



MaaT Pharma Publishes its Half Year 2023 Results and Provides a Business Update

- The ARES study on MaaT013 reached the required patient threshold for DSMB¹ planning in early Q4.23
- The European Medicines Agency (EMA) has granted MaaT033 orphan drug designation aiming to improve overall survival in patients undergoing HSCT²
- First patient was dosed in the IASO Phase 1b pilot study in Amyotrophic Lateral Sclerosis (ALS) with MaaT033
- Completion within 12 months of the manufacturing facility in partnership with Skyepharma and transfer of MaaT Pharma's Production and Development capabilities to the new 17,200 sq ft site
- As of June 30, 2023, cash and cash equivalents were €35.1 million, anticipated cash runway into Q2 2024
- Revenues of €1.4 million in H1 2023

Lyon, France, September 26th, 2023 - 6:00 pm CET – [MaaT Pharma \(EURONEXT: MAAT – the “Company”\)](#), a clinical-stage biotechnology company and a leader in the development of **Microbiome Ecosystem Therapies™ (MET) dedicated to enhancing survival for patients with **cancer**, today announced its half year financial results for the six-month period ended June 30, 2023 and provided a business overview.**

“Over the first half of 2023, we laid a solid foundation for clinical development and manufacturing scale-up. Regarding MaaT013, our onco-hematology lead product, the lifting of the FDA hold and the upcoming DSMB review for our Phase 3 trial represent pivotal moments in our development. In addition, our second asset, MaaT033, has received orphan drug designation from the EMA, highlighting the pressing medical need for improved treatments in HSCT. Achieving these significant milestones reflects MaaT Pharma's unwavering commitment to progress and innovation.” **stated Siân Crouzet, Chief Financial Officer of MaaT Pharma.** *“These achievements also contribute to the overall positive trends in the global microbiome landscape, as demonstrated by the industry's latest positive clinical data and the recent approval of the third microbiome drug by regulatory agencies.”*

¹ Data Safety Monitoring Board

² Hematopoietic Stem Cell Transplant

Pipeline Highlights

MET-N platform

MaaT013

- **In onco-hematology:**
 - [In April 2023](#), MaaT013 clinical results in its early access program for 81 patients, previously communicated during the 64th annual meeting of the American Society of Hematology (ASH), were presented during the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023).
 - In [April 2023](#), the U.S. Food and Drug Administration (FDA) lifted the clinical hold and cleared the Investigational New Drug (IND) application for MaaT013 in patients with aGvHD³. MaaT Pharma intends to consult with the FDA on the next steps of the regulatory process to bring MaaT013 to US patients in the most expeditious way possible while the Company continues the late-stage clinical development of MaaT013 in Europe with the ongoing international multicenter, open-label, single arm, pivotal Phase 3 trial (ARES).
 - As a post-period event, [in July 2023](#), the Company announced that clinical data on MaaT013 as a treatment for aGvHD was published in [eClinicalMedicine](#), one of the Lancet Discovery Science suite's journals.
 - As a post period event, the Company announces that the ARES study has recruited the required number of patients and that the DSMB is planned for early Q4.23.
- **In immuno-oncology:**
 - The [PICASSO](#) study, sponsored by APHP, is largely on track for data readout now expected by end of 2024/early 2025. This is the only double-blind randomized clinical trial in the field evaluating a microbiome approach (MaaT013) to enhance the efficacy of Immune Checkpoints Inhibitors (ICI) treatments in patients with metastatic melanoma.
 - With more than half of the patients now having completed their week 9 visit, the Company is in a position to receive biomarker data from its partner.

MaaT033

- **In onco-hematology:**
 - [In April 2023](#), MaaT033 data of Phase 1b study CIMON, previously communicated during the 64th annual ASH meeting, were also presented at the EBMT 2023.
 - As a post period event, [in September 2023](#), the Company announced that the European Medicines Agency (EMA) had granted MaaT033 orphan drug designation aiming to improve overall survival in patients undergoing HSCT and had recognized the significant benefit that MaaT033 could therefore bring to this patient's population. The status offers key benefits including market exclusivity, clinical protocol assistance, waivers or reductions in regulatory fees.

³ acute Graft Versus Host disease

- **In neurodegenerative diseases:**
 - As a post period event, the Company announces that the first patient was dosed in the IASO Phase 1b pilot study ([NCT05889572](#)) in ALS (also known as Lou Gehrig's disease in the US and Charcot's disease in French-speaking countries). The Company has developed the clinical trial in partnership with the French patients' association *Tous en Selles contre la SLA*.

MET-C platform

MaaT034

- **In combination with immune checkpoint inhibitors in solid tumors**
 - MaaT034 is the first member of the MaaT03X co-culture family from the MET-C platform. First in human is scheduled for 2025, with the manufacture of the first clinical batch in 2024.
 - As a post period event, the Company announces that two posters have been accepted for the 38th Annual Meeting of Society for Immunotherapy of Cancer (SITC), Nov 1-5, 2023 in San Diego, CA USA.

