

# Mauna Kea Technologies

Creators of Cellvizio<sup>®</sup>

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# Company Snapshot

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company’s flagship product, Cellvizio®, has received clearance/approval for a wide range of applications in the United States and more than 40 countries around the world. For more information, visit [www.maunakeatech.com](http://www.maunakeatech.com).

<b>Founded</b>	2000
<b>Office Locations</b>	<ul style="list-style-type: none"> <li>• Paris, France (Headquarters)</li> <li>• Allston, MA, USA</li> <li>• Shanghai, China</li> </ul>
<b>Full-Time Employees*</b>	101
<b>Year of IPO</b>	2011
<b>Exchange/Ticker</b>	Euronext Paris: MKEA
<b>Number of Shares*</b>	30,558,480



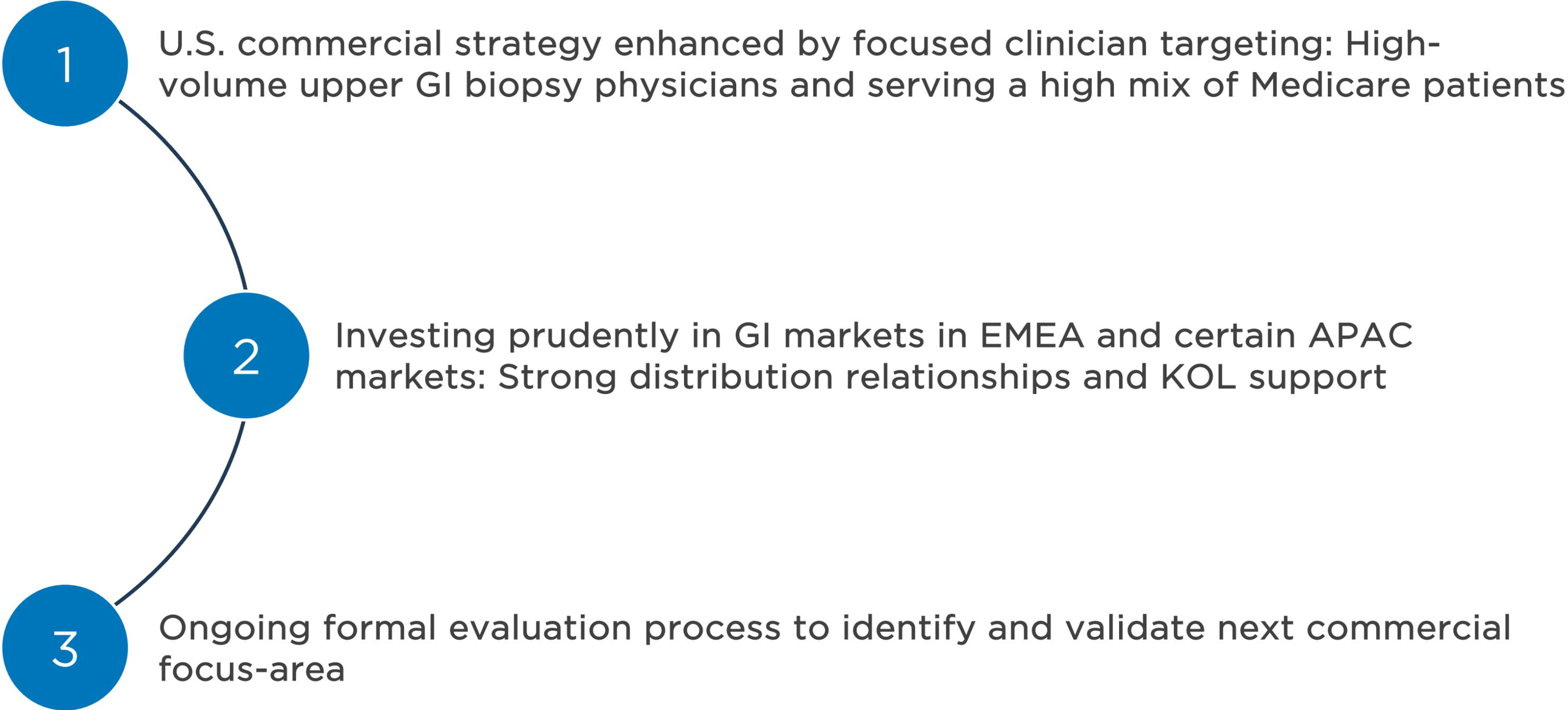
# Mauna Kea Technologies - A Compelling Platform Opportunity...

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- 1 Transformational probe-based and needle-based Confocal Laser Endomicroscopy (CLE) platform
- 2 Focused commercial strategy primarily in the U.S. and in certain ROW markets
- 3 Formal process of evaluating new clinical indications to fuel long-term growth profile
- 4 Broad IP portfolio: 248 issued and 23 pending patents on Cellvizio® technologies
- 5 Strong regulatory support: Approved in 40+ countries; 18 U.S. FDA 510(k) clearances
- 6 Enhanced management depth of expertise across multiple indications and market segments

# ...Supported by a Focused Value Creation Strategy

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# What is Cellvizio®? An Adjunct to Existing Biopsy Techniques to Improve Diagnostic Accuracy, Enhancing the Standard of Care...

