# BioSenic provides third quarter 2024 Business Update

## BioSenic is actively seeking one or more new assets through a merger or acquisition process

**Mont-Saint-Guibert, Belgium, October 28, 2024, 7.00 am CEST – BIOSENIC** (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune and inflammatory diseases, as well as cell repair, today provides its business update for the third quarter, ended 30 September 2024.

### Key highlights

- In July 2024, BioSenic signed of global licensing, supply and commercialization agreements with Phebra Pty Ltd. related to the adaptation of the License Agreement and the MDA signed earlier in May 2021, when Phebra became a minority shareholder in Medsenic SAS.
- In July 2024, BioSenic filed of the continuation patent application US 18/763,376 with the United States Patent & Trademark Office (USPTO) to provide protection for the use of arsenic trioxide (ATO) for the prevention and treatment of sepsis syndrome.
- In July 2024, BioSenic released new in-depth analysis of its positive phase 2 clinical data for optimal administration scheme for its next late-stage trial of arsenic trioxide (ATO) targeting cGvHD.
- In August 2024, BioSenic announced the granting of a key patent by the Japan Patent Office to expand protection of the arsenic trioxide (ATO) platform.
- In August 2024, BioSenic announced that the European Patent Office (EPO) has granted an important new EU patent to its subsidiary Medsenic "method for treating relapsing-remitting multiple sclerosis using arsenic trioxide".
- In September 2024, Véronique Pomi-Schneiter stepped down as BioSenic's Deputy CEO.
- In September 2024, BioSenic announced (i) the start of the search for new assets through an M&A process (the interests of shareholders of Medsenic SAS will be assessed for this purpose), (ii) a reduction in its costs, (iii) the start of discussions with its creditors with a view to the sale of some of its assets, (iv) a change in the composition of its board of directors and (v) the securing of its financing for the next few months by means of an amendment to the convertible bond contract with GTO 15 allowing it to draw up to a further EUR 1.5 million, including at least two tranches of EUR 0.2 million net without any liquidity conditions.
- In October 2024, Carole Nicco stepped down from her roles as Chief Scientific and Operations Officer of BioSenic to focus on the subsidiary Medsenic SAS.

### Financial highlights

- Net cash at the end of September 2024 amounted to € 0,52 million [(1)].
- Upon receipt of the next tranche of €210,000 under the existing convertible bonds program with GTO15, BioSenic anticipates having sufficient cash to carry out its business objectives until the end of the year. BioSenic will continue to require additional financing over 2025 and therefore actively evaluates various options.

### Outlook for the remainder of 2024 and 2025

- Following the homologation judgement of 13 June 2024, BioSenic will take the necessary decisions to implement the approved plan and, notably, to retrocede its rights to the JTA and ALLOB technologies to the Walloon Region and to stop all activities in relation to such technologies.
- The Medsenic Phase II clinical study with arsenic trioxide in the first-line treatment of cGvHD has been completed and

provided positive results. A Phase III study with oral arsenic trioxide in the first-line treatment of cGvHD, for which Medsenic received positive pre-IND response from the FDA, is currently anticipated to start in 2024. A Phase IIa clinical trial for systemic lupus erythematosus ("SLE") had previously established safety for the patient and efficacy on the course of the autoimmune disease. Positive preclinical work gives good grounds for a Phase II clinical trial on systemic sclerosis ("SSc"). Phase IIb clinical trials for SLE and SSc are in the planning stage with the protocols for both studies being ready.

- 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 II clinical trials is therefore not envisioned before 2025.
- Maximum cost reduction and disciplined cash management will remain a key priority, and the situation will be closely and actively monitored.
- BioSenic will actively initiate the search for new assets through M&A processes.
- Negotiations with BioSenic's creditors will also be initiated as part of the potential sale of BioSenic's stake in Medsenic and other intellectual property assets held by BioSenic, and with a view to continuing the debt restructuring effort initiated following the court's approval of the plan.
- Medsenic is preparing a refinancing via an equity raise.

(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.*

## *For further information, please contact:*

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