

Creators of Cellvizio[®] — the Real-Time In Vivo Cellular Imaging Platform

Corporate Presentation – January 2022



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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 imaging guided surgery.



Transforming Interventional Cancer Care with Cellvizio[®]

- Mauna Kea Technologies is a global medical device company that has developed and commercialized the **Cellvizio®** platform, which is FDA 510(k) cleared and CE marked
- Proprietary platform technology that enables in vivo cellular imaging in real time for the identification and precise targeting of suspicious abnormal cells during interventional procedures
- Our focus is the rapidly expanding market of Interventional Pulmonology, a \$1.3B U.S. addressable market opportunity
 - Cellvizio is positioned as a must-have complement to novel endoluminal robotics platforms
- We are currently serving the interventional gastroenterology market, a \$2.2B U.S. addressable market opportunity with applications in esophageal cancer, pancreatic cancer, and food intolerance/allergy



Management Team & Board of Directors



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Interim Chief Executive Officer and Director, Human Resources



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Pentax Medical. Trinity Western Univ.

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Management

Team



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Addressing a Critical Unmet Need in Lung Cancer Detection



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

- Navigation to a lung nodule is difficult and imprecise
 - 80% of lung nodules are located outside the airway¹
- Endoluminal robotics platforms were created to solve challenges with navigation and access

However, even with advanced technology:

- There is no direct visualization because of the location of nodules outside the airways
 - Biopsy needles are used blindly through the airway wall, resulting in poor diagnostic yield varying from 38.5% to 63.7%²
- Time to diagnosis remains too long
 - More than 90% of patients have a long delay (5–6 months) before receiving a definite diagnosis of lung cancer³

Heuvelmans, A. Et al. Relationship between nodule count and lung cancer probability in baseline CT lung cancer screening: the NELSON study. Lung Cancer, 2017.
 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.
 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.







The Solution: 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.

The Cellvizio System

Components:

Touchscreen User Interface

- Confocal Miniprobe™
- Combined Laser Scanning Unit and Confocal Processor



Cellvizi

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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 0.8 mm miniprobe that fits inside a 19 gauge transbronchial needle



Celvizio® SEE CELLS. CHANGE LIVES.

See Like You've Never Seen Before

Biopsies

- Random samples
- 1000x histology
- Ex vivo microscopic analysis

Cellvizio[®]

- Targeted biopsies
- Whole, in situ living tissue
- In vivo
- Unlimited number of images
- Differentiate "normal" vs. "areas of concern"





Endoscopy

- 30x
- Macroscopic analysis



Only Cellvizio can reveal key cellular information in real time



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



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

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







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

- Lung Cancer / Lung Nodules
 - Est. 275,000 lung biopsy procedures in the U.S. annually
 - Targeting better diagnostic yield, diagnostic accuracy, and therapeutic management with Cellvizio
 - Biopsies are performed either via robotic-assisted bronchoscopy or manual bronchoscopy, with or without ancillary navigation or imaging technologies
 - 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 capital purchases

\$1.3B

Addressable

Market

Opportunity



Business Model and Commercial Metrics





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

Total U.S. Upper GI Market

Cellvizio Targeted Growth Strategy



- 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

Compelling Annual Recurring **Revenue** Opportunity

\$2.2B TAM

\$220M

Annual Recurring Revenue

Business Model and Value to the Market

- Cellvizio consists of capital (system) and disposables (reusable probes), with flexible acquisition models including pay-per-use models in the U.S.
- Depending on geography, customers are supported via a direct sales team or through a distributor relationship
 - New market opportunities are supported through strategic partnerships
- Within the U.S., the Company maintains ~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 physicians
- Cellvizio adds value at every step of the patient journey in 4 distinct applications:



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%

Sharma P. et al. Real-time Increased Detection of Neoplastic Tissue in Barrett's Esophagus with probe- based Confocal Laser Endomicroscopy: Final Results of a Multi-center Prospective International Randomized Controlled Trial. GIE 2011. Bertani H. et al. Improved Detection of Incident Dysplasia by Probe-Based Confocal Laser Endomicroscopy in a Barrett's Esophagus Surveillance Program. Digestive Diseases and Sciences, 2013. M. Canto, et al. In vivo endomicroscopy improves detection of Barrett's esophagus-related neoplasia: a multicenter international randomized controlled trial, GIE 2013. Richardson C. et al. Real-time diagnosis of Barrett's esophagus: a prospective, multicenter study comparing confocal laser endomicroscopy with conventional histology for the identification of intestinal metaplasia in new users. Surgical Endoscopy 2018. Desai, Madhav et al. Increasing prevalence of high-grade dysplasia and adenocarcinoma on index endoscopy in Barrett's esophagus over the past 2 decades: data from a multicenter U.S. consortium. GIE 2019. Krishna SG, et al. Endoscopic Ultrasound-Guided Confocal Laser Endomicroscopy Increases Accuracy of Differentiation of Pancreatic Cystic Lesions. Clinical gastroenterology and hepatology: the official clinical practice journal of the American Gastroenterological Association. 2019.

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	confocal laser end	Cory Richardson ³ O - Paul Colavita ² - Christy Dunst ³ - John Francis Ruckley ⁷ - William Bultzapa ⁸ - Joseph Rumetto ⁴ - P	Bagnato ⁴		
	Florian Guisier ^{1,2} , Pierre Bohs ^{3,3} , I Pierre Vera ^{2,3} , Luc Thiberville ^{1,2} , M	An Thomas Wang [®] - Alvin Zfass ¹⁰ - Paul Severson [®]		Received: 14 February 2020 / Accepted: 28 April 2020 IO Springer Science +Business Media, LLC, port of Springer Nature 21	123
	1 Department of Pulmonology, Therapic C Rosen University Hospital, Rosen, France Rosen, France, Nuclear Medicine Technology	See Necessived: 10 April 2018 / Accepted: 4 September 2018 © Springer Science+-Business Media, LLC, part of Springer Nature 2018		Abstract Background Confocal laser endomicroscopy (CLE) is	a novel endoscopic adjunct that allows real-time in vivo histological
	Hospital, Rouen, Prance, 4 Cytology& Pr	m Abstract		examination of mucosal surfaces. By using intravenor musts that facilitate an optical biowy in real time. Cl	as or topical fluorescent agents. CLE highlights certain macosal cle- II to back used in different econo putation including the
	* mathieu salaun @ univ-tsuen.ht	Introduction Endoscopic evaluation with high-definition w Protocolly in the current standard of curre for the detection of R	hise light e	gastrointestinal tract. These has been numerous stadie	es evaluating this technology in gastrointestinal endoscopy, our aim
	Abstract	gies have become available to provide real-time diagnosis of tissue biopsy. Probe-based confocal laser endomicroscopy (p	intestinal m CLE) pro-	was to evaluate the safety, value, and efficacy of this is Methods. The Society of American Gastrointestinal an Committee (TAVAC) performed a PubMed/Medline d	chnology in the gastroantestnat tract. d Endoscopic Surgeons (SAGES) Technology and Value Assessment atabase search of clinical studies involving CLE in May of 2018. The
	Bestanna	capturing digital images that become optical biopsies. This s lance as compared to the Seattle Protocol.	tody exam	 literature search used combinations of the keywords: c ontical histology, advanced antiocontic imaging, and 	onfocal laser endomicroscopy, pCLE, Cellvizio, in vivo microscopy, petical diamonis. Biblio reachies of law refinances were searched for
MaxIV, Plan N, In and an olig	Background	Methods Patients undergoing BE screening or surveillance	endescopy	relevant studies not covered by the PubMed search. C	ase reports and small case series were excluded. The manufacturer's
als to assess	Ins on the basis of the genetic ana	using pCLE was interpreted in real time. Endoscopists per 8.5 membre and no formed training in control outboling. Sent	forming pl	website was also used to identify key references. The U	nited States Food and Drug Administration (U.S. FDA) Manufacturer
ing cancer to EGM. control later	plex mutations, bypass molecular a	were reviewed by a blinded expert in optical biopsy interpret	ation.	And User facility and Device Experience (MAUDE) or inturies.	database was searched for reports regarding the device manufaction
12(7): #0180576.	The aim of this study was to develo	p Results Early pCLE users identified significantly more patien	ts with IM	Results The technology offers an excellent safety pro	file with rare adverse events related to the use of fluorescent agents.
the of South Linkson	test for EGFR inhibitors sensitivity	with visible columnar lined esophagus (75 vs. 31, p < 0.0001)	more paties), but not is	It has been shown to increase the detection of dyspias cancer, and dyspiasia associated with inflammatory b	to Barrett's esophagas, gastric autaepithelial neoplasia/early gastric owel disease when compared to standard screening protocols. It also
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16	Eriptinib resistant (A549, H460, H1	Conclusion Optical biopsy using pCLE technology allows for exechances. Consequently, pCLE is considerably more sensitia	r the real-ti e in the det	Conclusions: CLE has an excellent safety profile. CLE rathelogies.	can increase the diagnostic accuracy in a number of gostrointestinal
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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 gastric cancer, gastric intestinal neoplasia, pancreatic cystic lesions, indeterminate biliary strictures, and IBD."	American Foregut Society "Cellvizio is integral to the patients suffering from re much needed diagnostic esophagus and/or have B
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 comprehensive assessment of patients suffering from gastroesophageal reflux disease	American Gastroenterolo Paper "workshop panelists agre endoscopists who have m incorporation of valuable (diagnostic accuracy) wit (specific technologies), us esophagus patients is app

