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What We Do

We help clinicians secure their decisions and achieve better outcomes with our Cellvizio® real-time in vivo cellular imaging platform, with applications in interventional pulmonology, gastroenterology, and molecular image-guided surgery.



Our Mission: Transforming Interventional Cancer Care with Cellvizio®

Mauna Kea Technologies is a global medical device company that has developed and commercialized Cellvizio[®], a proprietary platform supported by 250 issued patents, 20 FDA 510(k) clearances, broad CE mark, and regulatory clearances in China, Japan, and Korea.

Cellvizio enables in vivo cellular imaging in real time for the identification and precise targeting of suspicious abnormal cells during interventional procedures

Leading use cases include:

- Visualization of intraoperative molecular imaging agents
- Definitive classification of pancreatic cysts
- Interventional gastroenterology procedures

- Lung cancer diagnosis and staging, including during robotic-assisted bronchoscopy





Cellvizio[®] in vivo cellular imaging platform

Cellvizio is the **real-time in vivo cellular imaging platform**: The only technology in the world that delivers visualization with the clarity of extremely high-magnification and has the flexibility to access virtually any part of the human body through interventional endoscopy/bronchoscopy procedures.





Portfolio of Miniprobes

- Plug-and-play device made of tens of thousands of optical fibers
- Proprietary architecture and function
- Compatible with any endoscope and standard reprocessing method
- AQ-Flex[™] is a 0.9 mm miniprobe that fits inside a 19 gauge transbronchial needle





Cellvizio[®] Reveals Key Invisible Information

Cellvizio is a breakthrough advanced imaging platform...





...providing real-time microscopic information

...proven to help physicians make a transformative change in how they diagnose and treat patients

Cellvizio®



Mauna Kea Technologies



Creating Value in Three Large Healthcare Markets



Key development focus, strategic partnership with the Lung Cancer Initiative (LCI) at Johnson & Johnson

> Fluorescence guided surgery partnership with Telix Pharmaceuticals Endoluminal intervention partnership for lung cancer with On Target Laboratories, Inc.

Current global in-market activity with optimized commercial resources





Addressing a Critical Unmet Need in Lung Cancer Detection





Cellvizio Needle-based Cellular Imaging is Giving Sight to Blind Needles



- Easy to use
- Compatible with all endoluminal platforms
- Quickly becoming a must-have for interventional pulmonologists





Cellvizio Needle-based Cellular Imaging is Giving Sight to Blind Needles

With Cellvizio[®], you can target and visualize from the inside of the nodules³.

1. Manley C, Kramer T, et al. Needle based confocal laser endomicroscopy for the diagnosis of peripheral lung nodules by robotic navigational bronchoscopy. ERS 2021



Cellvizio guidance resulted in repositioning the needle in 35% of robotic-assisted bronchoscopy cases based on an initial study led by Dr. Christopher Manley at Fox Chase Cancer Center¹







Early and Efficient Detection of Lung Cancer Has Been an Elusive Goal



Navigation to a lung nodule is difficult and imprecise Endoluminal robotics platforms can help with navigation and access However, they provide no direct visualization for the 80% of nodules outside the airways

1. Heuvelmans, A. Et al. Relationship between nodule count and lung cancer probability in baseline CT lung cancer screening: the NELSON study. Lung Cancer, 2017. 2.Ost D.E. et al. Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions. Results of the AQuIRE Registry. Am J Respir Crit Care Med, 2017. 3. Gildea, T. et al., 2017. A retrospective analysis of delays in the diagnosis of lung cancer and associated costs. Clinicoecon Outcomes Res, May. pp. 261-269.



Biopsy needles are used to blindly poke through the airway wall, resulting in poor diagnostic yield varying from 38.5% to **63.7%**²

More than 90% of patients have a long delay (5–6 months) before receiving a definite diagnosis of lung cancer³





Pursuing a \$1.3B U.S. Addressable Revenue Opportunity

Lung Cancer / Lung Nodules

management with Cellvizio

technologies

capital purchases

Global Burden of Disease Cancer Collaboration JAMA Oncol. 2017, Yale Medicine, GLOBOCAN 2018, European Respiratory Society, Wells Fargo Securities Global Research Department, Internal analysis

\$1.3B

Addressable

Market

Opportunity

- Est. 275,000 lung biopsy procedures in the U.S. annually
- Targeting better diagnostic yield, diagnostic accuracy, and therapeutic
 - Biopsies are performed either via robotic-assisted bronchoscopy or manual bronchoscopy, with or without ancillary navigation or imaging
 - All of these technologies, including robotic platforms, can leverage Cellvizio to drive improved clinical and patient outcomes

\$1.3B TAM is comprised of \$360M recurring revenue and \$950M for





Cellvizio Placements and Utilization Steadily Growing in Interventional Pulmonology Facilities Across the U.S.



