BioSenic announces 2023 full year results

BioSenic stopped the patient recruitment for its Phase 2b ALLOB trial in mid-2023.

BioSenic has prepared a global restructuring plan covering the years 2024-2032 and will actively pursue follow-up actions.

BioSenic expects to use the proceeds from anticipated future fundraising as a priority to progress its Phase 3 clinical trial in cGvHD.

Mont-Saint-Guibert, Belgium, June 6, 2024, 9:00pm CEST – 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 and full year financial results for the year ending 31 December 2023, prepared in accordance with IFRS as adopted by the European Union.

"2023 has been an intense year with the continuous advancement of BioSenic's most successful lines of work in autoimmune diseases with its ATO platform, alongside the preparation of the right conditions for a debt restructuring following the reverse merger of October 2022. The time is ripe to implement the full restructuring plan as approved by BioSenic's creditors, following the expected homologation decision by the Enterprise Court of Nivelles. The most promising projects will be selected for BioSenic's active development, starting with our Phase 3 trial for the treatment of chronic graft-versus-host disease (cGvHD), and the company needs strong financial support from our investors in this respect". **said Prof. François Rieger, President and CEO of BioSenic.**

Clinical and corporate highlights (including post-period events)

- In January 2023, BioSenic strengthened its scientific team with the appointment of Dr. Carole Nicco, PhD, as Chief Scientific Officer (CSO).
- In January 2023, BioSenic appointed Yves Sagot as a member of the Board of Directors and Independent Director.
- In March 2023, BioSenic re-evaluated the results of its Phase 3 trial of its enhanced viscosupplement JTA-004 targeting knee osteoarthritis (OA). The Company indeed announced that it has used the statistical analysis capabilities of Artialis to study the results of the Phase 3 JTA-004 trial in the subset of patients with the most painful and inflammatory form of knee osteoarthritis (OA). This allows BioSenic to distinguish a group of patients, representing about one third of the total patients, who show a pain-relieving effect of JTA-004 not only superior to placebo but also to the active comparator. 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 3 clinical study.
- In March 2023, BioSenic published new data on the mechanism of action of arsenic trioxide (ATO) to prevent autoimmune diseases in a peer-reviewed paper (Frontiers in Immunology). This new data shows that combination of ATO with copper salts can allow BioSenic to work towards reducing the dosage of ATO in future trials overall and maintain efficacy. This new formulation data has been completed following pre-clinical activities and does not constitute data validated through clinical trial.
- In April 2023, BioSenic appointed Lieven Huysse, MD, as permanent Chief Medical Officer (CMO).
- In April 2023, BioSenic received European patent from EPO, for further therapeutic development in cancer, infectious and immune diseases. The patent covers the therapeutic use of a new composite formulation of anti-inflammatory compounds with unique advantages. This new formulation lowers the dosage of arsenic trioxide by combining it with copper salts to maintain therapeutic efficacy, with the potential of administration through multiple routes, including intravenous, oral, and other novel routes of administration.
- In May 2023, BioSenic identified key biomarkers for cGvHD and submitted patent to EPO. The technology covered by the patent applies to a method and kit for diagnosing and monitoring cGvHD in an individual who has undergone an

allogeneic hematopoietic stem cell transplantation and treated with ATO for a cGvHD. The patent describes biomarkers to be used to determine if the condition of a patient worsens or improves following standard or new treatments for cGvHD. This international patent could allow the development of an industrial biomarker analysis kit which could generate a turnover of 30 to 40 million euros globally.

- In June 2023, BioSenic put Phase 2b ALLOB trial on hold. This decision follows negative results obtained for the primary endpoint in the exploratory Phase 2b trial (ALLOB 2b), which focused on the safety and efficacy of the treatment when applied too early, 3 days after fracture.

- In August 2023, BioSenic received a Chinese patent protecting the combined use of metal ions and arsenic salts. This patent (ZL202080040613.1) covers the use of its ATO platform in combination with metal ions like copper, which has the potential to improve the treatment of autoimmune diseases.

- In September 2023, BioSenic published data providing additional key indications of its lead API (Active Pharmaceutical Ingredient) arsenic trioxide (ATO) to treat systemic sclerosis (SSc) in a peer-reviewed international journal.

- In September 2023, completed of a post-hoc analysis of its phase 2 clinical trial of ATO, finding the best scheme for administration of an efficient treatment of cGvHD. The analysis will be used to decide on the best oral ATO's posology for BioSenic's forthcoming phase 3 clinical trial.

- 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 late-stage clinical development, following a post hoc analysis showing 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 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 June 2024, BioSenic's board of directors acknowledged the resignation of Mr Yves Sagot as an independent director of the Company, with effect from the Company's 2024 ordinary general meeting.

Financial highlights (including post-period events)

- In February 2023, BioSenic received EUR 1 million from Pregene company in accordance with terminated license agreement.