Most pathologists' labs use conventional microscopy which is antiquated technology that has not evolved in decades



### Current Standard

- Random biopsy protocols
- Dead tissue
- Ex vivo
- One image
- Limits ability to make real-time decisions



Cellvizio is the world's smallest microscope; a significant leap forward, advancing pathology technology and shrinking a large system onto the head of a sub-3mm probe



### Cellvizio System + Miniprobes

- Targeted biopsies
- Whole, live tissue
- In vivo
- Unlimited number of images
- Facilitates early detection and clinical intervention

# ...By Integrating With Existing Procedure Workflows and Revealing Key Invisible Information...

The Cellvizio Confocal Laser Endomicroscopy (CLE) platform incorporates seamlessly into the existing procedure workflow via the scope working channel (pCLE), through the needle (nCLE), or with laparoscopic or robotic systems



pCLE  
(Probe/Catheter)

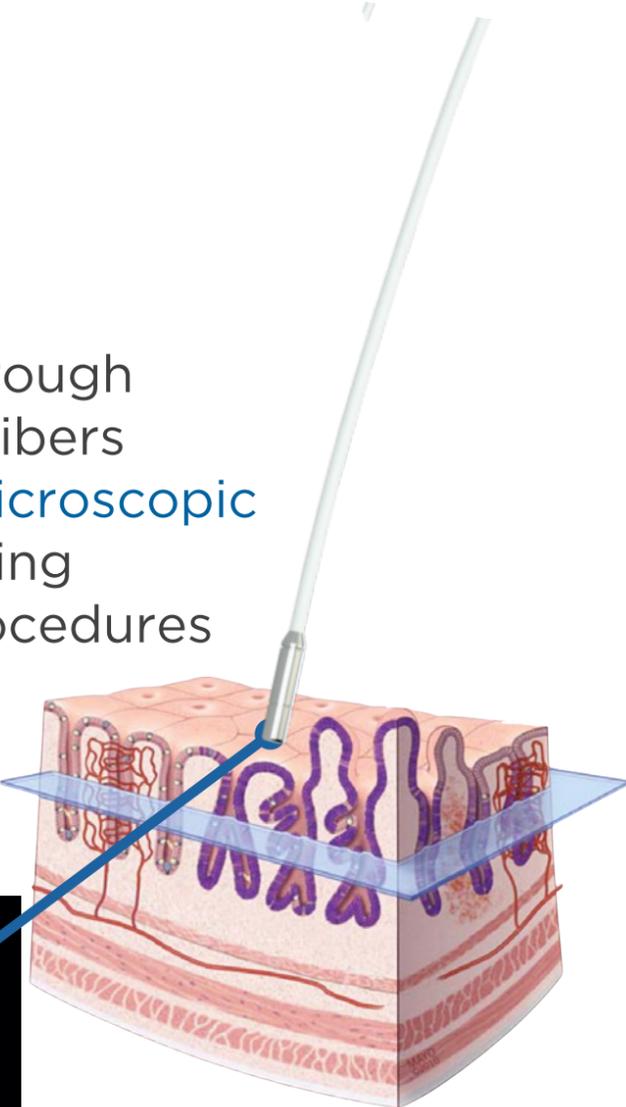
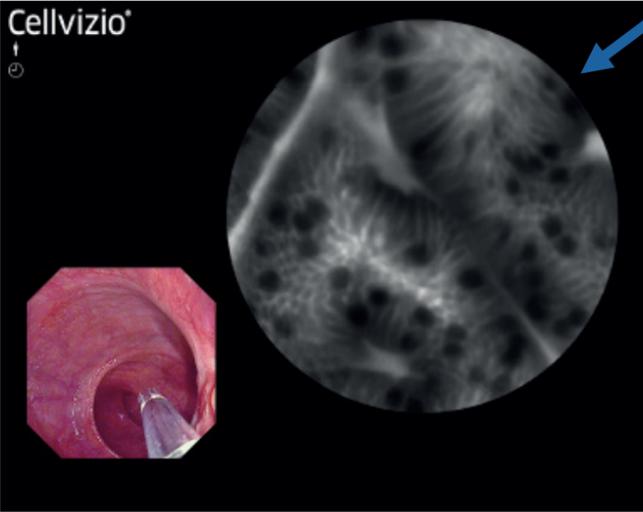


nCLE  
(Through the Needle)



pCLE  
(Laparoscopic/Robotic)

Proprietary scanning through 30,000 custom optical fibers produces 12 real-time microscopic sections per second during standard endoscopy procedures



# ...and Enabling Better Informed Patient Management

## DETECT DISEASES EARLIER

Confirm disease status and progression early enough to perform clinical intervention

