# MAUNA KEA TECHNOLOGIES REPORTS FULL-YEAR 2012 RESULTS IN LINE WITH EXPECTATIONS

# 2012 sales grew 76% to €8.8 million Growth of operating expenses slowed in the second half of 2012 Company ended year with strong cash position at €37.6 million Gross margin reached record 69%

**PARIS (March 26, 2013)** – Mauna Kea Technologies (NYSE Euronext : MKEA, FR0010609263), leader in the optical biopsy market and developer of Cellvizio<sup>®</sup>, the fastest way to see cancer, today announced its full financial results for the 12 months ended December 31, 2012.

Thousands of euros (€) – IFRS	December 31, 2012	December 31, 2011
Revenue		
Sales	8,810	5,016
Other Revenue	1,472	960
Total Revenue	10,282	5,976
Operating Expenses		
Cost of Goods Sold	(2,705)	(1,583)
Gross Margin	69%	68%
Research & Development	(3,262)	(2,291)
Sales & Marketing	(12,527)	(6,281)
Overhead	(3,684)	(3,271)
Share-based Payments	(1,073)	(654)
Total Expenses	(23,251)	(14,079)
Operating Income (Loss)	(12,969)	(8,103)
Net Earnings (Loss)	(13,056)	(7,909)

# Fiscal Year 2012 Sales Up 76%

Fiscal year 2012 sales grew by 76% to €8.810 million. Sales of Cellvizio<sup>®</sup> to hospitals and clinics, the company's key target market, grew by 69% to €7.461 million in 2012, while Cellvizio sales for preclinical research more than doubled to €1.349 million, an increase of 129%.

The breakdown of 2012 sales by product type and geography highlights strong growth in equipment sales (sales of Cellvizio systems) and consumables (sales of multi-use confocal miniprobes used with Cellvizio systems), which increased 82% and 96% to  $\leq 6.172$  million and  $\leq 2.003$  million, respectively.

Sales in the Americas region accounted for nearly half of the company's sales (48%), while the EMEA (Europe, Middle East and Africa) and APAC (Asia-Pacific) regions constituted 36% and 16% of sales, respectively.



Other revenues totaled  $\pounds$ 1.472 million, driven mainly by grants associated with the company's collaboration under the PERSEE project and  $\pounds$ 0,975 million in research tax credit.

As of December 31<sup>st</sup>, 2012, Mauna Kea Technologies has an installed base of 283 Cellvizio systems worldwide with 185 in hospitals and clinical care facilities and 98 in pre-clinical research facilities. At year-end, 102 Cellvizio systems were installed in North America, including 95 in the United States, while 142 systems have been installed in EMEA, 38 systems in APAC, and one system in Latin America.

# Gross margin reaches a record high

Gross margins continued to improve, reaching a record 69% in 2012, compared to 68% and 65% in 2011 and 2010, respectively. The increase is largely attributable to an increase in the average selling price of systems and miniprobes.

	H2 2012	H1 2012	H2 2011	H1 2011
Sales (€ million)	5.3	3.5	3.2	1.8
Sequential Growth	50.4%	10.1%	75.6%	-
OPEX (€ million)	12.1	11.1	8.6	5.4
Sequential Growth	9.3%	28.3%	59.7%	-

# Sales Growth Significantly Outpaces Sequential Increase in Operating Expenses

The company finished recruiting its direct sales forces for the United States and France early in the second half of 2012. Consequently sequential growth in operating expenses began to slow in comparison to sequential sales growth in the second half of the year.

The company ended the year with a net loss of  $\leq 13.056$  million. As of December 31, 2012, the company reported cash and cash equivalents of  $\leq 37.6$  million. Mauna Kea Technologies had 121 employees as of December  $31^{st}$ , 2012 compared to 88 employees at the end of 2011.

"Optical biopsy is becoming established as a standard of care in gastroenterology and in other disciplines, paving the way for better care for patients," Sacha Loiseau, Chief Executive Officer of Mauna Kea Technologies, stated. "The healthy growth in Cellvizio system and miniprobe sales – in spite of the very bleak global business environment – reflects the medical community's adoption of the technology as a vital tool to improve the diagnosis and treatment of patients with many of the world's most common diseases. The investments we made in our commercial organization at the beginning of 2012, coupled with the growing body of clinical data and positive reimbursement milestones in the U.S. have helped us lay a strong foundation for success in our key markets. We continue to manage our substantial cash resources while delivering on our goals to increase the utilization of optical biopsies across clinical applications and regions around the globe."



