BioSenic announces 2022 full year results

ALLOB Phase IIb topline results foreseen in Q2 2023

ATO Phase III to be launched in 2023

Ongoing discussions for key partnerships with lead clinical assets

Mont-Saint-Guibert, Belgium, April 27, 2023, 7am CET – BIOSENIC (Euronext Brussels and Paris: BIOS), the company specializing in serious autoimmune and inflammatory diseases and cell repair, today announces its business update and full year financial results for the year ending 31 December 2022, prepared in accordance with IFRS as adopted by the European Union.

"BioSenic's creation from the merger between Bone Therapeutics and Medsenic in October 2022 has resulted in a multi-platform and multi-target biotechnology company. These two platforms specialize in severe autoimmune/inflammatory diseases, as well as cellular repair for orthopedics. This increases the chance of therapeutic and clinical successes, and enables a cross-pollination between the scientific teams," **said Prof. François Rieger, President and CEO of BioSenic.** *"For our ATO platform, we are now in final preparations for the launch of our Phase III study in 2023, and two Phase IIb studies later on. For our cell therapy platform, the ALLOB Phase IIb trial is expecting to report in Q2 2023. Having now extended and updated our senior management and board, BioSenic is well set to establish value adding business collaborations and to further strengthen our financial position. This will enable us to drive our therapies through clinical development and deliver therapeutic options to patients suffering from a range of conditions with few therapeutic options."*

Clinical and operational highlights (including post-period events)

In March 2022, BioSenic redefined its strategic priorities to concentrate specifically on the development of its most advanced clinical asset, ALLOB. BioSenic implemented a number of actions to reduce its cost base to enable completion of its Phase IIb study. As a result, BioSenic focused its R&D activities to support the clinical development of ALLOB and all activities related to the development of the pre-clinical iMSCg platform as well as all other non ALLOB related activities, had been stopped.

In July 2022, BioSenic announced an optimized statistical analysis and the implementation of an interim analysis for the ongoing Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB. The amendment enabled a reduction of approximately 20% of the required patient numbers from 178 patients to 132 evaluable patients while maintaining the same statistical power. In addition, BioSenic would also introduce an interim analysis based on the assessment of radiological data from approximately 66 evaluable patients at 3 months post-administration. The interim analysis would provide an opportunity to document the efficacy of ALLOB and to achieve a relevant clinical milestone at an earlier time point.

In October 2022, BioSenic regained worldwide rights to its allogeneic, off-the-shelf, bone cell therapy platform ALLOB further to the unilateral termination notice received from Shenzhen Pregene Biopharma Co., Ltd. ("Pregene"). Pregene's termination was, according to Pregene written communication, "*necessitated by [alleged] regulatory reasons that due to the [purported] introduction of new laws and regulations, projects involving foreign human cell and related clinical trials will be, prohibited [in the future] in mainland China*". Regaining all development manufacture and commercialization rights of ALLOB from Pregene entitled BioSenic to negotiate rights for ALLOB with, LinkHealth, and other partners.

In November 2022, BioSenic provided an update on its systemic autoimmune disease platform. The autoimmune disease platform had completed a successful phase IIb trial targeting cGVHD (chronic Graft vs Host Disease), with a demonstrated efficacy of more than 75%. The phase III study of the autoimmune disease platform in cGvHD has been designed to reach the market as quickly as possible through the framework of an expedite 505b2 FDA regulatory pathway. In addition to cGVHD, BioSenic announced the preparation a randomized placebo-controlled phase IIb study with ATO in Systemic Lupus Erythematosus. Furthermore, promising preclinical data gathered by Medsenic provided clinical data to support a phase II clinical trial with ATO targeting systemic sclerosis.

In February 2023, BioSenic announced an optimization its ongoing Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB and completion of patient recruitment. The cohort of treated patients, amounting to 57 patients, is found to be sufficient for a sufficient level of significance. BioSenic's new statistical analysis plan leads to a more objective scoring for judging the result of its innovative cell repair treatment. A RUST score difference higher than 1.26 will be considered statistically relevant. Further to the decision to end recruitment and proceed towards a full set of meaningful results, the ALLOB subscription rights shall become exercisable based on the results at month three after patient treatment, if the difference in the mean RUST scores between the placebo's arm patient population and the treated ALLOB population is found higher than 1.26 in the new statistical analysis on the effectively recruited 57 patients.

