

**SEE
CELLS**



**CHANGE
LIVES**

Cellvizio®

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

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A hand wearing a white nitrile glove holds a medical instrument with a glowing blue tip. The background is a deep blue, and the lighting is soft, highlighting the texture of the glove and the instrument. The overall mood is clinical and futuristic.

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

Management Team



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

Novartis, Sandoz,
sanef groupe



Shui Gautheron
Chief Financial Officer

EnTrust Global,
Permal Group



François Lacombe, Ph.D.
Chief Scientific Officer

Astrophysics programs:
ISOCAM, ADONIS, NAOS



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

SuperSonic Imagine,
Philips Healthcare, ATL
Ultrasound



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

Intrasense,
Quantum Surgical



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Vice President, International Sales

Tyco, Saint-Gobain



Cameron Lee
Vice President, U.S. Sales

Pentax Medical,
Trinity Western Univ.



Daryl Donatelli
Vice President, Global Marketing

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Bausch + Lomb
(Bausch Health),
Convergent Dental

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Founder of Mauna Kea Technologies



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Managing Director of Kohlberg Kravis Roberts (KKR)



Jacquelin ten Dam, Director
*Chief Financial Officer,
MIMETAS*



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*President, Hospitals & Health Systems,
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Molly O'Neill, Director
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Medforth Global Healthcare Education Group*



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

Addressing a Critical Unmet Need in Lung Cancer Detection

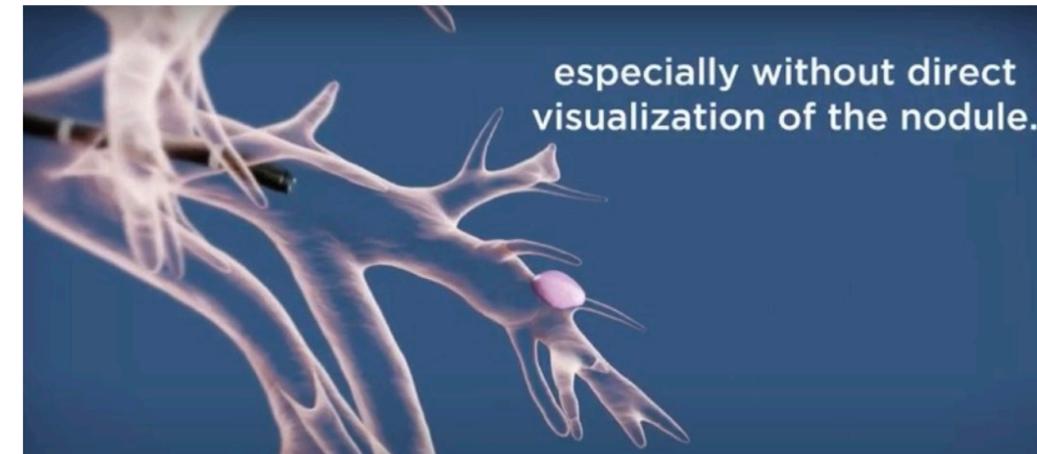
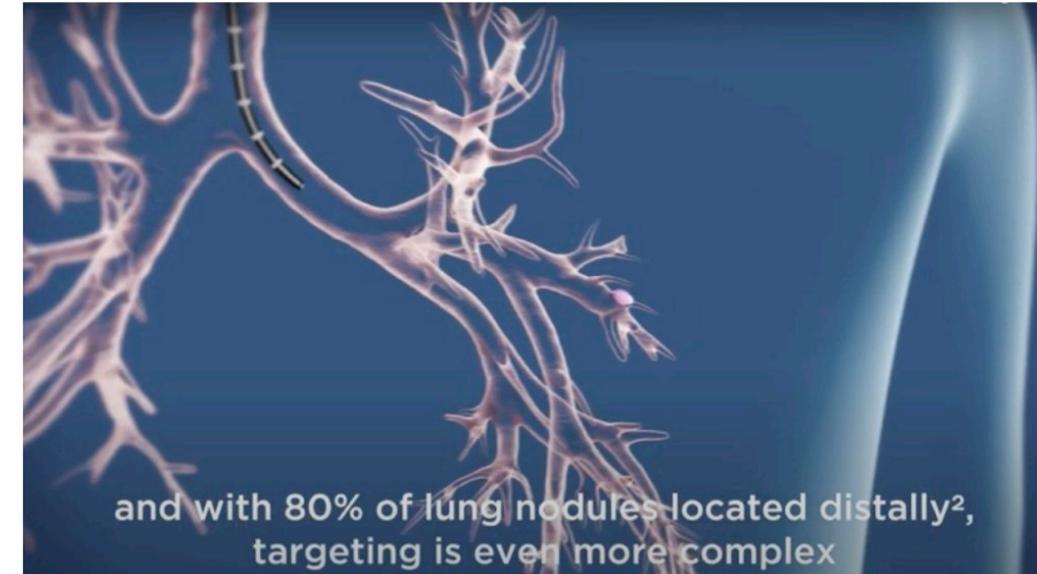