Monarch® is a registered trademark of Auris Health, Inc., a subsidiary of Ethicon, Inc. Ion® is a registered trademark of Intuitive Surgical.



Building Momentum in Interventional Pulmonology

FDA 510(k) Clearance of AQ-Flex[™] 19 Probe for Use with Transbronchial Needles

Strategic Equity Investment of €7.5M by Johnson & Johnson Innovation

> January 2020

January 2019

Clinical Study

Publication in European Respiratory Journal Demonstrating Accuracy of nCLE for Lung Cancer Diagnosis

Publication in Respiration Highlighting Value of nCLE and Robotic-Assisted Publication in *Thorax* Bronchoscopy Highlighting nCLE as a **Real-Time Detection** Tool for Lung Cancer Start of Enrollment in January **CLEAR** peripheral lung 2022 cancer multi-center clinical trial Strategic Equity January Investment of €6M by 2021 Johnson & Johnson Innovation Completion of Enrollment in Robotic-Assisted Bronchoscopy Start of Enrollment in + nCLE Clinical Study **Robotic-Assisted** Bronchoscopy + nCLE





Molecular Imaging with Cellvizio®





Molecular Imaging (MI): Illuminating Cancer with Cellvizio® and Novel Molecular Compounds

Rooted in nuclear medicine procedures for the past few decades, MI has now translated to other modalities including fluorescence imaging

MI transcends the requirements for, and limitations of, non-specific fluorescence imaging by specifically targeting cancer cells

MI's applications are wide ranging and include :

- reducing surgery positive margin rates (prostate, kidney, brain, etc.)

- real-time characterization of suspicious lesions for single-procedure interventions (lung nodules, lymph nodes, and more)



Cellvizio is the only (regulatory-cleared) platform that can illuminate highly specific molecular compounds in vivo during endoluminal procedures







Molecular Imaging Partnerships and Timeline

Mauna Kea and Telix Pharmaceuticals have formed the IRiS Alliance for precision surgery

Our goal is to create a unique advanced imaging platform to empower surgeons in order to reduce positive margin rates and improve surgical outcomes for prostatectomies and nephrectomies patients among other applications



Mauna Kea and On Target Laboratories, Inc. have formed a clinical research and product development collaboration for interventional bronchoscopy

Our first goal is to explore and establish the value of molecular image-guided procedures for the identification and diagnosis of lung cancer







Mauna Kea Technologies

Breaking News: First of Its Kind U.S. FDA 510(k) Clearance

laparoscopic, and needle-based procedures

- Pioneering category of medical procedures: MIP (molecular image-guided procedures)
- Designed to provide Cellvizio the unique clinical ability to visualize tissues to which the molecular agents bind
- Allows the potential for real-time visualization of cancer at the cellular level during minimally invasive interventions

Cellvizio[®] now cleared for use in a new category of molecular imaging-guided endoscopic,







Interventional GI with Cellvizio®





U.S. Interventional GI Strategy: Targeting High-Volume Upper GI Physicians

Total U.S. Upper GI Market



- 14,700 GI physicians across a range of gastrointestinal specialties
- 3,400+ facilities

Targeting 1,500 GI physicians with high volume of upper GI biopsies (EGDs) and high mix of Medicare patients

1,100 facilities

Definitive Healthcare 2018 procedure data; CMS.gov 2018 public data; Cellvizio annual recurring revenue opportunity based on 550,000 annual EGD with biopsy procedures multiplied by per-procedure cost; Association of American Medical Colleges physician data; Internal analysis

Cellvizio Targeted Growth Strategy



Compelling Annual Recurring Revenue Opportunity

\$2.2B TAM

\$220M

Annual Recurring Revenue



Business Model and Value to the Market

models including pay-per-use models in the U.S. relationship

New market opportunities are supported through strategic partnerships physicians

Cellvizio adds value at every step of the patient journey in 4 distinct applications:

MONITOR

the progression of disease over time

CLASSIFY

indeterminate areas of concern

- Cellvizio consists of capital (system) and disposables (reusable probes), with flexible acquisition
- Depending on geography, customers are supported via a direct sales team or through a distributor
- Within the U.S., the Company maintains \sim 90 active accounts as of the end of 2021, the majority of which have been added as part of a new U.S. commercial strategy targeting 1,500 high volume GI



ASSESS

point-in-time reactions as they happen in real time

GUIDE

surgical interventions





Robust Level I Clinical Data Drives Compelling Reimbursement



Over 1,000 Clinical Studies and Publications Validating Technology

Demonstrated Significant Increase in Diagnostic Performance as an Adjunct to Standard of Care

• Improve diagnostic yield to reduce sampling error • **Double the sensitivity** vs. HD-WLE and NBI alone • Triple the detection of dysplasia vs. HD-WLE and random biopsies Increase accuracy of differentiating malignant and benign lesions up to 97%





Strong Medical Society Backing

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) TAVAC Endorsement "CLE can increase diagnostic performance across gastrointestinal endoscopic indications compared to current standard of care, such as improving diagnostic yield for chronic GERD, Barrett's Esophagus, early gastr cancer, gastric intestinal neoplasia, pancreatic cystic lesions, indeterminate biliary strictures, and IBD."

American Society of General Surgeons (ASGS) Position Statement

Supports the use of CLE for the comprehensive assessment of patients who are at risk for Barrett's esophagus as well as being integral to the comprehensi assessment of patients suffering from gastroesophagea reflux disease

College of American Pathologists (CAP) In Vivo Microscopy (IVM) for the Evaluation of BE BE patients can be better served if biopsies are more targeted; CLE can help target higher yield and more diagnostic sites

1. Al-Mansour M R et al. SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy. Surg Endosc. (2020) doi: 10.1007/s00464-020-07607-3. 2. AFS Position Paper (2019). Confocal Laser Endomicroscopy for Barrett's diagnosis and surveillance, available at: https://www.americanforegutsociety.org/ wp-content/uploads/sites/21/2021/04/AFS-Position-paper-CLE.pdf Accessed May 10, 2021. 3. ASGS review of Confocal Laser Endomicroscopy, available at: https://theasgs.org/position-statements/position-statements/position-statement-on-confocal-laser-endomicroscopy/. Accessed May 10, 2021. 4. Sharma P et al. White Paper AGA: Advanced imaging in Barrett's Esophagus. Clinical Gastroenterology and Hepatology (2015). 5. CAP IVM Resources. Available at https://www.cap.org/member-resources/councils-committees/in-vivo-microscopy-committees/in-vivo-microscopy-topic-center. Accessed May 10, 2021.



ric	American Foregut Society (AFS) Position Paper "Cellvizio is integral to the comprehensive assessment of patients suffering from reflux disease. This technology fills a much needed diagnostic gap in patients at risk for Barrett's esophagus and/or have Barrett's."
n ive al	American Gastroenterological Association (AGA) White Paper "workshop panelists agreed that in the hands of endoscopists who have met the preservation and incorporation of valuable endoscopic innovation thresholds (diagnostic accuracy) with enhanced imaging techniques (specific technologies), use of the technique in Barrett's esophagus patients is appropriate."



Mauna Kea Technologies







Commercial Metric: Cellvizio[®] Consumable and PPU Revenue

Utilization of Cellvizio continues to increase globally each year U.S. consumable (probe) and PPU revenue demonstrate adoption of Cellvizio in the targeted market segment Case volumes have been impacted at various times in 2020 and 2021 as a result of the COVID-19 pandemic and its effect on elective procedures Revenue in 2021 grew vs. prior years as the U.S. commercial organization worked to compensate for elective procedure decline by leveraging next-generation Cellvizio system sales



All figures in € thousands © 2022 Mauna Kea Technologies









Strategic Outlook







Strategic Outlook

Mauna Kea Technologies' unique in vivo cellular imaging platform addresses key unmet needs in medicine and surgery The Company has established key strategic relationships addressing large market opportunities following years of clinical and product development efforts

