

Mauna Kea Technologies Announces its Sales and Achievements For the Second Quarter 2024

Q2 2024 Sales Up 48% vs. Q1 but Down 20% Year-on-Year¹ as U.S. Systems Sales Scheduled for the Second Half of 2024 and Temporary Reimbursement Reduction Impacting PPU Revenue

***U.S. PPU Volume Again Exceeding 1,000 Procedures for the 3rd Quarter in a Row
52% in Q2 2024 Sales in Europe and RoW***

***Several System Sales in New Food Intolerance and Lung Nodule Applications
Reaffirming 2024 Guidance over 20% Sales Growth¹***

Paris and Boston, July 25, 2024 – 5:45 p.m. CEST – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces its unaudited sales and achievements for the second quarter and first half 2024, ended June 30, 2024.

Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies, commented: *"In the first half, we leveraged prior investments in staff and process to deliver strong PPU volume in the United States, supported by new installation sites that produced a rapid scaling of procedure volume, results that further demonstrate both the clinical value of Cellvizio and the professionalism of our teams. While we are encouraged by the improving productivity in our U.S. sales organization, we will continue to evaluate ways to increase our support to care providers. After a second quarter 2024 impacted by an unfavorable basis for comparison, given that last year system sales were concentrated in the second quarter, and the reduction in procedure reimbursement rates that we consider temporary, we expect systems sales to accelerate in the U.S. over the rest of the year. We also saw positive developments in several emerging applications: food intolerance, pulmonary nodules and pancreatic cysts. Reversing the low penetration rate of our massive total addressable market remains a core element of Mauna Kea's value creation strategy. I am grateful for the progress our product development teams are making to integrate best-in-class AI and connectivity technologies into Cellvizio, enhancements we believe will greatly benefit patients and practitioners. Finally, the recent obtaining of the business license in China represents an important milestone to support the ramp-up of our JV with Tasly giving us the means to fully tackle this market. Building on these achievements and expecting a catch up in sales in the second half 2024, we are confident to achieve our 2024 guidance of growth in sales over 20%."*

¹ Excluding licensing revenues

Highlights of First Half 2024

- **Solid and Sustainable PPU (Pay-per-Use) Activity in Gastroenterology in the United States**

PPU volumes are now firmly established on a sustainable basis, exceeding 1,000 procedures per quarter compared to approximately 650 procedures on average before Q2 2023. New accounts are achieving significant procedure volumes of 20 to 40 procedures per month, thanks to optimized center selection and more effective onboarding and training methods.

During the first semester of 2024, 3 new accounts were activated and 3 long-inactive accounts were reactivated using the same onboarding methods. Given the extensive historical system base, Mauna Kea plans to continue reactivating dormant accounts while enrolling new ones.

<i>PPU invoiced</i>	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024
Number of procedures	686	613	589	693	1,013	887	1,361	1,017	1,062

- **Activity Launch in Food Intolerance**

The first steps towards significant activity in food intolerance were taken this semester with the establishment of 3 centers of excellence in the United States and Europe aimed at training physicians on this indication. Several workshops have also been conducted throughout the semester to promote the use of Cellvizio in this application. In total, 3 systems dedicated to this application were sold, including 1 in the United States to Stanford University, and 2 in Germany, contributing to revenue growth.

To optimally structure this activity and provide it with the necessary operational and financial resources, the company recently announced the creation of a dedicated subsidiary, CellTolerance. The goal is to commercialize a unique science-based program for the detection and treatment of food intolerances, which will integrate data into a comprehensive dataset trained by AI to achieve unprecedented clinical insights. This data could ultimately serve pharmaceutical and nutrition companies to design personalized treatments, optimize nutritional plans and predict individual responses to therapies and dietary interventions. It is also envisioned that CellTolerance could quickly open its capital to venture capital funds specializing in these fields to fund the development of its program independently.

- **New Addressable Indications: Pancreatic Cysts and Pulmonary Nodules**

Beyond food intolerance, the use of Cellvizio has advanced in two other indications:

- Firstly, the CHRU of Nancy, France, with the renowned team of Professor Renaud, has acquired a Cellvizio, becoming the first thoracic surgery service in Europe to adopt Mauna Kea's technology. This allows access to all areas of the lungs and real-time visualization of tissue architecture, significantly increasing early lung cancer diagnosis from 75% to 90%.
- Furthermore, very positive data on the use of Cellvizio in pancreatic cysts were presented at the Digestive Disease Week® (DDW) Conference in Washington, D.C. in May. It was shown that Cellvizio is far superior to conventional methods for classifying, characterizing, and risk-stratifying pancreatic cystic lesions, with

a sensitivity and accuracy of 98%. Given the challenges in diagnosing pancreatic cancer and low effectiveness of traditional methods, leading to late diagnoses for false negatives or unnecessary interventions for false positives, this advancement offers great hope for patients. This also paves the way for significant market opportunity for Mauna Kea and for potential commercial partnerships.

