

MEDESIS PHARMA 2023 FIRST-HALF BUSINESS AND EARNINGS

Montpellier (France), October 27, 2023 - 6pm CET – **MEDESIS PHARMA, a pharmaceutical biotechnology company developing drug candidates with Aonys[®], its proprietary buccal nanodroplet active ingredient administration technology, is reporting its half-year earnings at June 30, 2023 and providing an update on the development of its activities.**

Priority clinical and preclinical development programs moving forward

- **NanoLithium[®] program for the treatment of psychoses associated with Alzheimer's Disease:**

The study was prepared with Professor Jacques Touchon (former Dean of Montpellier School of Medicine and Chairman of the last Global Conference of Alzheimer's Disease). The national coordinating center (CHU Toulouse) opened in May 2022, followed by another in June (Montpellier), while the other six university hospital centers (Paris, Lille, Lyon, Marseille, Limoges and Strasbourg) opened between September 7 and the end of 2022. The 68 subjects have been included in the study, with the final subject integrated on October 16, 2023.

The first phase of the treatment is placebo-controlled and analyzes changes in the mental and behavioral disorders associated with this disease. The results of this phase are expected for March 2024.

All the patients have received and are continuing to receive the treatment (open non-placebo study) for an additional nine months with the criteria relating to the disease's progression analyzed at the end of the study: brain scans and biomarkers. The results of this second phase will be obtained in November 2024.

- **NanosirRNA[®] HD program for the genetic treatment of Huntington's Disease:**

A proof of concept study based on a mouse model expressing the same genetic anomaly as that found in 20% of people with Huntington's Disease is being carried out with Professor Amber Southwell's team at the University of Florida in the United States. The three-week treatment has shown good levels of tolerance and not revealed any toxicity. This study has not shown any effect on the expression of the gene or protein. However, the effect of the siRNAs tested in vitro on cell cultures was also negative. Analyses are underway to enable a full interpretation of the results and to readjust the development program for siRNAs with Huntington's Disease (identification of new leads and optimization of the regimen). This preclinical program is covered by a grant obtained in July 2022 from AFM-TELETHON for €150k per year over two years (2022-2024).

- **Oncology development programs**

1/ Potentiation of the therapeutic efficacy of the oncolytic viruses by inhibiting the expression of the intracellular interferon protein, targeting the gene IFNAR-1 with an siRNA formulated in the Aonys microemulsion. Two studies have been carried out and achieved positive results with the company TRANSGENE.

2/ Inhibition of the expression of the gene from cyclin D1 which is overexpressed in many aggressive cancers, including breast cancer. This study has been carried out working with a team from INSERM and has been covered in a scientific publication(*).

- **The three treatments aimed at large populations contaminated or irradiated following a civil or military nuclear accident** continue to be at the heart of the geopolitical and energy stakes seen currently. Developed in collaboration with the French Atomic Energy Commission (LRT-CEA), which carried out all the studies

on animals contaminated by radionuclides (NU01 Plutonium decorporation and NU02 Cesium decorporation), and with the French Armed Forces Biomedical Research Institute (IRBA) for studies on irradiated animals.

These products are protected by international patents registered or in the process of being registered in most nuclear countries around the world. Their therapeutic activity has been demonstrated and an additional program is required with a pharmaceutical development for industrial production and a tolerance study on healthy volunteers to demonstrate their safety before incorporating the products into the emergency stocks put in place by States.

An application for funding for the radioprotection product was not successful in France, while another application is being prepared for public funding in the United States.

Progress with collaborative programs

- **A collaboration agreement** was signed in March 2023 with the company Partner International to look for pharmaceutical partners and biotech companies with a view to signing licenses for our programs, and specifically a partner to handle the development, registration and marketing of the NanoLithium product for the treatment of Alzheimer's Disease.
- **Collaboration program with the company Transgene:** Despite the very good results achieved demonstrating the presence of the administered siRNAs inside the tumor, Transgene has chosen to not continue with this development for internal strategic reasons. This program is currently being presented by Partner International to pharmaceutical firms involved in oncolytic virus development.

The search for pharmaceutical partners in North America for oncology developments with interfering RNAs is continuing to move forward.

Safeguard proceedings (event after the reporting period)

The dispute between the Company and Bpifrance, which resulted in a ruling by Montpellier's commercial court on May 10, 2023 ordering MEDESIS PHARMA to pay the principal sum of €1.4m, has been referred to Montpellier's court of appeal by the Company, which disputes this ruling. Medesis Pharma is willing to prioritize an agreement with the public investment bank, which has a mission to support French businesses. The Company is still open to the possibility of reaching a mutually beneficial agreement to resolve the current differences. To date, Bpifrance has not responded to the proposals for negotiations.

