

Mauna Kea Technologies Reports H1 2023 Financial Results

Strong H1 sales growth (+101%) and significant reduction in current operating loss (-78%)

Generated YTD net profit, supported by contribution from the Tasly J.V.

Continued demonstration that strategy pivot is benefiting financial performance

Building pipeline of new partnership opportunities

A webcast will be hosted today:

- At 10:00 am (Paris time) in French, accessible [here](#)
- At 2:00 pm (Paris time) in English, accessible [here](#)

The replay will be available on the Mauna Kea Technologies website in the [Investors section](#).

Paris and Boston, September 28, 2023 – 8:00 am 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 financial results for the first half 2023, ended June 30, 2023, as approved by the Board of Directors on September 27, 2023.

H1 2023 Highlights

- Total H1 sales up +101% at €6.8m driven by U.S. growth and revenue from the Tasly J.V.
- Current operating income up +€3.8m and operating loss reduced by 78%
- Positive operating income of €6.6m thanks to IP transfer to the Tasly J.V.
- Cash and cash equivalents at €6.3m as of June 30, 2023, up €3.1m from December 31, 2022
- Leadership upgrades and increased sales force efficiency producing sustained momentum in U.S. direct sales
- Accelerating implementation of the Tasly J.V., including onboarding of new sales and marketing resources in China
- Ongoing investments in Cellvizio platform, notably in A.I.
- Building pipeline of new opportunities to monetize existing IP portfolio through additional partnerships

<i>(in €K) – IFRS</i>	H1 2023	H1 2022	Change - €K	Change - %
Total Sales	6,815	3,391	3,420	+101%
Total Revenue	7,142	3,708	3,434	+93%
<i>Gross margin rate</i>	<i>77%</i>	<i>73%</i>		<i>+4pts</i>
Current Operating Income (loss)	(1,100)	(4,957)	3,857	-78%
Operating Income	6,648	(5 042)	11,690	<i>n/a</i>
Net Result	2,799	(6,212)	9,011	<i>n/a</i>

Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies, commented: *“I am very encouraged by the overall momentum achieved by the Group since our strategic repositioning. Not only have sales nearly doubled over the period, but the discipline of our organization has also produced a meaningful reduction of operating losses while increasing the global addressable market for Cellvizio. More importantly, we are now seeing the initial financial benefits of our partnership with Tasly Pharmaceutical and expecting a ramp-up in our commercial operations thanks to our Joint Venture that will increasingly contribute to Mauna Kea’s reported sales. In parallel, we have accelerated our product development investments, particularly in A.I., to both increase the clinical benefit of Cellvizio for patients and enhance our value proposition to current and future strategic partners. Finally, I have growing confidence in the capabilities of our team and the market opportunity for our technology.”*

Highlights of activity update for the first half 2023

- **COMPANION STUDY WITH THE MONARCH™ PLATFORM BY JOHNSON & JOHNSON MEDTECH:** A new clinical study published in the peer-reviewed journal *Respirology*¹ provided further robust evidence that the combination of needle-based confocal laser endomicroscopy (nCLE) with the Monarch™ Platform could be used for tool-in-lesion confirmation with an additional important criterion for granuloma detection, an essential capability for patients with suspected sarcoidosis;
- **COMPANION STUDY WITH THE ION® PLATFORM BY INTUITIVE:** A new multi-site clinical study sponsored by Mayo Clinic is underway, combining nCLE and robotic-assisted bronchoscopy with the Ion platform from Intuitive Surgical. This study aims to improve the accuracy and speed of positioning biopsy tools in the center of peripheral lung nodules;
- **NEW INFLAMMATORY BOWEL DISEASE (IBD) INSTALLATION:** Cellvizio® has been installed at the University College Cork - APC Microbiome Ireland, a leading research center for Inflammatory Bowel Disease (IBD). Previous publications have demonstrated Cellvizio's effectiveness in visualizing intestinal barrier healing, a superior biomarker for IBD. This installation opens the door to using Cellvizio in the development of IBD therapies, a market valued at over \$20 billion;
- **CHINESE JOINT VENTURE COMPLETED AND FUNDED:** The formal set-up of the J.V. with Tasly Pharmaceutical was finalized at the beginning of the year with the allocation of 44.1% of the J.V. shares to Mauna Kea Technologies against the transfer of certain intellectual property assets and licenses. Mauna Kea Technologies now owns assets of €13.6 million at 30 June 2023, corresponding to the valuation of its stake in the J.V.

Mauna Kea Technologies has also received a total of \$9 million relating to the license agreement and technology transfer, and is expected to receive a further \$1 million in the coming months according to milestones. During the semester, Tasly Pharmaceutical and Mauna Kea Technologies have worked jointly to quickly get the J.V. up and running by the end of the year, with the recruitment of key staff for the J.V. leadership as well as the sales and marketing teams. At Mauna Kea Technologies, a J.V. alliance manager has been recruited, and the transfer of the sales team to the J.V. is scheduled for the beginning of Q4 2023.