Steps taken in Jan. 2022 to extend cash runway, enabling Company to deliver on strategic objectives

Future milestones :

Further demonstrate Cellvizio's value in robotic-assisted and manual endoluminal procedures

Secure additional strategic relationships aligned with large market opportunities

Continue to enhance product features within the nextgeneration Cellvizio platform





Sales and Financial Performance FY 2021 & Q1 2022





2021 Sales and Revenue





Q1 2022 Sales

By Category

In €k – IFRS standards	Q1 2022	Q1 2021	Δ vs. N-1	%Δ
Systems	930	546	384	70%
Consumables	633	719	(86)	(12%)
Services	322	311	11	4%
Total Sales	1,886	1,576	310	20%

Ramp up of the sales Systems: +70% vs. Q1 2021

Sales of Consumables decreased by 12%, whereas sales of Services slightly increased, up 4%

By Geography

In €k – IFRS standards	Q1 2022	Q1 2021	Δ vs. N-1	%Δ
				= . (
U.S.	1,396	649	746	115%
APAC	29	444	(415)	(93%)
EMEA & ROW	461	483	(22)	(4%)
Total Sales	1,886	1,576	310	20%

Good stability of sales in the US: +115% vs. Q1 2021

- Some delayed capital deals from 2021 realized in Q1 2022
- Achieved a 17% increase YOY in PPU volumes at ASCs, which is and has been Mauna Kea's primary target market

Slight decrease in Europe & ROW by 4% vs. Q1 2021

Delay of the renewal of a major contract (to mid-April)

Strong impact of COVID-19 in China





2021 Income Statement

In €k – IFRS standard	s 2021	2020	Δ vs. N-1	%Δ
Sales	7,700	6,526	1,174	18 %
Gross Profit	5,711	4,378	1,333	30%
% gross margin	74.2%	67.1%		
Other Income	839	1,416	(577)	(41%)
R&D Expens	ses (580)	(877)	297	34%
M&S Expens	ses (2,229)	(2,054)	(175)	(9%)
G&A Expens	ses (3,162)	(2,566)	(596)	(23%)
Total Expenses	(5,971)	(5,497)	(474)	(9%)
R&D Pay	roll (2,371)	(2,184)	(187)	(9%)
M&S Pay	roll (5,730)	(6,094)	364	6%
G&A Pay	roll (2,601)	(2,618)	17	1%
Total Payroll	(10,702)	(10,896)	194	1%
EBITDA	(10,123)	(10,599)	476	4%
D	&A (656)	(744)	88	12%
Share-based paym	ent (548)	(616)	68	11%
EBIT	(11,327)	(11,959)	632	5%
Non-current operating income	<mark>(891)</mark>	143	(1,033)	
Financial result	(1,227)	(975)	(252)	
Net profit / (loss)	(13,445)	(12,791)	(654)	

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Total sales for the 2021 full year increased by 18% year-over-year, driven by:

- The dynamic in the US (+17%) & Europe & RoW (+66%)
- Whereas the APAC region (-11%) is still impacted by the pandemic

Strong improvement of the gross margin, up 30% vs. 2020, achieving a gross margin ratio of 74.2% vs. 67.1% in 2020

Thanks to a favourable sales mix and increase in the sales price of new platforms with lower production costs in 2021

Non-current operating income of €0.9m resulting from the Corporate restructuring

Negative financial result impacted by higher impairment of the US subsidiary's advance on current account in 2021 vs. 2020 and higher financial expenses

Stable net loss at €13.4m





2021 Consolidated Balance Sheet

In €k – IFRS standards	2021	2020	In €k – IFRS standards	2021	2020
Non-current assets	6,083	6,149	Total of Equity	(10,333)	(12,077)
Intangible assets	3,371	3,072	Issued capital	1,784	1,224
Property, plant and equipement	1,233	1,451	Share premium Reserves	111,920 (110,759)	98,286 (98,504)
Right of use (IFRS 16)	1,124	1,344	Foreign currency translation		
Non-current financial assets	355	282	on reserve	168	(292)
Current assets	18,667	14,460	(Profit / (loss)	(13,445)	(12,791)
Inventories & Work in	3,013	2,687	Total non-current liabilities	27,754	26,421
progress	,	,	Long-term loans	26,899	26,242
Trade receivables	1,532	1,907	Non-curent provisions	855	179
Other current assets	2,228	1,202	Total current liabilities	7,329	6,265
Current financial assets	29	58	Short-term loans and	1,797	722
Cash and cash	11.866	8,606	borrowings	- ,	
equivalents	,	,	Trade payables	1,667	1,475
Total of assets	24,751	20,609	Other current liabilities	3,865	4,068
			Total Equity and Liabilities	24,751	20,609

