



MaaT Pharma Announces 2025 Annual Results and Provides Business Updates

- Potential Pivotal Year for MaaT013 (Xervyteg®):
 - Marketing Authorization Application (MAA) in Europe for MaaT013 (Xervyteg®) submitted to the European Medicines Agency (EMA) in June 2025
 - EMA feedback expected mid-2026 per current EMA timelines
 - Commercial readiness continues, with the Clinigen agreement in place and the Early Access Program (EAP) successfully transferred
 - Active discussions ongoing with the Food and Drug Administration (FDA) to assess potential clinical activities with the European pathway advancing as the primary focus for now
 - EAP Revenues in 2025 of €4.4 million in 2025, a 38% increase over 2024, and the highest revenues generated from the EAP to date
- Pipeline progress continues:
 - MaaT033, currently in Phase 2b potentially pivotal trial (PHOEBUS), is ongoing and continued to demonstrate a favorable safety profile, with six DSMB reviews completed in 2025. Topline results for PHOEBUS study are now expected in Q4 2028 (instead of Q4 2027)
 - MaaT034 promising preclinical data presented at major scientific conferences
- €37.5 million financing agreement signed with the European Investment Bank (EIB), structured in four tranches; Tranches A (€3.5 million) drawn in October 2025, and Tranche B (€6 million) in process
- As of December 31, 2025, cash and cash equivalents were €24.9 million
- Cash runway to August 2026, including the upcoming EIB Tranche B funding of €6.0 million

Lyon, France, March 31, 2026, 7.30 a.m. 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 reports the 2025 full-year annual results and provides business updates.

“2025 was a year of strong clinical momentum for MaaT Pharma, marked by major advances across our hemato-oncology portfolio and progress in immuno-oncology. In 2026, we are approaching a potentially transformative milestone with the EMA review of MaaT013 (Xervyteg®), while continuing to expand our oncology platform. We believe MaaT Pharma is well-positioned as a leader in microbiome-driven therapies and we remain focused on advancing our pipeline with the ambition to bring new therapeutic options to patients with high unmet needs. “ **stated Hervé Affagard, CEO and co-founder of MaaT Pharma.**

Pipeline highlights

In Hemato-Oncology

2025 was an important year for MaaT Pharma, marked by continued progress for MaaT013 (Xervyteg®) and steps that reinforced the Company’s position in microbiome-based therapies in hemato-oncology. Looking ahead, 2026 is expected to be a pivotal year, as MaaT013 (Xervyteg®) advances through the EMA review process toward a potential first-in-class approval in oncology. The MAA submitted to the EMA is supported by results from the open-label, single-arm pivotal ARES trial, together with a dataset generated through the EAP. As a “first in class” potentially setting the foundations for future standards, MaaT013 (Xervyteg®) is being developed in the field of rare diseases and currently represents the Company’s most advanced drug candidate. Its development takes place in an environment characterized by specific pharmaceutical, clinical and regulatory questions, notably related to the innovative nature of its therapeutic approach. MaaT013 (Xervyteg®) is the most advanced step toward validating the Company’s oncology platform, which holds scalability potential, notably with MaaT033, an oral form, as the next expansion driver.

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

- In [January 2025](#), the Company announced positive topline results from the pivotal ARES Study evaluating MaaT013 (Xervyteg®) in aGvHD, meeting its primary endpoint with a significant gastrointestinal overall response rate at Day 28 of 62% and demonstrating the unprecedented efficacy of MaaT013 (Xervyteg®) as third-line treatment of aGvHD with gastrointestinal involvement (GI-aGvHD) consistent with communicated EAP results.
- In [March 2025](#), the Company announced a positive outcome from the final DSMB meeting on ARES trial, confirming the remarkable efficacy results and positive risk/benefit profile of MaaT013 (Xervyteg®) in third-line GI-aGvHD.
- In [June 2025](#), the Company announced the submission of a MAA to the EMA for MaaT013, under the registered brand name of MaaT013 (Xervyteg®). The EMA submission followed the positive opinion from EMA Pediatric Committee received in [March 2025](#) on the Pediatric Investigation Plan for MaaT013 (Xervyteg®), a key milestone achieved towards the MAA submission to the EMA.