## REDUCE MISSED DIAGNOSES

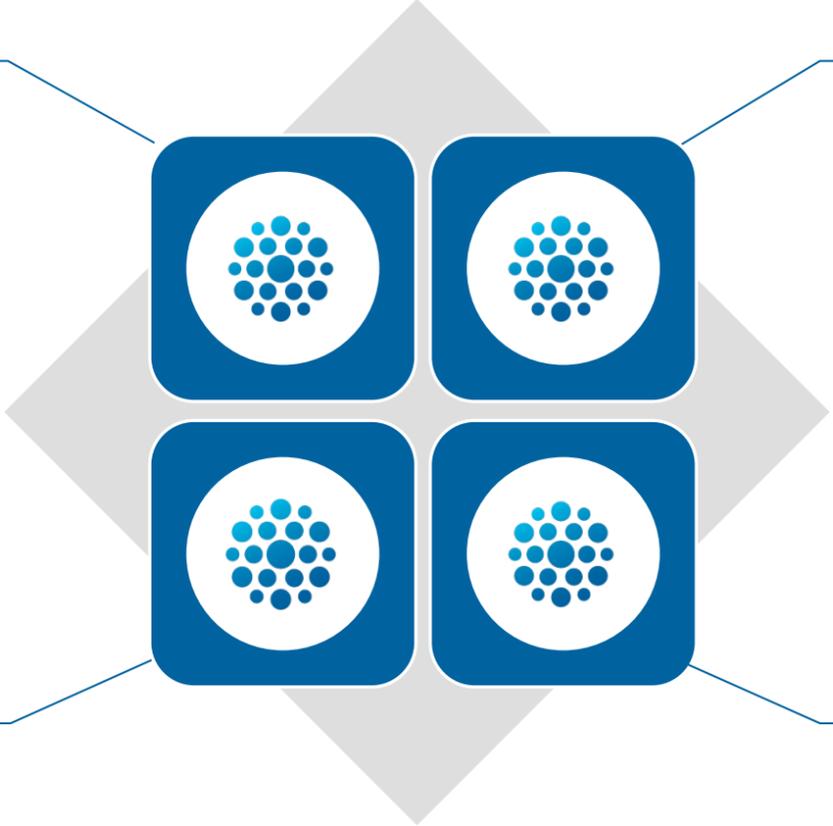
Higher diagnostic yield enables characterizing diseases like Barrett's Esophagus before progression to esophageal cancer

## REDUCE UNNECESSARY SURGERIES

Rule-out tumor malignancy with high specificity and sensitivity prior to surgical intervention

## PRACTICE CONSERVATIVE MEDICINE

Assess and confirm margins and ensure as much healthy tissue as possible is preserved



Cellvizio adds clinical and economic value at every step of the patient journey, impacting diagnostic accuracy and managing costs, all in real-time

# Cellvizio U.S. Gastroenterology Market: Targeted Growth Strategy

## Total U.S. Upper GI Market



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

## Cellvizio Target Market



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



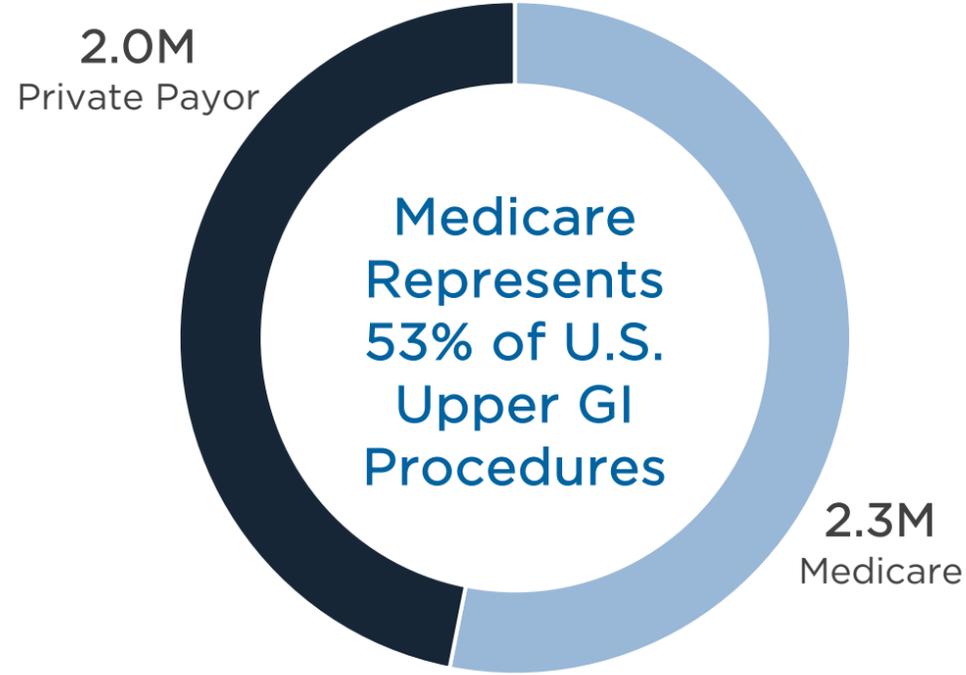
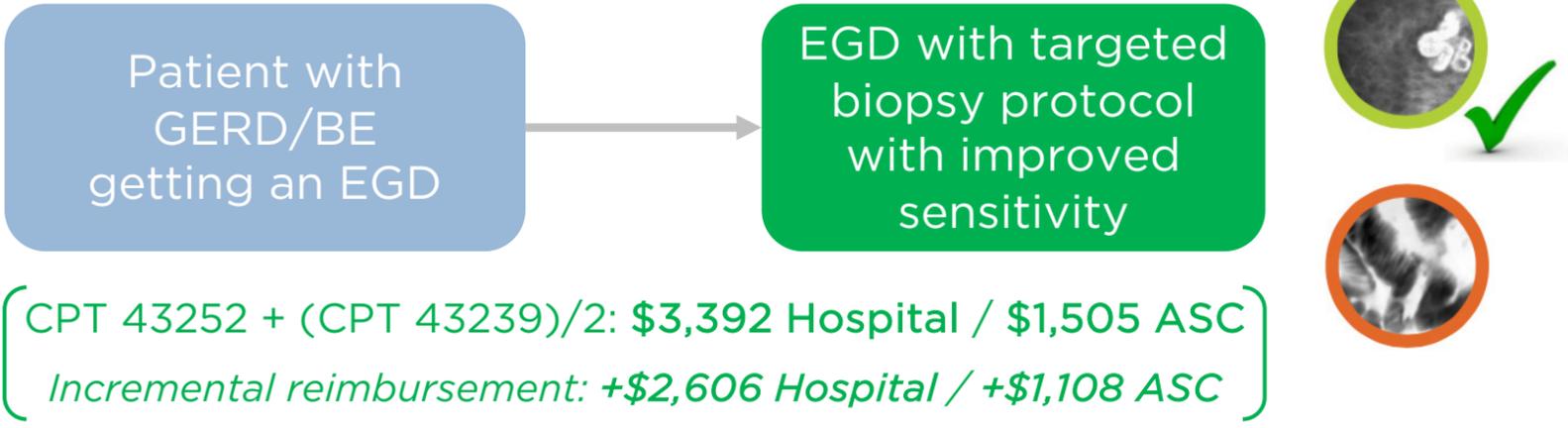
# Established Reimbursement in Largest Patient Group in GI Market