Corporate update

- [In February 2023](#), the Company announced the successful completion of a capital increase of approximately €12.7 million supported by its existing shareholders including Seventure Partners, PSIM Fund represented by Bpifrance Investissement, Biocodex, Invus, Céleste Management, Skyviews Life Sciences and Tocqueville.
- [In June 2023](#), MaaT Pharma announced new appointments to the Board of Directors and Executive team, to align with the Company's long-term vision and goals:
 - Karim Dabbagh as Chairman and Nadia Kamal as Director, both independent.
 - Philippe Moyen as Chief Operating Officer.
- [In June 2023](#), MaaT Pharma also announced the appointment of Guillaume Debroas as Head of Investor Relations.
- As a post period event, [in July 2023](#), MaaT Pharma announced joining the Microbiome Therapeutics Innovation Group (MTIG).
- As a post period event, in September 2023, the Company and Skyepharma announced completion of the cGMP manufacturing facility and the transfer of MaaT Pharma's Production and Development teams to the new site.
- As a post period event and with deep sorrow, MaaT Pharma announces the sudden passing of Professor Gervais Tougas, who served as our part time acting Chief Medical Officer. The Company has initiated a search for a full-time replacement.

Key Financial Results

The key unaudited financial results for the first half of 2023 are as follows:

Income Statement

In thousands of euros	2023.06	2022.06
Revenue	1 378	494
Cost of Goods Sold	(284)	(72)
Gross Margin	1 095	422
Other Income	2 659	1 793
Sales and distribution costs	(541)	(140)
General and administrative costs	(2 097)	(2 115)
Research and development costs	(9 650)	(7 328)
Operating Income (loss)	(8 534)	(7 368)
Financial Income	258	-
Financial Expense	(159)	(50)
Net financial income (expense)	99	(49)
Income (loss) before income tax	(8 435)	(7 417)
Income tax expense	-	-
Net Income (loss) for the period	(8 435)	(7 417)

Prepared in accordance with international standards, IFRS

Revenues totaled €1.4 million for the half year ended June 30, 2023, compared with €0.5 million in the half year ended June 30, 2022, reflecting the increase in demand from healthcare professionals and the treatment of an increased number of patients.

Operating loss amounted to €8.5 million in the first half of 2023 compared with €7.4 million in the first half of 2022, an increase of €1.2 million. This increase reflects the growth of research and development costs which have risen from €7.3 million in the first half of 2022 to €9.7 million in 2023, representing an overall increase of €2.3 million and fully consistent with the advancement of the Company's research programs, offset in part by the R&D tax credit of €2.7 million included in "Other Income".

The net loss amounts to €8.4 million as of June 30, 2023, compared with €7.4 million as of June 30, 2022, reflecting the growth of the Company and in particular the investment in R&D.

The average number of employees has increased from 39 over the first half of 2022 to 47 for the same period of 2023. As of June 30, 2023, there were 51 employees, of which 39 were dedicated to research and development.

Cash Position

As of June 30, 2023, total cash and cash equivalents were €35.1 million, as compared to €35.2 million as of December 31, 2022.

Over the first half of 2023, the net decrease in cash position amounted to €0.2 million compared with €4.9 million in the first half of 2022. Nonetheless, cash used to finance operations increased by €5.9 million for compared with the first half of 2022 due to the increased in operating expenses, particularly associated with research and development. Cash inflows related to financing activities amounted to €13.2 million as a result of the capital increase of approximately €12.7 million supported by its existing shareholders in February 2023, in addition to financing of the 2022 R&D tax credit for a total of €3.1 million offset by loan repayments totaling €1.5 million.

Total financial debt (including lease liabilities) totaled €13.0 million as of June 30, 2023, of which €0.6 million relates to state-backed loans (“PGE”).

Based on the development plans and corresponding cash needs, the Company believes it has sufficient cash to finance its activities into the second quarter of 2024.

The Company has updated its corporate presentation, which can be downloaded here: <https://www.maatpharma.com/investors/>

Upcoming financial communication*

- November 9, 2023 – Q3 2023 Results

**Indicative calendar that may be subject to change.*

Upcoming investor and scientific conferences participation

- September 27, 2023 – 6th edition - Forum LPB Valeurs Régionales
- October 4, 2023 – KBC Securities Life Sciences Conference
- October 4-5, 2023 – Portzamparc Seminar Biotech & Health
- October 9-10, 2023 – Investor Access Event
- November 1-5, 2023 – 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)

About MaaT Pharma

MaaT Pharma, a clinical-stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has launched, in March 2022, an open-label, single-arm Phase 3 clinical trial in patients with acute GvHD, following the achievement of its proof of concept in a

Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of biomarkers for microbiome-related conditions. The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice. MaaT Pharma is listed on Euronext Paris (ticker: MAAT).



Forward-looking Statements

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements.

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