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# See Cells. Change Lives.

By creating the first platform to image the human body at the cellular level, we've changed the way physicians see and treat their patients.



### Mission

With Cellvizio®, our advanced cellular imaging platform, we provide partners and providers with cutting edge technologies to transform interventional cancer care.

# Who we are

- Creator of Cellvizio<sup>®</sup>, a proprietary imaging platform that produces real-time, in vivo images used to identify and target abnormal cells
- An intellectual property complex including 250+ issued patents, 20 FDA 510(k) clearances and CE mark, Category I CPT® codes in the US
- Tens of thousands of patient procedures in 20 countries, >1,000 clinical papers on the use of Cellvizio
- A JV and licensing agreement in China with Tasly Pharmaceutical
- Collaborations with the Lung Cancer Initiative at Johnson & Johnson and Telix Pharmaceuticals - J&J is a key shareholder



#### Our Seasoned Team has Decades of Combined Industry Experience



Sacha Loiseau, Ph.D. Chairman and CEO Founder







**Yves Gosset** Acting Chief Financial Officer







François Lacombe, Ph.D. Chief Scientific Officer







**Bruno Villaret** Vice President, International Sales







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







**Daryl Donatelli** Vice President, Global Marketing & U.S. Sales







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



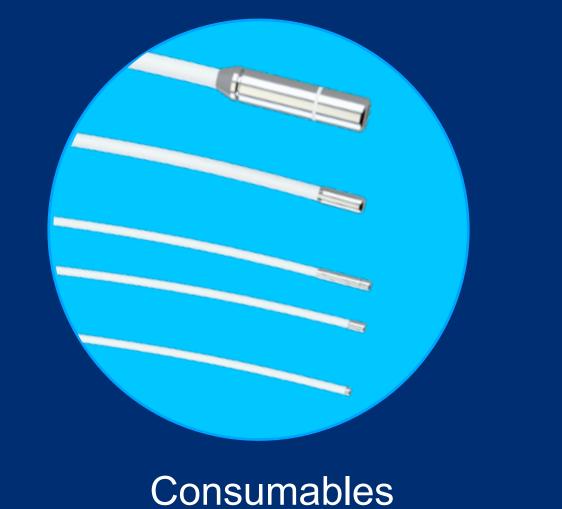


## Cellvizio®: a Proprietary In Vivo Cellular Imaging Platform

The only real-time probe-based in vivo functional and dynamic cellular imaging platform



#### **Portfolio of Miniprobes**

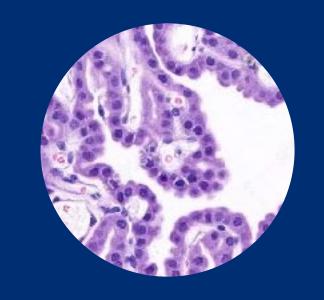


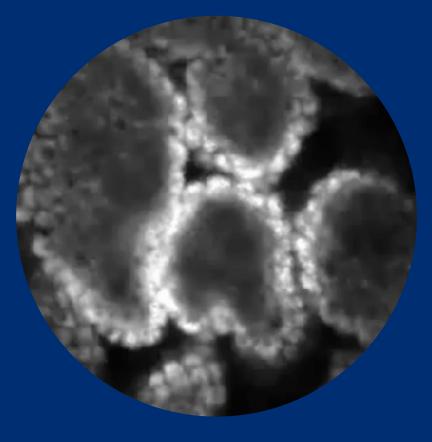
### Cellvizio Provides Real-Time In Situ Functional Cellular Imaging

