



## MAUNA KEA TECHNOLOGIES REPORTS FIRST HALF 2019 FINANCIAL RESULTS

Mauna Kea Technologies will host a conference call today at 6:00 PM (CET / Paris time) / 12:00 PM (ET / New York time) to discuss the Company's first half 2019 financial 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: 37049464#. 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: 418874832#.

Paris and Boston, September 23, 2019 – 5:45 PM CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced first half 2019 financial results for the six months ended June 30, 2019.

*“Our first half of 2019 financial performance reflects solid execution against our strategic priorities for 2019,”* stated **Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies**. *“Consumables sales were the largest contributor to our year-over-year growth in first half of 2019 period, reflecting strong execution of our primary strategic priority: driving utilization of Cellvizio in the U.S. Gastrointestinal (GI) market, and in targeted geographies outside the U.S. Specifically, over the first half of 2019, we have experienced growth in total sales of consumables of 72% year-over-year, driven primarily by growth in sales of consumables to pay-per-use customers in the U.S. of 160% year-over-year. Outside the U.S., the Asia-Pacific region has been notably strong with sales increasing 106% year-over-year fueled by sales of both new systems and consumables.”*

Mr. Gershon continued: *“In addition to the solid sales performance over the first half of 2019, we are also prioritizing our operating expenditures to support our strategic growth plans while preserving our capital resources. We were extremely pleased to announce the new partnership with the European Investment Bank which provided us with the requisite growth capital to execute our plan and the more attractive borrowing terms significantly enhances our cash flow profile over the five-year borrowing period. We are also making progress towards our third strategic priority for 2019, evaluating the interventional pulmonology market as a new clinical indication for Mauna Kea's next commercial focus area. The long-term growth opportunity for Mauna Kea remains extremely compelling and our recently enhanced balance sheet gives us further confidence in our ability to execute our strategic growth objectives going forward.”*

### First Half 2019 Financial Summary

- Total revenue<sup>1</sup> for the first half of 2019 increased €1.3 million, or 39.6% year-over-year to €4.5 million.
- As previously reported, total sales for the first half of 2019 increased €1.2 million, or 45.4% year-over-year, to €3.9 million
  - Consumables sales increased €0.9 million, or 72.4% year-over-year, to €2.1 million
    - Consumables sales related to the pay-per-use program increased 160.1% year-over-year
  - Systems sales increased €0.4 million, or 37.7% year-over-year, to €1.3 million
  - Services sales decreased 1.2% year-over-year to €0.5 million
- The Company placed 10 new Cellvizio systems under its PPU program in the first half of 2019, compared to 16 in the first half 2018

<sup>1</sup> Total Revenue includes Research Tax Credit and other tax credits of €576,000 in the first half 2019 period, compared to €525,000 in the prior year period.



- Gross margin was 62.7%, compared to 63.5% in the first half of 2018
- Operating loss was €6.6 million, compared to operating loss of €6.5 million in the first half of 2018
- Net loss was €8.1 million, compared to net loss of €6.8 million in the first half of 2018
- As of June 30, 2019, the Company had a cash balance of €0.0 and total debt obligations of €6.4 million, including €2.7m of bank overdraft, compared to €8.6 million of cash and €7.1 million of total debt obligations, as of December 31, 2018.
- On July 3, 2019, the Company announced it had received the first tranche of €11.5 million under a financing agreement concluded on June 20, 2019 with the European Investment Bank (“EIB”). The Company redeemed the non-dilutive bond financing with IPF Partners. The financing with IPF Partners was comprised of two bond tranches of €4.0 million and €5.0 million, issued in February 2017 and May 2019, respectively. The Company repaid both tranches fully on 28 June 2019 for a total amount of €10.7 million.
- As of July 3, 2019, and following the restructuring of its debt, the Company had €8.8 million of cash available.