Higher current assets of €18.6m resulting from:

Increase in inventories & work in progress as well as other current assets

Improvement of the Equity deficit to €10.3m (vs. €12.1m in 2020)

Capital increase by Johnson & Johnson and Armistice Capital (including a €13.6m premium issuance)

Long-term debt remained stable at €26.9m, mainly including:

- EIB loan: €19.5m
- Guaranteed loan by State: €4.0m











2021 Cash Flow Statement

In €k – IFRS standards	2021	202
Cash flow from operating activities Δ in WCR related to business activities	(9,824) (450)	(9,6 4
Cash from operations	(10,274)	(7,99
Acquisition Disposals & Δ in loans and advance payment	(1,097) (44)	(1,08 82
Cash from investments	(1,141)	(99
Free cash flows	(11,415)	(8,9
Capital increase New Loans issuance PERSEE grant Net financial interest paid Tax Credit pre financing Reimbursement of debt on lease (IFRS16) & others	14,252 - 504 (261) 711 (550)	- 10,0 - (12 (1,63 (56)
Cash from financing Cash beginning of period Cash end of period	14,656 8,606 11,866	7,68 9,98 8,60
Change in cash	3,260	(1,3

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- 76)

Increase of the cash position to €11.9m (vs. €8.6m in 2020), driven by:

- The increase in net financing cash flow (€14.7m):
 - Net proceeds of €11.4m recorded following the capital increase by Johnson & Johnson and Armistice Master Fund Ltd.

Cash position aimed at further developing Cellvizio[®], platform and clinical studies, financing restructuring plan initiated end of **2021** and working capital requirements





Corporate Information





Management Team & Board of Directors



Nicolas Bouvier *Interim Chief Executive Officer and Director, Human Resources*



Shui Gautheron Chief Financial Officer



François Lacombe, Ph.D. *Chief Scientific Officer*



Management Team

Aline Criton, Ph.D. Chief Clinical and Regulatory Affairs Officer



Frédéric Banégas, Ph.D., MBA Chief Technology Officer



Daryl Donatelli *Vice President, Global Marketing*



Bruno Villaret *Vice President, International Sales*



Cameron Lee Vice President, U.S. Sales

Novartis, Sandoz, sanef groupe

EnTrust Global, Permal Group

Astrophysics programs: ISOCAM, ADONIS, NAOS

SuperSonic Imagine, Philips Healthcare, ATL Ultrasound

Intrasense, Quantum Surgical

Boston Scientific, Bausch + Lomb (Bausch Health), Convergent Dental

Tyco, Saint-Gobain

Pentax Medical, Trinity Western Univ.



Sacha Loiseau, Ph.D., Chairman of the Board Founder of Mauna Kea Technologies



Christopher McFadden, CFA, Director *Managing Director of Kohlberg Kravis Roberts (KKR)*



Board of Director

Jacquelien ten Dam, Director Chief Financial Officer, MIMETAS



Molly O'Neill, Director *Chief Growth and Strategy Officer, Medforth Global Healthcare Education Group*



Claire Biot, Director *Vice President, Life Sciences Industry, Dassault Systèmes*



Stock Information

STOCK MARKET DATA

- Listed on Euronext Paris regulated market, Compartment C
- Initial listing: July 6, 2011
- Number of outstanding shares: 44,299,635
- Market cap: €29M

IDENTIFICATION CODES

- ISIN: FR0010609263
- Ticker: MKEA
- Bloomberg: MKEA.FP
- Reuters: MKEA.PA

ANALYST COVERAGE

GILBERT DUPONT Guillaume Cuvillier

ODDO BHF Martial Descoutures Shirihane Kouadri

SHAREHOLDERS STRUCTURE



Other Institutionals 9%

Johnson & Johnson 24%

Retail 56%







Thank You