On 16 March 2023, BioSenic announced that it has used the statistical analysis capabilities of Artialis to study the results of the Phase III 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. By identifying three subtypes of OA, amongst which a subtype of OA patients with more severe symptoms and inflammation, 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 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.

On 30 March 2023, BioSenic published new data providing additional details about the mechanism of action of its lead API arsenic trioxide (ATO) to prevent autoimmune diseases has now been published 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.

On 18 April 2023, BioSenic received a key European patent from EPO, for further therapeutic development in cancer, infectious and immune disease. 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.

Corporate highlights (including post-period events)

In March 2022, BioSenic redefined its strategic priorities to concentrate specifically on the development of its most advanced clinical asset, ALLOB. In that context, several members of BioSenics' management team transitioned to depart BioSenic in alignment with the focus in activity. This included Miguel Forte (CEO), Tony Ting (CSO), Stefanos Theoharis (CBO) and Lieve Creten (CFO).

In May 2022, BioSenic signed the definitive subscription agreement for a maximum EUR 5 million convertible bonds (CBs) facility arranged by ABO Securities, through its affiliated entity Global Tech Opportunities 15. ABO Securities has committed to subscribe to up to EUR 5 million in CBs. The CBs would be issued and subscribed in ten tranches.

In August 2022, BioSenic signed a binding contribution agreement with Medsenic, a privately held, clinical stage biopharmaceutical company incorporated in France, to combine the operations of both companies by means of a share for share exchange. The acquisition would result in the business combination of Bone Therapeutics and Medsenic to create BioSenic, a speciality biopharma company.

In October 2022, BioSenic announced the closing of its acquisition of a majority participation in Medsenic. Medsenic' shareholders contributed fifty-one percent (51%) of the total outstanding share capital of Medsenic, valued at EUR 40,800,207, at a subscription price per share of EUR 0.45, which valued BioSenic at EUR 10 million. In exchange for the in-kind contribution of 51% of Medsenic' shares, 90,668,594 shares were issued by BioSenic to Medsenic shareholders. Pr. Francois Rieger, chairman and CEO of Medsenic, was appointed as chairman and CEO of BioSenic SA. Other board members appointed were Ms Véronique Pomi-Schneiter, deputy CEO of Biosenic, formerly in charge of Medsenic operations, Mr Jean-François Rax, representing Cap Innovest, Ms Revital Rattenbach, independent director and Mr Terry Sadler, independent director. The Executive leadership team consisted of François Rieger (CEO), Véronique Pomi-Schneiter (deputy CEO), and Anne Leselbaum (CMO). Furthermore, 24,463,421 ALLOB subscription rights were granted

to all existing shareholders. These subscription rights allow holders to subscribe for a new share of the company if the ALLOB Phase IIB results are positive at a subscription price per share of EUR 0.45. The existing shareholders of Medsenic agreed to contribute in kind the totality of the remaining Medsenic shares held by within the next 24 - 36 months from the completion of the combination.

In December 2022, BioSenic appointed Michel Wurm, M.D. as Chief Medical Officer ad interim to succeed Anne Leselbaum, M.D. Michel was responsible for the development of both of BioSenic's cell therapy and autoimmune disease platforms.

On 18 January 2023, BioSenic appointed Dr Carole Nicco as Chief Scientific Officer. Carole oversees the development of pipeline across BioSenic's cell therapy and autoimmune disease platform and is responsible for R&D programs.

On 27 January 2023, BioSenic appointed Yves Sagot as Independent Director. Yves Sagot replaced Terry Sadler as an Independent Director and Member of the Board at BioSenic.

On 21 February 2023, BioSenic announced it received EUR 1 million (minus 6% taxes) from Pregene in accordance with the terminated license agreement. BioSenic regained worldwide rights to its allogeneic, off-the-shelf, bone cell therapy platform ALLOB further to the unilateral termination notice received from Shenzhen Pregene Biopharma Co., Ltd. ("Pregene") in October 2022. BioSenic has started preliminary discussions with Pregene, Link Health and other potential partners to move forward with the development and commercialization of ALLOB in other geographies, including the US.