- In June 2023, BioSenic has obtained an official appointment of Yves Brulard to reach a negotiated agreement with certain main creditors to preserve the value of BioSenic for the benefit of all stakeholders.

- In June 2023, BioSenic entered into an agreement with the ABO Securities subsidiary, Global Tech Opportunities 15, to secure short term financing based on the existing convertible bond program. Subject to the terms and conditions of the agreement, BioSenic shall be entitled to draw down three tranches of each EUR 0.3 million in June, July, and August under the existing convertible bond program, for an aggregate principal amount of EUR 0.9 million.

- In July 2023, BioSenic has achieved a standstill agreement from the main historical creditors for a period of 3 to 4 months. 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 based on the existing convertible bond program, BioSenic anticipates having sufficient cash to carry out its business objectives until October 2023.

- In September 2023, BioSenic reached an agreement with Patronale, Monument and the European Investment Bank for the restructuring of its key financial debts.

- In October 2023, BioSenic reached a definitive agreement with Global Tech Opportunities 15 (GTO15) with respect to the finalization of the existing convertible bonds program. GTO15 funder two tranches of EUR 300,000 each (minus a commission of 10%) of the existing convertible bonds program.

- In December 2023, BioSenic signed a term sheet with Singapore based TrialCap Pte. Ltd. and/or other lenders for a proposed debt and equity financing. BioSenic is seeking the funds to continue its clinical development, backed by previous highly promising Phase 2 and pre-clinical results of arsenic trioxide (ATO).

- In 2023, total operating income amounted to € 0.54 million, a slight increase compared to the same period in 2022 (€ 0.27 million). Operating loss for the period amounted to € 6.36 million, compared to € 2.32 million in 2022.

- BioSenic ended 2023 with € 0.12 million in cash and cash equivalents. Net cash used for the period amounted to € 1.73 million, compared to an increase of € 1.09 million over the same period of 2022.

- 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 February 2024, BioSenic raised EUR 500,000 via a private placement.

- In April 2024, BioSenic filed a debt restructuring plan with the clerk's office of the Nivelles Enterprise Court, with a view to requesting the Court to open private judicial reorganization proceedings by collective agreement and to obtain the agreement of creditors on a plan to reorganize BioSenic's debt. Please refer to the press releases of 11 April 2024,12 April 2024 and 26 April 2024 on this subject for further information.

- In April 2024, in view of the debt restructuring plan, BioSenic postponed its annual general meeting of the shareholders.

- In May 2024, BioSenic provided its business update for the first quarter, ended the 31 March 2024.

- In May 2024, the Enterprise Court of Nivelles registered the positive votes of the majority of BioSenic's creditors on the debt restructuring plan.

Outlook for the remainder of 2024

In accordance with the BioSenic's debt restructuring plan, BioSenic envisages 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 2 clinical study with arsenic trioxide in the first-line treatment of cGvHD has been completed and provided positive results. A Phase 3 study with oral arsenic trioxide in the first-line treatment of cGvHD, for which Medsenic received an encouraging pre-IND response from the FDA, is currently anticipated to start. A Phase 2a 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 2 clinical trial on systemic sclerosis ("SSc"). Phase 2b clinical trials for SLE and SSc are in the planning stage.

BioSenic is currently preparing the best conditions for a successful fundraising. BioSenic Group expects for 2024 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 II clinical trials is therefore not envisioned before 2025.

Disciplined cost and cash management will remain a key priority. The operating cash burn for the full year 2024 is in the range of € 7.00 million and a financing cash burn of approximately EUR 0.80 million. The situation will be actively and closely monitored. BioSenic anticipates having sufficient cash to carry out its business objectives until Q3 2024, assuming amongst other full issuance of the Convertible Bonds and the renegotiation of the terms of the ongoing loans.

Consolidated statement of comprehensive income

(in thousands of euros)	For the year ended 31 December	
	2023	2022
Revenue	0	0
Other Operating income	543	266
Total revenues and operating income	**543**	**266**
Research and development expenses	(3,931)	(1,030)
General and administrative expenses	(3,651)	(1,554)
Operating profit/(loss)	**(7,040)**	**(2,318)**
Financial income	59	11
Impairment expenses	(16,094)	0
Financial expenses	(5,954)	(741)
Result Profit/(loss) before taxes	**(29,028)**	**(3,049)**
Income taxes	7	0
Result Profit/(loss) for the period	**(29,021)**	**(3,049)**
Thereof attributable to:		
Owners of the Company	(28,778)	(2,041)
Non-controlling interests	(243)	(1,008)
Other comprehensive income		
Remeasurements of post-employment benefit obligations	(6)	(4)
TOTAL COMPREHENSIVE INCOME/(LOSS) OF THE PERIOD	**(29,027)**	**(3,053)**
Thereof attributable to:		
Owners of the Company	(28,781)	(2,043)
Non-controlling interests	(246)	(1,010)
Basic and diluted loss per share (in euros)	**(0.21)**	**(0.02)**