○ **Successful Class II Medical Device Business License in China Obtained**

Thanks to the business license issued by the Shanghai Municipal Medical Products Administration, the Tasly JV is now operational and ready to address the Chinese market, with first units of systems and probes sales recorded. With this milestone, Tasly Mauna Kea Medical Engineering Technology can engage in the wholesale distribution of Class II medical devices across China, paving the way to its commercial development and market expansion there.

○ **Renewal of the PACEO equity line with Vester Finance**

In order to maintain an equity financing reserve, the Company has renewed its PACEO line with Vester Finance, on identical terms to the previous expired operation². This renewal was decided by the Company's Board of Directors, in accordance with the 18th resolution of the General Shareholders' Meeting of June 6, 2024³, and did not give rise to the preparation of a notice ("*prospectus*") subject to AMF approval. Assuming this financing facility were to be drawn down in full, a shareholder holding 1.00% of Mauna Kea Technologies' share capital prior to its implementation would see his or her stake fall to 0.92% of the share capital on a non-diluted basis⁴ and 0.94% of the share capital on a diluted basis⁵.

Second Quarter & First Half 2024 Sales by Category*

<i>(in €k) – IFRS</i>	Q2 2024	Q2 2023	Change %	H1 2024	H1 2023	Change %
Systems	509	699	-27%	579	1,086	-47%
Consumables	815	1,100	-26%	1,686	1,761	-4%
Services	390	382	+2%	607	700	-13%
Total sales excl. license	1,714	2,180	-20%	2,871	3,546	-19%
License fees	503	499	+1%	1,004	3,301	-70%
Total sales	2,217	2,680	-17%	3,875	6,848	-43%

*Unaudited figures

In the second quarter of 2024, total sales amounted to €2.2m, down 17% mainly due to lower system sales, compared to a strong comparative quarter last year. It must be noted that 80% of U.S. system sales in 2023 were recorded in the second quarter, while no system sales were recorded in the second half. In this sense, for the second half of 2024, the H2 2023 will provide a softer basis for comparison.

² "[Mauna Kea Technologies secures an equity line financing with Vester Finance limited to a maximum of 11.4% of the capital](#)", on May 31, 2023

³ Authorization to increase the Company's capital, without shareholders' preferential subscription rights, for the benefit of a category of persons with defined characteristics

⁴ Based on 64,702,127 shares outstanding as of June 30, 2024

⁵ On the basis of 17,864,548 shares that may be issued on exercise of dilutive instruments issued by the Company to date

Consumable sales were impacted by a temporary reimbursement reduction from CMS (Centers for Medicare & Medicaid Services), notably affecting PPU revenue despite a significant growth in volume.

Services grew by 2%, thanks to renewed contracts in the U.S. and additional billing to Johnson & Johnson for the CLEAR study.

In the first half of 2024, total sales amounted to €3.9m, a decrease of 43% compared to the first half of 2023 sales. As a reminder, the Company received a \$2.5m upfront fee from the Tasly JV in Q1 2023 for know-how relating to the transferred patents.

Second Quarter & First Half 2024 Sales by Geography*

<i>(in €k) – IFRS</i>	Q2 2024	Q2 2023	Change %	H1 2024	H1 2023	Change %
United States	982	1,669	-41%	1,736	2,520	-31%
EMEA & ROW	732	482	+52%	1,082	949	+14%
Asia Pacific	-	30	-100%	54	77	-30%
Total sales excl. license	1,714	2,180	-20%	2,871	3,547	-19%
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In the U.S., sales were down by 41% compared to the strong second quarter in 2023, with three systems sold then versus one system sold this quarter to Stanford University. The exact timing of system sales remains inherently difficult to predict.

In contrast, sales in Europe and the Rest of the World increased by 52%, driven by strong probe demand during the quarter.

Second Quarter 2024 Sales in Unit*

<i>Units (#)</i>	Q2 2024	Q2 2023	Change
New systems sold**	5	7	-2
New systems placed***	3	2	+1
Total systems	8	9	-1
Consumables delivered	126	152	-26

*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

Next financial release:

Financial results for the first half of 2024 and sales for the third quarter of 2024, on October 30, 2024 after market close.

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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