Early and Efficient Detection of Lung Cancer Has Been an Elusive Goal

- 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



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.

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:

- 1 Touchscreen User Interface
- 2 Confocal Miniprobe™
- 3 Combined Laser Scanning Unit and Confocal Processor

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

SEE CELLS. CHANGE LIVES.

Biopsies

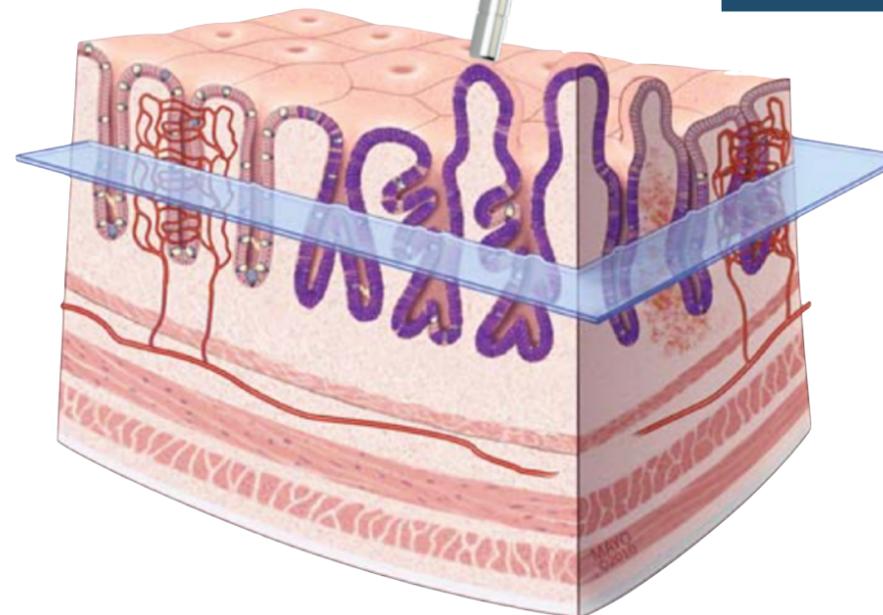
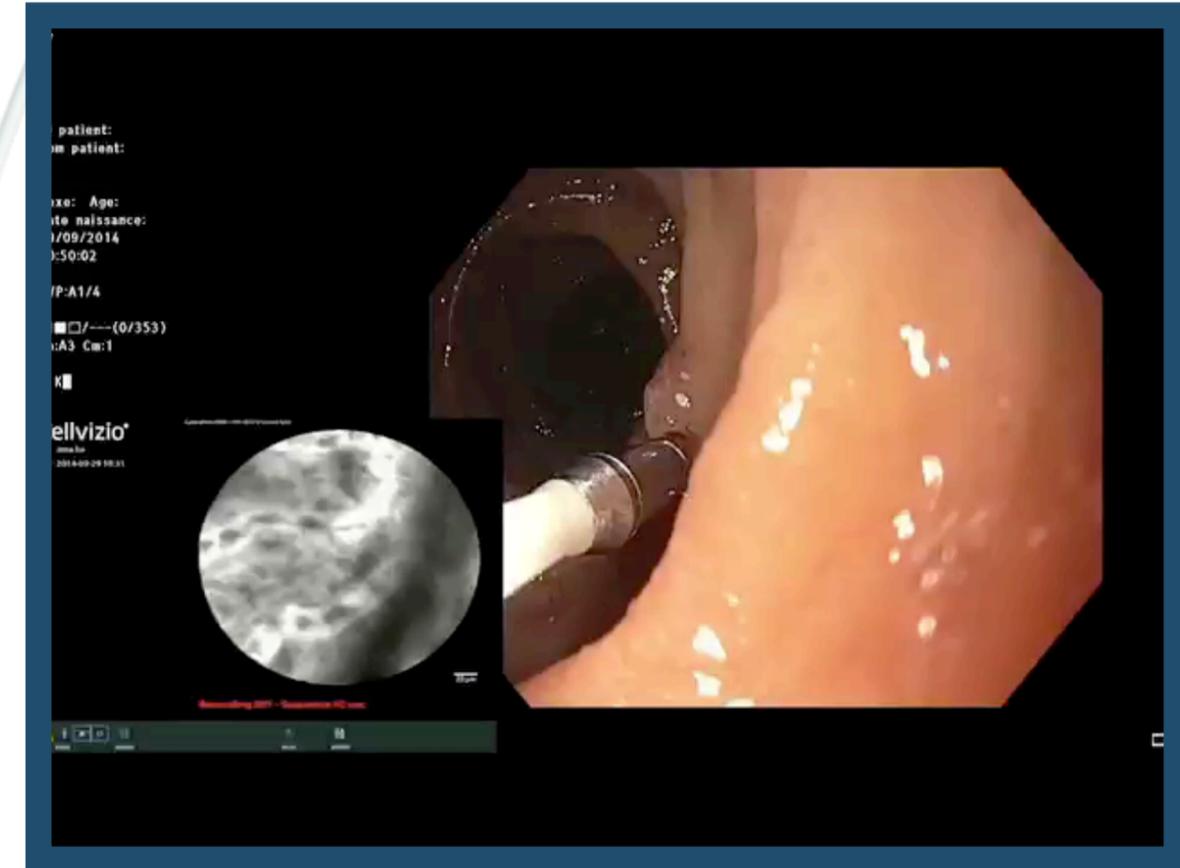
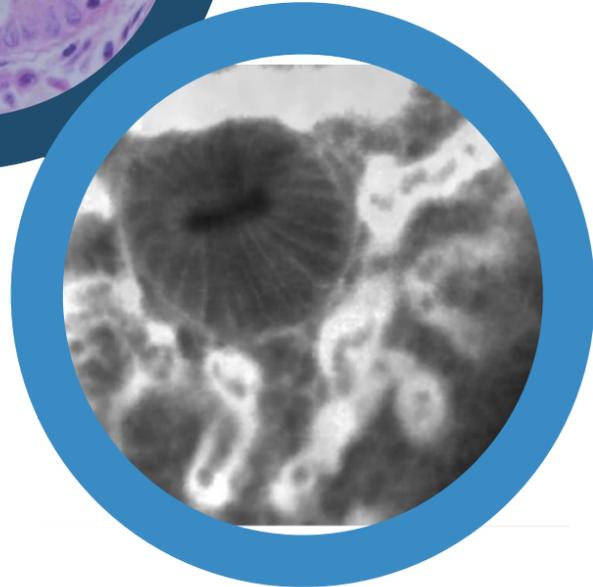
- Random samples
- 1000x histology
- Ex vivo microscopic analysis

