



MaaT Pharma Publishes its Half Year Results and Provides a Business Overview

- For the first half of 2022 turnover was €0.5 million and cash and cash equivalents were €38.4 million as of June 30, 2022
- Significant milestones achieved in clinical and cGMP manufacturing programs over first half of 2022:
 - Initiation of pivotal open-label, single-arm, Phase 3 trial of MaaT013 in acute Graft-vs-host-Disease in Europe in Q1 2022
 - Initiation of a Phase 2a trial, sponsored by AP-HP, of MaaT013 in combination with immunotherapies in patients with metastatic melanoma in Q2 2022
 - Completion and publication of positive topline results of Phase 1b dose-finding clinical trial of MaaT033 in hemato-oncology
 - Partnership with Skyepharma to establish cGMP manufacturing facility, entirely dedicated to microbiome drug candidates

Lyon, France, September 29th, 2022 - 6:00 pm CET – [MaaT Pharma \(EURONEXT: MAAT – the “Company”\)](#), a French clinical-stage biotech and a pioneer in the development of Microbiome Ecosystem Therapies™ (MET) dedicated to improving survival outcomes for patients with cancer, today announced its half year financial results for the six-month period ended June 30, 2022 and provided a business overview.

Hervé Affagard, CEO and co-founder of MaaT Pharma stated, “We are proud of the progress of our clinical and manufacturing programs as we have delivered on the objectives we had set ourselves at the time of our IPO on Euronext in 2021, even if the current capital markets remain challenging for several companies in our industry. Notably, the first half of 2022 has been marked by an important milestone for MaaT Pharma as we started our pivotal single-arm, open-label Phase 3 trial. We are satisfied with the ongoing patient enrollment for this trial, despite the public health context in the first half of the year. We are looking forward to initiating a Phase 2b for our second drug candidate, MaaT033, by the end of this year. Additionally, the construction of our new cGMP manufacturing facility is taking shape, which will be key to prepare for the entry of the first of our MaaT03X candidates into clinical study by the end of 2023. MaaT03X, a new generation of co-cultured drug candidates, is a donor-independent, highly scalable, and indication-specific product design, which has the potential to be a game-changer in improving patient responses to immunotherapies. We have watched closely the positive vote from an Advisory Committee convened by the FDA¹ for the first marketing

¹ <https://www.ferring.com/fering-receives-positive-vote-from-u-s-fda-advisory-committee-for-rbx2660/>

authorization application for a microbiome drug product to treat infectious diseases, that uses technology similar to our native technology. In this context, we hope to soon see the first approval of such a candidate, which would represent a major regulatory milestone for the whole industry.”

Key Financial Results

The key unaudited financial results for the first half of 2022 are as follows:

Income Statement

In thousands of euros	06/30/2022	06/30/2021
Revenue	494	385
Cost of Goods Sold	(72)	(27)
Gross Margin	422	357
Other Income	1 793	1 189
Sales and distribution costs	(140)	(87)
General and administrative costs	(2 115)	(1 058)
Research and development costs	(7 328)	(4 384)
Operating income (expense)	(7 368)	(3 983)
Financial Income	0	0
Financial Expense	(50)	(64)
Net financial income (expense)	(49)	(64)
Income (loss) before income tax	(7 417)	(4 047)
Income tax expense	-	-
Net Income (loss) for the period	(7 417)	(4 047)

Prepared in accordance with international standards, IFRS

Revenues totaled €0.5 million for the half year ended June 30, 2022, which include compensation invoiced from the compassionate access program generating a gross margin of €0.4 million.

Operating loss amounted to €7.4 million compared with €4.0 million in the first half of 2021, an increase of €3.4 million. This increase reflects the growth of research and development costs which have risen from €4.4 million in the first half of 2021 to €7.3 million in 2022, representing an overall increase of €2.9 million and fully consistent with the advancement of activities, offset in part the R&D tax credit of €1.8 million included in “Other Income”:

- **MaaT013:**
 - Phase 3 clinical trial, ARES, was initiated with the first patient dosed in March 2022. Regulatory authorization was obtained by the Company, to date, in six European countries – France, Germany, Spain, Austria, Belgium, and Italy.
 - MaaT Pharma continues to pursue the Early Access Program in France as in 2021, allowing patients to benefit from early access to the MaaT013 therapy, mainly for the treatment of acute Graft-vs-host-Disease. As of today, the Company has safely treated over 140 patients with MaaT013 in Europe.
 - The proof-of-concept Phase 2a trial, PICASSO, was initiated in April 2022 to evaluate MaaT013's impact on the efficacy of Immune Checkpoint Inhibitors (ICI) treatment in patients with metastatic melanoma. The trial is sponsored by AP-HP with MaaT Pharma supplying drug candidates and performing the microbiome profiling of patients using its proprietary gutPrint® platform.
- **MaaT033:** Phase 1b clinical trial, CIMON, has been completed with confirmation of principal positive results in June 2022 enabling the Company to define the dosing regimen for the next development phase.
- **MaaT03x:** Pre-clinical trials proceed as planned.
- **Partnership with Skyepharma** to establish cGMP manufacturing facility dedicated to ecosystem microbiome-based therapeutics which is expected to be operational in 2023. A second down payment was made to Skyepharma by the Company in the first half of 2022.

