

Mauna Kea Technologies Reports H1 2024 Financial Results and Q3 2024 Sales

***Confirmation of lower breakeven point trajectory with 9% Reduction
in Operational Expenses***

Q3 2024 Sales Growth of +24%¹ Driven by New System Sales in the U.S. and Europe

Official Launch of the Food Intolerance Platform CellTolerance®

***Sales Pipeline Strengthened thanks to Recent Positive Clinical Results in Pancreatic
Cysts and Lung Cancer***

Reaffirming Guidance of 20% Annual Sales Growth¹

Paris and Boston, October 15, 2024 – 6:30 pm CEST – Mauna Kea Technologies (Euronext: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces its financial results for the first half 2024, ended June 30, 2024, as approved by the Board of Directors on October 11, 2024 and sales for the third quarter 2024. The half-year financial report is available on the Company's website.

Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies, commented: *"As we look to year-end, I am pleased that the professionalism and commitment of the Mauna Kea organization combined with expanding recognition of the clinical value of Cellvizio is creating a clearer path to producing profitable growth. In the third quarter, we achieved growth in systems sold and a 29% y/y increase in consumables delivered while obtaining important clinical study results in lung and pancreatic cancers. Publications by leading authors also contribute to our commercial success and create new strategic partnerships opportunities. At the same time, we are working diligently to consolidate our foundation, including implementing rigorous cost reduction initiatives that both extend our cash runway and accelerate Mauna Kea's path to profitability. Finally, we are working on the launch of CellTolerance® before year-end at a major French wellness clinic. With further sales gains expected in the U.S. and at our Chinese joint venture, we confirm our 2024 revenue target."*

¹ Excluding licensing revenues

H1 2024 Financial Highlights*

<i>(in €k) – IFRS</i>	H1 2024	H1 2023	H1 2022
Total Revenue	4,269	7,142	3,708
Current Operating Income	(3,695)	(1,100)	(4,957)
Non-current Operating Income	24	7,748	85
Operating Income	(3,671)	6,648	(5,042)
Net Profit	(4,686)	2,799	(6,212)

*Unaudited figures

The first half of 2024 is being compared with a particularly strong first half of 2023, which saw exceptional items due to the creation of a joint venture with Tasly. This partnership generated a one-time revenue boost of \$2.5m for know-how associated with transferred patents, along with a capital gain of €7.7m related to the patent transfer to the joint venture.

As a consequence, the operating result shows a €3.7m loss in H1 2024, compared to a positive result of €6.6 million in 2023. However, this is a 25% improvement from 2022, reflecting a cost-control policy aimed at lowering the break-even point.

Third Quarter & Nine Months 2024 Sales by Category*

<i>(in €k) – IFRS</i>	Q3 2024	Q3 2023	Change %	9M 2024	9M 2023	Change %
Systems	333	3	-	917	1,089	-16%
Consumables	676	795	-15%	2,361	2,556	-8%
Services	239	212	+13%	841	911	-8%
Total sales excl. license	1,248	1,010	+24%	4,119	4,556	-10%
License fees	491	499	-2%	1,495	3,801	-61%
Total sales	1,739	1,509	+15%	5,614	8,357	-33%

*Unaudited figures

During the third quarter of 2024, total sales excluding license fees amounted to €1.2m, up 24% thanks to higher system sales both in the U.S. and Europe. Consumable sales were impacted by the temporary reimbursement reduction from CMS, notably affecting PPU² revenue despite stable procedure volume. Services grew by 13%, thanks to renewed maintenance contracts in the U.S.

Overall revenue, excluding license, is trailing behind on a 9-month basis at -10%, to €4.1m, given the back-loaded nature of the year, in particular on system sales from all regions, including the U.S. and China.

² Pay per Use

Activity update

 - **U.S. activity**

<i>PPU invoiced</i>	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024
Number of procedures	613	589	693	1,013	887	1,361	1,017	1,062	888

In the third quarter of 2024, Mauna Kea continued to benefit from high volumes compared to previous years, despite the third quarter traditionally being a slower period due to the summer season. During this period, a new multi-system account was signed and is set to become active in October.

Additionally, a Cellvizio system was sold to the University of Maryland in Baltimore, while a second system was in the process of being finalized at the end of the quarter.

