

Mauna Kea Technologies publishes Q1 2022 sales and its 2021 financial results

Following its 2021 restructuring, Company experiences stable U.S sales growth, including improved gross margin and anticipated reductions in operating losses

Webinar | April 21st 2022 at 7:00 pm

https://us02web.zoom.us/webinar/register/WN_KuWBx3iYSMyew6PkI3LfeA

Paris and Boston, April 21, 2022 – 5 :45 pm CEST – Mauna Kea Technologies (Euronext: MKEA), inventor of Cellvizio[®], the multidisciplinary probe and needle confocal laser endomicroscopy (p/nCLE) platform, today announced financial results (unaudited) for the year ended December 31, 2021, and its sales for the first quarter ended March 31, 2022¹.

Nicolas Bouvier, interim CEO of Mauna Kea Technologies, declares : *"At the end of 2021, we made the difficult decision to transform the Company's commercial model in order to reduce operating expenses, improve capital efficiency and increase the pace of investment in our highest potential clinical applications. Our restructuring reflected, in part, our experience over the past 5+ years in which significant operating losses failed to produce adequate returns for our shareholders". Bouvier continued, "As we enter Q2, I am grateful for the resiliency of Mauna Kea's employees and equally pleased by the early evidence that legacy Cellvizio users continue to rely on our technology to provide superior clinical care to their patients. Finally, we are encouraged to see early returns on our renewed efforts to build an expanded portfolio of clinical partners and intellectual property, including a new collaboration with On Target Labs and a major regulatory approval from the FDA in the field of molecular imaging. "*

Financial summary for the year 2021

- 2021 revenues of €7,700K, up by €1,174K, up +18% compared to 2020
- Total revenues² in 2021 at €8,539K, up by €596K, up +8% compared to 2020
- Gross margin rate in 2021 significantly improved, at 74.2% compared to 67.1% in 2020
- Current operating loss of €11,327K, reduced by €632K compared to 2020
- Non-current expenses of €891K following the announcement of the restructuring plan, bringing the operating loss to €12,218K, compared to €11,816K in 2020
- Net loss of €13,445k, down €654k from 2020
- Cash position of €11.8 million at the end of 2021 and total long-term debt of €26,9 million, compared to €8.6 million in cash and €26.2 million in long-term debt, as of December 31, 2020.

¹ This press release presents the results for the year ended December 31, 2021, based on the consolidated financial statements of Mauna Kea Technologies as of December 31, 2021 (unaudited). The audit procedures by the Statutory Auditors are in progress. The audited consolidated financial statements will be available before April 30 on the maunakeatech.com website.

² Total revenue for 2021 includes €635,000 of research tax credit and €204,000 of RI PERSEE grant, compared to €711,000 of research tax credit and €615,000 of U.S. government grant in the prior period.

Estimated Consolidated financial results for the year 2021 (Unaudited) *

<i>(in K€) – IFRS</i>	2021	2020	Var, €	Var, %
Sales	€ 7 700	€ 6 526	€ 1 174	18%
Other revenues	€ 839	€ 1 416	(€ 577)	(41%)
Total Revenues	€ 8 539	€ 7 942	€ 596	8%
Cost of Goods Sold	(€ 1 989)	(€ 2 148)	€ 159	-
Gross Margin	€ 5 711	€ 4 378	€ 1 333	30%
<i>Gross Margin rate (%)</i>	<i>74,2%</i>	<i>67,1%</i>		
Research & Development	(€ 3 310)	(€ 3 232)	(€ 78)	2%
Sales & Marketing	(€ 7 620)	(€ 8 120)	€ 500	(6%)
G&A	(€ 6 399)	(€ 5 785)	(€ 614)	11%
Share-based Payments	(€548)	(€616)	€ 68	(11%)
Total operating expenses	(€ 19 866)	(€ 19 901)	€ 35	-
Current operational result	(€ 11 327)	(€ 11 959)	€ 632	-
Non current operational result	(891)	143	(1 033)	-
Operational Result	(12 218)	(11 816)	(402)	-
Financial Result	(€ 1 227)	(€975)	(€ 252)	-
Net Result	(€ 13 445)	(€ 12 791)	(€ 654)	-

*Totals may not add up due to rounding

In 2021, revenues amounted to €7,700K, an increase of €1,174K compared to the previous period, up +18%. This increase is mainly due to the increase in activity in the United States and in EMEA & ROW, which grew by +17% and +66% respectively year-on-year, offsetting the -11% decline in sales in the Asia-Pacific market.

Gross profit increased by €1,333K, or +30% year-on-year, to €5,711K from €4,378K in the previous period. The gross margin rate was 74.2%, compared to 67.1% in 2020. This improvement is mainly due to a favorable sales mix and to the increase in the selling price of new platforms with lower production costs in 2021.

Total operating expenses in 2021, excluding cost of goods sold, are stable at €17,877K compared to €17,753K in 2020. The decrease in Marketing and Sales expenses (-6%) is offset by an increase in general expenses (+11%), which are related to the payment of fees and to projects for the search for financing and other operations. In addition, the Company maintained its R&D expenses at €3,310K, a level similar to that of 2020, in order to pursue the projects carried out and in particular the commercialization of the new platform as of October 1, 2021.

The operating loss for the year 2021 is thus reduced to €11,327K, compared to €11,959K for the year 2020.