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

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eed that in the hands of het the preservation and endoscopic innovation thresholds h enhanced imaging techniques se of the technique in Barrett's propriate."



^{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/positionstatements/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-committee/in-vivo-microscopy-topic-center. Accessed May 10, 2021.

Strategic Outlook



Creating Value in Three Large Healthcare Markets



Key development focus, strategic partnership with the Lung Cancer Initiative at J&J

Fluorescence guided surgery, partnership with Telix Pharmaceuticals



Building Momentum in Interventional Pulmonology

- Prospective, multi-center clinical study with a combination of the Monarch[®] Platform from Auris Health, Inc. and Cellvizio, to begin Q1 2022
 - Strategic collaboration with the Lung Cancer Initiative at J&J
 - J&J made 2 strategic equity investments of €7.5m and €6m
 - J&J owns approximately 24.5% of MKEA stock
- Other clinical initiatives with both robotic-assisted and manual bronchoscopy platforms are ongoing
- Significant clinical and product milestones expected in 2022 and 2023



(Johnson & Johnson INNOVATION JJDC



Molecular Imaging: Bringing Precision to Surgery

- Mauna Kea and Telix Pharmaceuticals have formed the IRiS Alliance for precision surgery
- The goal of the IRiS Alliance is to create a unique advanced imaging platform to empower surgeons in order to reduce positive margin rates and improve surgical outcomes
- Combining Telix's unique molecular compounds that combine PET tracers and Fluorophores with Cellvizio's in vivo cellular imaging platform
- Current clinical focus: prostate and kidney cancer



IRiS Alliance









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 tactics:
 - Further demonstrate Cellvizio's value in roboticassisted 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 Q3 YTD 2021



2021 Q3 YTD Sales: +23% Year-Over-Year

2021 Q3 YTD Sales

	Actual	Last Year	V LY%
Systems	1,962	1,448	36%
Consumables	2,282	1,851	23%
Services	844	845	0%
Total	5.087	4.144	23%

	Actual	Last Year	V LY%
APAC	1.045	1.107	-6%
EMEA & ROW	1,565	728	115%
U.S.	2,478	2,309	7%
Total	5,087	4,144	23%

- increased 23% year-over-year
- U.S. sales increased 7%, APAC sales increased 115% year-over-year
- Systems sales increased 36%
- Services sales were essentially flat

All figures in € thousands

Total sales for the first nine months of 2021

decreased 6%, and EMEA & ROW sales

• Consumables sales increased 23%, driven by a 30% increase in probe shipments



OpEx Reductions Offset Sales Decrease and Drive EBIT Improvement

P&L STATEMENT	06/30/2021	30/06/2020 (R)	∆ vs. N-1 (k€)	∆ vs. N-1 (%)
Sales	3,314	2,100	1,215	58%
Gross Margin	2,344	1,257	1,087	86%
GM%	71%	60%		
Other revenues	548	1,064	(517)	(49)%
R&D Expenses	(315)	(372)	57	(15)%
M&S Expenses	(821)	(971)	150	(15)%
G&A Expenses	(1,597)	(1,415)	(182)	13%
Total Expenses	(2,733)	(2,758)	25	(1)%
R&D Payroll	(1,149)	(977)	(172)	18%
M&S Payroll	(2,824)	(3,014)	190	(6)%
G&A Payroll	(1,566)	(1,098)	(468)	43%
Total Payroll	(5,539)	(5,089)	(450)	9%
EBITDA	(5,381)	(5,526)	145	(3)%
Depreciation	(371)	(509)	138	(27)%
Share based payment	(346)	(184)	(163)	89%
EBIT	(6,098)	(6,218)	120	(2)%
NET PROFIT /(LOSS)	(6,691)	(6,710)	19	(0)%
Total expenses	(8,644)	(8,357)	(287)	3.4%
Opex w/o Dep & SBP (*) Restated Gross Margin	(8,272)	(7,847)	(425)	5.4%