## Attractive Economics for Hospital and ASC Customers

### WITHOUT Optical Endomicroscopy



### WITH Optical Endomicroscopy



- Cellvizio has 3 dedicated Category 1 CPT codes covering endomicroscopy in upper GI endoscopy procedures, including GERD, Barrett’s Esophagus, and pancreatic cystic lesions

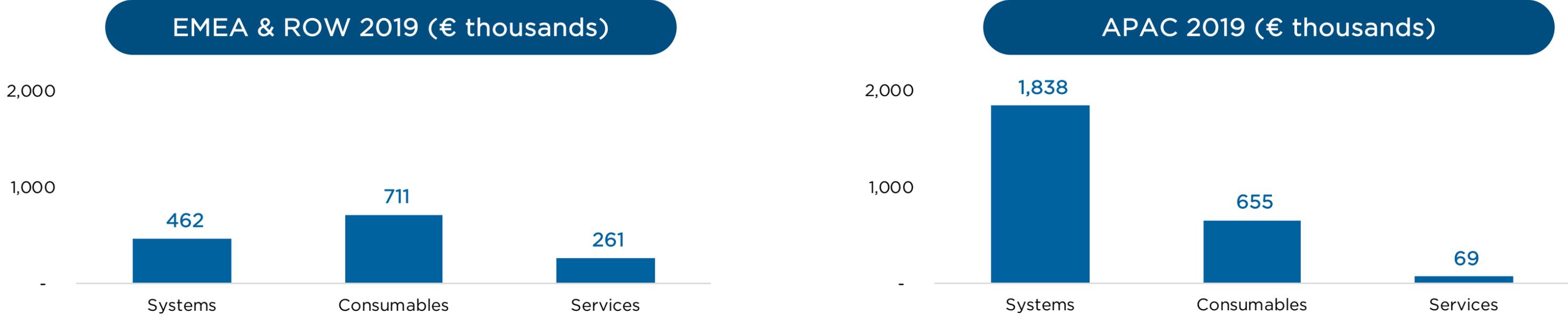
**Favorable Economic Model for Cellvizio Customers  
 = Tailwind for System Adoption and Utilization**

# Executing an Enhanced, Focused U.S. Commercial Strategy

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- Established base of ~80 active Cellvizio systems in the U.S. drove €2.8M consumables revenue in 2019
  - Expect U.S. to be primary driver of total company consumable growth again in 2020
- Commercial strategy in 2020 enhanced by targeting high-volume upper GI biopsy (EGD) physicians, key driver of future utilization and consumable growth
- Multiple options for customer adoption: capital purchase, pay-per-use (PPU), and piloting a new capital lease program

# Rest-of-World (ROW) Revenue Growth Focused on Select Geographies and Indications



- Investing prudently in EMEA and certain APAC markets, all GI-focused, strong distribution relationships and KOL support
  - Proactive strategy to exit 20 markets in 2019; to enhance strategic focus and optimize capital allocation outside the U.S.
- EMEA (approx. 17% of total clinical revenue)
  - Future growth from two primary markets, France and Germany
- APAC (approx. 35% of total clinical revenue)
  - Long-lasting business relationship with a reliable distribution partner in China

# Ongoing Formal Evaluation Process to Validate Next Commercial Focus-Area



- Formal, disciplined process to evaluate range of clinical indications
- Multi-step process, begins with screening, ends with commercially scaling the new indication

First one under evaluation is **interventional pulmonology**



- Validated market opportunity for robotic interventional pulmonology
- Strategic equity investment by Johnson & Johnson Innovation – JJDC, Inc.
- Collaboration with J&J’s Lung Cancer Initiative (LCI) team

Second indication under evaluation – compelling potential opportunity in **IBS / food allergies**



- Food allergy or intolerance affects 11% of global population
- Current diagnostic methods are unreliable, and patients continue to suffer without clear treatment
- Cellvizio enables real-time observation of mucosal response to food antigens, providing certainty vs. current testing methodologies

Important strategic evaluation process to identify the next growth engine for Mauna Kea

