Mauna Kea Technologies reports its Financial Results for the First Half of 2022

Improvement in gross margin driven by a more favorable sales mix and reduction in operating loss

Solid business activity following strategic repositioning and reallocation of resources

Cash position as of June 30, 2022 at €5.3 million

Webinar (French only) | November 16, 2022, 6:00 pm CET

https://app.livestorm.co/p/2bd2a372-04cb-4a29-b097-2b16b116f064

The replay will be available on the Mauna Kea Technologies website in the investors section.

Paris and Boston, November 16, 2022 - 5:45 p.m. CET - Mauna Kea Technologies (Euronext: MKEA), inventor of Cellvizio®, the multi-disciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announced its financial results for the first half of 2022 ended June 30, 2022.

"First half 2022 financial results are in line with our expectations and reflect the ongoing implementation of the strategic repositioning. This transition, initiated end of 2021, has yielded first tangible results, including the recently announced formation of a Joint Venture in China with Tasly Pharmaceutical," said Sacha Loiseau, Chairman and CEO of Mauna Kea Technologies. "In parallel, we have continued to strengthen Mauna Kea's core technology assets, including favorable clinical study results in novel therapeutic areas, the systematic enhancement of our imaging platform, and additional regulatory approval in the U.S.. On balance, while 2022 has been a challenging transition year, I have growing confidence in Mauna Kea's capacity to better capitalize on the significant commercial potential of Cellvizio as we enter 2023."

Financial summary for the first half of 2022

- Increase in gross margin to 73% vs. 71% in H1 2021
- Current operating loss reduced by 19% to €4,957K from €6,099K in H1 2021
- Net loss of €6,212K compared to €6,691K in the first half of 2021
- Total revenues for H1 2022 at €3,391K, up slightly by €77K, i.e. +2% compared to the previous period in 2021
- Total revenues for the first half of 2022 slightly down by €154K (-4%) compared to the first half of 2021, to €3,708K
- Cash position of €5.3 million at the end of June 2022 and total long-term debt of €26.4 million, compared to €11.9 million in cash and €26.9 million in long-term debt at December 31, 2021

Subsequent events

 Creation of a Joint Venture and conclusion of licensing agreements between Mauna Kea Technologies and Tasly Pharmaceutical

On July 11, Mauna Kea Technologies announced the signing of a strategic agreement to create a Joint Venture (JV) with a Chinese pharmaceutical company, Tasly Pharmaceutical. On November 7, the Joint Venture was legally incorporated as *Tasly Mauna Kea Medical Engineering Technology Co. Ltd*, based in the Chinese province of Zheijang, with a share capital of RMB 250 million (€35 million¹).

Under terms of their agreement, this partnership includes:

- The marketing of broad Cellvizio indications in China,
- The development and global commercialization of a dedicated Cellvizio in the fields of Neurology and Neurosurgery, and
- The manufacturing of a dedicated Cellvizio platform for the Chinese market.
- Sacha Loiseau appointed as Chief Executive Officer

On October 4, Sacha Loiseau, cofounder and Chairman of the Board of Directors of Mauna Kea Technologies, was appointed as Chief Executive Officer. Mr. Sacha Loiseau is now Chairman and Chief Executive Officer of Mauna Kea Technologies.

 Successful clinical study on the prediction of major adverse events in patients with Inflammatory Bowel Disease (IBD) using Cellvizio

Mauna Kea Technologies announced the successful completion of a long-term prospective clinical study on the prediction of remission or relapse in patients with chronic Inflammatory Bowel Disease (IBD) using Confocal Laser Endomicroscopy with Cellvizio®. The results were published in *Gastroenterology*, the flagship journal of the American Gastroenterological Association. The study prospectively showed that the predictive value of intestinal barrier healing assessed dynamically and functionally by confocal laser endomicroscopy (Cellvizio®) was far superior to that of endoscopic and histologic remission in predicting long-term remission or relapse in a large cohort of IBD patients in clinical remission.

Consolidated financial results for the first half of 2022*

(In €K) - IFRS	H1 2022	H1 2021	Var. €	Var. %
Sales	3,391	3,314	77	+2%
Other revenues	318	548	(230)	(42%)
Total Revenues	3,708	3,862	(154)	(4%)
Cost of Goods sold	(911)	(971)	(60)	(6%)
Gross margin rate (%)	73%	71%		
Research & Development	(1,990)	(1,584)	406	+26%
Sales & Marketing	(2,841)	(3,605)	(764)	(21%)
General expenses	(2,767)	(3,442)	(675)	(20%)
Share-based Payments	(155)	(359)	(204)	(57%)
Total operating expenses	(8,665)	(9,961)	(1 296)	(13%)
Current operating income	(4,957)	(6,099)	(1 142)	(19%)
Non-current operating income	(85)	-		
Operating income	(5,042)	(6,099)	(1,057)	
Net financial income & other expenses	(1,170)	(592)	(578)	(98%)
Net Result	(6,212)	(6,691)	(479)	(7%)

^{*}Totals may not add up due to rounding

¹ As of November 6th, 2022.

Total revenues for the first half of 2022 amounted to €3,391K, up slightly by +2% compared to the previous period.

First-half sales mainly benefited from the good momentum of Systems and Services sales, up by 11% and 22% respectively.

By geography, first-half sales in the United States were up 35% year-on-year, despite a reduced sales force. The decline in Consumables sales was primarily due to the national shortage of fluorescein in the United States. In the EMEA & ROW region, sales were up +6 %, while sales in the Asia-Pacific market were down -61%, as the latter remained impacted by pandemic restrictions.

Gross margin for the first half of 2022 sets at 73%, up 200 bps compared to 71% in the previous period, thanks to a more favorable sales mix in the first half of 2022.

Operating expenses, excluding cost of goods sold, decreased by €1,237K from a period to another, to €7,753K. This change is explained by lower Sales & Marketing expenses (-21%), administrative expenses (-20%) and share-based payments (-57%), while Research & Development expenses increased slightly by 405 K€.

As a result, the operating loss improved to -€5,042K, compared to -€6,099K in the first half of 2021. The restructuring of Mauna Kea Technologies and the reallocation of resources to the R&D department have led to this improvement.

After taking into account all these items, the net loss for the first half of 2022 was -€6,212K€, an increase of 479 K€ compared to the previous period.

As of June 30, 2022, the Company's cash position sets at €5.3 million and total liabilities amounted to €26.4 million, compared with €11.9 million in cash and €26.9 million in total liabilities as of December 31, 2021. The change in cash and cash equivalents during the period breakdowns as follows:

- €6.2 million of cash consumed by operating activities,
- €0.1 million of cash used in investment activities,
- €0.3 million of cash from financing activities.

As of June 30, 2022, Mauna Kea Technologies employed 71 people, compared to 87 as of December 31, 2021.

The consolidated financial statements for the first half of 2022 have been audited and the audit reports are now published.

The 2022 half-year financial report will be available before November 30, 2022 on the Company's website, in the section Investors.

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and markets Cellvizio®, the real-time in vivo cell imaging platform. This technology provides unique in vivo cellular visualization that allows physicians to monitor disease progression over time, assess responses as they occur, classify areas of uncertainty and guide surgical interventions. The Cellvizio platform is used in many countries around the world and in several medical specialties and is transforming the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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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 Techonologies' 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' 2021 Universal Registration Document filed with the Autorité des marchés financiers (AMF) on October 18, 2022 under number D-22-0773, which is available on the Company's website (www.maunakeatech.fr), as well as the risks associated with changes in economic conditions, 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.