Operating result for 2021 is down slightly, by 402 K€, or -3% compared to the previous year, to -12,218 K€. This decrease is due to the recording of a non-current expense of 891 K€ following the announcement of the restructuring plan at the end of last year.

After taking into account a financial result of -1,227 K€, compared to -975 K€ in 2020, the net loss for the year 2021 amounts to 13,445 K€, compared to 12,791 K€ in 2020.

As of December 31, 2021, the Company had a cash position of €11.8 million, with long-term debt of €26.9 million, compared with €8.6 million in cash and €26.2 million in long-term debt as of December 31, 2020. The change in cash and cash equivalents during 2021 is partly explained by the net proceeds of the €11.4 million capital increase completed in September 2021 with Johnson & Johnson and the Armistice Master Fund Ltd.

The purpose of this financing is to support the development of the Cellvizio® platform, to continue clinical studies, to finance the restructuring plan initiated at the end of 2021 and to meet working capital requirements.

The company benefits from an equity line of credit with Kepler Cheuvreux, which acts as a financial intermediary, and which should enable it to raise €2.0 million³ on the market over the next 12 months.

As of December 31, 2021, the Company is in compliance with the contractual commitment under the terms of the documentation signed with the EIB, under which the Company must have at all times available cash of at least €4 million.

The Company considers that it is able to meet its future operating requirements.

Mauna Kea Technologies had 87 employees as of December 31, 2021, compared to 98 as of December 31, 2020.

Post-close highlights

- **Strategic repositioning**

In January 2022, Mauna Kea Technologies announced a Board-approved expense reduction plan with the goal of focusing financial resources to support its new strategic direction. The plan calls for reducing consolidated operating expenses by approximately 40% in 2022. Operating expenses for the first quarter of 2022 have already been significantly reduced. On the commercial side, the Company has reduced its direct sales investments in the United States and optimized its marketing and sales activities.

- **Collaboration with On Target Laboratories**

In March 2022 Mauna Kea Technologies announced a new clinical research and product development collaboration in the area of molecular imaging-guided interventions with On Target Laboratories, a privately held biotechnology company developing intraoperative molecular imaging agents to target and illuminate cancer during surgery. This collaboration was established to develop the combined clinical and technological knowledge of both companies, initially focusing on interventional pulmonology and lung cancer, with the possibility of expanding this collaboration to other indications.

- **Major regulatory milestone reached for molecular imaging and precision medicine**

On April 12th, 2022, Mauna Kea Technologies received the first FDA 510(k) clearance for the use of Cellvizio in a new class of molecular imaging-guided endoscopic, laparoscopic and needle-based procedures with On Target Labs' Cytalux molecular marker.

- **Covid-19 pandemic**

Despite the impact of the pandemic on the business, the Company was unable to benefit from government aid during the past fiscal year as it had in 2020. The health crisis continued to negatively impact the Company's business activity during the first quarter of 2022, particularly in the Asian markets.

- **Conflict in Ukraine**

Mauna Kea Technologies indicates that it has no activity or business ties with Russia or Ukraine; however, the consequences of this conflict, direct or indirect, cannot be accurately quantified at this time.

³ The shares will be issued on the basis of the volume-weighted average share price over the two trading days preceding each issue, less a maximum discount of 6.0%. These conditions allow Kepler Cheuvreux to guarantee the subscription of the shares over the duration of the contract. The estimated amount of €2 million is calculated with 3.6 million shares at €0.6, applying a 6% discount.

First Quarter 2022 sales by category :

<i>(in K€) –IFRS</i>	Q1 22	Q1 21	Var, €	Var, %
Systems	930	546	384	70%
Consumables	633	719	-86	-12%
Services	322	311	11	4%
Sales total	1 886	1 576	310	20%

**Totals may not add up due to rounding*

Revenues for the first quarter of 2022 amounted to €1,886K, up +20% compared to the previous year. First quarter sales benefited from the strong growth in systems sold, up by +70%. Sales of consumables and services were stable compared to the first quarter of 2021.

First quarter 2022 sales by geographic area:

<i>(in K€) –IFRS</i>	Q1 22	Q1 21	Var, €	Var, %
United States	1 396	649	746	115%
Asia Pacific	29	444	-415	-93%
EMEA & ROW	461	483	-22	-4%
Total Sales	1 886	1 576	310	20%

**Totals may not add up due to rounding*

The evolution of sales by region for the first quarter of 2022 reflects a 115% increase in sales in the United States, including certain catch-ups from the end of 2021. In Asia, activity was strongly penalized by Covid-19 and the various confinements put in place in this zone. In Europe, sales momentum was slightly below that recorded in Q1 2021.

First quarter 2022 unit sales:

UNITS (#)	Q1 22	Q1 21	Var%
NEW SYSTEMS SOLD	7	6	17%
NEW SYSTEMS PLACED	0	7	-100%
TOTAL SYSTEMS	7	13	-46%
PROBES DELIVERED	91	146	38%

Cellvizio system shipments declined 46% year-over-year to 7 units in Q1 2022, compared to 13 total shipments in the prior period. First quarter 2022 shipments include 7 new systems sold and no new system placements with U.S. customers. Deliveries of consumable probes declined 38% year-over-year in Q1 2022.



Financial calendar : Second quarter 2022 sales, July 21, 2022 after market close.

The 2021 annual financial report will be available before April 30, 2022 on the company's website.

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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Mauna Kea Technologies

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