MaaT Pharma Publishes its Half Year 2025 Results and Provides a Business Update

- Positive results from Phase 3 trial for MaaT013 in acute Graft-versus-Host disease (aGvHD); topline results showed a 62% gastrointestinal overall response rate at Day 28 and 1-year expected Overall Survival of 54%, demonstrating high efficacy and significant clinical improvement over currently available therapies.
- Marketing Authorization application of Xervyteg® (MaaT013) in aGvHD submitted to the European Medicines Agency (EMA) in June 2025.
- Signature of a license and commercial agreement with Clinigen to facilitate patient access across Europe. €10.5 million upfront payment received and €18 million additional payments depending on the achievement of pre-specified regulatory and sales milestones. The Company will also be eligible to receive royalty payments on both EAP treatments and net commercial sales of a percentage in the mid-thirties and regular cash flow as per the supply agreement of Xervyteg®.
- Signature of a €37.5 million, 4-tranche financing from the European Investment Bank (EIB). The financing will support the advancement of its late-stage hemato-oncology clinical programs including the lead-asset Xervyteg® for the treatment of aGvHD and the second drug candidate, MaaT033, currently being evaluated in a Phase 2b randomized controlled trial in improving survival for patients receiving allo-HSCT.
- As of June 30, 2025, cash and cash equivalents were €15 million, excluding the initial Clinigen payment and the EIB financing. Including the €10.5 million Clinigen payment and the upcoming €3.5 million EIB tranche A, the cash runway is extended until end of February 2026.
- Revenues of €2.4 million in H1 2025, compared to €1.7 million in H1 2024, +41%, linked to a continuous increase in demand for Xervyteg® in the Early Access Program, in all regions.

Lyon, France, September 17th, 2025 - 7:30 am 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, 2025, and provided a business overview.

"In the first half of the year, MaaT Pharma achieved key clinical and regulatory milestones, bringing us closer to providing a much-needed therapeutic option for patients with aGvHD and to becoming the first Company to bring a microbiome medicine to market in Europe. With the EMA submission of Xervyteg® (MaaT013), our Clinigen partnership, and the EIB financing, we have strengthened both our operations and financial position. These achievements illustrate our strategy to advance development while preserving shareholder value through a balanced mix of dilutive and non-dilutive funding. As we move into the second half of 2025, we remain focused on execution, preparing with Clinigen for potential market entry, and strengthening our leadership in microbiome-based therapies," **stated Eric Soyer, Chief Financial Officer of MaaT Pharma.**

Pipeline Highlights

In Hemato-Oncology

Acute Graft-versus-Host Disease (aGvHD) – Xervyteg® (MaaT013)

- In January 2025, the Company announced positive topline results from the pivotal Phase 3 ARES Study evaluating Xervyteg®(MaaT013) in aGvHD. The study met its primary endpoint with a significant gastrointestinal overall response rate at Day 28 of 62% and demonstrates the unprecedented efficacy of Xervyteg® as third-line treatment of aGvHD with gastrointestinal involvement (GI-aGvHD) consistent with communicated EAP results.
- In March 2025, the Company received positive opinion from European Medicines Agency (EMA).Pediatric Committee on the Pediatric Investigation Plan for Xervyteg®(MaaT013), a key milestone achieved towards the Marketing Authorization Application (MAA) submission to the EMA.
- In March 2025, the Company announced a positive outcome from the final DSMB meeting on ARES Phase 3 trial, confirming the remarkable efficacy results and positive risk/benefit profile of MaaT013 in third-line GI-aGvHD.
- In June 2025, the Company announced the submission of a Marketing Authorization Application (MAA) to the EMA for its lead drug candidate MaaT013, under the registered brand name of Xervyteg®. If approved, the Marketing Authorization would establish Xervyteg® as the first microbiota therapeutic approved by the EMA, the first one in hemato-oncology worldwide and the first approved therapy in third-line GI-aGvHD.

