



MAUNA KEA TECHNOLOGIES REPORTS FIRST HALF 2021 FINANCIAL RESULTS

Paris and Boston, September 23, 2021 – 5.45 PM CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announced first half 2021 financial results for the six months ended June 30, 2021.

First Half 2021 Financial Summary:

- Total revenue* for the first half of 2021 increased €0.7 million, or 22% year-over-year, to €3.9 million
- As previously reported, total sales for the first half of 2021 increased €1.2 million, or 58% year-over-year, to €3.3 million
- Current operating loss for the first half of 2021 increased €0.1 million, or 2% year-over-year, to €6.1 million
- Net loss for the first half of 2021 was €6.7 million, compared to €6.7 million in the prior year period
- As of June 30, 2021, the Company had a cash balance of €3.4 million and total debt obligations of €28.2 million, compared to €8.6 million of cash and €27.0 million of total debt obligations, as of December 31, 2020.

Recent Operating Highlights:

- On July 6, 2021, the Company announced completion of enrollment of the observational clinical study combining nCLE and robotic-assisted bronchoscopy, using both Cellvizio and the Monarch® Platform from Auris Health, Inc., part of Johnson & Johnson Medical Devices Companies, for the diagnosis of peripheral lung nodules (Clinicaltrials.gov: NCT04441749).
- On August 24, 2021, the Company announced that it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its next-generation Cellvizio® platform and all associated Confocal Miniprobes™ for a new clinical indication for visualization of blood flow when used in conjunction with a fluorescent dye, fluorescein, as a drug-device combination (K212322). This marked the 19th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.
- On September 20, 2021, the Company announced that it entered into a new research collaboration agreement with the Lung Cancer Initiative (“LCI”) at Johnson & Johnson¹ to advance the validation of Cellvizio as a real-time biopsy guidance tool during robotic-assisted bronchoscopy to potentially reduce the near-miss rate of peripheral lung cancer.
- On September 20, 2021, the Company announced the execution of equity subscription agreements with Johnson & Johnson Innovation – JJDC, Inc. (JJDC), one of the Company’s existing shareholders, and a leading US-based healthcare fund, Armistice Capital Master Fund Ltd. The net proceeds from this offering are expected to be approximately €11.5 million. The Company estimates that the net proceeds of the offering, as well as any additional drawings on the equity line that the company has with Kepler Cheuvreux, as the case may be, will enable it to finance its activities and strategy until the end of the third quarter of 2022.

Management Commentary:

“Our first half of 2021 financial results reflect solid execution and improvement in the global operating environment,” stated Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. Our new targeting strategy in the U.S. GI market focused on high-volume upper GI clinicians continues to result higher utilization per system and we continue to support our GI customers in our primary global markets outside the U.S.”

¹ The legal entity of the Lung Cancer Initiative at Johnson & Johnson is Johnson & Johnson Enterprise Innovation Inc.

*Total revenue for the first half of 2020 included €337,000 in research tax credits and €615,000 in U.S. government grants, compared to €350,000 in research tax credits and €198,000 in BPI grant on the PERSEE project in 2021.



“We were pleased to announce an important new clinical study and an expanded agreement as part of our collaboration with the Lung Cancer Initiative at Johnson & Johnson and we believe these announcements reflect the progress we have made in our strategic collaboration with LCI and the potential impact of real-time in vivo cellular imaging with Cellvizio, combined with the Monarch Platform, particularly as it relates to using Cellvizio for real-time tool-in-lesion confirmation during robotic-assisted bronchoscopy procedures. We were also pleased to announce the execution of equity subscription agreements with JJDC, our largest existing shareholder, and a new investor, Armistice Capital Master Fund Ltd. The proceeds from this offering will help us execute our strategic growth initiatives, including the expansion of our Cellvizio® real-time in vivo cellular imaging platform, and our goal of improving patient care in the years to come.”

First Half of 2021 Consolidated Financial Results:

<i>(in € millions) – IFRS</i>	First Half 2021	First Half 2020	€ Chg. Y/Y	% Chg. Y/Y
Operating Revenue				
Sales	€ 3.3	€ 2.1	€ 1.2	58%
Other Income	€ 0.6	€ 1.1	(€ 0.5)	(49%)
Total Revenue	€ 3.9	€ 3.2	€ 0.7	22%
Cost of Sales	€ 1.0	€ 0.8	€ 0.1	15%
Gross Profit	€ 2.9	€ 2.3	€ 0.6	25%
<i>Gross Margin (%)</i>	<i>70.7%</i>	<i>59.9%</i>		
Research & Development	€ 1.6	€ 1.5	€ 0.1	9%
Sales & Marketing	€ 3.6	€ 4.0	(€ 0.4)	(11%)
Administrative Expenses	€ 3.4	€ 2.9	€ 0.6	21%
Share-Based Payments	€ 0.4	€ 0.2	€ 0.2	96%
Total Operating Expenses	€ 10.0	€ 9.4	€ 0.6	6%
Current Operating Profit (Loss)	(€ 6.1)	(€ 6.2)	€ 0.1	(2%)
Interest & Other expense (income), net	€ 0.6	€ 0.5	€ 0.1	20%
Net Profit (Loss)	(€ 6.7)	(€ 6.7)	€ 0.0	0%

*numbers may not tie due to rounding

Gross profit for the first half of 2021 period increased €0.6 million, or 25% year-over-year, to €2.9 million, compared to €2.3 million for the first half of 2020 period. Gross margin for the first half of 2021 period was 70.7%, compared to 59.9% in the first half of 2020 period.

Operating expenses, excluding COGS, for the first half of 2021 period increased €0.45 million, or 5% year-over-year, to €9.0 million, compared to €8.5 million for the the first half of 2020 period. The increase in total operating expenses was driven by a €0.6 million increase in administration expenses, a €0.2 million increase in share-based payments and €0.1 million increase in research & development expense, offset partially by a €0.4 million decrease in sales & marketing expenses, compared to the first half of 2021 period.

Current operating loss for the first half of 2021 period decreased €0.1 million, or 2% year-over-year, to €6.1 million, compared to an operating loss of €6.2 million for the first half of 2020 period. Interest and other expenses, net increased €0.1 million, to €0.6 million, compared to €0.5 million for the first half of 2020 period. Net loss for the first half of 2021 period was €6.7 million, compared to a net loss of €6.7 million for the first half of 2020 period. The decrease in net loss was primarily driven by the decrease in operating loss as well as a €0.1 million increase in interest and other expenses, compared to the prior year period.

As of June 30, 2021, the Company had a cash balance of €3.4 million and total debt obligations of €28.2 million, compared to €8.6 million of cash and €27.0 million of total debt obligations, as of December 31, 2020.



The change in cash and cash equivalents during the period of the first half of 2021 can be broken down as follows:
€5.7 million of cash consumed in operating activities,
0.9 million € of cash consumed in investment activities,
1.4 million € of cash generated by additional financing.

The consolidated accounts for the half year 2021 period have been audited and legal audit reports are currently being issued.

Next Sales Results Announcement:

Third quarter of 2021 sales - October 28, 2021 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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Disclaimer

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