Medesis Pharma requested and obtained approval, on September 29, 2023, for safeguard proceedings to be opened with Montpellier's commercial court. These proceedings may last up to 12 months and protect companies that have not gone into default in order to allow them to resolve their difficulties and continue operating. They aim to provide a framework that makes it possible to overcome the difficulties encountered and ensure the continuity of the Company's activities. For Medesis Pharma, this process has led to the temporary suspension of its financial and fiscal obligations.

28 of Medesis Pharma's longstanding shareholders have shown their confidence and support by committing to make a current account contribution of around €400,000 to enable the business to continue operating and to help secure the financing required for the developments underway, and specifically its phase 2 clinical trial on NanoLithium for the treatment of Alzheimer's Disease, which is underway at eight clinical investigation centers.

2023 first-half earnings

The unaudited financial statements for the first half of 2023, prepared in accordance with French GAAP, were approved by the Executive Board during its meeting on October 25, 2023 and submitted to the Supervisory Board on the same day.

Corporate accounts (€)	June 30, 2023 (6 months)	June 30, 2022 (6 months)	December 31, 2022 (12 months)
Net revenues	0	0	0
Total operating income	267,547	35,851	197,297
EBIT	(1,678,497)	(1,839,595)	(3,243,567)
Financial income and expenses	(133,746)	237	930
Non-recurring income and expenses	(8,768)	5,202	14,105
Net income	(1,616,063)	(1,574,476)	(2,748,931)
Shareholders' equity	(2,596,421)	116,623	(1,057,832)
Liabilities	3,571,398	2,295,074	(2,322,130)
Transferable securities	0	1,400,000	0
Cash and cash equivalents	138,876	341,070	255,052
Balance sheet total	1,722,786	3,000,743	1,915,615

During the first half of 2023, Medesis Pharma focused on moving forward with the programs detailed previously. The Company did not record any revenues over the period.

The Company's EBIT came to €(1,678k), compared with €(1,879k) for the first half of 2022.

Operating expenditure (excluding staff costs, taxes and depreciation) for the period totaled €1,209k, representing more than 62% of expenses for the period. R&D costs on the projects presented, excluding staff costs, represent more than 47% of operating expenditure for the period. Staff costs including social security contributions came to more than 29% of total expenses for the period, with a headcount of less than 11 people. The cash position at June 30, 2023 represented €139k. In connection with the safeguard proceedings opened, various longstanding shareholders have made a commitment to provide €400k in the form of shareholder current account contributions. These contributions are currently being finalized. The Company currently has financing in place through to the end of November 2023.

Contacts are underway with a view to securing capital contributions at the start of December and making progress to set up licensing partnerships, particularly in view of the progress made with its clinical trial on NanoLithium for the treatment of Alzheimer's Disease.

The negative figure for corporate income tax of €(204,948) corresponds to the research tax credit (CIR) recorded at June 30, 2023.

Liabilities at June 30, 2023 represented €3,571k, up +€1,249k from December 31, 2022. This difference is linked mainly to the €1,200k of bond debt recorded during the first half of 2023, corresponding to the contract for convertible bonds set up with Nice & Green.

The other liabilities primarily concern reimbursable subsidies and advances for €1.6m, with €1.3m disputed by the Company, as well as €544k of trade payables and €123k of tax and employee-related liabilities.

Publication of the 2023 half-year financial report

The 2023 half-year financial report is available to the public and was filed today with the French Financial Markets Authority (AMF). It can be consulted on the company's website at: <https://www.medesispharma.com/reports-and-documents/>

(*) Julien Champagne, Laetitia K. Linares, Benjamin Maurel, Alexandre Zampieri, Maeva Moreno, Ivanna Fuentes, Emeric Dubois, Dany Severac, Adrien Decorsière and Frédéric Bienvenu.

[TAG-RNAi overcomes off-target effects in cancer models.](#)

[Springer Nature](#), published September 26, 2019.

About Medesis Pharma

To advance the treatment of serious diseases without effective treatments, Medesis Pharma creates drug candidates based on its proprietary Aonys® technology for the oral administration of active ingredients in nanodroplet form, enabling active ingredients to be effectively delivered to all cells, with passage through the blood–brain barrier (BBB).

This innovative approach is being applied to future drugs to treat major diseases that do not have effective treatments: Alzheimer's disease, Huntington's disease, and resistant cancers.

Medesis Pharma is also developing treatments dedicated to populations contaminated or irradiated after a civil or military nuclear accident.

French biopharmaceutical company based near Montpellier, Medesis Pharma is the author of 15 scientific publications, holds 12 patent families and 72 patents, resulting from 17 years of research.

Medesis Pharma shares are listed on Euronext Growth Paris: FR001844464 - ALMDP

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