Mauna Kea Technologies Reports Full Year 2023 Results and Q1 2024 Sales

Full Year 2023 Sales increased +42%¹ to €10.5m €1.2m positive full-year operating income +47% growth in Q1 2024 in U.S PPU volume

Recent Telix strategic investment and restructured EIB loan improve capital profile 2024 guidance set over +20% organic sales growth, excluding licensing income

Webcast to be held today at 6:00 pm (in French)

Paris and Boston, April 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 reported its financial results for the full year 2023 and its sales for the first quarter 2024.

For full year 2023, total Group sales increased by 42% to €10.5m, driven by the strong volume growth of the PPU business in the U.S. and the substantial contribution of licensing sales. The Group's operating income for 2023 significantly improved to €1.2m (compared with a loss of -€9.1m in 2022), reflecting the positive impact of the Group's strategic partnership with the Tasly J.V.

Cash and cash equivalents stood at €8.0m as of December 31, 2023, up €4.8m since December 31, 2022 notably thanks to the capital increase reserved to Telix Pharmaceuticals.

In Q1 2024, the pay-per-use (PPU) business, which accounts for 50% of sales in the United States, continued to track to the favorable utilization trends observed in 2023, with volumes up 47% year-on-year.

Commenting on the results, **Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies observed,** "2023 marks the conclusion of an intensive period of transformation for the Company, initiated in late 2021 with a focus on forging strategic partnerships and enhancing the momentum and productivity of our operations notably in the U.S. I am very pleased with the progress we have made in delivering our commitments which include, on one hand, the establishment of a strategic partnership with Tasly in China and the expansion of our collaboration with Telix in uro-oncology—now our leading shareholder, and on the other hand, the operational excellence with a sustained increase in the number of Cellvizio procedures in the United States, surpassing the significant milestone of 1,000 procedures per quarter, alongside a notable reduction in operating losses and strengthening of the balance sheet."

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¹ At current exchange rates

Highlights Full Year 2023

In 2023, Mauna Kea Technologies escalated its ambitious transformation strategy initiated in late 2021, aiming to set the company on a path of sustainable and profitable growth while strengthening its financial structure.

(in €k) – IFRS	FY 2023	FY 2022	Change		
(111 EK) - 11 N3	F1 2023	F1 2022	€k	%	
Total sales	10,480	7,479	+3,001	+40 %	
Gross margin	8,405	5,475	+2,930	+54 %	
Current operating income	(5,686)	(8,983)	+3,297	-37 %	
Operating income	1,231	(9,062)	+10,293	-	
Net profit (loss)	(3,727)	(11,180)	+7,453	-67 %	

On the sales front, the company experienced significant expansion in the U.S. market for PPU procedures, more effectively meeting the expectations and needs of care centers compared to traditional system sales. This approach proved to be also more sustainable. Thanks to precise targeting and the enhanced efficiency of the tightened sales team, activity progressively increased over the year, with average monthly usage doubling compared to the start of the year. This trend continued into the first quarter of 2024, with procedure volumes increasing by 47% compared to the previous year.

To leverage its technology in new indications and territories, the company also formed a joint venture in China with Tasly Pharmaceutical. This strategic collaboration is allowing rapid access to a significant commercial potential in the Chinese market, while also facilitating technological expansion in neurology and neurosurgery. This partnership generated \$9 million proceeds in 2023, of which \$4.8 million were recognized in sales in 2023.

Financially, the company significantly reduced its operational loss, thanks to an improvement in operational performance and cost reduction initiatives, particularly in marketing and administration. Thanks to a significant reduction in net loss and the capital increase from Telix's investment at the end of the year, Mauna Kea's financial structure has also been strengthened with a significant reduction in equity deficit. Currently, Mauna Kea is supported by two major strategic investors, Telix Pharmaceuticals and Johnson & Johnson, who hold nearly 40% of the capital. Furthermore, the company received increased support from the European Investment Bank, which agreed to restructure its €21.3 million debt and postpone final maturities by 4 years to 2028 and 2029².

On the technological front, Mauna Kea continues to invest in R&D for its flagship product and recently partnered with V7, a leading AI and data labeling company, to develop a cutting-edge infrastructure for AI applications with Cellvizio.

2024 Priorities and Financial Guidance:

In 2024, Mauna Kea Technologies intends to confirm its growth trajectory both through the sale of systems, probes and procedures but also by forging new strategic partnerships. The Group will lean on:

² "Mauna Kea Technologies Executed Agreement to Restructure of its Existing Loan Agreement with the European Investment Bank", on April 24, 2024

- The continued growth of the U.S. activity especially in PPU with an emphasis in procedure volumes and the acquisition of new accounts;
- The operational ramp-up of the JV in China and the first orders for systems and probes;
- The full-scale commercial launch of the food intolerance activity;
- The conclusion of new strategic partnerships.

The Group also sets financial targets for the year, specifically:

- Over +20% sales growth excluding licensing income, driven by volume growth in the U.S.;
- A two-fold increase in the production of Cellvizio systems to meet demand across the different markets and to support the ramp-up of the JV in China and the launch of the food intolerance activity;
- A reduction in operational loss thanks to the growth of activity and a continued cost cutting efforts;
- A strengthened financial structure.

