



MAUNA KEA TECHNOLOGIES REPORTS SECOND HALF AND FULL YEAR 2020 FINANCIAL RESULTS AND FIRST QUARTER OF 2021 SALES

Strong 2H'20 financial results driven by 27% sales growth and a 15% reduction in net loss compared to prior year period

The Company expects to deliver 25% to 30% sales growth for full year 2021 period

Paris and Boston, April 22, 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 second half and full year 2020 financial results for the twelve months ended December 31, 2020 and its sales for the first quarter of 2021.

“Over the second half of 2020, we delivered 20% growth in total revenue and strong financial results as evidenced by the improvement in both our current operating loss, and our net loss, by 11% and 15%, respectively, year-over-year,” stated Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. “Our second-half sales increased 27% year-over-year – reflecting the overall improvement in the global operating environment. We remain encouraged by the indications during the second half of 2020, that the global capital equipment environment continues to recover and the 63% growth in system shipments we reported in the first quarter of 2021 provides further confidence. We reported first quarter sales growth of 7% year-over-year driven by 14% growth in consumables sales and we continue to expect improving consumable demand as the global recovery continues to progress and customers around the world return to normal case-loads.”

Mr. Gershon continued: “We remain confident that our commercial strategy is well founded and our results in recent quarters continues to reflect that our new targeting strategy in the U.S. GI market focused on high-volume upper GI clinicians is working. We are driving adoption of Cellvizio in this targeted group and, importantly, we are seeing higher utilization per system as evidenced by upper GI procedures representing a higher percentage of their total procedure mix each year. We expect strong execution of this strategy in 2021 to result in the U.S. representing the largest contributor to total Company sales growth year-over-year. Outside of the U.S., we will continue to focus on leveraging our strong distribution relationships, and KOL support, in EMEA and certain APAC markets. Assuming the global capital equipment recovery continues to progress as we move through 2021, we expect to drive total sales growth in the range of 25% to 30% year-over-year in 2021. Finally, we will continue our formal evaluation process for identifying a new clinical indication for Mauna Kea’s next commercial focus-area and look forward to continued progress in the area of Interventional Pulmonology, specifically in combining nCLE and robotic navigational bronchoscopy, using both Cellvizio and the Monarch™ Platform as part of our collaboration with the Lung Cancer Initiative at Johnson & Johnson.”

Second Half 2020 Financial Summary (*):

- Total revenue for the second half of 2020 increased €0.8 million, or 20% year-over-year, to €4.8 million
- As previously reported, total sales for the second half of 2020 increased €0.9 million, or 27% year-over-year, to €4.4 million
- Current Operating loss decreased €0.7 million, or 11% year-over-year, to €5.7 million
- Net loss decreased €1.1 million, or 15% year-over-year, to €6.1 million.

**Full Year 2020 Financial Summary:**

- Total revenue¹ for full year 2020 decreased €0.6 million, or 7% year-over-year, to €7.9 million
- As previously reported, total sales for full year 2020 decreased €0.9 million, or 12% year-over-year, to €6.5 million
- Gross margin was 67.1% for full year 2020, compared to 65.6% for full year 2019²
- Current Operating loss decreased €1.1 million, or 8% year-over-year, to €12.0 million
- Net loss decreased €2.5 million, or 16% year-over-year, to €12.8 million
- As of December 31, 2020, the Company had a cash balance of €8.6 million and total long term debt obligations of €26.2 million, compared to €10.0 million of cash and €15.5 million of total long term debt obligations, as of December 31, 2019.

Sales Summary for First Quarter 2021:

- Total sales for the first quarter of 2021 increased €0.1 million, or 7% year-over-year, to €1.6 million
 - Consumables sales increased €0.1 million, or 14% year-over-year, to €0.7 million
 - Systems sales decreased €9 thousand, or 2% year-over-year, to €0.6 million
 - Services sales increased €24 thousand, or 8% year-over-year, to €0.3 million.

2021 Revenue Outlook:

Assuming the global capital equipment recovery continues, the Company expects to increase sales in the range of 25% to 30% year-over-year for the twelve months ending December 31, 2021.