## Strategic Equity Investment of €7.5M by Johnson & Johnson Innovation – JJDC, Inc.

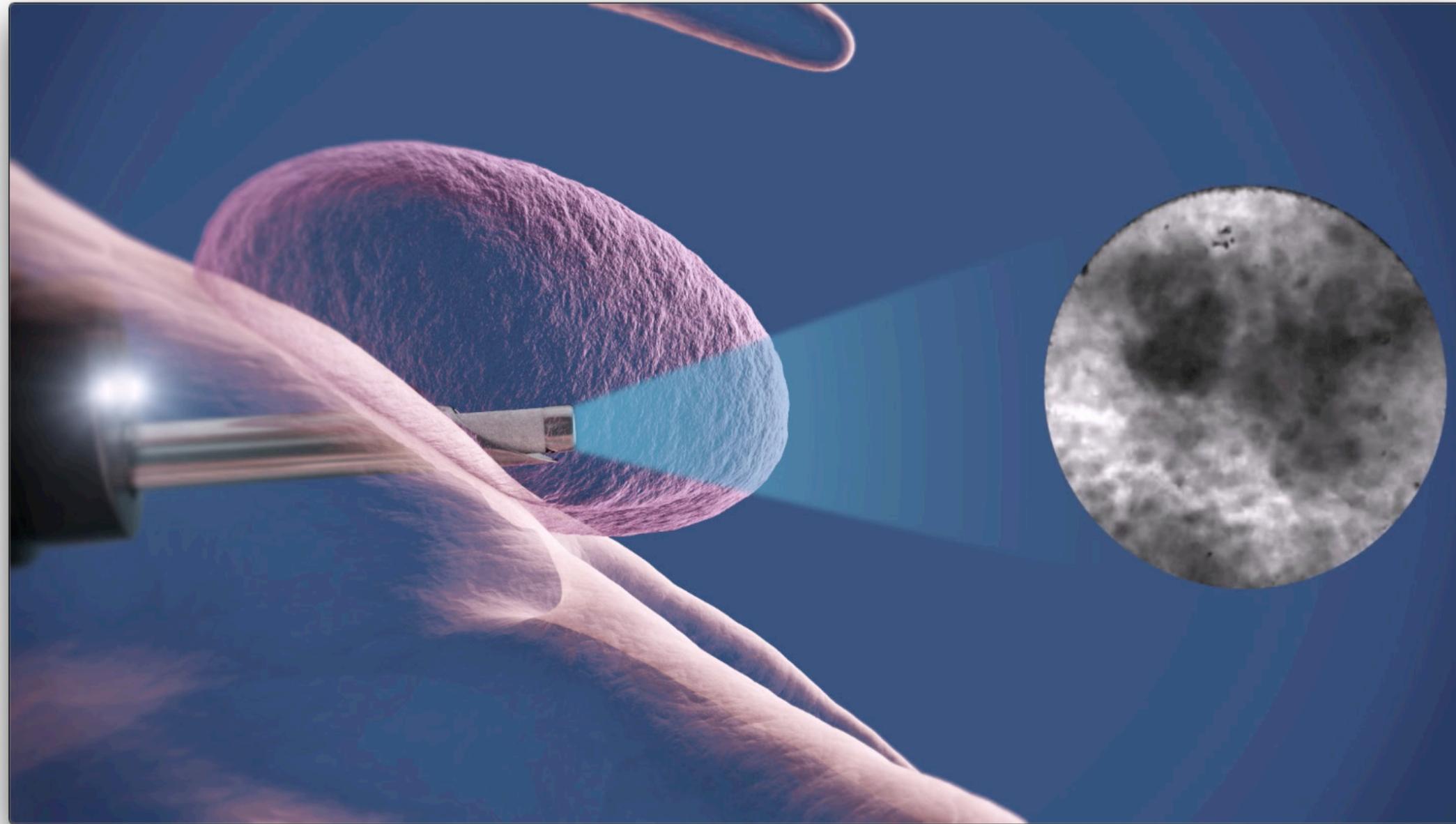
**Strategic investment** will advance the collaboration of Mauna Kea with the Lung Cancer Initiative at J&J, which is working to develop new diagnostic and therapeutic approaches for lung cancer with significant unmet need

**Cellvizio platform and AQ-Flex™ 19 (nCLE)** is a viable option for use with the new emerging robotic and existing advanced navigation platforms

**JJDC owns approximately 17.5%** of the total ordinary shares of Mauna Kea post investment

**Agreement represents a significant strategic inflection point for Mauna Kea, particularly in that it provides a capital infusion that will support the execution of the strategic growth initiatives**

# Cellvizio Enables Real-Time Visualization and Staging from Inside Lung Nodules and Lymph Nodes, Helping Characterize Lesions<sup>1</sup>



Cellvizio can diagnose and stage lung nodules with 90% accuracy<sup>1</sup>, leading to better informed patient management

<sup>1</sup>Wijmans L. et al. Needle-based confocal laser endomicroscopy (nCLE) for real-time diagnosing and staging of lung cancer, *European Respiratory Journal*, 2019.

# Pipeline of Innovation Continues at Mauna Kea, Driving Long-Term Growth

## Recent FDA Clearances

- 510(k) clearance for the Cellvizio® 100 series and all associated Confocal Miniprobes™ for the indication of visualization of blood flow when used in conjunction with a fluorescent dye, fluorescein, as a drug device combination
- 510(k) clearance for the use of AQ-Flex™ 19 Confocal Miniprobe™ through existing bronchoscopes, transbronchial needles and other bronchoscopic accessories

## 2020 Milestones

- Next-generation Cellvizio platform
  - Advanced platform for future product and service introductions, including AI
  - Integrates easily with laparoscopic, advanced navigation, and robotic systems
  - Significant reduction in footprint
  - All-new user interface and easy-to-use touchscreen
  - FDA clearance and CE Marking received Feb. and March, 2020, respectively
  - Targeting limited launch in 2H 2020
- Molecular imaging (development)
  - Two areas of interest:
    - Fluorescence-guided surgery (tissue characterization to eliminate false positives)
    - Evaluate patient response to drug treatment at the cellular level