Cellvizio®

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

Endoscopy

- 30x
- Macroscopic analysis



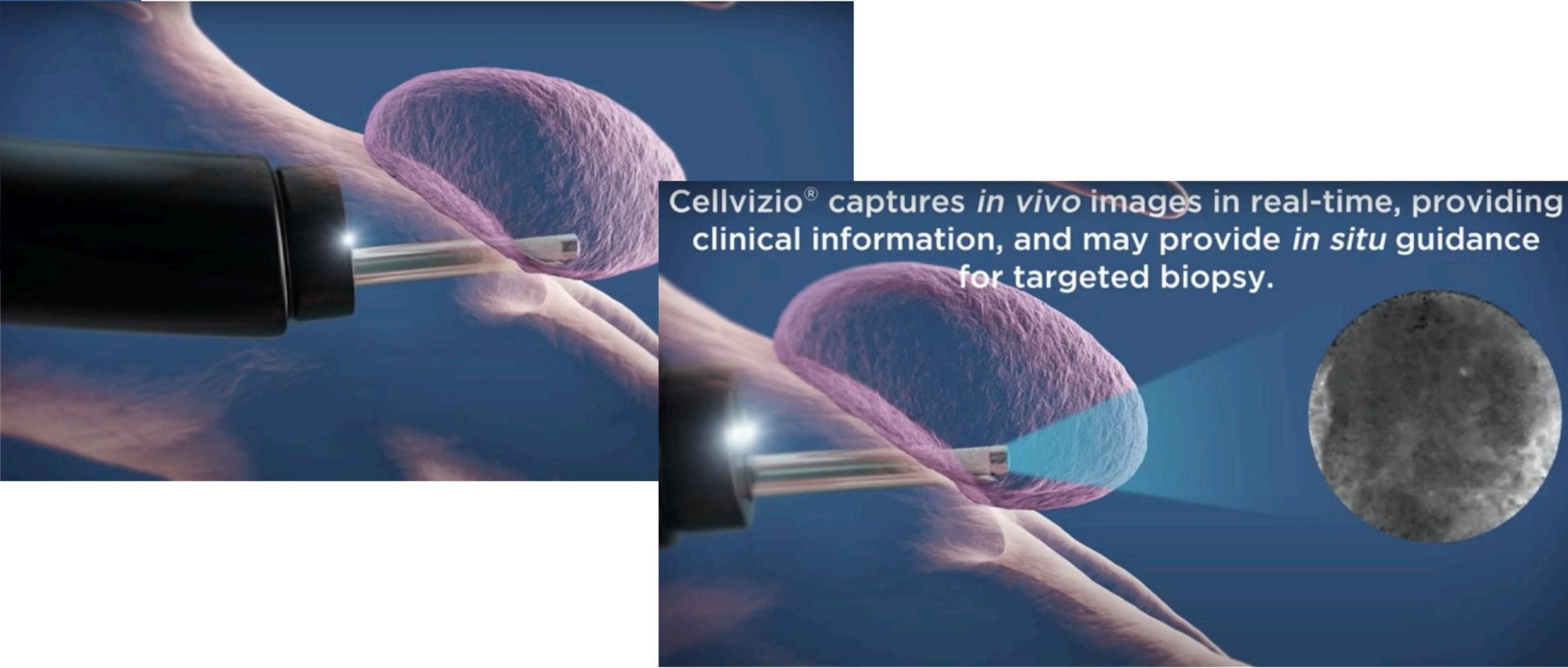
Only Cellvizio can reveal key cellular information in real time

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

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



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



Cellvizio[®] captures *in vivo* images in real-time, providing clinical information, and may provide *in situ* guidance for targeted biopsy.

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



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

Cellvizio Targeted Growth Strategy



- Targeting 1,500 GI physicians with high volume of upper GI biopsies (EGDs) and high mix of Medicare patients
- 1,100 facilities

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:

MONITOR

the progression of disease over time

CLASSIFY

indeterminate areas of concern



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.

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 (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.”

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 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.”

