



MAUNA KEA TECHNOLOGIES REPORTS FULL FINANCIAL RESULTS FOR FIRST HALF OF 2020 AND PRELIMINARY THIRD QUARTER OF 2020 SALES

1H'20 financial results driven primarily by a 10% reduction in total operating expenses (without COGS) and a 17% reduction in net loss compared to prior year period

Preliminary Third Quarter Total Sales Increase 2% to 11% year-over-year; U.S. Sales up 1% to 3%

Paris and Boston, September 22, 2020 – 5:45pm CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announced full financial results for the first half of 2020 ended June 30, 2020 and its preliminary sales for the third quarter. Given the significant uncertainties associated with pace of recovery from the COVID-19 pandemic, the Company has elected to provide, in this context, specific information on current-quarter expected revenue trends. Preliminary sales figures for the third quarter are unaudited.

Preliminary Sales Summary for Third Quarter 2020 (Unaudited figures)

- Preliminary sales for the third quarter of 2020 are expected in a range of €1.8 million to €2.0 million, representing growth of approximately 2% to 11% year-over-year
 - *Preliminary Q3'20 Sales by Geography:*
 - U.S. sales are expected to increase approximately 1% to 3% year-over-year
 - Rest of World (ROW) sales are expected to increase approximately 4% to 19% year-over-year
 - *Preliminary Q3'20 Sales by Category:*
 - Consumables sales are expected to decrease approximately 27% to 23% year-over-year
 - Systems sales are expected to increase approximately 46% to 60% year-over-year
 - Services sales are expected to increase approximately 21% to 29% year-over-year

First Half 2020 Financial Summary

- Total revenue¹ for the first half of 2020 decreased €1.3 million, or 30% year-over-year, to €3.2 million.
 - Total revenue for the first half of 2020 was significantly impacted by the global crisis caused by the coronavirus, or COVID-19.
- As previously reported, total sales for the first half of 2020 decreased €1.8 million, or 47% year-over-year, to €2.1 million
 - Consumables sales decreased €1.1 million, or 52% year-over-year, to €1.0 million
 - Systems sales decreased €0.8 million, or 59% year-over-year, to €0.6 million
 - Services sales increased €36 thousand, or 7% year-over-year, to €0.6 million
- Gross margin was 67.2% in the first half of 2020 period, compared to 62.7% in the first half of 2019 period
- Total operating expenses (without COGS) decreased €1.0 million, or 10% year-over-year, to €8.7 million
- Operating loss decreased €0.4 million, or 6% year-over-year, to €6.2 million
- Net loss decreased €1.4 million, or 17% year-over-year, to €6.7 million
- As of June 30, 2020, the Company had a cash balance of €4.2 million and total long term debt obligations of €16.1 million, compared to €10.0 million of cash and €15.5 million of total long term debt obligations, as of December 31, 2019.

¹ Total Revenue in the first half 2020 period includes €1,064,000 from research tax credit and U.S. government grant, compared to €576,000 of research tax credit in the prior year period.



- In July 2020, the Company announced it had drawn down the €6m second tranche of their €22.5 million loan agreement with the European Investment Bank and announced it received financing approvals from BNP Paribas and Bpifrance for a total of €4 million in non-dilutive financing in the form of French state-guaranteed loans (Prêts Garantis par l'Etat, or PGE in France).

“We are pleased to see the business return to year-over-year growth in the third quarter driven by continued improvement in our underlying business trends as customers around the world begin to return to normal case-loads,” stated Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. “We are also encouraged by the strong new system adoption trends we experienced during the third quarter and believe this reflects both the improving health of the global capital equipment environment, and, early evidence that our new U.S. targeting strategy is well-defined.”

Mr. Gershon continued: “Despite the challenging operating environment during the first half of 2020 which resulted in year-over-year declines in revenue, we reported strong improvement in our gross margins and reduced our total operating expenses (without COGS) and net loss by 10% and 17%, respectively, year-over-year. We have further enhanced our financial condition with non-dilutive financings and the drawdown of the second tranche of our financing agreement with the European Investment Bank. Together, these actions should provide sufficient liquidity to manage the business through the third quarter of 2021. We also made progress towards our third strategic priority for 2020, our formal evaluation process for identifying a new clinical indication for Mauna Kea’s next commercial focus-area. We are encouraged by the work we have done thus far in Interventional Pulmonology, specifically in starting a pilot clinical study, 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. We are also continuing to push other new potential indications through the formal evaluation process, and we look forward to updating investors as initiatives develop this year.”

First Half of 2020 and Recent Operating Highlights:

- On January 8, 2020, the Company announced a publication that demonstrates how Cellvizio positively impacts the diagnostic yield and the clinical management of pancreatic cystic lesions (PCL).
- On January 27, 2020, the Company announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for the Cellvizio® 100 series and all associated Confocal Miniprobes™ for the additional indication of visualization of blood flow when used in conjunction with a fluorescent dye, fluorescein, as a drug device combination. This marked the 17th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.
- On March 3, 2020, the Company announced it obtained 510(k) clearance (K193416) from the U.S. Food and Drug Administration (FDA) and CE marking of the next-generation Cellvizio® endomicroscopy platform, built with the company’s new proprietary system architecture. This marked the 18th U.S. FDA 510(k) clearance of the Cellvizio® pCLE/nCLE platform.
- On April 23, 2020, the Company announced it obtained confirmation from the EIB of its consent to disburse the second tranche of their €22.5 million loan for an amount of €6m with revised terms.
- On May 26, 2020, the Company announced that the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee (TAVAC) published a review on the safety and efficacy of confocal laser endomicroscopy as a diagnostic tool for the evaluation of gastrointestinal pathologies. This article, entitled “SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy,” was published in a peer reviewed international journal, *Surgical Endoscopy* (doi.org/10.1007/s00464-020-07607-3).
- On June 24, 2020, the Company announced that, as part of its collaboration with the Lung Cancer Initiative at Johnson & Johnson, Christopher Manley, M.D., Director of Interventional Pulmonology and Assistant Professor of Medicine at Fox Chase Cancer Center (FCCC) in Philadelphia, and Jouke T. Annema, M.D., Ph.D.,