General and administrative expenses amounted to €2.1 million for the first half of 2022 compared with €1.1 million in 2021 reflecting the structuring of the Company to meet the needs of being listed on the Euronext exchange and in support of the clinical and development programs and the associated infrastructure required.

The net loss amounts to €7.4 million as of June 30, 2022, compared with €4.0 million as of June 30, 2021, reflecting the growth of the Company and in particular the investment in R&D.

Average employees evolved from 32 in the first half of 2021 to 43 in 2022 following the strengthening of clinical operations, clinical development, manufacturing, quality assurance, and administrative teams.

Cash Position

As of June 30, 2022, total cash and cash equivalents were €38.4 million, as compared to €43.3 million as of December 31, 2021.

The net decrease in cash position of €4.9 million between December 31, 2021, and June 30, 2022, is primarily due to cash used to finance operations for €7.1 million, cash used for investing of €0.2 million, offset by net cash inflows related to financing activities of €2.4 million essentially from the receipt of funds of €2.7 million in bank loans from BNP Paribas and Caisse d'Epargne Rhone Alpes (CERA). Total financial debt (including lease liabilities) totaled €8.3 million as of June 30, 2022, of which €1.0 million relates to state-backed loans ("PGE"). Additional draws down, up to €4.4 million, are expected to be made in the second half of 2022 from existing facilities signed with CIC and Bpifrance.

Based on the development plans and corresponding cash needs, the Company believes it has sufficient cash to finance its activities up until the end of the third quarter of 2023.

Major milestones achieved in the first half of 2022

Clinical and operational development

In Europe, MaaT013, the Company's lead asset, is currently being evaluated in two clinical trials launched in Q1 2022:

- Ongoing pivotal open-label, single-arm Phase 3 trial in Europe evaluating the safety and efficacy of MaaT013 in acute Graft-versus-Host-Disease.
- Ongoing randomized, placebo-controlled Phase 2a proof-of-concept clinical trial, sponsored by AP-HP, evaluating MaaT013 in combination with Immune Checkpoint Inhibitors (ICI) for patients with metastatic melanoma.
- In the U.S., interactions are ongoing with the Food & Drug Administration (FDA) to extend MaaT013 clinical trial in the U.S., which remains on clinical hold following an FDA communication received in August 2022 requiring additional information on the safety and efficacy of the Company's "pooling" approach.

In June 2022, the Company confirmed positive topline results for its Phase 1b trial evaluating MaaT033, the Company's oral-form drug candidate, for patients with blood cancer. Having demonstrated promising preliminary and interim engraftment data, the study was completed early in January 2022.

In February 2022, the Company announced its partnership with Skyepharma to build the largest cGMP facility in France entirely dedicated to microbiome-based drug candidates, expected to be operational in 2023. The investment is shared by MaaT Pharma and Skyepharma totaling €8.1 million.

Next key milestones expected

End of second half of 2022

In Q4 2022, the Company expects to initiate a pivotal Phase 2b trial evaluating MaaT033, the first oral drug candidate, to prevent complication of allo-HSCT². This randomized, double-blind, placebo-controlled study will include 341 patients and evaluate safety and efficacy of MaaT033 in improving overall survival and preventing allo-HSCT complications for patients with blood cancers.

First half of 2023

Regarding the ongoing Phase 3 trial with MaaT013, a first data review is expected after enrollment of half the patients in the study.

² Allo-HSCT = allogeneic hematopoietic stem cell transplantation. More than 20,000 patients receive allo-HSCT each year (Global Data 2020).

Regarding the ongoing proof-of-concept Phase 2a trial evaluating MaaT013 in association with ICI for patients with metastatic melanoma, a first internal data review focusing on safety and some biomarker data is expected.

Upcoming financial communication*

- November 8, 2022 – Revenues and Cash Position Quarter 3

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

Upcoming investor conference participation

- October 4, 2022 – Biotech Health Seminar – Portzamparc BNP Paribas
- October 6-7, 2022 – Investor Access Event
- October 13-14, 2022–HealthTech Innovation Days #4 (HTID)
- November 29, 2022 – *Investir* Day

Upcoming scientific conference participation

- November 8-10, 2022 – 9th International Human Microbiome Consortium (IHMC) Congress
- November 9-11, 2022 – 21st *Société Francophone de Greffe de Moelle et de Thérapie Cellulaire* (SFGM-TC) Congress
- December 10-13, 2022 - 64th American Society of Hematology (ASH) Annual Meeting

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, a Phase 3 clinical trial for patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, supports the development and expansion of its pipeline by determining novel disease targets, evaluating drug candidates, and identifying 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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