Sacha Loiseau concluded, "2024 is the start of an exciting phase of growth for the Company, driven by the ongoing positive momentum in the United States in the field of esophageal and gastric cancer, major clinical results in pancreatic cysts, anticipated to contribute to incremental sales growth, the first orders from our joint venture in China and the launch of our food intolerance business. All these achievements and the solid foundations laid over the past two years have created a strong intrinsic value for Mauna Kea, which, while clear to our partners, is not reflected in our current capitalization. We remain confident that this will be the case in the near future, and thank our long-term shareholders for their support. Resilience remains the key to success"

Consolidated Financial Statements

The Board of Directors approved the consolidated financial statements on 24 April 2024. The consolidated financial statements have been audited and the Statutory Auditors' report is in the process of being issued. Mauna Kea's comprehensive audited financial statements will be available in due course on maunakeatech.com.

Webcast

A webcast for investors and analysts (held in French) will begin today at 6pm CEST. Participants can access the webcast here.

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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Additional Financial Information

Details of FY 2023 Results

Consolidated income statement for the full year 2023

(in fk) IEBS	FY 2023	FY 2022	Change		
(in €k) – IFRS	F1 2023	F1 2022	€k	%	
Product sales	6,218	7,479	-1,261	-17 %	
Licensing sales	4,262	-	+4,262	-	
Total sales	10,480	7,479	+3,001	+40 %	
Other revenue	547	631	-84	-13 %	
Total revenue	11,027	8,111	+2,916	+36 %	
Cost of sales	(2,118)	(2,004)	-114	+6 %	
Research & Development expenses	(3,860)	(4,068)	+208	-5 %	
Sales & Marketing expenses	(5,618)	(5,800)	+182	-3 %	
General & Administrative expenses	(5,004)	(4,894)	-110	+2 %	
Share-based payments	(113)	(324)	+211	-65 %	
Current operating income (loss)	(5,686)	(8,983)	+3,297	-37 %	
Non-current operating income	6,918	(80)	+6,998	-	
Operating income	1,231	(9,062)	+10,293	-	
Share of equity affiliates	(2,528)	-	-2,528	-	
Financial result	(1,956)	(2,118)	+162	-8 %	
Income taxes	(475)	-	-475	-	
Other operating income/expenses	(464)	425	-889	-	
Net profit	(3,727)	(11,180)	+7,453	-67 %	

Total sales

Total Group sales amounted to €10.5m, up 42% at constant exchange rates, driven by the strong volume growth of the PPU business in the U.S. and the substantial contribution of licensing sales.

With regard to license sales, the Group recognized over the year \$2.3m from the licensing agreement and \$2.5m received as part of the technology service fees.

Other revenue

The other revenue amounted to €0.5m corresponding to the research tax credit for the year.

Cost of goods sold

Cost of sales came to €2.1m reflecting a total gross margin of 66% over product sales excluding license for the full year 2023 vs. 73% last year due in particular to the placement of several systems in PPU accounts in the

United States, higher depreciation of low-rotation inventory and older-generation systems, as well as to inflation in the production costs of certain components.

Research and development expenses

Research and development costs were down by 5% over the period at €3.9m, with the slight drop in R&D investments offsetting a rise in personnel costs.

Sales and marketing expenses

Sales and marketing expenses were down by 3% over the period at €5.6m thanks to tight control over marketing costs despite the increase in sales in the U.S.

General and administrative expenses

General expenses were slightly up by +2% over the period at €5.0m, impacted by the reorganization of the finance team completed at the end of the first half resulting in higher consulting fees.

Share-based payments

The impact from share-based payments was significantly lower than last year reflecting a large number of cancellations of equity instruments following US-based employee departures resulting from the strategic realignment.

Current Operating Income

Current operating income increased sharply by €3.3m to -€5,7m over the period thanks to the sales increase and the reduction of operational costs.

Operating Income

The Group's operating income was positive at €1.2m, compared with a loss of -€9.1m in 2022, favorably impacted by the recognition of exceptional income of €6.9m over the period corresponding to the Group's gain on the transfer of patents to the Tasly J.V.

Net Profit

Net profit came to a loss of -€3.7m, compared with a loss of -€11.2m in 2022.

Cash Flow from operating activities

In 2023, cash flow from operating activities amounted to -€0.7m, compared with -€8.8m a year before, thanks to sales growth and payments associated with the licensing agreement signed with Tasly Pharmaceutical.

Cash position as of December 31, 2023

Cash and cash equivalents stood at €8.0m at December 31, 2023, up €4.8m on December 31, 2022 notably thanks to the capital increase reserved to Telix Pharmaceuticals.

Details of First Quarter 2024 Sales

The first quarter of 2024 was affected by a high basis of comparison, due to the proceeds of \$2.5 million received from Tasly Pharmaceutical in 2023 resulting from with the technology fee invoiced to the JV.