From H&E histology... one image - static view

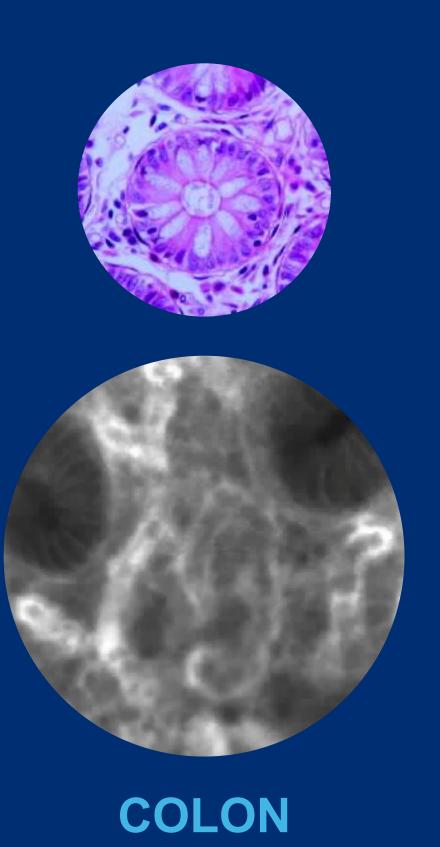
#### ...to Cellvizio®

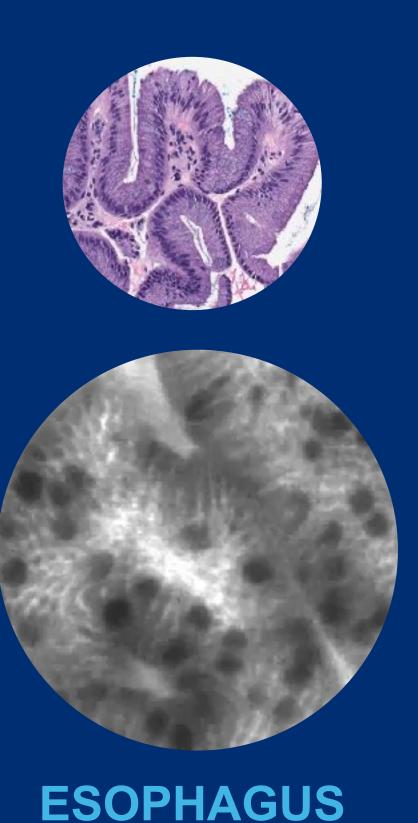
**Hundreds of live** microscopic images per minute: a unique dynamic functional view of biological tissues





**BRAIN** 







"Patients are better served if biopsies can be better targeted. That's where in vivo microscopy comes in."

### Investment Thesis

### 2021

2022 and

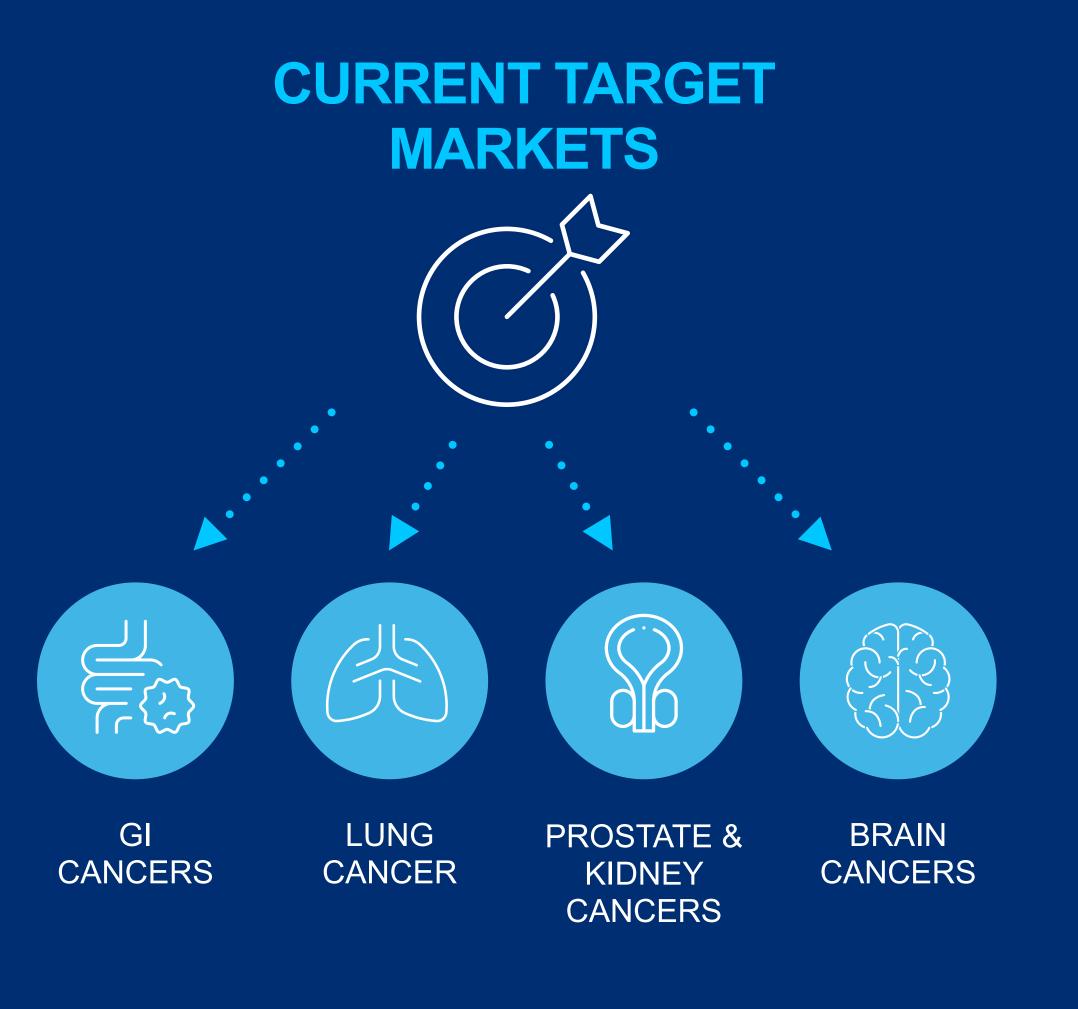
In 2021, building on a decade of invaluable experience and investments, the Company made a strategic decision to pivot from direct marketing to strategic partnerships with leading medtech/pharma firms.