Second Half of 2020 and Recent Operating Highlights:

- On November 4, 2020, the Company announced the publication of a peer-reviewed meta-analysis and of an international Delphi consensus report based on a systematic, evidence-based review of endoscopic ultrasound (EUS) guided needle-based confocal laser endomicroscopy for pancreatic cystic lesion (PCL) evaluation.
- On December 15, 2020, the Company announced an exclusive scientific and clinical research collaboration in the field of molecular imaging guided urologic oncology. The Telix and Mauna Kea scientific and clinical research collaboration is called the “Imaging and Robotics in Surgery (IRiS) Alliance,” or “IRiS Alliance,” and was created to further develop the combined technological capabilities of both companies.
- On December 17, 2020, the Company announced the cooptation by the Board of Ms. Jacquélien ten Dam as an Independent Director, effective immediately. Ms. ten Dam replaces Dr. Jennifer Tseng, who tendered her resignation from the Board after 3 years of service.
- On February 9, 2021, the Company announced the publication of a peer-reviewed study on pancreatic cystic lesion (PCL) risk stratification using artificial intelligence (AI) models for nCLE image classification and the publication of a new peer-reviewed meta-analysis on endoscopic ultrasound (EUS) guided nCLE for PCL evaluation.
- On March 17, 2021, the Company announced that it is supporting research to determine if Cellvizio can be effective in severe acute and/or long COVID-19 patients suffering from lingering respiratory complications. Mauna Kea Technologies is offering in-kind funding to researchers evaluating what role Cellvizio may play in the care management of COVID-19 patients, by assessing lung fibrosis and microvascularization changes, and alveolar and capillary morphology damages; symptoms observed in severe acute and/or long COVID-19 patients with mild to severe respiratory infections.

¹ Total Revenue in the full year 2020 period includes €711,000 from research tax credit and €615,000 U.S. government grant, compared to €1,077,000 of research tax credit in the prior year period.

² The income statement at December 31, 2019 has been restated to take into account a change in the presentation of the amortization of systems made available to customers under Pay-Per-Use contracts in the United States with approximately €0.3 million of amortization now included in cost of goods sold compared to sales & marketing previously. As of December 31, 2020, this amortization was approximately €0.3 million and are reported in cost of goods sold. Gross margin for twelve months ended 2020 and 2019, under the prior presentation of amortization, would have been 71.7% and 69.6%, respectively.

(*) H2 financials not audited

**Full Year 2020 Consolidated Financial Results:**

<i>(in € millions) – IFRS</i>	Full Year 2020	Full Year 2019²	€ Chg. Y/Y	% Chg. Y/Y
Operating Revenue				
Sales	€ 6.5	€ 7.4	(€ 0.9)	(12%)
Other Income	€ 1.4	€ 1.1	€ 0.3	31%
Total Revenue	€ 7.9	€ 8.5	(€ 0.6)	(7%)
Cost of Sales	€ 2.1	€ 2.6	(€ 0.4)	(16%)
Gross Profit	€ 4.4	€ 4.9	(€ 0.5)	(10%)
<i>Gross Margin (%)</i>	<i>67.1%</i>	<i>65.6%</i>		
Research & Development	€ 3.2	€ 3.2	€ 0.1	2%
Sales & Marketing	€ 8.1	€ 8.7	(€ 0.6)	(6%)
Administrative Expenses	€ 5.8	€ 6.2	(€ 0.4)	(6%)
Share-Based Payments	€ 0.6	€ 1.0	(€ 0.3)	(35%)
Total Operating Expenses	€ 17.8	€ 19.0	(€ 1.2)	(6%)
Current Operating Profit (Loss)	(€ 12.0)	(€ 13.0)	€ 1.1	(8%)
Interest & Other expense (income), net	€ 0.8	€ 2.2	(€ 1.4)	(63%)
Net Profit (Loss)	(€ 12.8)	(€ 15.3)	€ 2.5	(16%)

*numbers may not tie due to rounding

2) The income statement at December 31, 2019 has been restated to take into account a change in the presentation of the amortization of systems made available to customers under Pay-Per-Use contracts in the United States with €0.3 million of amortization now included in cost of goods sold compared to sales & marketing previously. As of December 31, 2020, this amortization was €0.3 million and are reported in cost of goods sold.

Gross profit for the full year 2020 period decreased €0.5 million, or 10% year-over-year, to €4.4 million, compared to €4.9 million for the full year 2019 period. Gross margin for the full year 2020 period was 67.1%, compared to 65.6% in the full year 2019 period.

Total operating expenses for the full year 2020 period decreased €1.2 million, or 6% year-over-year, to €17.8 million, compared to €19.0 million for the full year 2019 period. The decrease in total operating expenses was primarily driven by a €0.6 million decrease in sales & marketing expenses, a €0.4 million decrease in administration expenses and a €0.3 million decrease in share-based payment, offset partially by a €0.1 million increase in research and development expenses, compared to the full year 2019 period.