#### First Half 2019 Operating Highlights:

- On February 25, 2019, the Company announced that it had received U.S. Food and Drug Administration (FDA) 510(k) clearance for the use of the Cellvizio AQ-Flex 19 Confocal Miniprobe through existing bronchoscopes, transbronchial needles and other bronchoscopic accessories. This marked the 16th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.
- On May 6, 2019, the Company announced the publication of a prospective study (ClinicalTrials.gov Identifier: [NCT02689050](https://clinicaltrials.gov/ct2/show/study/NCT02689050)) that demonstrates the potential of nCLE to aid in the diagnosis and staging of lung cancer. The article, entitled “Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer,” was published in the *European Respiratory Journal* (2019, DOI: 10.1183/13993003.01520-2018) and can be downloaded here: <https://erj.ersjournals.com/content/early/2019/03/15/13993003.01520-2018>.
- On May 17, 2019, the Company announced the presentation of 17 abstracts supporting Cellvizio® at the Digestive Disease Week® (DDW) Conference. These abstracts focus on Barrett’s esophagus, inflammatory bowel disease, food allergy, pancreatic cyst and other gastrointestinal diseases. Studies are focused on how the use of Cellvizio® potentially impacts patient management and improved outcomes.
- On June 17, 2019, the Company announced the reimbursement coverage of confocal laser endomicroscopy, specifically for Barrett’s esophagus, through the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM) published in the Official Journal of the French Republic.

#### First Half 2019 Sales by Category:

(in € thousands) – IFRS	1H 2019	1H 2018	% Chg. Y/Y
Systems	1,349	980	38%
Consumables	2,063	1,197	72%
<i>o/w pay-per-use program</i>	801	308	160%
Services	525	531	(1%)
<b>Total Sales</b>	<b>3,937</b>	<b>2,707</b>	<b>45%</b>

Total sales for the first half of 2019 were €3.9 million, up 45% year-over-year. First half of 2019 sales growth was driven primarily by a 72% increase in consumables sales and a 38% increase in systems revenue, which offset a 1% decrease in services sales in the period. Total consumables sales were driven by a 160% increase

in consumables sales related to the pay-per-use program fueled by utilization-related demand following the Company's success in driving new system placements in this program throughout 2018. Consumables sales to customers in the pay-per-use program represented 39% of total consumables sales in the first half of 2019, compared to 26% in the prior year period.

#### First Half 2019 Units Sales by Type:

Units (#)	1H 2019	1H 2018	% Chg. Y/Y
New Systems Sold	15	9	67%
New System Placements	10	16	(38%)
Consumable Probe Shipments	461	269	71%

Total Cellvizio System shipments increased 67% year-over-year to 15 in the first half of 2019 period, compared to 9 total shipments in the prior year period. New system placements under the Company's pay-per-use program represented 40% of total shipments in the first half of 2019 period, compared to 64% in the prior year period. Total consumable probe shipments increased 71% year-over-year to 461 in the first half of 2019 period, compared to 269 in the prior year period.

#### First Half 2019 Sales by Geography with split by activity (Clinical / Pre-clinical):

(in € thousands) – IFRS	1H 2019	1H 2018	% Chg. Y/Y
<b>U.S. &amp; Canada<sup>2</sup></b>	<b>1,629</b>	<b>1,326</b>	<b>23%</b>
Clinical	1,612	1,291	24%
Pre-clinical	17	35	(50%)
<b>Asia-Pacific</b>	<b>1,497</b>	<b>727</b>	<b>106%</b>
Clinical	1,491	561	166%
Pre-clinical	6	166	(96%)
<b>EMEA &amp; ROW</b>	<b>810</b>	<b>654</b>	<b>24%</b>
Clinical	675	356	89%
Pre-clinical	135	297	(55%)
<b>Total Clinical Sales</b>	<b>3,778</b>	<b>2,209</b>	<b>71%</b>
<b>Total Pre-clinical Sales</b>	<b>159</b>	<b>498</b>	<b>(68%)</b>
<b>Total Sales</b>	<b>3,937</b>	<b>2,707</b>	<b>45%</b>

#### Clinical sales

Total clinical sales for the first half of 2019 period were €3.8 million, up 71% year-over-year, driven by a 106% increase in sales in the Asia-Pacific region, a 23% increase in sales in the U.S. and Canada regions and a 24% increase in sales in the EMEA and Rest of World regions.

#### Pre-clinical sales

Total pre-clinical sales were €26 thousand and €159 thousand in the second quarter and first half of 2019 periods, respectively, representing 1% of total sales and 4% of total sales, compared to 13% of total sales and 18% of total sales, respectively, in the prior periods.

<sup>2</sup> US & Canada sales previously reported with LATAM sales as Americas.