- Announced plans to develop a partnership-focused commercial strategy and close first important partnership deal
- Significantly reduced commercial spending on the GI market (but maintained its revenue)
- Cut costs, increased cash runway
- Reoriented product development to focus on higher potential clinical use cases
- Implemented agile development process delivering new product enhancements twice a year

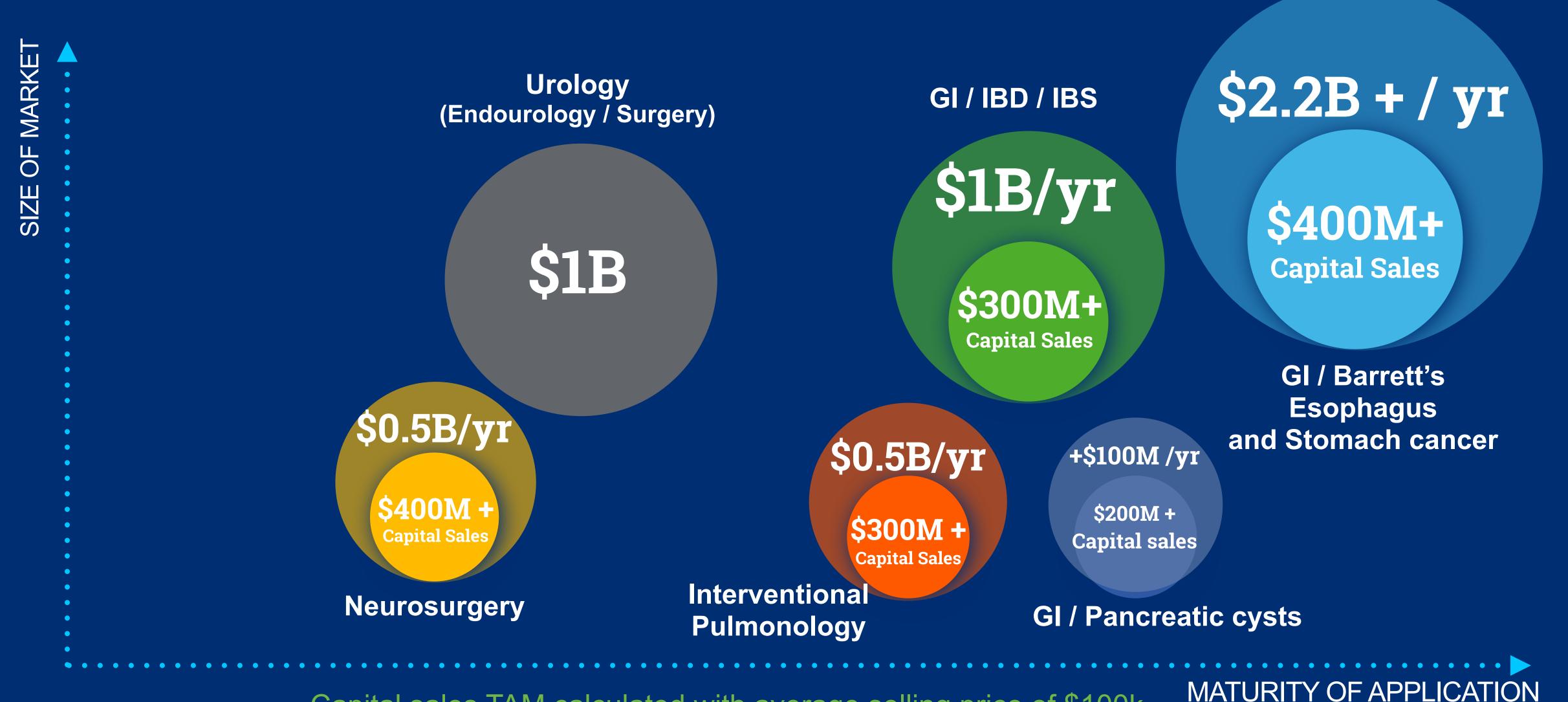
# Our Business Strategy

We target commercial-scale biopharma / medtech companies selling oncology-focused solutions where Cellvizio's advanced imaging technology can differentiate clinical effectiveness and patient outcomes

- More capital efficient business model
- Robust and stable gross margin profile
- Access to large addressable markets
- Accelerates the pace of Intellectual Property monetization
- More predictable financial results



# We Are Addressing Large Market Opportunities



Capital sales TAM calculated with average selling price of \$100k Recurring revenue calculated with procedure price range \$500-\$1000



### We Have a Replicable Partnership Development Process in Place

#### STAGE









#### **Application**

Where Cellvizio provides a clear differentiated solution to major clinical conundrums.



#### Market

**Evaluate market size and hurdles to adoption in** light of all other data including commercial scale partners



#### **Ecosystem**

Integrate into the existing ecosystem: Navigation, Robotics, Endoscopy, Augmented Reality, etc



#### **Partner**

Engage the commercial scale partner to address the market in the most efficient way



#### Clear focus on market-pull indications

Large addressable markets in key geographies

20 years of experience in integration with complementary technology platforms

A large and active pipeline of potential commercial scale partners

# We Have Built a Solid Pipeline for Cellvizio Partnerships

APPLICATION	ECOSYSTEM	STAGE	CLINICAL DEVELOPMENT	GRANTED REG. APPROVAL	IN MARKET	COMMERCIAL PARTNERSHIPS