Current Operating loss for the full year 2020 period was €12.0 million, compared to an operating loss of €13.0 million for the full year 2019 period. The decrease in operating loss was driven by the €0.5 million decrease in gross profit, offset by the €1.2 million decrease in total operating expenses and by the €0.3 million increase in 'other income,' compared to the prior year period.

Net loss for the full year 2020 period was reduced at €12.8 million, compared to a net loss of €15.3 million for the full year 2019 period. The decrease in net loss was primarily driven by the decrease in operating loss as well as a €1.4 million decrease in interest and other expenses, compared to the prior year period.

As of December 31, 2020, the Company had a cash balance of €8.6 million and total long term debt obligations of €26.2 million, compared to €10.0 million of cash and €15.5 million of total long term debt obligations, as of December 31, 2019. The change in cash during the full year 2020 period was driven by €8.0 million of cash used in operating activities, €1.0 million of cash used in investing activities, offset partially by a €7.7 million of cash from financing activities. Following a review of its liquidity risk, the company concluded it is able to meet its cash flow requirements through second quarter of 2022.

As of December 31, 2020, Mauna Kea Technologies had 98 employees, compared to 101 as of December 31, 2019.



The consolidated accounts for the full year 2020 period have been audited and legal audit reports are currently being issued.

First Quarter 2021 Sales by Category:

<i>(in € millions) – IFRS</i>	Q1 2021	Q1 2020	€ Chg. Y/Y	% Chg. Y/Y
Systems	0.6	0.6	(0.0)	(2%)
Consumables	0.7	0.6	0.1	14%
Services	0.3	0.3	0.0	8%
Total Sales	1.6	1.5	0.1	7%

Total sales for the first quarter of 2021 were €1.6 million, up 7% year-over-year. First quarter sales results were driven by a 14% increase in sales of consumables and an 8% increase in services sales, partially offset by a 2% decrease in system sales, compared to the prior year period.

First Quarter 2021 Sales by Geographic Region:

<i>(in € millions) – IFRS</i>	Q1 2021	Q1 2020	€ Chg. Y/Y	% Chg. Y/Y
United States	0.6	0.8	(0.2)	(22%)
Asia-Pacific	0.4	0.5	(0.0)	(6%)
EMEA & ROW	0.5	0.2	0.3	188%
Total Sales	1.6	1.5	0.1	7%

The change in total sales for the first quarter of 2021, by geographic region, was driven primarily by a 188% increase in sales to customers in the EMEA and ROW regions, offset partially by lower sales to customers in the U.S. and Asia-Pacific regions, which decreased 22%, and 6%, respectively, year-over-year.

First Quarter 2021 Units Sales by Type

Units (#)	Q1 2021	Q1 2020	% Chg. Y/Y
New Systems Sold	6	6	0%
New System Placements	7	2	250%
Total System Shipments	13	8	63%
Consumable Probe Shipments	146	107	36%

Total Cellvizio System shipments increased 63% year-over-year to 13 in the first quarter of 2021, compared to 8 total shipments in the prior year period. First quarter of 2021 shipments included 6 new systems sold and 7 new system placements to U.S. customers driven by the Company's new targeting strategy in the U.S. GI market which is focused on high-volume upper GI clinicians. Consumable probe shipments increased 36% year-over-year in the first quarter of 2021 driven by continued improvement in underlying business and procedure trends as the global recovery continues to progress.

Mauna Kea Technologies will host a conference call today at 6:00 PM (CEST / Paris time) / 12:00 PM (ET / New York time) to discuss the Company's full year 2020 financial results and first quarter sales results and to provide a business update. The conference call will be hosted by Robert L. Gershon, CEO, and Christophe Lamboeuf, CFO. To access the conference call, please use one of the following dial-in numbers at least 5 minutes prior to the scheduled start time and follow the instructions: USA: +1 646-722-4916 / UK: +44 (0)20 7194 3759 / FR: +33 (0)1 72



72 74 03. The passcode for the conference call is: 96787831 #. Following the conclusion of the live call, a replay will be available for 90 days. To access the replay, please dial one of the following numbers: USA: +1 (646) 722-4969 / UK: +44 (0)20 3364 5147 / FR: +33 (0)1 70 71 01 60. The passcode for the replay is: 425000722 #.

Next Sales Results Announcement:

Second quarter and first half of 2021 sales - July 22, 2022 after market close



Financial calendar

Please note that the 2021 financial calendar is available on the Mauna Kea Technologies website:

<https://www.maunakeatech.com/en/investors/financial-calendar>

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 revolutionizing the way physicians diagnose and treat patients — making a transformative change in medicine. For more information, visit www.maunakeatech.com.

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Disclaimer

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