# **Recent Developments and Highlights**

# **Record Number of Cellvizio Studies Published in 2012**

- Over 66 papers on the benefits of optical biopsies across indications were published.
- Publications during 2012 supported the use of Cellvizio in new applications including needlebased procedures in the pancreas and stomach cancer.
- Additionally, gastroenterologists in Japan and Germany used Cellvizio to view the enteric nervous system of the digestive tract during an endoscopy procedure for the first time. Study findings were published in the November 2012 issue of *Gastroenterology*, the leading medical journal in the digestive field.
- There was also an increase in publications validating the use of Cellvizio optical biopsies for irritable bowel disease (IBD) and syndrome (IBS), Barrett's Esophagus (BE), colorectal diseases, and cancers of the bile and pancreatic ducts.

# **U.S. Reimbursement Highlights**

• On January 1<sup>st</sup> 2013, new Category I CPT codes for the use of Cellvizio in the digestive tract were implemented. Payment from Medicare/Medicaid for these codes had been established at \$927 per procedure. The company recently launched an information and support initiative to help its customers obtain coverage from private insurers.

#### **Cellvizio Optical Biopsy Probe CE Marked For Urological Applications**

• In December 2012, the company's Cellvizio optical biopsy probe for urological applications received CE mark approval for use during cystoscopy procedures in Europe. First indication will be bladder cancer surveillance.

#### Regulatory Clearance in Brazil, Canada, Turkey, Russia, and China

- In December 2012, Mauna Kea Technologies received regulatory approval for Cellvizio from the State Food and Drug Administration (SFDA) in China. The company has a strategic partnership with FUJIFILM (China), for the expansion of Cellvizio optical biopsy distribution throughout China.
- The company received regulatory clearance in Brazil in June 2012 to sell its Cellvizio 100 Series optical biopsy system throughout the country, which is the largest medical device market in South America.
- In 2012, the company also received regulatory clearance from Health Canada, the Canadian Federal department responsible for medical device approval, the Turkish Ministry of Health, and the Russian Ministry of Health to sell both the Cellvizio 100 optical biopsy system and the AQ Flex 19 miniprobe throughout Canada, Turkey, and Russia. These countries are among the most dynamic medical device markets in the world.

#### Company Reports First Cellvizio System Sales in Japan, World's Second Largest Healthcare Market

 At the beginning of 2013, physicians at Japanese medical schools, including the Hirosaki University Graduate School of Medicine in Aomori, have acquired two Cellvizio systems to better understand stomach, pancreatic and esophageal cancers, as well as common functional gastrointestinal and motility disorders such as irritable bowel syndrome (IBS), gastro esophageal reflux disease (GERD) and chronic constipation.



#### **Revolutionary Cellvizio Dual Band Color Lab Imaging System Launched**

 Cellvizio Dual Band, launched September 2012, incorporates color into the state-of-the-art molecular imaging system that allows researchers to visualize both structural and functional information of tissue inside animals' bodies in real time.

#### Next Quarterly Financial Press Release: 2013 First Quarter Sales, April 16, 2013 (post-market)

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

Mauna Kea Technologies is a global medical device company dedicated to the advent of optical biopsy. The company researches, develops and markets innovative tools to visualize and detect cellular abnormalities during endoscopic procedures. Its flagship product, Cellvizio<sup>®</sup>, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers high-resolution cellular views of tissue inside the body. Large, international, multicenter clinical trials have demonstrated Cellvizio's ability to help physicians more accurately detect early forms of disease and make treatment decisions immediately. Designed to improve patient outcomes and reduce costs within a hospital, Cellvizio can be used with almost any endoscope. Cellvizio has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use in the GI tract, biliary and pancreatic ducts and lungs. For more information on Mauna Kea Technologies, visit <u>www.maunakeatech.com</u>

<u>United States</u> Erich Sandoval Tel: +1 917 497 2867 esandoval@lazarpartners.com France and Europe NewCap. Investor Relations and Financial Communication Pierre Laurent / Florent Alba Tel: +33(0)1 44 71 94 94 maunakea@newcap.fr

> MKEA LISTED NYSE EURONEXT

Mauna Kea Technologies Eric Cohen Vice President, Finance Tel: + 33 1 70 08 09 86 eric@maunakeatech.com

#### Disclaimer

This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in Mauna Kea Technologies ("the Company") in any country. This press release contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. Unfavorable developments in connection with these and other risks and uncertainties described, in particular, in the Company's prospectus prepared in connection with its IPO and on which the French Autorité des marches financiers ("AMF") granted its visa number 11-236 on June 230, 2011, could cause the Company to fail to achieve the objectives expressed by the forward-looking statements above.