 - **U.S. Reimbursement**

Since the beginning of 2024, Mauna Kea has been working closely with the Centers for Medicare & Medicaid Services (CMS) to restore the reimbursement of procedures to APC Level 3, as it was prior to 2024. The downgrade to level 2 is due to hospital reporting errors on the cost of Cellvizio procedures.

The Company has been actively engaging with its network to resubmit the correct data to CMS. Additionally, the Company is collaborating with key opinion leaders and industry associations to advocate for appropriate reimbursement of these procedures. Mauna Kea estimates the year-to-date impact of the reimbursement change has been \$559k.

In addition, Mauna Kea received a strong endorsement from The American Foregut Society, a leading organization of gastroenterologists and surgeons working to improve patient outcomes for various conditions, including esophageal diseases. The formal request has been made for health insurance providers to update their medical coverage policies to include Cellvizio and confocal laser endomicroscopy (CLE) as covered services.

 - **CellTolerance® in Food Intolerance**

Over the last months, CellTolerance® has been structuring its offering under the leadership of Benoît Chardon, Senior Advisor of Mauna and renowned expert in the creation of new product categories and brands. A completely new branding, website (see www.cell-tolerance.com), and materials were launched. Masterclasses were organized in Europe and the United States with doctors and registered dietitians to introduce the program. Initial interactions took place with aesthetic centers with the goal of signing new agreements in the near term. Overall, the momentum is strong and promising.

- Other indications

New positive data³ has been published regarding the use of Cellvizio to improve the diagnostic yield in bronchoscopy with the goal to detect and treat lung cancer at an earlier stage, which is one of the main public health goals worldwide. Professor Stéphane Renaud at the University Hospital of Nancy evaluated the use of Cellvizio's nCLE platform in combination with Electromagnetic Navigation Bronchoscopy (ENB) to characterize suspicious pulmonary nodules and prepare them for surgical resection when necessary. The results underscore the potential of nCLE to rapidly and accurately identify malignant lesions, with a sensitivity of 96.43% and specificity of 100%, while reducing the risks associated with traditional diagnostic methods, including ionizing radiation.

These results could pave the way for significant interest from industrial partners.

Q4 2024 Outlook

The Group reaffirms its target of achieving sales growth exceeding 20% in 2024, excluding licensing revenues. Based on current trading, the Group expects an acceleration in sales during the fourth quarter, driven mainly by:

- Growth of pay-per-use activity in the U.S. More specifically, during the third quarter, a new account was secured with the placement of three systems, which is expected to contribute significantly to volume growth. Additionally, five new PPU accounts are expected to be signed within the quarter.
- A substantial pipeline of 10-15 systems in the U.S., some of which are anticipated to close by the end of the year.
- System sales to the Tasly J.V.

Additionally, Mauna Kea will start a pilot project for the CellTolerance® program within a major renowned aesthetic care center in France, which is expected to quickly expand across its entire network.

³ "Assessment of needle-based confocal laser endomicroscopy (nCLE) as a tool for real-time diagnosis of non-small cell lung cancer"
<https://jtd.amegroups.org/article/view/89316/html>

Detailed Financial Update for the First Half 2024*

<i>(in €k) – IFRS</i>	H1 2024	H1 2023	Change - %
Product sales	2,867	3,552	-19%
Licensing sales	1,004	3,263	-69%
Total sales	3,871	6,811	-43%
Other revenue	398	326	+22%
Total Revenue	4,269	7,142	-
Cost of goods sold	(963)	(811)	+19%
<i>Gross margin on Product sales</i>	66%	77%	-11pts
Research and development expenses	(1,917)	(1,947)	-2%
Sales and marketing expenses	(2,597)	(2,738)	-5%
General and administrative expenses	(2,309)	(2,821)	-18%
Share-based payments	(178)	75	-
Total Expenses	(7,964)	(8,242)	-5%
Current Operating Income	(3,695)	(1,100)	-236%
Non-current Operating Income	24	7,748	-100%
Operating Income	(3,671)	6,648	-155%
Financial Result	(171)	(762)	-78%
Income taxes	-	(1,458)	-100%
Share of equity affiliates	(844)	(1,629)	48%
Net Profit	(4,686)	2,799	-

*Unaudited figures

Total sales

The Group's total revenue amounted to €3.9m, a decrease of 43%, primarily due to an exceptional income of \$2.5m received from the Tasly JV for know-how related to transferred patents. In the first half of 2024, license revenues reflected the linear recognition over three years of the \$6.5m received from Tasly under the licensing agreement.