**First Half 2019 Consolidated Financial Results:**

<i>(in € thousands) – IFRS</i>	<b>2019</b> (June 30, 2019)	<b>2018</b> (June 30, 2018)	<b>% Change Y/Y</b>
<b>Operating Revenue</b>			
Sales	3,937	2,707	45.4%
Other Income	576	525	9.7%
<b>Total Revenue</b>	<b>4,512</b>	<b>3,232</b>	<b>39.6%</b>
Cost of Sales	(1,468)	(987)	48.7%
<b>Gross Profit</b>	<b>2,469</b>	<b>1,720</b>	<b>43.5%</b>
<i>Gross Margin (%)</i>	62.7%	63.5%	
Research & Development	(2,050)	(2,235)	(9.3%)
Sales & Marketing	(4,597)	(4,376)	5.1%
Administrative Expenses	(2,578)	(2,069)	24.6%
Share-Based Payments	(432)	(43)	910.3%
<b>Total Operating Expenses</b>	<b>(9,658)</b>	<b>(8,724)</b>	<b>10.7%</b>
<b>Operating Profit (Loss)</b>	<b>(6,614)</b>	<b>(6,479)</b>	<b>1.6%</b>
<b>Net Profit (Loss)</b>	<b>(8,096)</b>	<b>(6,836)</b>	<b>18%</b>

Gross profit in the first half of 2019 increased €0.7 million, or 43.5% year-over-year, to €2.5 million, compared to €1.7 million last year. Gross margin in the first half of 2019 period was 62.7%, compared to 63.5% in the first half of 2018. The primary driver of the decrease in gross margin in the first half of 2019 was an unfavourable margin mix related to the 106% growth in sales to the APAC region in the first half of 2019 period.

Total operating expenses in the first half of 2019 increased €0.9 million, or 10.7% year-over-year, to €9.7 million, compared to €8.7 million last year. The increase in total operating expenses was primarily driven by:

- an increase in administration expenses of €0.5 million, or 24.6% year-over-year, to €2.6 million, driven by investments made in the second half 2018 to strengthen the management team,
- an increase in share-based payment of €0.4 million, or 910.3% year-over-year, to €0.4 million, driven by the allocation of free shares and stocks options in 2018,
- an increase in sales and marketing expenses of €0.2 million, or 5.1% year-over-year, to €4.6 million, driven by commercial and marketing investments required to support the deployment of the pay-per-use model in the U.S.;

The increase in total operating expenses in the first half of 2019 was partially offset by lower depreciation and provisions which were €0.7 million, compared to €0.9 million last year. Research and development expenses were €2.0 million, compared to €2.2 million, last year. The decrease in R&D expenses was driven by higher capitalized costs compared to last year; the Company's investment in R&D-projects remained constant in the first half of 2019.

Operating loss in the first half of 2019 period was €6.6 million, compared to €6.5 million last year. The increase in operating loss was driven by the €0.7 million increase in gross profit, offset by the €0.9 million increase in operating expenses compared to the prior year period.

Net loss in the first half of 2019 period was €8.1 million, compared to €6.8 million in the prior year period. The increase in net loss was primarily driven by non-recurring financial costs of €1.7 million associated to the early repayment of the IPF Partners bond financing.

On June 28, 2019, the Company redeemed all non-dilutive bond financing with IPF Partners for a total amount of €10.7 million. The financing with IPF Partners was comprised of two bond tranches of €4.0 million and €5.0 million, issued in February 2017 and May 2019, respectively.



As of June 30, 2019, the Company had a cash balance of €0.0 and total debt obligations of €6.4 million, including €2.7m of bank overdraft, compared to €8.6 million of cash and €7.1 million of total debt obligations, as of December 31st, 2018.

On July 3, 2019, the Company announced it had received the first tranche of €11.5 million under a financing agreement concluded on June 20, 2019 with the European Investment Bank ("EIB"). As of July 3, 2019, and following the restructuring of its debt, the Company had €8.8 million of cash available.

Cash used in operating and investing activities in the first half 2019 period totaled €4.8 million, compared to €5.9 million in the prior year period.

Mauna Kea Technologies had 99 employees as of June 30, 2019, compared to 98 as of June 30, 2018.

The consolidated accounts for the first half 2019 period have been audited and legal audit reports are currently being issued.

**Next Sales Results Announcement:**

Third quarter of 2019 sales – October 17, 2019 after market close

**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, China, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit [www.maunakeatech.com](http://www.maunakeatech.com)

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