- In June 2025, the Company presented positive updated data in Early Access Program for 173 patients at the 2025 annual EHA Congress supporting the high efficacy and good safety profile of Xervyteg®. This dataset confirms the breakthrough potential of Xervyteg® for aGvHD patients with limited treatment options.
- In July 2025, the Company announced the signature of a license and commercial agreement with Clinigen, a global specialty pharmaceutical services group and a leading European player in hospital distribution and market access, to streamline the pathway for ensuring access to this medicine across Europe. With this partnership, MaaT Pharma demonstrates its capability to supply products to pharmaceutical companies, including those specializing in rare diseases while ensuring scale-ups for commercial. The Company received an upfront payment of €10.5 million and could receive additional payments of up to €18 million depending on the achievement of pre-specified regulatory and sales milestones. The Company will also be eligible to receive royalty payments on net sales of a percentage in the mid-thirties and regular cash flow as per the supply agreement.
- Final results from the pivotal ARES study, including 12-month overall survival data, are expected before the end of 2025 and will be incorporated into the filing dossier. Data are also being submitted in a peer reviewed journal and upcoming scientific congress.
- The potential marketing authorization could be delivered around mid-2026 (if approved), then enabling the start of the commercialization of Xervyteg® in Europe in the second half of 2026.
- In parallel, the Company continues discussions with the FDA for a dedicated pivotal study in the U.S., with the objective of enabling the earliest possible access to Xervyteg® for U.S. patients. Such a study could be initiated in 2026, subject to regulatory confirmation as MaaT Pharma continues watching the evolving regulatory policies and process in the United States, and subject to appropriate financing.
- The Company continues to expand its U.S. footprint through its Early Access Program, with recurring patient requests now coming from three leading hospitals: City of Hope (Duarte-Los Angeles, CA), Massachusetts General Hospital (Boston, MA), and the University of Alabama Hospital (Birmingham, AL).

Allogenic Hematopoietic Stem Cell Transplant (allo-HSCT) - MaaT033

- Over the past 12 months, four DSMB safety assessments were conducted for MaaT033 in the Phase 2b PHOEBUS randomized trial designed to be pivotal: three routine evaluations and one interim analysis focused on excess mortality. All confirmed a favorable safety profile and recommended continuation of the trial without modifications.
- The last patient enrollment in the trial is anticipated for mid-2026, with 1-year Overall Survival results expected in H2 2027.

In Immuno-Oncology

Xervyteg® and MaaT033 – Exploratory trials using the MET-N platform (donor derived conducted as Investigator-Sponsored Trials (ISTs) to inform further developments

- In March 2024, the Company completed patient recruitment for the Phase 2a randomized clinical trial (NCT04988841) (PICASSO) sponsored by AP-HP in Paris and in collaboration with INRAE and Institut Gustave Roussy, evaluating Xervyteg® in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®), in metastatic melanoma patients. The primary endpoint is to assess whether the safety of Xervyteg® combined with ipilimumab and nivolumab differs from that of ipilimumab and nivolumab plus placebo. The Company provided its Xervyteg® drug candidate and placebo and contributes to the microbiome profiling of patients using its proprietary gutPrint® AI research engine, while the trial investigator-sponsor handled recruitment, treatment and is overseeing data collection and analysis. Data readout is expected in H2 2025 as previously announced.
- In May 2024, the Company announced its participation in the IMMUNOLIFE 'RHU' (university hospital trial) 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 will be tested as a concomitant treatment to cemiplimab (Regeneron), an anti-PD1 therapy, to assess the potential increase in response rate in patients who have received antibiotics. The primary endpoint will be the disease control rate (DCR), defined as the proportion of patients who do not exhibit disease progression (CR, PR, or SD) according to RECIST 1.1 criteria. This investigator-sponsored, randomized, multicenter Phase 2 trial will evaluate MaaT033 in patients with advanced non-small cell lung cancer (NSCLC), with MaaT Pharma supplying the investigational product. The trial is expected by the sponsor to start in H2 2025.