• H1 2021 sales increased 58%

- GM% increased to 71% in H1 2021 vs. 60% in H1 2020 due to a favorable sales & pricing mix.
- OPEX (excluding COGS & Dep°) increased by 5%
 - Increase in G& payments
 - Reduction of expenses and T&L in Sales and Marketing
 - Frozen or postponed new hires
- Depreciation decreased by 27% due to lower PPU placements in H1 2021 with the ongoing COVID-19 pandemic
- Net consolidated loss in H1 2021 is flat at €6.7M compared to €6.7M in H1 2020

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Increase in G&A expenses and share-based



Balance Sheet

ASSETS	06/30/2021	30/06/2020 restated	EQUITY AND LIABILITIES
Non-current Assets			Equity
Intangible assets	3,505	3,072	Issued capital
Property, plant and equipment	1,445	1,451	Share premium
Right of use	1,345	1,344	Reserves
Non-current financial assets	295	282	Foreign currency translation on reserve
Total of non-current assets	6,592	6,149	Profit / (Loss)
			Total of equity
Current assets			
Inventories & Work in progress	2,652	2,687	Non-current Liabilities
Trade receivables	1,228	1,907	Long-term loans
Other current assets	2,105	1,202	Non-current provisions
Current financial assets	88	58	Total of non-current liabilities
Cash and cash equivalents	3,428	8,606	
Total of current assets	9,500	14,460	Current liabilities
			Short-term loans and borrowings
TOTAL OF ASSETS	16,092	20,609	Trade payables
			Other current liabilities
			Total of current liabilities

All figures in € thousands

TOTAL OF EQUITY AND LIABILITIES

/30/2021	30/06/2020 restated
1,261	1,224
99,184	98,286
(111,067)	(98,504)
(125)	(292)
(6,691)	(12,791)
(17,439)	(12,077)
9,053	26,242
277	179
9,329	26,421
19,213	722
2,181	1,475
2,807	4,068
24,201	6,265
16,092	20,609



Cash Flow Statement: Significant Reduction in Operating Cash Burn

(in K€)	06/30/2021	30/06/2020 restated
Cash from operations	(5,153)	(5,391)
Δ in inventories	285	(26)
Δ in trade receivables	707	776
Δ in trade payables	(900)	647
Δ in other receivables and payables	(580)	(17)
Δ in working capital	(487)	1,381
Operating cash flows	(5,640)	(4,011)
Capex (PPE and Intangibles)	(919)	(893)
Free cash Flows	(6,559)	(4,903)
Capital increase	0	0
Exercise of share options	933	0
New debt issuance	0	0
Debt repayment	0	0
Net financial interest paid	(17)	(21)
Tax Credit pre financing	711	(565)
Reimbursment of debt on leases (IFRS 16) & Others	(271)	(276)
Other operations	17	(15)
Cash flow from financing activies	1,373	(877)
Net FX differences	8	9
Net cash flows	(5,178)	(5,771)
Cash BoP	8.606	9.982
Cash EoP	3,428	4.211

- in H1 2020
- Steps taken in Jan. 2022 to extend cash strategic objectives
- In H1 2021, €5.7M of cash consumed in operating activities plus €0.9M of cash offset by €1.4M of cash generated by additional financing
- expenses

 Cash used in operating and investing activities totaled €5.2M in H1 2021 compared to €5.8M

runway, enabling Company to deliver on

consumed in investment activities, partially

 CapEx comprised of systems placed in payper-use in the US and capitalization of R&D



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: €32M

ANALYST COVERAGE

- **GOETZ PARTNERS SECURITIES** Chris Redhead
- **GILBERT DUPONT** Guillaume Cuvillier
- **ODDO BHF** Martial Descoutures Shirihane Kouadri

IDENTIFICATION CODES

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

SHAREHOLDERS STRUCTURE

Founders & Registered shares 3%







Thank You