- In [July 2025](#), the Company signed a license and distribution agreement and commercial supply agreement for MaaT013 (Xervyteg[®]) with [Clinigen](#). 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, including €12 million upon the Marketing Authorization for MaaT013 (Xervyteg[®]) in Europe. 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.
- In [December 2025](#), the Company presented the topline results of the ARES pivotal trial evaluating MaaT013 (Xervyteg[®]) in aGvHD during the ASH 2025 annual congress and also announced the final results from the pivotal ARES study with a confirmed 1-year overall survival of 54%, confirming durable survival benefit in this high-risk patient population known for extremely poor prognosis. Results have been submitted in a peer-reviewed journal.
- As a post period event, MaaT Pharma has transitioned the EAP to Clinigen in January 2026. Given Clinigen's strength and expertise, this allows the Company to leverage the European infrastructure of Clinigen, in Europe and expand patient access. The Transfer of the EAP to Clinigen also allows to test and validate the supply chain, contributing to the commercial readiness in view of the potential MAA approval of MaaT013 (Xervyteg[®]).
- As a post period event, the final results of the ARES pivotal trial evaluating MaaT013 (Xervyteg[®]) in aGvHD were presented during an [oral presentation](#) during the presidential symposium at EBMT 2026 Annual Congress on March 23, 2026 and during an oral presentation at the national Congress of the French Hematology Society (SFH) on March 27, 2026.
- MaaT013 (Xervyteg[®]) is currently under review by the EMA. To date, the MAA has progressed in line with the predefined timeline established by the EMA. Based on the status of the procedure, the indicative guidance on review timing remains current. As the review process progresses toward the next phase, the Company will continue to assess ongoing regulatory feedback that may influence the timing and remains proactively engaged in all potential regulatory interactions to ensure appropriate preparation for the next steps of the EMA review.
- As part of its U.S. market access strategy, the Company continues to evaluate regulatory pathways that could support a future FDA submission, in line with FDA expectations for innovative therapies in aGvHD. Interactions with the FDA remain active as the Company refines the most appropriate clinical study design and timelines for the U.S. With European regulatory progress underway, and with the Company currently prioritizing efforts in Europe, the U.S. market remains the next major step in its global development strategy. As a result, the initiation of a U.S. study, previously anticipated for 2026, could now be expected after the outcome of the Company's ongoing MAA review with the EMA. Readiness

activities are underway, with no significant cash impact, to ensure a potential launch in a timely manner of the future clinical study in the U.S, pending appropriate funding.

- Additionally, the Company continues to expand its U.S. footprint through its EAP, with recurring patient requests now coming from six leading hospitals: City of Hope (Duarte- Los Angeles, CA), Massachusetts General Hospital (Boston, MA), the University of Alabama Hospital (Birmingham, AL), Miami Cancer Institute (Miami, FL), Chicago Medical Center (Chicago, IL) and Advocate Lutheran Hospital (Park Ridge, IL).

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

- MaaT033, as an oral microbiotherapy based on the same drug substance as MaaT013(Xervyteg®), holds the potential for value-creation by enabling broad ambulatory use and expanding the addressable patient population through a prophylactic approach. As the first oral asset of the platform, MaaT033 indicates the Company's industrial scalability and further supports its long-term growth potential. MaaT033 builds on the pharmaceutical, clinical, and regulatory groundwork conducted with MaaT013 (Xervyteg®), on which the Company intends to rely for its development.
- In 2025, four DSMB safety assessments were conducted for MaaT033 in the Phase 2b PHOEBUS randomized trial designed to be pivotal: two routine evaluations and two interim analyses focused on excess mortality. All confirmed a favorable safety profile and recommended continuation of the trial without modifications. In January 2026, as a post period event, a third routine evaluation was conducted and reconfirmed the favorable safety profile of MaaT033 in this trial.
- The Company has strategically prioritized resources on the development of MaaT013 (Xervyteg®) in Europe in aGvHD. This focus impacts the timeline of the Phase 2 PHOEBUS trial with the last patient enrollment now anticipated in Q4 2027 (compared to mid-2026 as previously announced). Consequently, topline results (1-year overall survival) are now expected in Q4 2028 (compared to Q4 2027).

