



MaaT Pharma Announces 2022 Annual Results and Provides a Business Overview

- As of December 31, 2022, cash and cash equivalents were €35.2 million (prior to the capital raise in February 2023) and turnover was €1.4 million
- Significant milestones on clinical programs in 2022:
 - MaaT013:
 - Initiation in March 2022 of Phase 3 open label, single arm clinical trial in Europe for the treatment of acute Graft-versus-Host Disease (hemato-oncology)
 - Initiation in April 2022 of Phase 2a proof-of-concept trial, sponsored by AP-HP, to improve patients' responses to immunotherapies in metastatic melanoma (immuno-oncology)
 - MaaT033:
 - Completion of Phase 1b in January 2022 and topline results published in June 2022 for patients with acute myeloid leukemia following allogeneic hematopoietic stem-cell transplantation (allo-HSCT) and presentation of positive data at the 2022 ASH conference
 - Preparation ongoing for a Phase 2b trial to evaluate MaaT033 in improving overall survival and preventing complications in patients with blood cancers receiving allo-HSCT
- Successful capital raise in February 2023 of approximately €12.7 million with the support of current shareholders

Lyon, France, March 30, 2023, 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 reported the full-year 2022 annual results and provided a business overview.

Hervé Affagard, CEO and co-founder of MaaT Pharma states, “in 2022, we have successfully executed on key clinical and manufacturing objectives despite a difficult economic environment. With our lead asset, MaaT013, currently in a Phase 3 clinical trial in hemato-oncology, it is our ambition to make it quickly accessible to all patients fighting acute Graft-versus-Host Disease in need of a safe and effective therapeutic option. Our clinical development pipeline continues to progress with positive Phase 1b data for MaaT033 announced in 2022, the commencement of a Phase 2b trial in the first half of 2023 as well was the ongoing Early Access Program in Europe for MaaT013. With the construction of our manufacturing facility to be completed by mid-2023 and the roadmap we shared at the beginning of the year, we are excited

with the progress we have made to advance our microbiome therapies that we believe could become a new pillar in treating cancer."

Key Financial Results

The key audited financial results for the 2022 full year are as follows:

Income Statement

In thousands of euros	31 December 2022	31 December 2021
Revenue	1 430	972
Cost of Goods Sold	(339)	(166)
Gross Margin	1 091	806
Other Income	4 122	2 390
Sales and distribution costs	(347)	(217)
General and administrative costs	(4 111)	(2 727)
Research and development costs	(14 311)	(9 145)
Operating income (expense)	(13 557)	(8 893)
Financial Income	45	0
Financial Expense	(201)	(126)
Net financial income (expense)	(156)	(126)
Income (loss) before income tax	(13 713)	(9 019)
Income tax expense	-	-
Net Income (loss) for the period	(13 713)	(9 019)

Prepared in accordance with international standards, IFRS.

Revenues totaled €1.4 million for the year ended December 31, 2022, which includes compensation invoiced from the Early Access Program in France and for which data was presented at [the American Society of Hematology Annual Meeting in December 2022](#). The gross margin generated by the compassionate access program amounts to €1.1 million.

Operating expense amounted to €13.6 million compared with €8.9 million for 2021, an increase of €4.7 million. This increase reflects the growth of research and development costs which have risen from €9.1 million in 2021 to €14.3 million in 2022, representing an overall increase of €5.2

million and consistent with the advancement of clinical and operational activities as detailed in the 2022 key achievements' section below.

Other income of €4.1 million includes the R&D tax credit of €3.2 million, an increase of €1.2 million compared with prior year, which amounted to €2.0 million and in line with the growth of research and development activities.

General and administrative expenses amounted to €4.1 million compared with €2.7 million in 2021 reflecting the recurring costs and structuring of the Company to meet the needs of its listing on Euronext Paris regulated market and to support the different clinical and development programs.

The net loss amounts to €13.7 million for the year ended 31 December 2022 compared with €9.0 million for the year ended 31 December 2021.

Average annual employees evolved from 33 in 2021 to 43 in 2022 following the strengthening of the clinical and scientific teams, along with the R&D, technical and regulatory departments.

Cash Position

As of December 31, 2022, total cash and cash equivalents were €35.2 million, as compared to €38.4 million as of June 30, 2022, and €43.3 million as of December 31, 2021.

In thousands of euros	31 December 2022	31 December 2021
Net cash used in operating activities	(12 605)	(7 929)
Net cash used in investing activities	(815)	(238)
Net cash used in financing activities	5 364	31 558
Net change in cash and cash equivalents	(8 057)	23 391

The net decrease in cash position of €8.1 million between December 31, 2021, and December 31, 2022, is due to the financing of operations for a total of €12.6 million, offset by cash inflows from financing of €5.4 million. Cash inflows from financing reflects new financial debt, offset by debt repayments over 2022 €1.9 million. Total financial debt (including lease liabilities) totaled €11.4 million as of December 31, 2022, of which €0.9 million relates to state-backed loans ("PGE").