MaaT034 – Next-generation drug candidates with co-cultured technology (MET-C platform) to expand in solid tumors

- In April 2025, the Company presented new preclinical data for MaaT034, its next generation product, showing compelling anti-tumor efficacy results in germ-free mice at the American Association for Cancer Research (AACR) Annual Meeting 2025.

  Key results included:

  - Metagenomic analysis shows that MaaT034 reproduces the microbial functions of Xervyteg®, improves DC-mediated T cell activation and potentiates anti-tumor effects mediated by anti-PD-1 checkpoint blockade in vitro.
  - MaaT034 optimizes anti-PD1 mediated activity in tumor-bearing, germ-free mice. While anti-PD1 alone reduced tumor growth by 10%, the combination of anti-PD1 and MaaT034 resulted in a 83.7% tumor growth reduction (compared to a 24.2% reduction when using a single strain of *Akkermansia muciniphila*bacteria).

In Neurodegenerative Diseases

Amyotrophic Lateral Sclerosis (ALS) – MaaT033

- In May 2025, MaaT Pharma announced positive final Phase 1b results for MaaT033 in ALS, showing a favorable safety and tolerability profile supported by biomarker and microbiome analyses. Rapid and sustained microbial engraftment was observed, along with a slower rate of disease progression (ALSFRS-R slope to be interpreted with caution). The Company is seeking a partner to further advance clinical evaluation in ALS.

Corporate updates

- In March 2025, the Company announced the completion of a capital increase of €13 million with historical shareholders.
- In July 2025, the Company announced that it has secured a €37.5 million, 4-tranche financing from the European Investment Bank (EIB). The financing will support the advancement of its late-stage hemato-oncology clinical programs including the lead-asset Xervyteg®, recently partnered with Clinigen in Europe, and currently under regulatory review by the European Medicines Agency (EMA) for the treatment of aGvHD and the second drug candidate, MaaT033, currently being evaluated in a Phase 2b randomized controlled trial in improving survival for patients receiving allo-HSCT.
- Following the annual review of the Euronext Paris indices on September 11, 2025, the Scientific Index Committee has decided to include MaaT Pharma in the CAC Small, CAC Mid & Small, and CAC All-Tradable indices. In addition, during the first part of 2025, the Company's free float increased from 12.57% to 24.94%.
- MaaT Pharma announces evolution of its leadership team, with the appointment of:
    - Frédéric Fasano, Pharm.D, MBA, ICD.D, joining MaaT Pharma as Chief Strategy & Corporate Development Officer, following a long-standing collaboration as a strategic consultant to the Company. With a strong track record in corporate leadership across the pharmaceutical and biotech sectors — including nearly a decade as CEO of Servier Canada — Frédéric will play a pivotal role in shaping and executing MaaT Pharma's corporate strategy. He will also lead efforts to forge strategic partnerships and drive the Company's business growth.
    - Behzad Kharabi Masouleh, M.D. as Acting Chief Medical Officer, together with Emilie Plantamura, Pharm.D., Deputy Chief Medical Officer, will jointly oversee medical, clinical (including the Marketing Authorization Application process for Xervyteg® (MaaT013)), and pharmacovigilance activities. Dr. Kharabi brings extensive industry experience in hematology and cancer research across all stages of clinical development and has a proven track record of successfully advancing novel therapies to approval, having previously held senior positions at Johnson & Johnson, Kite Pharma/ Gilead Sciences, and T-Knife Therapeutics. The Company extends its gratitude to Gianfranco Pittari, M.D.,

Ph.D., for his commitment and contributions in advancing innovative therapies for patients in need and wishes him success as he pursues new opportunities.

- Sheri Simmons, Ph.D., as Acting Chief Scientific Officer. Sheri brings extensive experience in biotechnology, particularly in the microbiome field, having held scientific leadership positions at Seres Therapeutics, Johnson & Johnson's Microbiome Solutions team, and most recently at Seed Health, a leading probiotics company. In her new role, she will strengthen the Company's scientific leadership, overseeing preclinical research, AI/data initiatives, and supporting efforts toward the Marketing Authorization of Xervyteg® in aGvHD.