# Cellvizio is Supported by Strong IP Protection and Clinical Validation...

Cellvizio Technology Protected by 248 Issued Patents Globally

- Covering optics, optronics, image processing, and machine learning
- Additional 23 patents pending

Clinical Validation Portfolio of over 1,000 Studies and Publications

- Current imaging tools (HD-WLE, NBI) and untargeted conventional biopsies result in low diagnostic yield and poor sensitivity/specificity
- Since 2005, CLE's clinical contributions have been reported in more than 1,000 clinical publications worldwide on endomicroscopy

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.*

# ...and by Leading Societies



## 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/2019/11/AFS-Position-paper-CLE.pdf> Accessed January 28, 2020. 3. ASGS review of Confocal Laser Endomicroscopy, available at: <https://theasgs.org/position-statements/position-statement-on-confocal-laser-endomicroscopy/>. Accessed September 20, 2019. 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 April 2, 2019.

# Management Team & Board of Directors

## Management Team



**Robert L. Gershon**  
Chief Executive Officer

Bovie Medical,  
Covidien  
(Medtronic), Henry  
Schein



**Christophe Lamboeuf, CPA**  
Chief Financial Officer

Intrasense, General  
Electric, Ricoh, CS  
Telecom, Toshiba



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

Astrophysics  
programs: ISOCAM,  
ADONIS, NAOS



**Jack McCarthy**  
Chief Marketing Officer

Bovie Medical,  
Z-Medica, Covidien  
(Medtronic)



**Bruno Villaret**  
VP, International Sales

Tyco, Saint-Gobain



**Cameron Lee**  
VP, U.S. Sales

Pentax Medical,  
Trinity Western Univ.

## Board of Directors



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



**Robert L. Gershon**, Director  
Chief Executive Officer of Mauna Kea Technologies



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



**Jennifer F. Tseng**, M.D., Director  
Chief and Chair of Surgery,  
Boston University School of Medicine



**Joseph DeVivo**, Director  
Chief Executive Officer of InTouch Health, Inc.



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

# Sales and Financial Performance

## Full Year 2019 and First Quarter 2020



# 2019 Full Year Sales: 10% Growth vs. Last Year

## 2019 Sales

	Actual	Last Year	V LY%
Systems	2,301	2,683	-14%
Consumables	4,122	2,813	47%
<i>OW PPU</i>	1,682	890	89%
Services	1,007	1,265	-20%
<b>Total</b>	<b>7,430</b>	<b>6,760</b>	<b>10%</b>

	Actual	Last Year	V LY%
APAC	2,562	1,599	60%
EMEA & ROW	1,434	1,580	-9%
US & Canada	3,434	3,582	-4%
<b>Total</b>	<b>7,430</b>	<b>6,760</b>	<b>10%</b>

*All figures in € thousands*

- Sales to clinical customers for the full year 2019 period increased €1.5 million, or 27% year-over-year
- Consumables grew 47% and represents over 55% of overall revenue
- Systems sales decreased €0.4 million, or 14% year-over-year, to €2.3 million
- Sales in Asia-Pacific region increased 60% YOY fueled by sales of both new systems and consumables

# 2020 Q1 Sales: Significantly Impacted by COVID-19 Headwinds

## 2020 Q1 Sales

	Actual	Last Year	V LY%
Systems	555	559	-1%
Consumables	634	873	-27%
Services	285	284	0%
<b>Total</b>	<b>1,474</b>	<b>1,716</b>	<b>-14%</b>

	Actual	Last Year	V LY%
APAC	471	551	-14%
EMEA & ROW	168	453	-63%
US & Canada	834	712	17%
<b>Total</b>	<b>1,474</b>	<b>1,716</b>	<b>-14%</b>

All figures in € thousands

- Q1 total sales were down 14% versus last year
- Consumables sales down 27%
- US sales stronger than expected at +17% vs last year, driven by a capital sale and probe orders. Pronounced slowdown occurred related to COVID-19 throughout March
- APAC sales down 14% mainly driven by low consumables
- Strong impact of COVID-19 on ROW activity throughout Q1

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# Appendix

# Stock Market Data

## STOCK MARKET DATA

- Listed on Euronext Paris regulated market, Compartment C
- Initial listing: July 6, 2011
- Number of outstanding shares: 30,558,480
- Market cap: €54.3M\*