NEUROLOGIC CANCER	#surgery #navigation	4		US		ATASLY
LUNG CANCER	#endoluminal robotics #molecular imaging	3	Johnson-Johnson	—— GLOBAL ——	— GLOBAL →	OPEN
IBD / IBS	#endoscopy	3		—— GLOBAL ——	→ GERMANY	CURRENTLY DIRECT
PANCREATIC CYSTS	#needles #Al	3		GLOBAL -	→ GLOBAL	CURRENTLY DIRECT
ESOPHAGEAL and STOMACH CANCERS	#endoscopy #AI	3		GLOBAL -	→ GLOBAL	CURRENTLY DIRECT
PROSTATE and KIDNEY CANCERS	#surgical robotics #molecular imaging	2	TELIX	—— GLOBAL		OPEN





# Our Cellvizio Development Roadmap is Fully Aligned with Our Partners' Key Needs



**MOLECULAR CANCER IMAGING** 









**DATASETS** 

- Cellvizio nextgeneration advanced platform launched in 2021
- In vivo endoscopic visualization of targeted cancer cells
- 1st FDA clearance in 2022

Integrated navigation and data capture

**ROBOTIC** 

**IMAGING** 

- Smart needle probe localisation
- Agnostic exploration tools

- Advanced prototype developed for various applications in GI
- Pulmonary application in development
- In situ / In vivo endomicroscopic imaging data for multimodal datasets (under development)

## We Are Already Validating Our New Business Strategy





### JV and Licensing agreement with Tasly Pharmaceutical

- \$10 million upfront cash contribution to Mauna Kea
- JV now incorporated in Zhejiang province with \$35m registered capital
- Mauna Kea to own 44% of JV in exchange of certain IP rights and licenses
- **Expansion of Chinese market**
- Launch of a dedicated neurosurgery platform worldwide

### 1. Expanding the Chinese Market

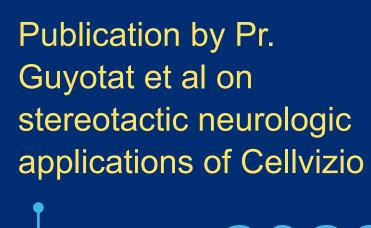
- Building on solid installed base of 46 systems in Eastern China and strong KOL support
- Expansion to entire territory with Tasly
- Accelerate Cellvizio commercial deployment in China: targeting 1,200+ Tier 3A hospitals at first
- Establish locally-assembled Cellvizio to expand addressable market