Key Financial Results

The key unaudited financial results for the first half of 2025 are as follows:

Income Statement

In thousands of euros	2025.06 (6 months)	2024.06 (6 months)
Revenue	2 427	1 721
Cost of Goods Sold	(790)	(537)
Gross Margin	**1 637**	**1 184**
Other Income	2 494	1 935
Sales and distribution costs	(491)	(308)
General and administrative costs	(3 611)	(2 872)
Research and development costs	(14 778)	(12 695)
Operating Income (loss)	**(14 749)**	**(12 756)**
Financial Income	87	161
Financial Expense	(422)	(262)
Net financial income (expense)	**(336)**	**(101)**
Income (loss) before income tax	**(15 085)**	**(12 856)**
Income tax expense	-	-
Net Income (loss) for the period	**(15 085)**	**(12 856)**

Prepared in accordance with international accounting standards IFRS

Revenues totaled €2.4 million as of June 30, 2025, compared with €1.7 million on June 30, 2024, mostly driven by the 37.5% increase in sales from the Early Access Program at €2.3 million vs €1.7 million in the previous year.

Operating loss was €14.7million in the first half of 2025 compared with €12.8 million in the first half of 2024. The €2.0 million increase was mostly attributable to research and development costs, which progressed from €12.7 million in the first half of 2024 to €14.8 million in the first half of 2025, consistent with the advancement of the Company's late stage clinical programs, in particular with the data analysis and regulatory activities for MaaT013 (Xervyteg®) and with the ongoing patient recruitment in the PHOEBUS Phase 2b trial in allogeneic-HSCT with MaaT033.

Cash Position

As of June 30, 2025, total cash and cash equivalents were €15.0 million, compared with €20.2 million as of December 31, 2024. The cash position as of June 30, 2025 does not include the upfront payment received from Clinigen's partnership in July 2025 and the upcoming Tranche A from the EIB expected in September 2025.

Over the first half of 2025, net cash utilization was €5.1 million. Net cash used in Operating and Investment activities was €15.4 million, in line with the operating loss for the period, while cash generated in the Financing activities was €10.3 million, with net proceeds from the €13 million capital raise in March 2025, while loan repayments were €1.6 million.

With the upfront payment from its commercialization agreement with Clinigen and the already available and upcoming first tranche from the loan agreement with the EIB, and with continued strong cash discipline, the Company believes it has sufficient cash to cover its current needs and planned development programs to the end of February 2026. The Company is pursuing several dilutive and non-dilutive financing options, leveraging on the financing initiatives announced over the summer, to further extend its cash horizon.

The Company has updated its corporate presentation available on its website: www.maatpharma.com/investors and has filed its half-year Financial Report to the AMF *(Autorité des Marchés Financiers).*

Upcoming financial communication and conferences*

- September 23, 2025: Lyon Pole Bourse Forum
- September 25, 2025: KBC Securities Life Sciences Conference, Brussels
- October 1, 2025: BNP-Portzamparc Conference
- October 7-8, 2025: Investor Access Event, Paris
- November 4, 2025: Publication of revenues and cash position for Q3 2025

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

About MaaT Pharma

MaaT Pharma is a leading, late-stage clinical company focused on developing innovative gut microbiome-driven therapies to modulate the immune system and enhance cancer patient survival. Supported by a talented team committed to making a difference for patients worldwide, the Company was founded in 2014 and is based in Lyon, France. As a pioneer, MaaT Pharma is leading the way in bringing the first microbiome-driven immunomodulator in oncology. Using its proprietary pooling and co-cultivation technologies, MaaT Pharma develops high diversity, standardized drug candidates, aiming at extending life of cancer patients. MaaT Pharma has been listed on Euronext Paris (ticker: MAAT) since 2021.

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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