## IDENTIFICATION CODES

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

## ANALYST COVERAGE

### GOETZ PARTNERS SECURITIES

Kieron Banerjee

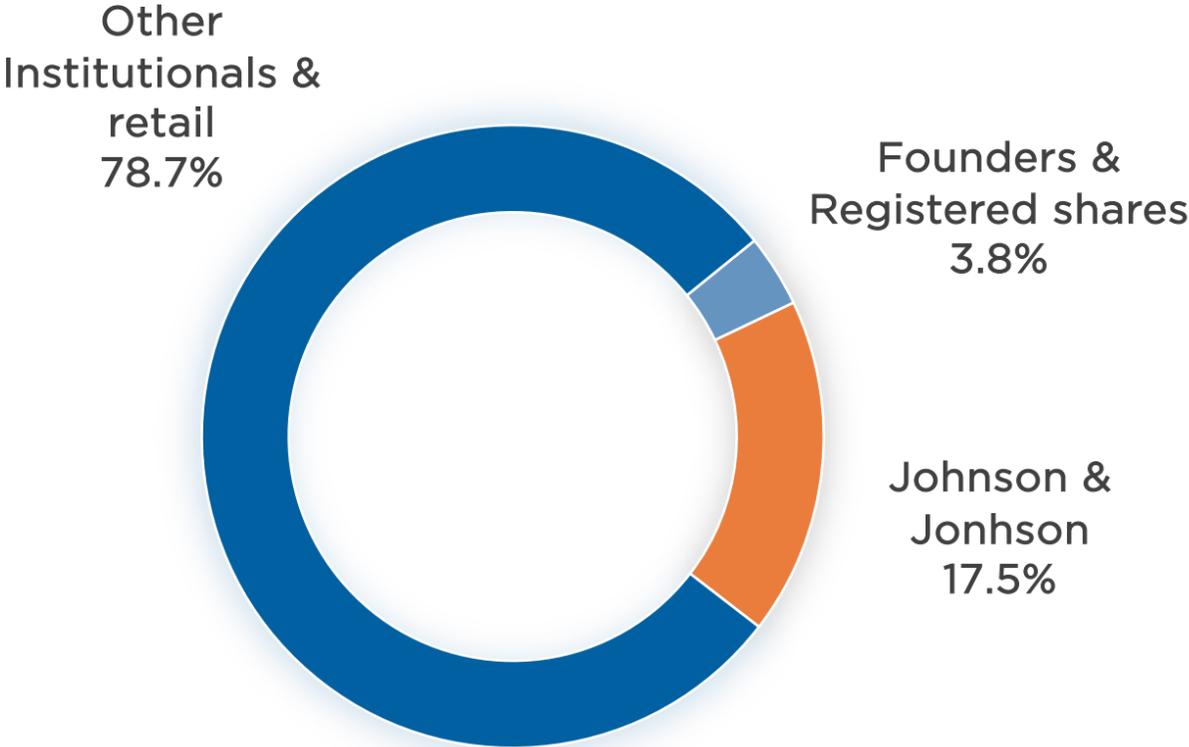
### GILBERT DUPONT

Guillaume Cuvillier

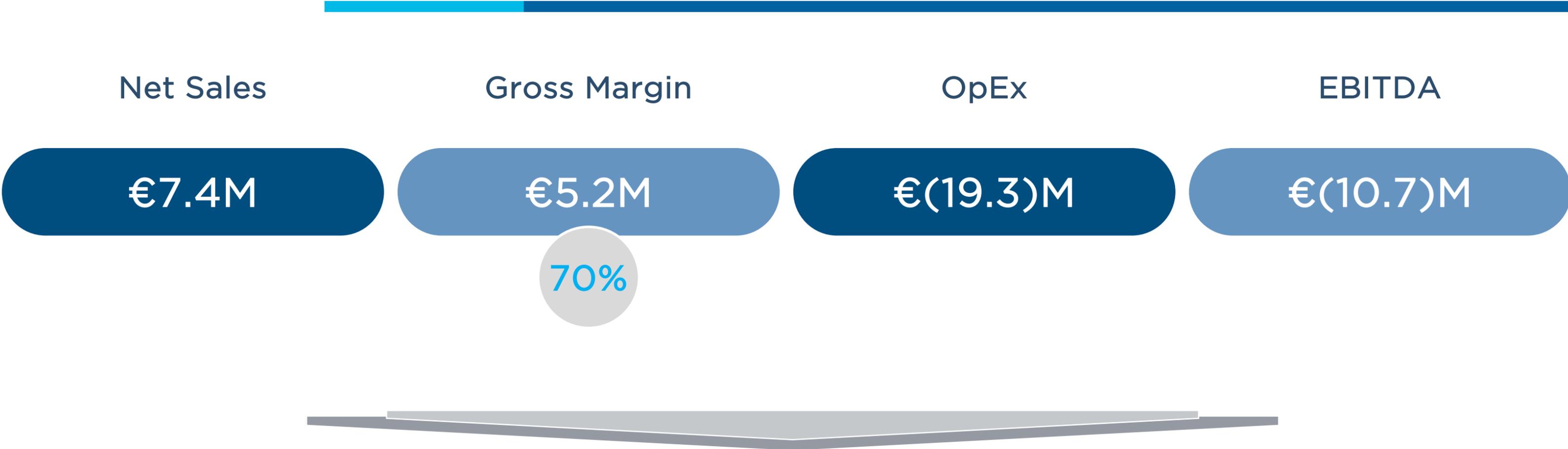
### ODDO BHF

Sebastien Malafosse  
Martial Descoutures

## SHAREHOLDERS STRUCTURE



# Full Year 2019 P&L



- 2019 sales increased 10% vs. 2018
- EBITDA loss stable compared to prior year thanks to sales growth and well-managed OpEx
- Gross margin remains stable

