# **FULL-YEAR 2013 RESULTS IN LINE WITH EXPECTATIONS**

- Full-year 2013 sales up 13%
- Full-year gross margin of 70%
- Rigorous cost control and stabilization of operating expenses
  - Significant reduction in cash burn

# Growth in Q1 2014 revenue: +21% to €2.2 million

Strong momentum in Clinical sales up 35%

**PARIS, April 9, 2014** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), leader in the field of optical biopsy, today reported its results for the year ended December 31, 2013, approved by the Board of Directors at its meeting on April 9, 2014, and its first-quarter sales for the three months to March 31, 2014.

Eric Cohen, Vice-President Finance of Mauna Kea Technologies, said: "In 2013, Mauna Kea Technologies posted sales growth of 13% while cutting operating expenses and significantly reducing its cash burn. Our full-year gross margin was stable at 70%. Over the first quarter of 2014, Clinical sales were up 35% and sales of Consumables were up 38%. Our growth rates are now back at a level that is more in keeping with our expectations. »

## **2013 RESULTS**

€ thousands – IFRS	Dec. 2013	Dec. 2012
Operating income		
Sales	9,977	8,810
Other revenue	939	1,472
Total revenue	10,915	10,282
Operating expenses		
Cost of goods sold	(3,042)	(2,705)
Gross margin	70%	69%
Research & development	(3,611)	(3,262)
Sales & marketing	(11,174)	(12,527)
General & administrative	(3,759)	(3,684)
Share-based payments	(851)	(1,073)
Total expenses	(22,437)	(23,251)
Operating result	(11,521)	(12,969)
Net profit / (loss)	(11,516)	(13,056)

#### Growth in 2013 sales: 13%

Full-year 2013 sales were €9,977 thousand (+13%). Sales to hospitals and clinics (use of Cellvizio® in care facilities) grew to €8,036 thousand (+8%). Sales to pre-clinical research facilities increased sharply to €1,941 thousand (+44%).

The breakdown of sales by product and by type shows slower growth in equipment (+11% to €6,835 thousand) than in consumables (+30% to €2,603 thousand). The geographical breakdown of 2013 sales is as follows: the Americas represented almost half of sales (45%), compared with 30% and 25% respectively for EMEA (Europe, Middle East and Africa) and APAC (Asia-Pacific), whose share was 9 percentage points higher than in 2012 thanks to strong momentum in China.

"Other revenue" totaled €939 thousand (compared with €1,472 thousand), mainly comprised of grants under the PERSEE robotic surgery program and a research tax credit in the amount of €732 thousand.

As of December 31, 2013, Mauna Kea Technologies had an installed base of 356 Cellvizio systems worldwide, of which 245 in care facilities and 111 in pre-clinical research facilities. At the end of 2013, 123 Cellvizio systems were installed in North America, (including 114 in the United States), 166 in EMEA, 60 in APAC and 7 in Latin America.

## Gross margin of 70%, an all-time high

The gross margin was 70%, its highest level since Mauna Kea Technologies was founded, compared with 69% and 68% in 2012 and 2011 respectively.

## Stabilization of operating expenses

	H2 2013	H1 2013	H2 2012	H1 2012
Sales (€ million)	5.7	4.3	5.3	3.5
Sequential change	+30.9%	-18.9%	+50.4%	+10.1%
Operating expenses (€ million)	11.2	11.2	12.1	11.1
Sequential change	+0.5%	-7.8%	+9.3%	+28.3%

Mauna Kea Technologies continued its policy of rigorous management of operating expenses, which were cut by 4% on an annual basis to €22,437 thousand (compared with €23,251 thousand). The Group continued its efforts in innovation, while at the same time cutting Sales & Marketing expenses, its biggest expense item, to €11,174 thousand (-11%). Operating result was in line with the Group's expectations at €(11,521) thousand.

The net result for the year was €(11,516) thousand.

In 2013, Mauna Kea Technologies also substantially reduced its net cash burn by approximately €4.7 million to €9.8 million (compared with €14,5 million in 2012), on available cash of €27.8 million as of December 31, 2013 (compared with €37.6 million as of December 31, 2012).

Mauna Kea Technologies' workforce totaled 112 employees as of December 31, 2013 (compared with 121 as of December 31, 2012).

#### **Q1 2014 SALES**

€ thousands	Q1 2014	Q1 2013	Change (%)
IFRS	March 31, 2014	March 31, 2013	
Sales	2,164	1,784	+21%

## Growth in first-quarter 2014 revenue: 21%

# By activity: strong momentum in Clinical sales

First-quarter 2014 sales totaled €2,164 thousand (+21%), driven by strong momentum in the Clinical activity, where sales totaled 1,941 thousand (+35%), while the Pre-clinical activity fell to €223 thousand (-35%). Revenue generated by sales to care facilities accounted for 90% of activity during the quarter, compared with 10% for pre-clinical sales.

#### By product and by nature: further robust growth in probes

Analysis of change in sales by product and by type highlights strong growth in sales of consumables to €590 thousand (+38%). Equipment sales increased to €1,383 thousand (+19%), and services sales were stable at €192 thousand (-1%).

By volume over the quarter, the company sold 16 systems and 157 probes (vs. 11 and 125 respectively in Q1 2013), representing growth of 45% for systems and 26% for probes. The net installed base of Cellvizio systems in hospitals and clinics increased by 15 in the three months to March 31, 2014, and the total installed base, including pre-clinical systems, was 372 at the end of the quarter.

## By geography: revenue doubled in EMEA

The geographical breakdown of quarterly sales highlights the performance in EMEA, which increased to €601 thousand (+105%) as a result of strong results in France. Sales increased to €999 thousand (+23%) in the Americas, and fell to €564 thousand (-17%) in APAC. The Americas, EMEA and APAC accounted for 46%, 28% and 26% of first-quarter 2014 sales respectively.