Professor of Pulmonary Endoscopy, Amsterdam University Medical Center, have received the authorization from FCCC IRB to start a pilot clinical study, combining nCLE and robotic navigational bronchoscopy, using both Cellvizio and the Monarch™ Platform from Auris Health, Inc., one of the Medical Devices Companies of Johnson & Johnson, for the diagnosis of peripheral lung nodules. This study is co-funded by the Lung Cancer Initiative at Johnson & Johnson and Mauna Kea Technologies (Clinicaltrials.gov: NCT04441749).

- On July 6, 2020, the Company announced it had drawn down the €6m second tranche of their €22.5 million loan agreement concluded on 20 June 2019 with the European Investment Bank.
- On July 17, 2020, the Company announced it received financing approvals from BNP Paribas and Bpifrance for a total of €4 million in non-dilutive financing in the form of French state-guaranteed loans (Prêts Garantis par l'Etat, or PGE in France).
- On July 23, 2020, the Company announced the appointment of Claire Biot, Ph.D., as an Independent Director, effective immediately. Dr. Claire Biot is currently employed as Vice-President Life Sciences Industry at Dassault Systèmes, “the 3DEXPERIENCE Company”.

First Half of 2020 Consolidated Financial Results:

<i>(in € millions) – IFRS</i>	First Half 2020	First Half 2019	€ Chg. Y/Y	% Change Y/Y
Operating Revenue				
Sales	€ 2.1	€ 3.9	(€ 1.8)	(47%)
Other Income	€ 1.1	€ 0.6	€ 0.5	85%
Total Revenue	€ 3.2	€ 4.5	(€ 1.3)	(30%)
Cost of Sales	€ 0.7	€ 1.5	(€ 0.8)	(53%)
Gross Profit	€ 1.4	€ 2.5	(€ 1.1)	(43%)
<i>Gross Margin (%)</i>	67.2%	62.7%		
Research & Development	€ 1.5	€ 2.1	(€ 0.6)	(29%)
Sales & Marketing	€ 4.2	€ 4.6	(€ 0.4)	(9%)
Administrative Expenses	€ 2.9	€ 2.6	€ 0.3	11%
Share-Based Payments	€ 0.2	€ 0.4	(€ 0.2)	(57%)
Total Operating Expenses	€ 8.7	€ 9.7	(€ 1.0)	(10%)
Operating Profit (Loss)	(€ 6.2)	(€ 6.6)	(€ 0.4)	(6%)
Interest expense (income), net	€ 0.5	€ 1.5	(€ 1.0)	(67%)
Net Profit (Loss)	(€ 6.7)	(€ 8.1)	(€ 1.4)	(17%)

*numbers may not tie due to rounding

Gross profit for the first half of 2020 period decreased €1.1 million, or 43% year-over-year, to €1.4 million, compared to €2.5 million for the first half of 2019 period. Gross margin for the first half of 2020 period was 67.2%, compared to 62.7% in the first half of 2019 period.

Total operating expenses for the first half of 2020 period decreased €1.0 million, or 10% year-over-year, to €8.7 million, compared to €9.7 million for the first half of 2019 period. The decrease in total operating expenses was primarily driven by a €0.6 million decrease in research and development expenses, a €0.4 million decrease in sales & marketing expenses and a €0.2 million decrease in share-based payment, offset partially by a €0.3 million increase in administration expenses, compared to the first half of 2019 period.

Operating loss for the first half of 2020 period was €6.2 million, compared to an operating loss of €6.6 million for the first half of 2019 period. The decrease in operating loss was driven by the €1.1 million decrease in gross profit, offset by the €1.0 million decrease in total operating expenses and by the €0.5 million increase in ‘other income’, compared to the prior year period.



Net loss for the first half of 2020 period was €6.7 million, compared to a net loss of €8.1 million for the first half of 2019 period. The decrease in net loss was primarily driven by the decrease in operating loss compared to the prior year period as well as an decrease in interest expenses, net, driven primarily by non-recurring financial costs of €1.7 million associated to the early repayment of the IPF Partners bond financing which impacted net loss results in the first half of 2019 but did not impact results during the first half of 2020 period.

As of June 30, 2020, the Company had a cash balance of €4.2 million and total long term debt obligations of €16.1 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 first half of 2020 period was driven by €4.0 million of cash used in operating activities, €0.9 million of cash used in investing activities, and €0.9 million of cash from financing activities.

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

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 first half of 2020 financial results and preliminary third 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: 80840227#. 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: 418950560#.

Next Sales Results Announcement:

Third quarter of 2020 sales – October 19, 2020 after market close



Financial calendar

Please note that the 2020 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 focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company's flagship product, Cellvizio®, has received clearance/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, and China. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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