



MaaT Pharma Publishes its Half Year 2024 Results and Provides a Business Update

- Positive efficacy and safety data of MaaT013 in aGvHD in the Early Access Program presented at the EBMT 2024 annual meeting with 63% GI-ORR at D28, a 49% one year and 42% 18 months Overall Survival (OS) in patients similar to those included in the ongoing Phase 3 ARES trial.
- Completion of patients' recruitment for the Phase 2b PICASSO trial sponsored by AP-HP evaluating MaaT013 in combination with immune checkpoint inhibitors (ICI) in metastatic melanoma.
- MaaT013 batches manufactured and ready to be distributed for clinical supply in the US and in Europe and advancement of the readiness phase for the initiation of clinical activities.
- Positive review by an independent Data Safety and Monitoring Board (DSMB) of the Phase 2b PHOEBUS trial evaluating MaaT033 for patients with blood cancers undergoing allo-HSCT, which recommended that the trial proceeds as planned without modification.
- Successful raise of €17.3 million in net proceeds upon completing an offering in May 2024.
- As of June 30, 2024, cash and cash equivalents were €31.2 million, anticipated cash runway extended into Q2 2025 after prioritization of resources around the delivery of Phase 3 topline results for MaaT013 in Europe.
- Revenues of €1.7 million in H1 2024, compared to €1.4 million in H1 2023, linked to a continuous increase in demand for MaaT013 in the Early Access Program.

Lyon, France, September 19th, 2024 - 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 through immune modulation, today announced its half year financial results for the six-month period ended June 30, 2024, and provided a business overview.

“Building on the positive data for MaaT013 in April 2024 presented at the EBMT Congress, and the success of our recent fundraising, we have dedicated the first half of 2024 to pursuing recruitment and preparing for the topline results of our ongoing Phase 3 clinical trial for MaaT013. This trial is designed to address the urgent unmet medical need of patients with acute graft-versus-host disease not responding to current treatments. Currently, patients requiring third-line treatment options face an 85% mortality rate within one year. Furthermore, by extending our cash runway by an additional quarter, we are well-positioned to deliver on our short-term milestones,” **stated Siân Crouzet, Chief Financial Officer of MaaT Pharma.**

Pipeline Highlights

MET-N platform

MaaT013

- **In hemato-oncology:**

- [In March 2024](#), the Company announced the launch of a retrospective multicenter trial called CHRONOS in Europe. Its primary objective is to provide the Company efficacy data for 3rd-line therapies for aGvHD patients not receiving MaaT013 or any microbiome intervention. This retrospective study does not impact cash projections as funding is already secured.
- [In April 2024](#), at the 50th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT), the Company presented promising extended survival data from the Early Access Program in Europe, involving 140 patients with steroid-refractory (SR) or steroid-dependent (SD) acute graft-versus-host disease with gastrointestinal involvement (GI-aGvHD) treated with MaaT013. Data highlighted a high response rate (Complete Response and Very Good Partial Response) to MaaT013, demonstrating a clear reduction in disease burden and improved Overall Survival (OS) at 18 months compared to published data.

- **In immuno-oncology:**

- [In March 2024](#), the Company informed on the completion of patient recruitment for the Phase 2a randomized clinical trial ([NCT04988841](#)) (PICASSO) sponsored by AP-HP and in collaboration with INRAE and Institut Gustave Roussy, evaluating MaaT013 in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®), in metastatic melanoma patients. A total of 70 patients have been enrolled since April 2022. The Company provided its MaaT013 drug candidate and placebo and will contribute to the microbiome profiling of patients using its proprietary gutPrint® AI research engine. As previously announced, data readout is expected in Q4 2024/Q1 2025.

MaaT033

- **In hemato-oncology:**

- [In May 2024](#), the Company announced its participation in the IMMUNOLIFE RHU program, a consortium including academic partners, such as Institut Gustave Roussy (IGR), a world-renowned center in the field of cancer treatment, and biotech companies. MaaT033, an oral, pooled fecal microbiotherapy, developed by MaaT Pharma will be tested as a concomitant treatment to cemiplimab (Regeneron), an anti-PD1 therapy, to assess the potential increase in response rate in patients having received antibiotics. This randomized multicenter Phase 2 clinical trial will include advanced non-small cell lung cancer (NSCLC) patients. The related costs for MaaT Pharma are limited to clinical product supply in line with previous cash projections. The trial is expected to start in H1 2025.

- As a post-period event, [in July 2024](#), the Company announced first DSMB positive review of the Phase 2b trial PHOEBUS and recommended continuation of the trial without modification. The DSMB concluded that the safety profile was acceptable and the treatment well-tolerated. The trial is an international, multi-center, randomized, double-blind, testing MaaT033, in patient receiving HSCT, an oral freeze-dried formulation against placebo, set to be conducted in up to 56 clinical investigation sites and is expected to enroll 387 patients ([NCT05762211](#)).
- Recruitment for PHOEBUS trial is ongoing in France, Germany, Spain, and Belgium, with the trial already approved in the Netherlands and the United Kingdom. Upcoming milestones include a second safety assessment by the DSMB expected in early Q1 2025. The interim analysis following the recruitment of 60 patients, is expected in H1 2025, instead of H2 2024. This slight delay is due to the strategic option taken by the Company's management in early 2024 to prioritize resources for the Phase 3 ARES trial and open new trial sites in countries outside France and Germany in a more sedate manner than originally planned.
- **In neurodegenerative diseases:**
 - [In February 2024](#), the Company announced a positive review by the DSMB on the Phase 1 clinical trial (IASO) evaluating MaaT033 in Amyotrophic Lateral Sclerosis (ALS) for the first 8 patients. The DSMB recommended that the trial proceed without modification.
 - [In May 2024](#), the Company announced the completion of patient recruitment for IASO.