In Immuno-Oncology

Leveraging the learnings of the MET-N platform in hemato-oncology, the MET-C platform represents a major mid-term inflection point for the Company. The Company has strengthened its platform with an enhanced co-cultivation manufacturing process and AI-enabled candidate design capabilities. Consistent with the Company's stage-gate strategy, MaaT034 is being developed as the first drug candidate in the immuno-oncology portfolio.

MaaT034 - Next-generation drug candidates with co-cultured technology

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

Key results indicated that:

- Metagenomic analysis shows that MaaT034 reproduces the microbial functions of MaaT013 (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).

Since 2022, the Company has implemented an exploratory strategy through two investigator-sponsored trials (IMMUNOLIFE sponsored by Gustave Roussy, and PICASSO, sponsored by AP-HP) using its donor-derived MET-N platform to better understand how the gut microbiome may overcome Immune-Checkpoint Inhibitors (ICI) resistance. Insights from these studies will inform on further development such as positioning across indications, treatment lines, and target populations.

As a post period event, in [January 2026](#), MaaT Pharma announced that the first patient was randomized in the IMMUNOLIFE trial evaluating the potential of MaaT033 in combination with Regeneron's Cemiplimab in enhancing disease control rate versus best investigator's choice in patients with advanced non-small cell lung cancer (NSCLC) who have developed resistance to PD-1/PD-L1 blockade following antibiotic (ATB) exposure and who present ATB-induced gut dysbiosis. The Company has also been informed by PICASSO's academic sponsor that topline results would not be available in Q4 2025 (as previously announced) and could now be expected in H1 2026.

- As the Company prioritized resources on its most late-stage assets, the Company is now focusing for MaaT034 in 2026 on GMP batches production and regulatory readiness and targets a First-in- Human trial start in 2027 (previously 2026), subject to appropriate funding, with a development strategy that will place a particular focus on the U.S. market.

Company Updates

- In 2025, MaaT Pharma strengthened its manufacturing position by advancing from clinical stage production toward commercial grade readiness. The Company advanced its supply chain for future commercial phase and in the context of the EAP transition to Clinigen. This positions the Company to support potential market entry for MaaT013 (Xervyteg®), contingent to EMA approval, and to sustainably support the growth of its broader oncology platform, including MaaT033 and MaaT034.

- In 2025, the Company announced that Jean-Marie Lefèvre, Chairman of the Board of Directors of Biocodex, resumes his role as Chairman of the Board of MaaT Pharma, following Karim Dabbagh's two-year tenure. Additionally, Dorothée Burkel, who served as an independent director since 2021, resigned from her position effective December 31, 2025, citing personal reasons. The Board of Directors of the Company would like to thank Mrs. Burkel for her contribution to the Board throughout her time in office.
- In 2025, MaaT Pharma strengthened its scientific leadership with the appointment of Dr. Sheri Simmons as Acting Chief Scientific Officer. Based in the U.S., she brings deep biotechnology and microbiome expertise from senior roles at Seres Therapeutics, Johnson & Johnson, and Seed Health. Sheri now oversees preclinical research and AI/data initiatives and supports the Company's efforts toward the Marketing Authorization of MaaT013 (Xervyteg®) in aGvHD. This appointment further reinforces a balanced organization combining long-standing expertise with newly added downstream capabilities.
- In 2025, the Company's shareholding structure evolved, with both liquidity and free float significantly increasing from the second half of 2025, also driven by the inclusion of MaaT Pharma in the CAC Small, CAC Mid & Small, and CAC All-Tradable indices. The free float now represents 29.8% of the share capital, reflecting a broader and more diversified investor base.