Product sales were impacted by a shift in system sales in the United States, most of which are expected in the second half of the year. Of note, in 2023, all systems sold in the U.S. were delivered in the first half of the year, resulting a high basis for comparison.

Other revenue

Other income amounted to €0.4m corresponding to the Research Tax Credit (CIR) for the first half of 2024, an increase of 22% compared to last year. This growth is largely driven by newly accredited CIR projects, particularly in the field of artificial intelligence.

Cost of goods sold

The cost of goods sold amounted to €1m, an increase of 19%, reflecting a total gross margin of 66% on product sales for the first half of 2024, down 11 points compared to last year. This decline in gross margin is mainly attributed to reduced system sales in the U.S., with sales concentrated toward the year's end, as well as lower CMS reimbursement rates for PPU procedures.

Research and development expenses

Research and development expenses amounted to €1.9m and remained stable over H1 2023 period.

Sales and marketing expenses

Sales and marketing expenses decreased by 5% during the period, reaching €2.6m, due to effective cost control and a reduction in sales commissions.

General and administrative expenses

General expenses decreased by 18% during the period, amounting to €2.3m. The first half of 2023 had been impacted by increased financial consulting fees related to the reorganization of the Finance team as well as commissions paid to Cenpontos Healthcare for its advisory role in the partnership with Tasly.

Share-based payments

Share-based payments had a negative impact of €0.2m during the period. The first half of 2023 had benefited from a significant number of cancellations of equity instruments following the departure of employees in the United States.

Current Operating Income

Given the decline in the Group's revenue in the first half of 2024 compared to the first half of 2023, the current operating loss amounted to -€3.7m.

Operating Income

The Group's operating result was negative in the first half of 2024, amounting to -€3.7m. The operating result for the first half of 2023 had benefited from the recognition of an exceptional income of €7.7m, corresponding to the capital gain from the Group's transfer of patents to the Tasly JV.

Net Profit/Loss

Net loss came to -€4.7m, compared with a profit of €2.8m in 2023.

Cash Flow from operating activities

In the first half of 2024, cash flow from operating activities amounted to -€3.8m, compared to €2.9m in the same period last year. This decrease is mainly due to the receipt in 2023 of \$6.5m (€6.2m) as part of the licensing agreement signed with the Tasly JV.

Cash position as of June 30, 2023

As of June 30, 2024, cash and cash equivalents amounted to €3.8m, providing financial visibility through the end of Q1 2025. Thus, the Company is now actively looking for new funding solutions to extend its financial visibility.

Availability of the 2024 half year financial report:

The 2024 half-year financial report is available on the Company's website, in the [Investors](#) section.

Third Quarter & Nine Months 2024 Sales by Geography*

<i>(in €k) – IFRS</i>	Q3 2024	Q3 2023	Change %	9M 2024	9M 2023	Change %
United States	815	824	-1%	2,551	3,344	-24%
EMEA & ROW	277	173	+60%	1,539	1,126	+21%
Asia Pacific	156	12	+1220%	210	89	+135%
Total sales excl. license	1,248	1,010	+24%	4,119	4,556	-10%
License fees	491	499	-2%	1,495	3,801	-61%
Total sales	1,739	1,509	+15%	5,614	8,357	-33%

*Unaudited figures

In the U.S., sales for Q3 2024 were down by 1% versus Q3 2023, amounting to €0.8m, mainly due to the impact of the temporary reimbursement reduction from CMS on PPU revenue. In contrast, sales in Europe and the Rest of the World increased by 60%, driven by system sales.

Third Quarter 2024 Sales in Unit*

Units (#)	Q3 2024	Q3 2023	Change
New systems sold**	2	-	+2
New systems placed***	3	4	-1
Total systems	5	4	+1
Consumables delivered	119	92	+27

*Unaudited figures

** The change in the number of new systems sold over the period may differ from that in reported sales, due to inventory adjustments and product mix variation

*** The reference date is the contract signature date, which may differ from the system installation date

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio® platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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