On 3 April 2023, BioSenic appointed Lieven Huysse, MD, as Chief Medical Officer to succeed Michel Wurm, M.D. Lieven is responsible for continued progression of both BioSenic late-stage assets (ALLOB MSC platform and autoimmune ATO platform).

Outlook for the remainder of 2023

In the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, BioSenic expects to report topline results by the second quarter of 2023.

In October 2022, BioSenic regained worldwide rights to develop, manufacture and commercialised ALLOB following the termination by Shenzhen Pregene Biopharma Co., Ltd ("Pregene") of the exclusive license agreement entered into between BioSenic, Pregene and Link Health Pharma Co., Ltd ("LinkHealth") in October 2020. Although regulatory changes in China have halted establishment of ALLOB in the Chinese market, BioSenic is conducting preliminary discussions with Pregene, LinkHealth and other potential partners to reach an agreement for the development and commercialization of ALLOB in other geographies, including in the U.S.

In March 2023, BioSenic has obtained new statistical analysis results from the JTA-004 Phase III clinical trial data. 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, is 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.

The Medsenic Phase II clinical study with arsenic trioxide in the first-line treatment of cGvHD is complete 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 2023. 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.

BioSenic Group, however, expects to use the existing cash and the proceeds of anticipated future fundraisings (via shares or (convertible) bonds) in priority for continuing the Phase IIb clinical trial for ALLOB and for progressing the Phase III clinical trial in cGvHD. As a result, it will only be possible to start the SLE and SSc Phase IIb clinical trials in 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 2024.

Following the restructuring of the management team and the appointment of Mr François Rieger as CEO and executive director, Ms Véronique Pomi-Schneiter as Deputy-CEO and executive director, Alexia Rieger as CIRO, Carole Nicco as CSO and Lieven Huysse as CMO, BioSenic is in the process of completing the management team with a new CFO.

The Company plans to raise funds in the form of a private placement of new shares in Q2 2023 in order to finance its activities. In addition, the Company continues to evaluate other funding options, such as the extension of the existing convertible bond program.

Disciplined cost and cash management will remain a key priority. The operating cash burn for the full year 2023 is in the range of €8-10 million and a financing cash burn of approximately EUR 1.7 million. The situation will be actively and closely monitored. BioSenic anticipates having sufficient cash to carry out its business objectives until June 2023, assuming amongst other full issuance of the Convertible Bonds and the renegotiation of the terms of the ongoing loans that will otherwise fall due in June 2023.

Consolidated statement of comprehensive income

(in thousands of euros)	2022	2021
Revenues	0	0
Other operating income	266	312
Total revenues and operating income	**266**	**312**
Research and development expenses	(1,030)	(619)
General and administrative expenses	(1,554)	(570)
Operating profit/(loss)	**(2,318)**	**(877)**
Financial income	7	0
Interest income	3	0
Financial expenses	(741)	(107)
Exchange gains/(losses)	1	0
Result Profit/(loss) before taxes	**(3,049)**	**(984)**
Income taxes	0	0
Net Income (Loss) for the period	**(3,049)**	**(984)**
Remeasurements of post-employment benefit obligations	(4)	(5)
Other comprehensive income	**(4)**	**(5)**
TOTAL COMPREHENSIVE INCOME/(LOSS) OF THE PERIOD	**(3,053)**	**(989)**
Profit/(loss) for the period attributable to the owners of the Company	(2,043)	(989)
Total comprehensive income/(loss) for the period attributable to the owners of the Company	(1,010)	(0)
Basic and diluted loss per share (in euros)	**(0,02)**	**(14,89)**

Consolidated Balance Sheet

Consolidated Assets IFRS per: *(in thousands of euros)*	**31/12/22**	**31/12/21**
Non-current assets	**24,698**	**38**
Goodwill	1,802	0
Intangible assets	17,293	0
Property, plant and equipment	1,419	13
Investments in associates	12	0
Other non-current assets	136	0
R&D Tax Credits	4,036	0
Financial assets	0	25
Current assets	**4,626**	**1,124**
Trade and other receivables	2,490	361
Other current assets	290	4
Financial assets	0	0
Cash and cash equivalents	1,846	759
TOTAL ASSETS	**29,324**	**1,162**