Consolidated Balance Sheet

Consolidated Assets IFRS per: (in thousands of euros)	**31/12/23**	**31/12/22**
Non-current assets	**7,713**	**24,698**
Goodwill	0	1,802
Intangible assets	2,989	17,293
Property, plant and equipment	698	1,419
Finance lease receivable	398	0
Investments in associates	12	12
Other non-current assets	135	136
R&D Tax Credits	3,480	4,036
Current assets	**1,846**	**4,626**
Trade and other receivables	1,315	2,490
Other current assets	272	290
Finance lease receivable	141	0
Cash and cash equivalents	117	1,846
TOTAL ASSETS	**9,559**	**29,324**

Consolidated Equity & Liabilities IFRS per: *(in thousands of euros)*	**31/12/23**	**31/12/22**
Share capital	6,275	4,774
Share premium	5,720	4,517
Accumulated losses	(34,887)	(5,723)
Other reserves	(20)	(42)
Equity attributable to owners of the parent	**(22,912)**	**3,526**
Non-controlling interests	207	(402)
Total Equity	**(22,705)**	**3,124**
Non-current liabilities	**16,420**	**15,847**
Interest bearing borrowings	16,340	15,779
Other non-current liabilities	80	68
Current liabilities	**15,844**	**10,353**
Interest bearing borrowings	11,821	8,013
Trade and other payables	3,871	2,236
Current tax liabilities	5	0
Other current liabilities	147	104
Total liabilities	**32,264**	**26,200**
TOTAL EQUITY AND LIABILITIES	**9,559**	**29,324**

Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows (in thousands of euros)	For the 12-months period ended 31 December 2023	2022
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(7,040)	(2,318)
Adjustments non-cash		
Depreciation, Amortisation and Impairments	243	60
Grants income related to recoverable cash advances	0	20
Grants income related to patents	0	(17)
Grants income related to tax credit	(279)	(36)
Other	(28)	32
Movements in working capital:		
Trade and other receivables (excluding public grants)	55	44
Trade and other Payables	1,634	175
Cash used in operating activities	**(5,417)**	**(2,040)**
Cash received from grants related to recoverable cash advances	61	61
Cash received from grants related to patents	11	0
Cash received from license agreement	940	0
Cash received from grants related to tax credit	935	69
Income taxes paid	0	0
Net cash used in operating activities	**(3,470)**	**(1,910)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	0	1
Acquisition of subsidiary	0	1,956
Purchases of property, plant and equipment	3	(5)
Disposal of property, plant and equipment	3	0
Net cash generated from investing activities	**6**	**1,952**
CASH FLOW FROM FINANCING ACTIVITIES		
Repayment of borrowings	(275)	(180)
Proceeds from government loans	0	26
Repayment of government loans	0	(81)
Proceeds from convertible borrowings	1,000	1,000
Repayments of lease liabilities	(186)	(4)
Repayments of interest free advances	(138)	(150)
Repayment of related parties loans	0	(13)
Interests paid	(28)	(31)
Transaction costs	(137)	(22)
Proceeds from issue of equity instruments of the Company	1,500	500
Net cash generated from financing activities	**1,735**	**1,045**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(1,729)**	**1,087**
CASH AND CASH EQUIVALENTS at beginning of the period	**1,846**	**759**
CASH AND CASH EQUIVALENTS at end of the period	**117**	**1,846**

Consolidated statement of changes in equity

Attributable to owners of the parent					Non-controlling interests	TOTAL EQUITY
(in thousands of euros)	**Share capital**	**Share premium**	**Accumulated Losses & Other reserves**	**Other elements of comprehensive income**		
Balance at 1 January 2022	**664**	**3,969**	**(7,298)**	**(5)**	**0**	**(2,670)**
Total comprehensive income of the period	0	0	(3,049)	(4)	0	(3,053)
Issue of share capital	874	4,372	0	0	0	5,246
Reverse acquisition:	3,236	(3,824)	4,546	43	(402)	3,598
1. Consideration paid for the reverse acquisition	*3,598*	*0*	*0*	*0*	*0*	*3,598*
2. Non-controlling interest	*(362)*	*(3,824)*	*4,546*	*43*	*(402)*	*0*
Other	0	0	79	(76)	0	3
Balance at 31 December 2022	**4,774**	**4,517**	**(5,723)**	**(42)**	**(402)**	**3,124**
Balance at 1 January 2023	**4,774**	**4,517**	**(5,723)**	**(42)**	**(402)**	**3,124**
Total comprehensive income of the period	0	0	(28,778)	(3)	(246)	(29,027)
Issue of share capital	1,500	1,792	0	0	849	4,141
Transaction costs	0	(137)	0	0	0	(137)
Acquisition of NCI without a change in control	0	(451)	(388)	26	6	(807)
Balance at 31 December 2023	**6,275**	**5,720**	**(34,887)**	**(20)**	**207**	**(22,705)**

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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