfully out-license some of its technology.

- The Court's judgement with respect to the submitted global restructuring plan covering the years 2024-2030 is expected shortly.
- Disciplined cost and cash management will remain a key priority and the cash situation will be actively and closely monitored.

(1) Unaudited numbers

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from its Medsenic's arsenic trioxide (ATO) platform. Key target indications for the autoimmune platform include graft-versus-host-disease (GvHD), systemic lupus erythematosus (SLE), and now systemic sclerosis (SSc).
Following the merger in October 2022, BioSenic combined the strategic positionings and strengths of Medsenic and Bone Therapeutics. The merger specifically enables Medsenic/Biosenic to develop an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral 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 the main Medsenic/BioSenic technology platform

*The **ATO platform** provides derived active products with immunomodulatory properties and fundamental effects on the activated cells of the immune system. 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).*

*Medsenic has been successful in a phase 2 trial with its intravenous formulation, **Arscimed®**, 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). Systemic sclerosis is now full part of the clinical pipeline of Medsenic/BioSenic. This serious chronic disease badly affects skin, lungs, or vascularization, and has no current effective treatment. Preclinical studies on pertinent animal models are positive, giving good grounds to launch a phase 2 clinical protocol, using new immunomodulatory formulations of APIs recognized to be active on the immune system.*

The company is currently focusing its present R&D and clinical activities on a selective, accelerated development of its autoimmune platform.

Note: The allogeneic cell therapy platform-originating from the previous listed company Bone Therapeutics company, may be of renewed interest by using isolated and purified differentiated bone marrow Mesenchymal Stromal Cells (MSCs) as a starting material for further isolation of passive or active biological subcellular elements. Indeed, these cells may provide new subcellular vesicles potentially able to deliver a unique and proprietary approach to organ repair. BioSenic is now involved in determining new patentable approaches in this complex area of cell therapy.

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