MET-C platform

MaaT034

- **In combination with immune checkpoint inhibitors in solid tumors**
 - [In April 2024](#), the Company presented [new in vitro data](#) characterizing the metabolites produced by MaaT034 and their impact on immune modulation at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego, California. MaaT034, the first product from MaaT Pharma's MET-C platform, is a ground-breaking full ecosystem synthetic microbiota product being developed for patients with solid tumors to improve responses to immunotherapy in combination with an ICI treatment, which represents a potentially large market. In today's challenging economic environment, the Company has prioritized resources to focus on MaaT013, specifically preparing marketing authorization activities in Europe and the upcoming Phase 3 topline results in Europe. This approach aimed at optimizing both short-term validation and clinical validation, has resulted in a deferral of activities related to MaaT034. Thus, clinical activities for MaaT034 are now expected to begin in 2026 and not 2025, as previously announced.

Corporate updates

- [In March 2024](#), the Company announced the appointment of Jonathan Chriqui, PharmD, as Chief Business Officer and member of the executive management team. Jonathan Chriqui will be responsible for MaaT Pharma's business development and partnering strategies.
- [In May 2024](#), the Company announced the successful completion of its offering of 18.2 million euros. The net proceeds from the Primary Offering were €17.3 million.
- [In May 2024](#), the Company announced the production of MaaT013 batches for clinical supply in the US, while advancing the readiness phase to initiate clinical activities. This includes ongoing discussions with prominent US clinicians in stem cell transplantation.
- [In June 2024](#), the Company announced the appointment of Gianfranco Pittari, M.D., Ph.D., as Chief Medical Officer. Dr. Pittari brings over 15 years of international experience in clinical research and drug development in hematology, oncology, and immunology. The Company also welcomed Carole Iffi, as head of Regulatory Affairs. Former Senior director, global regulatory lead at UCB, Carole Iffi brings over 25 years of expertise in regulatory affairs and will be instrumental in leading MaaT013 submission.

Key Financial Results

The key unaudited financial results for the first half of 2024 are as follows:

Income Statement

In thousands of euros	2024.06	2023.06
Revenue	1 721	1 378
Cost of Goods Sold	(537)	(284)
Gross Margin	1 184	1 095
Other Income	1 935	2 659
Sales and distribution costs	(308)	(541)
General and administrative costs	(2 872)	(2 097)
Research and development costs	(12 695)	(9 650)
Operating Income (loss)	(12 756)	(8 534)
Financial Income	161	258
Financial Expense	(262)	(159)
Net financial income (expense)	(101)	99
Income (loss) before income tax	(12 856)	(8 435)

Income tax expense	-	-
Net Income (loss) for the period	(12 856)	(8 435)

Prepared in accordance with international standards, IFRS

Revenues totaled €1.7 million as of June 30, 2024, compared with €1.4 million on June 30, 2023, an uplift almost 25%. While these figures reflect the continued increase in demand from healthcare professionals in France (where invoicing is possible), we confirm an increased uptake in other European countries.

Operating loss amounted to €12.8 million in the first half of 2024 compared with €8.5 million in the first half of 2023, an increase of €4.3 million. This increase reflects primarily the growth of research and development costs which have risen from €9.7 million in the first half of 2023 to €12.7 million in 2024, consistent with the advancement of the Company's research programs, in particular the late-stage clinical programs for MaaT013 and MaaT033. Other Income, including the R&D tax credit of €1.6 million decreased by €0.7 million in 2024 principally due to public funding received over the first half of 2024 offsetting expenses eligible for the R&D tax credit. The net loss amounts to €12.9 million as of June 30, 2024, compared with €8.4 million as of June 30, 2023, reflecting the advancement of the Company's late-stage assets and increased investment in R&D.

The average number of employees has increased from 47 over the first half of 2023 to 50 for the same period of 2024. As of June 30, 2024, there were 54 employees, of which 43 were dedicated to research and development.

Cash Position

As of June 30, 2024, total cash and cash equivalents were €31.2 million, as compared to €24.3 million as of December 31, 2023.

Over the first half of 2024, the net increase in cash position amounted to €6.9 million compared with the decrease by €0.2 million in the first half of 2023. This is driven by cash used to finance operations of €12.6 million in line with the increase in operating expenses, particularly for R&D and to a lesser extent G&A, offset by cash inflows related to financing activities of €19.5 million. Net cash inflows from financing activities include the share capital increase of €17.2 million in May 2024, financing of the 2023 R&D tax credit for a total of €3.5 million, receipt of lump sums from public reimbursable loans in connection with development of MaaT033 and MaaT034 for an amount of €2.7 million, offset by loan repayments totaling €1.8 million.

Total financial debt (including lease liabilities) totaled €17.2 million as of June 30, 2024, of which €3.5 million relates to financing of 2023 R&D Tax Credit.

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 2025, extending the cash runway by at least three months compared to prior communications as a result of prioritization and focusing resources on the delivery of the Phase 3 topline results for MaaT013 in aGvHD that is expected in mid-Q4 2024, deferral of certain industrialization activities related to MaaT034,

and stability of headcount. The Company is in active ongoing discussions to finance operations beyond the second quarter of 2025 and remains confident in extending its cash runway.

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

Upcoming financial communication and conferences*

- September 24, 2024: Lyon Pole Bourse Forum
- September 26, 2024: KBC Securities' Life Sciences Conference
- October 8-9, 2024: Portzamparc Conference
- October 15-16, 2024: Investor Access Event
- November 4-6, 2024: Bio-Europe
- November 5, 2024: Publication of revenues for Q3 2024

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

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 launched, in March 2022, an open-label, single arm, phase 3 clinical trial in patients with acute GvHD (aGvHD), 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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