College of American Pathologists (CAP) In Vivo Microscopy (IVM) for the Evaluation of BE

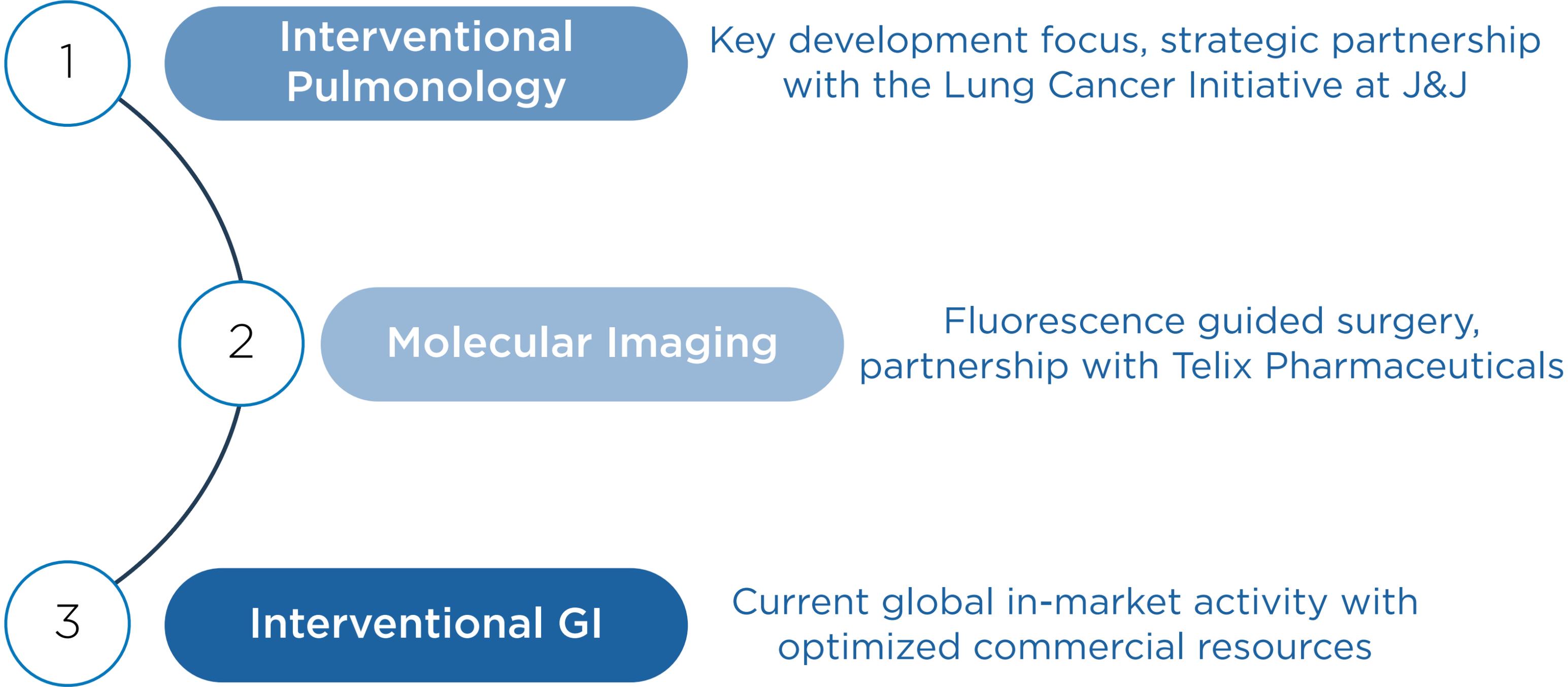
BE patients can be better served if biopsies are more targeted; CLE can help target higher yield and more diagnostic sites

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-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