Consolidated Equity & Liabilities IFRS per: *(in thousands of euros)*	**31/12/22**	**31/12/21**
Share capital	4,774	664
Share premium	4,517	3,969
Accumulated losses	(5,723)	(7,219)
Other reserves	(42)	(83)
Equity attributable to the owners of the Company	**3,526**	**(2,670)**
Non-controlling interests	(402)	-
Total Equity	**3,124**	**(2,670)**
Non-current liabilities	**15,847**	**2,338**
Interest bearing borrowings	15,779	2,273
Other non-current liabilities	68	65
Current liabilities	**10,353**	**1,494**
Interest bearing borrowings	8,013	1,252
Trade and other payables	2,236	208
Other current liabilities	104	34
Total liabilities	**26,200**	**3,832**
TOTAL EQUITY AND LIABILITIES	**29,324**	**1,162**

Consolidated Cash Flow Statement

(in thousands of euros)	2022	2021
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(2,318)	(877)
Adjustments non-cash:		
Depreciation, Amortization and Impairments	60	13
Share-based compensation	0	0
Grants income related to recoverable cash advances	20	0
Grants income related to patents	(17)	0
Grants income related to tax credit	(36)	0
Other	32	8
Movements in working capital:		
Trade and other receivables (excluding government grants)	44	10
Trade and other Payables	175	(187)
Cash used in operating activities	**(2,040)**	**(1,033)**
Cash received from grants related to recoverable cash advances	61	0
Cash received from grants related to tax credit	69	(34)
Income taxes paid	0	0
Net cash used in operating activities	**(1,910)**	**(1,067)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	1	0
Acquisition of subsidiary	1,956	
Purchases of property, plant and equipment	(5)	0
Purchases of intangible assets	0	0
Net cash generated from investing activities	**1,952**	**0**
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from borrowings	0	500
Repayment of borrowings	(180)	(56)
Proceeds from government loans	26	0
Repayment of government loans	(81)	0
Proceeds from convertible borrowings	1,000	891
Repayments of lease liabilities	(4)	(7)
Repayments of other financial liabilities	(150)	(125)
Repayment of related parties loans	(13)	0
Interests paid	(31)	(33)
Transaction costs	(22)	0
Proceeds from issue of equity instruments of the Company	0	0
Proceeds received from convertible loan	500	0
Proceeds from borrowings	0	500
Net cash generated from financing activities	**1,045**	**1,170**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**1,087**	**103**
CASH AND CASH EQUIVALENTS at beginning of the year	**759**	**656**
CASH AND CASH EQUIVALENTS at end of the year	**1,846**	**759**

Consolidated statement of changes in equity

(in thousands of euros)	Share capital	Share premium	Accumulated Losses & Other reserves	Other elements of comprehensive income	Non-controlling interests	Total
Balance at 1 January 2021	**664**	**3,969**	**(6,314)**	**0**	**0**	**(1,682)**
Total comprehensive income of the period	0	0	(984)	(5)	0	(989)
Issue of share capital	0	0	0	0	0	0
Transaction costs for equity issue	0	0	0	0	0	0
Equity component for Convertible Bonds	0	0	0	0	0	0
Allocation to the legal reserve	0	0	0	0	0	0
Share-based payment	0	0	0	0	0	0
Other	0	0	0	0	0	0
Balance at 31 December 2021	**664**	**3,969**	**(7,298)**	**(5)**	**0**	**(2,670)**
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*
Share-based payment	0	0	0	0	0	0
Other	0	0	79	(76)	0	3
Balance at 31 December 2022	**4,774**	**4,517**	**(5,723)**	**(42)**	**(402)**	**3,124**

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i), the allogeneic cell therapy platform ALLOB and (ii) the Arsenic TriOxide (ATO) platform. Key target indications for the platforms include Graft versus Host Disease (GvHD), Systemic lupus erythematosus (SLE), Systemic Sclerosis (SSc) and high-risk tibial fractures.
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 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

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.

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