The PPU business, which accounts for 50% of sales in the United States up 5 pts versus last year, is following the same favorable trend initiated in 2023, with volumes up 47% year-on-year and 52% in Ambulatory Surgical Centers (ASCs) only. The rise in volumes offsets the negative price effect in Ambulatory Surgical Centers (ASCs) linked to lower reimbursements from Medicaid & Medicare (CMS) services.

This price cut decided by CMS is attributable to erroneous procedure cost data reported by hospitals. The Company has been working hard for several weeks in collaboration with experts and end-user physicians to restore reimbursement to pre-existing levels and is confident that a price adjustment will happen in the foreseeable future.

In addition, several system sales were being finalized at the end of the 1^{st} quarter of 2024 and will therefore be booked in the 2^{nd} quarter of 2024.

CMS reimbursement in the United States

In 2024, sales of PPU in the United States are expected to be impacted by a reduction in reimbursement rates from the Centers for Medicare and Medicaid Services (CMS), a consequence of changes in the reimbursement calculation formula. Despite this setback, the anticipated increase in sales volumes is projected to completely counterbalance the effects of lower pricing.

This reimbursement adjustment stems from incorrect data submissions by hospitals, and Mauna Kea is actively engaging with CMS to rectify the calculation discrepancies. The Company is cautiously optimistic that a price adjustment will happen in the foreseeable future.

Quarterly Volume of PPU Procedures

	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
	2022	2022	2022	2022	2023	2023	2023	2023	2024
Volume of PPU procedures	678	686	613	589	693	1,013	899	1,361	1,017

The volume of PPU procedures continues the very positive trend initiated in 2023, with the number of quarterly procedures exceeding the significant threshold of 1,000 procedures per quarter. It should be noted that the first quarter was impacted by a one-off slowdown in the number of procedures following the renegotiation of rates with the various medical centers in the context of lower CMS reimbursements.

Fourth Quarter & Full Year 2023 Sales by Category

(in €k) – IFRS	Q1 2024	Q1 2023	Change		
		Q1 2023	€k	%	
Systems	70	387	-317	-82%	
Consumables	870	662	+209	+32%	
Services	216	318	-102	-32%	
License fees	501	2,802	-2,301	-82%	
Total sales	1,658	4,168	-2,510	-60%	

In the first quarter of 2024, total sales amounted to €1.7m, down 60% on the previous year, since in 2023 the Company had received \$2.5m from the JV as part of the technology transfer.

Consumables sales were up +32%, driven by continued growth in the PPU business and probe sales. Despite a significant drop in the price of PPU procedures due to lower CMS reimbursements, volume growth fully offset the unfavorable impact of price on revenues.

Sales of services were down over the quarter due to lower invoicing to Johnson & Johnson for the CLEAR study, which is now fully enrolled.

First Quarter 2024 & Full Year 2023 Sales by Geography

(in €k) – IFRS	Q1 2024	Q1 2023	Change		
		Q1 2023	€k	%	
United States	754	851	-97	-11%	
EMEA & ROW	349	468	-118	-25%	
Asia Pacific	555	2,849	-2,295	-81%	
Total sales	1,658	4,168	-2,510	-60%	

In the United States, sales were down 11%, mainly due to the delayed invoicing of a system that was under negotiation at the end of the quarter. Excluding systems, sales in the region were up 5%.

In Europe, sales of systems were also being finalized at the end of the first quarter, and will be booked in the second quarter.

As for sales in Asia-Pacific, the lower sales figure is due to the exceptional income of \$2.5m in respect of the technology transfer to the JV with Tasly.

First Quarter 2024 Sales in Unit

Units (#)	Q1 2024	Q1 2023	Change
New systems sold*	1	3	-2
New systems placed**	3	5	-2
Total systems	4	8	-4
Consumables delivered	139	104	+35

^{*} 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

Disclaimer

This press release contains forward-looking statements about Mauna Kea Technologies and its business. All statements other than statements of historical fact included in this press release, including, but not limited to, statements regarding Mauna Kea Technologies' financial condition, business, strategies, plans and objectives for future operations are forward-looking statements. Mauna Kea Technologies believes that these forward-looking statements are based on reasonable assumptions. However, no assurance can be given that the expectations expressed in these forward-looking statements will be achieved. These forward-looking statements are subject to numerous risks and uncertainties, including those described in Chapter 3 of Mauna Kea Technologies' 2022 Universal Registration Document filed with the Autorité des marchés financiers (AMF) on June 28, 2023 under number D-23-0545, which is available on the Company's website (www.maunakeatech.fr), as well as the risks associated with changes in economic conditions,

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

financial markets and the markets in which Mauna Kea Technologies operates. The forward-looking statements contained in this press release are also subject to risks that are unknown to Mauna Kea Technologies or that Mauna Kea Technologies does not currently consider material. The occurrence of some or all of these risks could cause the actual results, financial condition, performance or achievements of Mauna Kea Technologies to differ materially from those expressed in the forward-looking statements. This press release and the information contained herein do not constitute an offer to sell or subscribe for, or the solicitation of an order to buy or subscribe for, shares of Mauna Kea Technologies in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. The distribution of this press release may be restricted in certain jurisdictions by local law. Persons into whose possession this document comes are required to comply with all local regulations applicable to this document.