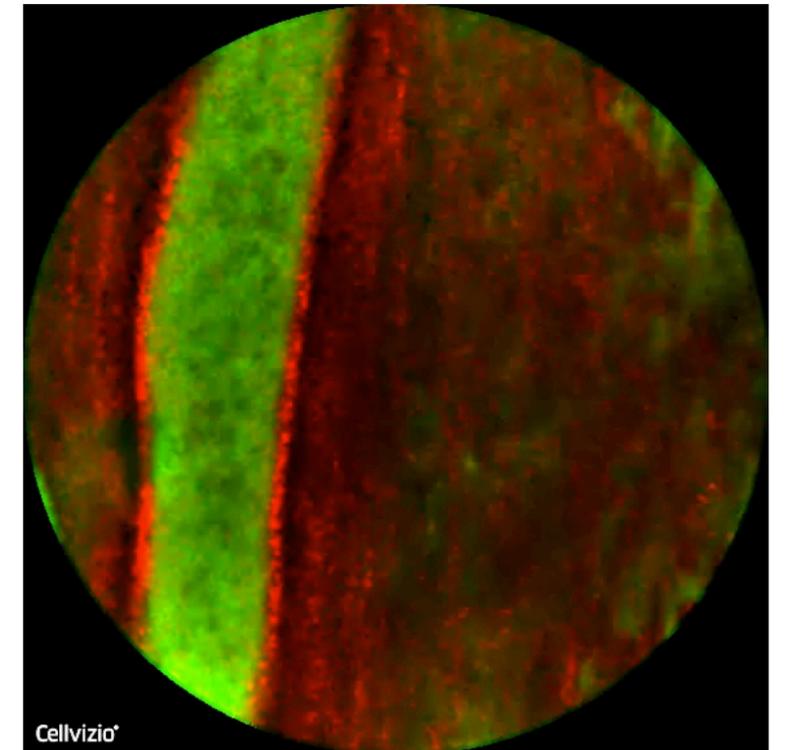
Building Momentum in Interventional Pulmonology

- Prospective, multi-center, open-label, single-arm clinical study with a combination of the Monarch[®] Platform from Auris Health, Inc. and Cellvizio
 - 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

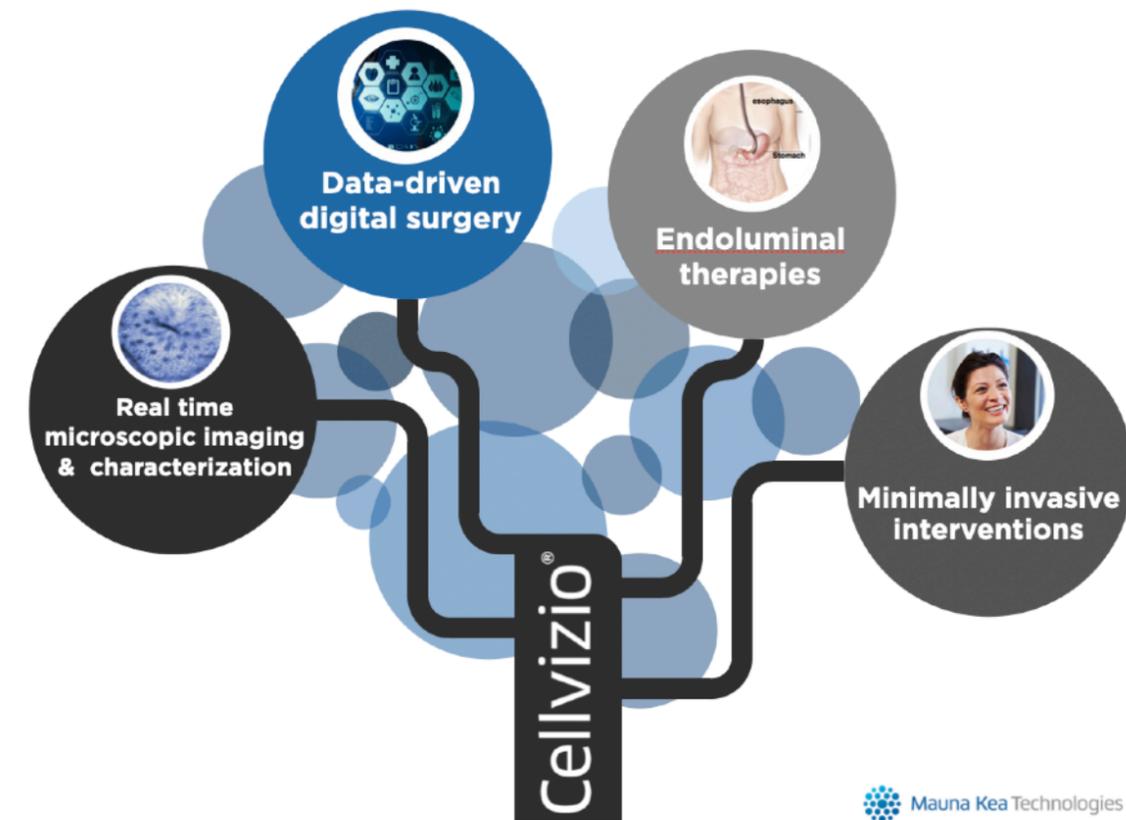
Molecular Imaging: Bringing Precision to Surgery