Based on the development plans, corresponding cash needs and following the capital increase in February 2023, the Company believes it has sufficient cash to finance operations into the second quarter of 2024.

2022 Key achievements

Pipeline highlights

MaaT013

- In March 2022, the Company announced the initiation of its [Phase 3 open label, single arm, pivotal trial, called ARES](#), evaluating MaaT013 in treating patients with acute Graft-versus-Host Disease (aGvHD). The trial is ongoing in six European countries including France,

Austria, Spain, Belgium, Germany, and Italy. In the US, interactions with the FDA remain active regarding MaaT013, for which US development is currently on clinical hold following an FDA communication received in August 2022. [In February 2023](#), the Company announced new discussions with the FDA which have been detailed in the section below “First half of 2023”.

- In April 2022, the Company announced the initiation of a [randomized, placebo-controlled Phase 2a](#), proof of concept, clinical trial in France sponsored by AP-HP, evaluating MaaT013’s impact on the efficacy of immune checkpoints inhibitors (ICI) treatments in patients with metastatic melanoma.
- In 2022, the Company continued the Early Access Program in Europe allowing patients to benefit from early access to the MaaT013 drug candidate, mainly for the treatment of aGvHD. As of today, the Company has safely treated over 160 patients with MaaT013 in Europe.
- In December 2022, the Company presented compelling consolidated data from 81 patients in the Early Access Program in France at [the American Society of Hematology Annual Meeting in December 2022](#).

MaaT033

- In the first half of 2022, the Company announced [positive topline results](#) for its Phase 1b open-label, dose-ranging clinical trial, called CIMON, investigating the maximum tolerated dose of MaaT033 in patients with acute myeloid leukemia or high-risk myelodysplastic syndrome who have undergone intensive chemotherapy and confirming clinical potential of MaaT Pharma’s oral drug candidate. These promising results support the launch of the Phase 2b clinical trial, called PHOEBUS, to improve overall survival and to prevent complications in patients with blood cancers receiving allo-HSCT.
- In December 2022, the Company presented the Phase 1b clinical data in a poster format at [the American Society of Hematology Annual Meeting](#).

MaaT03X

- In 2022, the Company has been consolidating *in vivo and in vitro* data with MaaT03X and continuing its product development characterization.

Financial highlight

- In [February 2022](#), the Company announced the construction of its cGMP manufacturing facility in France, dedicated to ecosystem microbiome-based therapeutics, in partnership with Skyepharma. A total down payment of €1.1 million has been made in 2022 for a total of €1.4 million cumulatively. The facility is expected to be operational by mid-2023.

First half of 2023

- In January 2023, the Company announced the expansion of its scientific research to neurodegenerative diseases with a first trial in Amyotrophic Lateral Sclerosis (ALS). The Company is now preparing to launch a Phase 1b pilot study to evaluate MaaT033 in ALS, following ANSM regulatory authorizations received in March 2023 - *the inclusion of the first patient is expected in H1 2023*.

- [In February 2023](#), the Company completed a successful capital increase of approximately €12.7 million with the support of current shareholders.
- The ongoing international multicenter open-label, single arm pivotal Phase 3 trial (ARES) evaluating MaaT013 in aGvHD is ongoing in Europe – *the Data and Safety Monitoring Board (DSMB) review is expected to take place at the end of the first half of 2023, if half of the patients have been recruited.*
- [In February 2023](#), the Company announced the receipt of a letter from the FDA indicating that the Agency agreed to a defined list of conditions that could enable clinical evaluation of MaaT013 in the U.S. These measures have since been included by the Company and submitted to the FDA. The communication from the FDA therefore provides a path forward regarding MaaT Pharma’s pooling technology for this trial.
- The Phase 2a proof-of-concept clinical trial evaluating MaaT033 in association with ICI in metastatic melanoma, sponsored by AP-HP, in France is ongoing - *biological biomarker data are expected in H1 2023 after half of the patients have been enrolled and achieved their evaluation 9 weeks after randomization.*
- The preparations are ongoing to initiate the randomized placebo-controlled Phase 2b trial (PHOEBUS) evaluating MaaT033 in improving overall survival and to prevent complications in allo-HSCT patients and the Company has received French and German regulatory authorizations in March 2023– *study is expected to start in Q2 2023.*

The Company’s universal registration document, which includes the annual financial report, will be available on MaaT Pharma’s website: www.maatpharma.com

Upcoming financial communication*

- May 9, 2023 – Revenues and Cash Position Quarter 1
- June 19, 2023 – Annual General Meeting
- July 27, 2023 – Revenues and Cash Position Quarter 2
- September 26, 2023 – Half-year Results 2023
- November 9, 2023 - Revenues and Cash Position Quarter 3

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

Upcoming investor conferences participation

- April 4, 2023 – Investor Access Conference, Paris
- April 26, 2023 – Kempen Life Sciences Conference, Amsterdam

Upcoming scientific conference participation

- April 23-26, 2023 – 49th Annual meeting of the European Bone Marrow Transplant, Paris
- June 28-30, 2023 – 8th Microbiome Movement – Drug Development Summit, Boston

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®, 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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