Financial highlights

The key financial audited results for the full year of 2025 are as follows.

Condensed Income Statement

In thousands of euros	31 December 2025 (12 months)	31 December 2024 (12 months)
Revenue	4 524	3 216
Other Income	4 421	3 831
Sales, General and Administrative costs	(8 220)	(6 923)
Research and Development costs	(29 054)	(27 302)
Operating income (expense)	(29 729)	(28 428)
Financial Income	227	401
Financial Expense	(1 560)	(878)
Net financial income (expense)	(1 332)	(477)
Net Income (loss) for the period	(31 061)	(28 904)

In accordance with IFRS international standards. Detailed financial information available [here](#) (French only) - The audit procedures for the 2025 financial statements were carried out by the Company's statutory auditors and the 2025 statutory accounts were closed by the Company's Board of Directors on March 25, 2026. The financial statements are available on the Company's website. The full financial reports will be included in the Company's Universal Registration Report (equivalent to the annual financial report), which will be filed with the Autorité des Marchés Financiers on 31 March 2026.

Revenues totaled €4.5 million for the year ended December 31, 2025, mostly comprised of compensation invoiced from the Early Access Program in France: €4.4 million EAP revenues in 2025, vs €3.2 million in 2024, a €1.2 million/38% increase year-over-year reflecting a growing adoption in the hemato-oncology medical community.

Other income of €4.4 million included R&D tax credits of €3.8 million in 2025, from €3.5 million in the prior year, and grants of €0.4 million in 2025, from €0.1 million in the prior year.

Research and Development expenses were €29.1 million in 2025, an increase of €1.8 million from 2024, consistent with the advancement of clinical and operational activities as detailed in the pipeline highlights section above.

Sales, General and Administrative expenses amounted to €8.2 million in 2025, compared with €6.9 million in 2024. The €1.3 million increase reflected higher sales & distribution expenses, in line with the increase in EAP revenues, increased expenses related to financing activities, and the strengthening of the team, including expert medical and regulatory consultants, to support the ongoing MAA process.

As a result, operating expenses amounted to €29.7 million in 2025 compared with €28.4 million for 2024, an increase of €1.3 million.

Net loss was €31.1 million for the year ended December 31, 2025, compared with €28.9 million for the year ended December 31, 2024.

Cash Position and Financing

As of December 31, 2025, total cash and cash equivalents were €24.9 million, as compared to €20.2 million as of December 31, 2024.

The net increase in cash position of €4.7 million over the 12-month period between December 31, 2024, and December 31, 2025, was related to a net cash utilization in Operating and Investing activities of €16.0 million, while cash generated in financial activities was €20.7 million, including €20.8 million in net equity capital raises and €3.2 million from new loans, while loan repayments and interests amounted to €3.3 million.

The Company estimates that its current cash position will enable it to finance its operations until June 2026, and until August 2026, taking into account the ongoing drawdown of Tranche B of the EIB loan, as previously announced. To strengthen its cash position, the Company could benefit from additional financing pursuant to the agreements signed in 2025, all of them subject to obtaining a Marketing Authorization for its drug candidate Xervyteg® (MaaT013): a milestone payment of €12 million from Clinigen upon obtaining the Marketing Authorization, and the drawdown of Tranche C of the EIB loan for €8 million, subject in particular to the granting of the Marketing Authorization and contractual financing conditions. The Company also continues to seek additional financing to support the development of its development portfolio.

Financial calendar*

- May 15, 2026: Publication of revenues & cash for Q1 2026
- June 16, 2026: Annual General Meeting
- September 15, 2026: Publication of H1 results
- November 16, 2026: Publication of revenues & cash for Q3 2026

*Indicative calendar that may be subject to change.

Upcoming conferences participation

- April 8-9, 2026 – Investor Access Event, Paris
- April 15-16, 2026 – Kempen Life Sciences Conference, Amsterdam
- June 22-25, 2026 – Bio International Convention, San Diego, CA
- June 24-25, 2026 – Portzamparc Conference Mid & Small Caps 2026, Paris

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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