¹ *Respirology*. 2023 Oct;28(10):934-941. doi: 10.1111/resp.14542. Epub 2023 Aug 10. <https://pubmed.ncbi.nlm.nih.gov/37562791/>

Strategy and Outlook

In 2022, the Group elected to pivot its strategy towards a more capital efficient, partnership-oriented approach to the commercialization of new clinical use cases. At the same time, Mauna Kea Technologies implemented a meaningful reduction in spending for sales and marketing infrastructure, particularly in the United States. This shift has led to significant and more efficient sales growth over the past twelve months, along with improved operating leverage given reduced operating expenses.

One of the core priorities today is to lead conversations with strategic partner candidates who are well-positioned to integrate Cellvizio's proprietary imaging technology into large scale clinical and commercial platforms, thereby enhancing product differentiation and improving market adoption.

The recent agreement with Tasy Pharmaceutical is illustrative of this approach, expanding the market reach of Mauna Kea Technologies into the very attractive Chinese domestic GI market while also capitalizing on Mauna Kea Technologies' development over the past decade of a clinical and regulatory framework to prepare for the launch of Cellvizio into the global neurosurgery market.

Finally, with an expanding body of medical research into the capacity of Cellvizio to improve the diagnosis of complex disease, including additional scientific publications and clinical studies, Cellvizio will benefit from meaningful, unrealized commercial opportunity in emerging clinical use cases, including inflammatory bowel disease (IBD), interventional pulmonology, and food sensitivity; each being the basis for a potential new strategic partnership.

In furtherance of its corporate strategy, Mauna Kea Technologies remains actively engaged in discussions with a number of global life science firms regarding new partnerships.

Financial Update for the First Half 2023

<i>(in €K) - IFRS</i>	H1 2023	H1 2022	Change - %
Product sales	3,552	3,391	+5%
Licensing sales	3,263	-	n/a
Total sales	6,815	3,391	+101%
Other revenue	326	318	+3%
Total Revenue	7,142	3,708	+93%
Cost of goods sold	(811)	(911)	-11%
<i>Gross margin on Product sales</i>	77%	73%	+4pts
Research and development expenses	(1,947)	(1,990)	-2%
Sales and marketing expenses	(2,738)	(2,841)	-4%
General and administrative expenses	(2,821)	(2,767)	+2%
Share-based payments	75	(155)	n/a
Total Expenses	(8,242)	(8,665)	-5%
Current Operating Income (loss)	(1,100)	(4,957)	-78%
Non-current Operating Income	7,748	(85)	n/a
Operating Income	6,648	(5,042)	n/a
Financial Result	(762)	(1,170)	-35%
Income taxes	(1,458)	-	
Share of equity affiliates	(1,629)	-	
Net Profit	2,799	(6,212)	n/a

Total sales

Total Group sales amounted to €6.8m, up 101%, driven by the growth in product sales and the substantial contribution of licensing sales.

Product sales were up +5% to €3.6m driven by consumables and the Pay-Per-Use business in the United States.

Licensing sales amounted to €3.3m due to the recognition of revenues from the strategic agreement signed with Tasly Pharmaceutical, with:

- The recognition of \$1.1m from the licensing agreement totalling \$6.5m and recognized linearly over 3 years;
- The proceeds of \$2.5m from technology service fees, fully recognized on June 30, 2023.

Other revenue

The other revenue amounted to €0.3m corresponding to the research tax credit for the half-year, up +3% compared to last year.

Cost of goods sold

Cost of sales came to €0.8m, down 11% reflecting a total gross margin of 77% over product sales for the first half of 2023, up 4 points versus last year thanks to a favorable sales mix.

Research and development expenses

Research and development costs were down by 2% over the period at €1.9m, 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 4% over the period at €2.7m thanks to tight control over marketing costs.

General and administrative expenses

General expenses were slightly up by +2% over the period at €2.8m, impacted by the reorganization of the finance team completed at the end of the first half resulting in higher finance consultancy fees.

Share-based payments

Share-based payments had a positive impact of €75K over the period, due to a large number of cancellations of equity instruments following employee departures in the US as a result of the strategic realignment.

Current Operating Income

Given the increase in Group revenues and the reduction in operating expenses in the first half of 2023, the operating loss before non-recurring items was sharply reduced by €3.8m over the period to -€1.1m.

Operating Income

The Group's operating income was positive in the first half of 2023 at €6.6m, compared with a loss of -€5.0m in 2022, favorably impacted by the recognition of exceptional income of €7.7m 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 €2.8m, compared with a loss of -€6.2m in 2022.

Cash Flow from operating activities

In the first half of 2023, cash flow from operating activities amounted to €2.9m, compared with -€6.2m a year before, thanks to sales growth and payments associated with the agreements signed with Tasly Pharmaceutical.

Cash position as of June 30, 2023

Cash and cash equivalents stood at €6.3m at June 30, 2023, up €3.1m on December 31, 2022, thanks to the increase in cash flow from operations and the cash inflows associated with the equity line with Vester Finance.

Availability of the 2023 half year financial report:

The 2023 half-year financial report is available on the Company's website, in the [Investors](#) section.

Next financial release:

Third quarter 2023 sales, on October 19, 2023.

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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