# FINANCIAL RESULTS FOR HALF YEAR 2014

- Total revenue increased 11%
  - Gross margin of 68%
- Cash balance of €20 million at June 30
- Strengthened commercialization platform

**PARIS, August 28, 2014** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263, PEA-SME eligible), a leader in the optical biopsy market, today reported its full financial results for the first half of the current financial year, ended June 30, 2014.

In €K - IFRS	H1 2014	H1 2013
	(June 30, 2014)	(June 30, 2013)
Operating Revenue		
Sales	4,569	4,320
Other income	537	271
Total revenue	5,106	4,591
Operating Expenses		
Cost of sales	(1,461)	(1,236)
Gross margin (%)	68%	71%
Research and Development	(2,084)	(1,859)
Sales & Marketing	(6,113)	(5,854)
General & Administrative expenses	(1,911)	(1,955)
Share-based payments	(794)	(286)
Total Operating Expenses	(12,364)	(11,191)
Operating profit / (loss)	(7,257)	(6,600)
Net Profit / (loss)	(7,324)	(6,612)

### Sales growth of 6% in the first half of the year, clinical sales up by 15%

In the first half of 2014, sales increased by 6% to €4,569K versus €4,320K in H1 2013. Clinical sales increased by 15% to €3,958K and pre-clinical sales decreased by 31% to €610K.

The product mix shifted towards consumables, which saw a 13% increase in sales to €1,252K, whereas the sales of systems remained stable at €2,942K. Sales of services grew 40% to €374K. Systems, consumables and services represented 64%, 27% and 8% of H1 2014 sales, respectively. In the half-year period, 36 Cellvizio systems were sold versus 32 systems in H1 2013 and the number of consumables sold increased by 22% as 355 miniprobes were sold versus 290 miniprobes in H1 2013.

In terms of the geographic mix, sales in the APAC region (Asia Pacific) increased by 14% to €1,492K, boosted by regulatory approval in Japan. The EMEA region (Europe, Middle East and Africa) saw strong growth of 37% to €1,219K. The Americas region fell by 13% to €1,857K, largely due to ongoing uncertainty around



healthcare reform in the United States, which has caused a temporary slow-down in adoption of new technologies. The Americas, APAC and EMEA accounted for 41%, 33% and 27% of first half 2014 sales, respectively.

At June 30, 2014, 392 Cellvizio systems were installed worldwide, with 277 located in hospitals and clinics and 115 in pre-clinical research centers. On a geographic basis, 130 Cellvizio systems were installed in North America, including 120 in the United States, 175 were in the EMEA region, 75 were in the APAC region and 12 were in Latin America.

Other income was €537K in the first half of 2014, up +92% versus H1 2013, and is primarily related to an increase in the Research Tax Credit from €168K in H1 2013 to €490K in H1 2014. This increase is associated with the fact that the company received no repayable advances during the half-year period, and with the increase in R&D expenses.

The gross margin declined to 68% versus 71% in H1 2013, due to discounts granted on the selling price of the systems and consumables in the United States.

Sales and Marketing costs were up 4% to €6,113K in the first half of 2014, reflecting the hire of new members of the sales team worldwide. Research and Development expenses increased 12% to €2,084K due to continued investment in improving the company's optical biopsy technology and the rising development costs of the next-generation Cellvizio technology.

Total operating expenses amounted to €12,364K in the half-year period versus €11,191K in H1 2013. Operating loss was €7,257K in the first half of 2014 versus €6,600K in H1 2013.

Net loss was €7,324K in the first half of 2014 versus a net loss of €6,612K in the same period of 2013.

During the first half-year of 2014, the Company utilized €7.8 million of cash versus €6.1 million in H1 2013. As of June 30, 2014, available cash was €20 million.

At June 30, 2014, Mauna Kea Technologies had 118 employees versus 113 employees a year earlier.

Sacha Loiseau, CEO and founder of Mauna Kea Technologies, commented: « The disappointing sales for the second quarter in the United States adversely impacted our financial results for the first half of 2014. However, we remain dedicated in our efforts to drive the adoption of Cellvizio in this geography as well as throughout the rest of the world. We continue to be optimistic about the opportunity in front of us for the remainder of the 2014 year ».

## **Recent Developments**

### Regulatory approvals and reimbursement coverage

- US health authorities provided for physician compensation for the use of the Cellvizio in the upper digestive tract. Since January 2014, US physicians have been receiving compensation determined by the health authorities for certain optical biopsy procedures using Cellvizio;
- Obtained 510(k) regulatory clearance from the FDA in the United States for the use of the Cellvizio in urology. This approval in urology expands the technology's range of medical applications beyond the areas of gastroenterology and pulmonology;
- Received regulatory approval to market the Cellvizio and miniprobes in Japan across several medical



specialties. Currently, Japan is the world's second largest market for medical devices and is the most innovative country in endoscopy;

• 510(k) regulatory clearance was granted in the United States for a new Cellvizio system using an infrared wavelength, a significant step forward in the company's "products" roadmap. The Cellvizio 785 nm technology opens new possibilities for microscopic imaging inside the human body.

## **Commercial expansion**

- Cellvizio was installed in three important private French clinics: Polyclinique Bordeaux Nord Aquitaine, Polyclinique Courlancy in Reims and the Arnault Tzanck Institute in Saint-Laurent du Var. These clinics are performing optical biopsy in gastroenterology, pulmonology and urology indications;
- The first Cellvizio system was installed in India at the Apollo Gleneagles Hospital in Kolkata, the flagship hospital for gastroenterology in India and a member of the Apollo Hospitals Group;
- Cellvizio was installed in three leading Brazilian hospitals in São Paulo, Rio de Janeiro and Porto Alegre.
   Concurrently, the company obtained marketing authorization from the Brazilian health authority ANVISA for AQ-Flex™ miniprobes for EUSFNA procedures in the pancreas and UroFlex™ for urological applications;
- On July 1, 2014, the Company appointed Sophie Baratte to the newly created position of Chief Commercial Officer. Ms. Baratte brings 25 years of experience marketing and selling medical devices and will be responsible for the execution of the company's commercial strategy as well as strengthening its marketing efforts.

### Clinical results and conferences: the medical value of optical biopsy

- Another successful International Conference of Cellvizio Users (ICCU) was held in April 2014, with more
  than 260 practitioners attending to discuss the advantages of the Cellvizio in various clinical indications.
  As part of this event, optical biopsy medical training sessions were set up in various countries and a
  complete accreditation program was implemented on the online Cellvizio training platform;
- Continuation of an extensive scientific program during the 2014 Digestive Disease Week (DDW), with more than 40 studies presented on the classification of indeterminate biliary strictures, the interpretation of images and the use of probe-based confocal laser endomicroscopy.

Next press release: third-quarter 2014 sales on October 15, 2014.

#### **About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. The company's flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers with high-resolution cellular imaging of internal tissues. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with practically all endoscopes. Cellvizio has 510(k) clearance from the United States Food and Drug Administration and CE Marking in the European Union for use in the gastrointestinal tract and the urinary and respiratory systems, for endoscopic exploration of the biliary and pancreatic ducts, and for fine-needle aspiration procedures. Cellvizio also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For further information on Mauna Kea Technologies, visit www.maunakeatech.com



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