- 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



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 robotic-assisted and manual endoluminal procedures
 - Secure additional strategic relationships aligned with large market opportunities
 - Continue to enhance product features within the next-generation 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%

All figures in € thousands

- Total sales for the first nine months of 2021 increased 23% year-over-year
- U.S. sales increased 7%, APAC sales decreased 6%, and EMEA & ROW sales increased 115% year-over-year
- Consumables sales increased 23%, driven by a 30% increase in probe shipments
- Systems sales increased 36%
- Services sales were essentially flat

OpEx Reductions Offset Sales Decrease and Drive EBIT Improvement

P&L STATEMENT	06/30/2021	30/06/2020 (R)	Δ vs. N-1 (k€)	Δ 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	(8,272)	(7,847)	(425)	5.4%

(*) Restated Gross Margin

- 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^o) increased by 5%
 - Increase in G&A expenses and share-based 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

Balance Sheet

ASSETS	06/30/2021	30/06/2020 restated	EQUITY AND LIABILITIES	06/30/2021	30/06/2020 restated
Non-current Assets			Equity		
Intangible assets	3,505	3,072	Issued capital	1,261	1,224
Property, plant and equipment	1,445	1,451	Share premium	99,184	98,286
Right of use	1,345	1,344	Reserves	(111,067)	(98,504)
Non-current financial assets	295	282	Foreign currency translation on reserve	(125)	(292)
Total of non-current assets	6,592	6,149	Profit / (Loss)	(6,691)	(12,791)
			Total of equity	(17,439)	(12,077)
Current assets			Non-current Liabilities		
Inventories & Work in progress	2,652	2,687	Long-term loans	9,053	26,242
Trade receivables	1,228	1,907	Non-current provisions	277	179
Other current assets	2,105	1,202	Total of non-current liabilities	9,329	26,421
Current financial assets	88	58			
Cash and cash equivalents	3,428	8,606	Current liabilities		
Total of current assets	9,500	14,460	Short-term loans and borrowings	19,213	722
			Trade payables	2,181	1,475
TOTAL OF ASSETS	16,092	20,609	Other current liabilities	2,807	4,068
			Total of current liabilities	24,201	6,265
			TOTAL OF EQUITY AND LIABILITIES	16,092	20,609

All figures in € thousands

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)
Reimbursement of debt on leases (IFRS 16) & Others	(271)	(276)
Other operations	17	(15)
Cash flow from financing activities	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

- Cash used in operating and investing activities totaled €5.2M in H1 2021 compared to €5.8M in H1 2020
- Steps taken in Jan. 2022 to extend cash runway, enabling Company to deliver on strategic objectives
- In H1 2021, €5.7M of cash consumed in operating activities plus €0.9M of cash consumed in investment activities, partially offset by €1.4M of cash generated by additional financing
- CapEx comprised of systems placed in pay-per-use in the US and capitalization of R&D expenses