# Strong Sales and Well-Managed OpEx

P&L STATEMENT (K€)	2019A	2018A	△ (K€)	△ %
<b>Sales</b>	<b>7,431</b>	<b>6,760</b>	<b>671</b>	<b>10%</b>
<b>Gross Margin</b>	<b>5,171</b>	<b>4,703</b>	<b>468</b>	<b>10%</b>
GM%	69.6%	69.6%		
<b>Other revenues</b>	<b>1,077</b>	<b>1,141</b>	<b>(64)</b>	<b>(6)%</b>
R&D Expenses	(614)	(1,516)	902	(60)%
M&S Expenses	(2,479)	(2,867)	388	(14)%
G&A Expenses	(2,584)	(1,986)	(598)	30%
<b>Total Expenses</b>	<b>(5,677)</b>	<b>(6,370)</b>	<b>693</b>	<b>(11)%</b>
R&D Payroll	(2,205)	(2,525)	320	(13)%
M&S Payroll	(6,076)	(5,416)	(660)	12%
G&A Payroll	(3,013)	(1,828)	(1,185)	65%
<b>Total Payroll</b>	<b>(11,294)</b>	<b>(9,770)</b>	<b>(1,524)</b>	<b>16%</b>
<b>EBITDA</b>	<b>(10,723)</b>	<b>(10,296)</b>	<b>(427)</b>	<b>4%</b>
R&D Depreciation	(341)	(613)	272	(44)%
M&S Depreciation	(423)	(814)	391	(48)%
G&A Depreciation	(589)	(136)	(453)	333%
<b>Depreciation</b>	<b>(1,353)</b>	<b>(1,564)</b>	<b>211</b>	<b>(13)%</b>
Share based payment	<b>(952)</b>	<b>(138)</b>	<b>(814)</b>	<b>590%</b>
<b>EBIT</b>	<b>(13,028)</b>	<b>(11,998)</b>	<b>(1,030)</b>	<b>9%</b>
R&D total expenses	(3,160)	(4,655)		
M&S total expenses	(8,978)	(9,098)		
G&A total expenses	(6,187)	(3,952)		
<b>Total expenses</b>	<b>(18,325)</b>	<b>(17,705)</b>		

- Full year Sales increased 10%
- Gross Margin % remained stable at 70%
- OPEX (excluding COGS) increased by 5% and drove negative EBITDA increase
  - G&A increase reflected investments made in the second half of 2018 to strengthen the management team
  - R&D decreased by 30% due to the capitalization of €0.8M of expenses and a good control of other expenses
- Depreciation decreased by 13% due to lower PPU placements in 2019
- Net consolidated loss in 2019 was €15.3M compared to €12.8M in 2018 and included €1.7M of non-financial expenses related to IPF debt repayment

# Balance Sheet

ASSETS	12/31/2019	12/31/2018	EQUITY AND LIABILITIES	12/31/2019	12/31/2018
<b>Non-current Assets</b>			<b>Equity</b>		
Intangible assets	2 343	1 838	Issued capital	1 223	1 008
Property, plant and equipment	1 696	1 985	Share premium	98 257	91 753
Right of use	1 630	n/a	Reserves	(84 130)	(72 072)
Non-current financial assets	173	133	Foreign currency translation on	176	74
<b>Total of non-current assets</b>	<b>5 842</b>	<b>3 956</b>	Profit / (Loss)	(15 272)	(12 785)
<b>Current assets</b>			<b>Total of equity</b>	<b>253</b>	<b>7 979</b>
Inventories & Work in progress	2 592	2 456	<b>Non-current Liabilities</b>		
Trade receivables	2 444	1 643	Long-term loans	15 499	6 457
Other current assets	2 701	3 019	Non-current provisions	299	422
Current financial assets	59	64	<b>Total of non-current liabilities</b>	<b>15 799</b>	<b>6 879</b>
Cash and cash equivalents	9 982	8 623	Short-term loans and borrowings	474	600
<b>Total of current assets</b>	<b>17 778</b>	<b>15 806</b>	Trade payables	2 275	2 087
<b>TOTAL OF ASSETS</b>	<b>23 621</b>	<b>19 762</b>	Other current liabilities	4 821	2 216
			<b>Total of current liabilities</b>	<b>7 570</b>	<b>4 904</b>
			<b>TOTAL OF EQUITY AND LIABILITIES</b>	<b>23 621</b>	<b>19 762</b>

- Trade Receivables increase reflects strong sales to China in Q3 and Q4
- Other current assets included R&D tax credit for 2018 and 2019

- Long term loans include new IEIB Debt for €11.5M
- Other current liabilities mainly comprise social debt

# Cash Flow Statement

(K€)	2019	2018
<b>Cash from operations</b>	<b>(12,105)</b>	<b>(10,874)</b>
Δ in working capital	1,834	(26)
<b>Operating cash flows</b>	<b>(10,271)</b>	<b>(10,900)</b>
Capex (incl. Loans and grants)	(1,416)	(1,246)
<b>Free cash Flows</b>	<b>(11,687)</b>	<b>(12,146)</b>
Capital increase	6,792	3,815
New debt issuance	11,500	
Debt repayment	(4,264)	
Net financial interest paid	(1,733)	(357)
Other (Tax credit Pre payment...)	742	(61)
<b>Cash flow from financing activities</b>	<b>13,037</b>	<b>3,397</b>
Net FX differences	10	16
<b>Net cash flows</b>	<b>1,359</b>	<b>(8,734)</b>
Cash BoP	8,623	0
Cash EoP	9,982	-8,892

- Increase in negative EBITDA primarily drove the change in cash
- Favorable change in Working Capital:
  - Favorable change in payables offset increase of receivables
  - Pre-paid research tax credit of €1.1M
- CapEx comprised of systems placed in pay-per-use program in the US; and €0.8M of capitalization of R&D expenses
- €6.8M net of J&J strategic capital increase
- New debt of €11.5M from EIB
- €4.2M of IPF debt repayment
- Cash used in operating and investing activities totaled €11.7M in 2019 compared to €12.1M in 2018

**Thank You**