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BioSenic reports half year 2023 results

The BioSenic Phase 2 clinical study with arsenic trioxide in the first-line treatment of chronic Graft versus Host disease (cGvHD) has been completed and provided positive results. In 2024, the BioSenic Group expects to prioritize the use of the proceeds of anticipated future fundraising for the progression of the Phase 3 clinical trial in cGvHD.

Mont-Saint-Guibert, Belgium, 7 September 2023, 7am CEST – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, today publishes its business update for the first half, ended 30 June 2023, prepared in accordance with IFRS as adopted by the European Union, and the outlook for the remainder of the year.

"BioSenic has made the best of its efforts on restructuring and accomplishing important technical steps in implementing key features of its Arsenic salts (ATO) and its cell repair platforms after succeeding its reverse merger between Medsenic and Bone Therapeutics 10 months ago" said François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic "Successfully interpreting clinical and scientific complex data – and specifically those inherited from the former Bone Therapeutics – gives us now the essential basic elements to develop our activities on licensing opportunities and further Phase 2/3 clinical trials. Our immediate leading project is a Phase 3 confirmatory trial on the efficacy of an oral formulation of arsenic trioxide on chronic Graft-versus-Host Disease, an autoimmune rare condition following allogeneic hematopoietic cells used for treating several types of leukaemia. We now expect a productive end of 2023 for further developing the best values of BioSenic."

Operational and Corporate highlights

- In January 2023, BioSenic strengthened its scientific team with the appointment of Dr. Carole Nicco, 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 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.
- 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. 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 safety and treatment timing efficacy.
- 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.

Financial highlights

- In February 2023, BioSenic received EUR 1 million from Pregene 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.
- During the first six months of 2023, total operating income amounted to EUR 0.37 million, a slight increase compared to the same period in 2022 (EUR 0.13 million).
- Operating loss for the period amounted to EUR 3.90 million, compared to EUR 3.96 million in H1 2022.
- BioSenic ended the first six months of 2023 with EUR 0.52 million in cash and cash equivalents. Net cash used for the period amounted to EUR 1.33 million, compared to EUR 0.39 million over the same period of 2022.

Outlook for the remainder of 2023 and 2024

- In March 2023, BioSenic has obtained new statistical analysis results from the JTA-004 Phase 3 clinical trial data. 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. Following disappointing Phase 3 clinical results, Biosenic terminated the agreement with the Walloon Region and Mr Bastianelli in 2022. The agreement with the Walloon Region has since been resumed, but there is still no agreement with Mr Enrico Bastianelli, which could give rise to co-ownership problems.
- 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 positive pre-IND response from the FDA, is currently anticipated to start in 2024. 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 with the protocols for both studies being ready.
- BioSenic is currently preparing a fundraising to be organized in Q3/Q4 2023. 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 2 clinical trials is therefore not envisioned before 2024.

Unaudited Interim Condensed Consolidated Statement of Comprehensive Income

<i>(in thousands of euros)</i>	For the six-months period ended	
	30/06/2023	30/06/2022
Revenues	0	0
Other operating income	365	125
Total revenues and operating income	365	125
Research and development expenses	(2,452)	(267)
General and administrative expenses	(1,813)	(336)
Other operating expenses	(1)	0
Operating profit/(loss)	(3,900)	(478)
Financial Income	35	0
Interest income	30	0
Impairment expenses	(16,094)	0
Financial expenses	(1,136)	(49)
Exchange gains/(losses)	1	0
Result Profit/(loss) before taxes	(21,063)	(527)
Income taxes	(24)	-
Result Profit/(loss) for the Period	(21,087)	(527)
Thereof attributable to:		
<i>Owners of the Company</i>	(20,843)	(527)
<i>Non-controlling interests</i>	(244)	0
Other comprehensive income	0	0
TOTAL COMPREHENSIVE INCOME/(LOSS) OF THE PERIOD	(21,087)	(527)
Thereof attributable to:		
<i>Owners of the Company</i>	(20,843)	(527)
<i>Non-controlling interests</i>	(244)	0
Basic and diluted loss per share (in euros)	(0,17)	(7,49)