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

IDENTIFICATION CODES

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

ANALYST COVERAGE

GOETZ PARTNERS SECURITIES

Chris Redhead

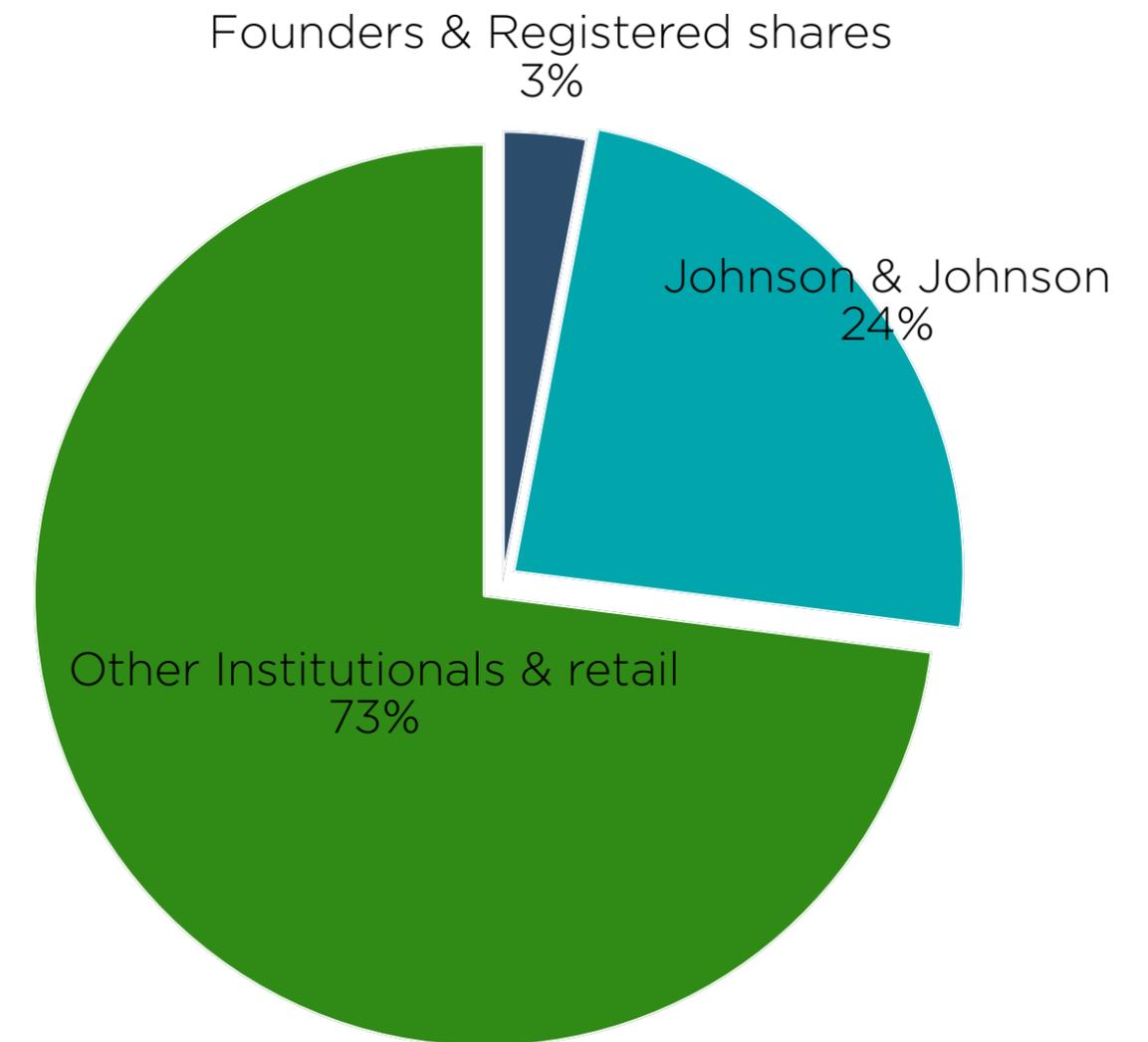
GILBERT DUPONT

Guillaume Cuvillier

ODDO BHF

Martial Descoutures
Shirihane Kouadri

SHAREHOLDERS STRUCTURE



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**CHANGE
LIVES**

Cellvizio®

Thank You



Mauna Kea Technologies