Sacha Loiseau, CEO of Mauna Kea Technologies, said: "2013 was marked by significant progress in the adoption and development of our range of products, with the launch of the AQ-Flex probe for the characterization of pancreatic cysts. In terms of business development, we reconstructed our sales force in the United States, our biggest market, and made a promising start in Asia, particularly in China, which has tremendous potential for growth. The clinical value of optical biopsy using Cellvizio is now established and acknowledged in several gastroenterology indications, allowing us to be confident in our continued growth."

## 2013: a year of achievements laying the foundations of optical biopsy worldwide

# Regulatory approval and commercial expansion

- CE marking for a full range of urology probes: CE marking for a third dedicated probe, forming a complete range of products presented for the first time at the French Congress of Urology, which brings together more than 2,000 practitioners.
- Signing of an exclusive five-year distribution partnership for Cellvizio with AMCO Inc. in Japan. This agreement was a key step forward in obtaining clearance to sell Cellvizio in the world's second-biggest market for endoscopy equipment after the United States.

- Marketing approval for the AQ-Flex™ 19 miniprobe for fine-needle aspiration procedures in the United States by the Food and Drug Administration (FDA). This miniprobe, already marketed in Europe, where it has obtained the CE marking, allows the realization of real-time optical biopsies during fine-needle cytopunction procedures under Endoscopic Ultrasound (EUS) in very important areas such as the pancreas, particularly cysts and pancreatic masses.
- Signing of several distribution agreements for Cellvizio LAB (pre-clinical research), continuing the expansion of the distribution network in North America (Quorum Technologies), Taiwan, Italy, Israel and Eastern Europe.

# Continued efforts in innovation and clinical progress

- Signing of a partnership agreement with Imperial College London to advance optical biopsy using Cellvizio:
  this partnership focuses on the development of new software features to be used with the Cellvizio
  platform. The initiative aims to develop new imaging possibilities to improve optical biopsy procedures
  and make them completely intuitive for practitioners, regardless of their specialty.
- Launch of the first endomicroscopy virtual assistant (EVA), a unique optical biopsy operating system that transforms the use of Cellvizio.
- Significant presence of Cellvizio at several major gastroenterology conferences: 30 presentations
  dedicated to the benefits of optical biopsy at the United European Gastroenterology Week in Berlin, the
  annual meeting of the American College of Gastroenterology in San Diego, and the Japanese Digestive
  Disease Week in Tokyo.
- Presentation of the results of 13 new studies on the value of optical biopsy using Cellvizio in many key indications including diagnosis of pancreatic cysts and cancer of the stomach.
- Registration of endomicroscopy with Cellvizio by the German Institute for Medical Documentation and Information in the final 2014 list of OPS codes for the reimbursement of associated medical and surgical procedures. This code became effective on January 1, 2014, and applies in all German hospitals offering optical biopsy.
- Initiation of a major study in several leading specialized centers in the United States to measure the
  impact of Cellvizio in the diagnosis of lung cancer. Existing studies have shown that images of lung cells
  obtained with Cellvizio can extend the scope and diagnostic accuracy of bronchoscopy procedures,
  thereby reducing the need for expensive and invasive procedures.

# **Recent events**

## Installation of three Cellvizio systems in Brazil

April 2014: Three leading Brazilian hospitals in São Paulo, Rio de Janeiro and Porto Alegre now offer their patients optical biopsy using Cellvizio. The Group has also obtained marketing authorization from ANVISA, the Brazilian health authority, for its AQ-Flex™ miniprobes for echo-puncture procedures in the pancreas and Uroflex™ for urological applications.

#### Installation of Cellvizio in three prestigious private hospitals in France

March 2014: Three prestigious private hospitals in France, Polyclinique Bordeaux Nord Aquitaine, Polyclinique Courlancy in Reims and Institut Arnault Tzanck in Saint-Laurent du Var, now offer optical biopsy using Cellvizio to patients in their region, in gastroenterology, pulmonology and urology.

# 510(k) clearance in the United States for use of Cellvizio in urology

March 2014: Optical biopsy using Cellvizio has now been approved in the United States for a variety of applications in urology, in particular for imaging the bladder during cystoscopy procedures, as well as the ureter, in which traditional biopsies are difficult to perform and inefficient.

# Installation of the first Cellvizio system in India

February 2014: Installation of Cellvizio, at the Apollo Gleneagles Hospital in Kolkata, a leading hospital in gastroenterology in India, part of the Apollo Hospitals group.

# Establishment by the American health authorities of reimbursement for practitioners for use of Cellvizio in the upper gastrointestinal tract

January 2014: The new schedule established by the health authorities in the United States provides for reimbursement of practitioners in the range of \$149-186 per medical procedure under CPT codes for optical biopsy procedures in the upper gastrointestinal tract using Cellvizio.

Next press release: Second-quarter 2014 sales on July 16, 2014.

Mauna Kea Technologies confirms that it is eligible for the PEA-PME tax arrangement (French equity investment account for small and medium enterprises), the implementing decree of which was published in the Official Journal of the French Republic (Journal Officiel) on March 4, 2014 (Decree No. 2014-283). The new accounts enjoy the same tax advantages as the conventional equity investment account (PEA), on the condition that 75% of funds are invested in the securities of small and medium enterprises, 50% of which in shares, up to a maximum amount of  $\[ \in \]$ 75,000.

#### **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 for real-time visualization and detection of cellular anomalies 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. Cellvizio was designed to help physicians with their diagnosis, improve patient care, and reduce hospital costs. It can be used with virtually any endoscope. 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.

For further information on Mauna Kea Technologies, visit <u>www.maunakeatech.fr</u>

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