Unaudited Interim Condensed Consolidated Statement of Financial Position

Consolidated Assets IFRS per: (in thousands of euros)	30/06/2023	31/12/2022
Non-current assets	7,848	24,698
Goodwill	0	1,802
Intangible assets	2,995	17,293
Property, plant and equipment	786	1,419
Finance lease receivable	469	0
Investments in associates	12	12
Other non-current assets	135	136
R&D Tax Credits	3,452	4,036
Current assets	2,544	4,626
Trade and other receivables	1,676	2,490
Other current assets	214	290
Finance lease receivable	135	0
Cash and cash equivalents	519	1,846
TOTAL ASSETS	10,392	29,324

Consolidated Equity & Liabilities IFRS per: (in thousands of euros)	30/06/2023	31/12/2022
Equity attributable to owners of the parent	(16,882)	3,526
Share capital	5,224	4,774
Share premium	4,594	4,517
Accumulated losses and other reserves	(26,652)	(5,723)
Other reserves	(48)	(42)
Equity attributable to owners of the parent		
Non-controlling interests	(646)	(402)
Total Equity	(17,528)	3,124
Non-current liabilities	15,764	15,847
Interest bearing borrowings	15,696	15,779
Other non-current liabilities	68	68
Current liabilities	12,156	10,353
Interest bearing borrowings	9,339	8,013
Trade and other payables	2,728	2,236
Other current liabilities	89	104
Total liabilities	27,920	26,200
TOTAL EQUITY AND LIABILITIES	10,392	29,324

Unaudited Interim Condensed Consolidated Statement of Cash Flows

Consolidated Statement of Cash Flows (in thousands of euros)	For the six-month period ended 30 June	
	2023	2022
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(3,900)	(478)
Adjustments for:		
Depreciation and Amortisation	101	5
Grants income related to tax credit	(115)	0
Grants income related to withholding tax	(47)	
Other	(68)	0
Movements in working capital:		
(Increase)/Decrease in Trade and other receivables (excluding government grants)	(34)	14
Increase/(Decrease) in Trade and other Payables	492	22
Cash used by operations	(3,570)	(438)
Cash received from license agreement	940	0
Cash received from grants related to tax credit	700	187
Net cash used in operating activities	(1,930)	(251)
CASH FLOW FROM INVESTING ACTIVITIES		
Disposal of intangible assets	17	0
Disposal of property, plant and equipment	3	0
Purchases of property, plant and equipment	(12)	0
Purchases of intangible assets	(1)	0
Net cash generated from investing activities	7	0
CASH FLOW FROM FINANCING ACTIVITIES		
Repayment of borrowings	(150)	(45)
Proceeds from convertible borrowings	550	0
Repayment of lease liabilities	(84)	(2)
Repayment of other financial liabilities	(75)	(75)
Interests paid	(13)	(16)
Transaction costs	(81)	
Proceeds from issue of equity instruments	450	0
Net cash generated from financing activities	596	(137)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,327)	(388)
CASH AND CASH EQUIVALENTS at beginning of the period	1,846	759
CASH AND CASH EQUIVALENTS at end of the period	519	371

Unaudited Interim Condensed Consolidated Statement of Changes in Shareholders' Equity

<i>(in thousands of euros)</i>	Attributable to owners of the parent				Non-controlling interests	TOTAL EQUITY
	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	(527)	0	0	(527)
Issue of share capital	74	3,837	0	0	0	3,911
BALANCE AT 30 JUNE 2022	738	7,806	(7,825)	(5)	0	714
BALANCE AT 1 JANUARY 2023	4,774	4,517	(5,723)	(42)	(402)	3,124
Total comprehensive income of the period	0	0	(20,843)	0	(244)	(21,087)
Issue of share capital	450	158	0	0	0	609
Transaction costs for equity issue	0	(81)	0	0	0	(81)
Other	0	0	(85)	(6)	0	(91)
BALANCE AT 30 JUNE 2023	5,224	4,594	(26,652)	(48)	(646)	(17,528)

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.

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