## 2. Launching a Dedicated Cellvizio Platform for Neurosurgery

#### A key application 10 years in the making



Zeiss launches the **Convivo Confocal** Neuro-endomicroscope

2023

2020

2021

**Tasly Mauna Kea Medical Engineering Technology Co., Ltd.** to develop CLE products for brain surgery

2016

Publication on 150 cases of Cellvizio imaging on intracranial and intraspinal lesions showing great promise

2015

Mauna Kea gathers major opinion leaders at AANS and validates Cellvizio value propositions for neurology applications

FDA Clearance for Cellvizio in neurology procedures, with the Cranioflex probe



strategic partnership in Neurology / Neurosurgery **ATASLY** 

2022

Mauna Kea and Tasly sign

Publication "Confocal Laser Endomicroscopy in Oncological Surgery" by Charalampaki et al clearly defining Endomicroscopy's key advantages and value propositions in Neurosurgery

# Illustrative Cellvizio cases

Cellvizio for lung cancer

# Lung Cancer Diagnosis: Fighting the Numbers

1 million lung biopsies performed annually worldwide



But

Only 6%

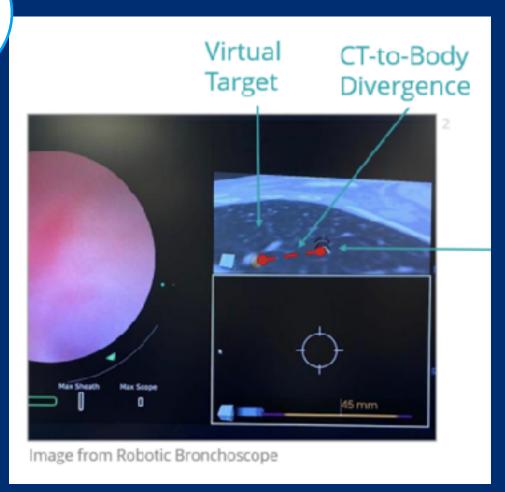
of lung cancer cases diagnosed at an early stage

Lung cancer responsible for more deaths than colon, breast, and prostate cancers combined

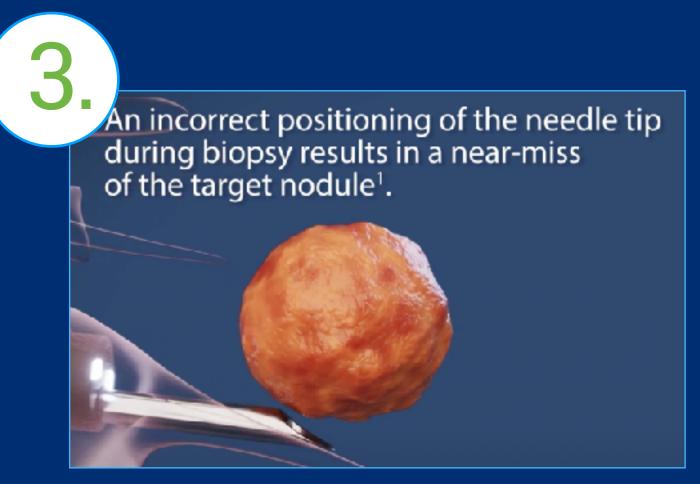
# Navigation and Robotics Suffer from Low Diagnostic Yield

80%

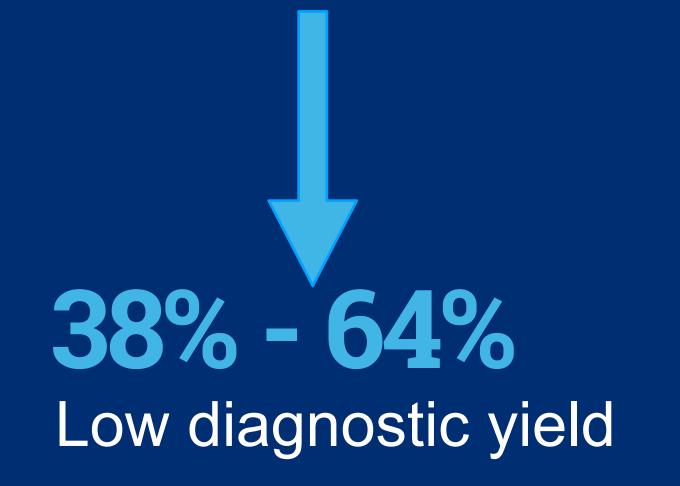
of lung nodules located outside the airways with no direct visualization



Lack of direct visualization and CTto-body divergence strongly limit **Advanced Navigation and Endoluminal Robotics platforms** 



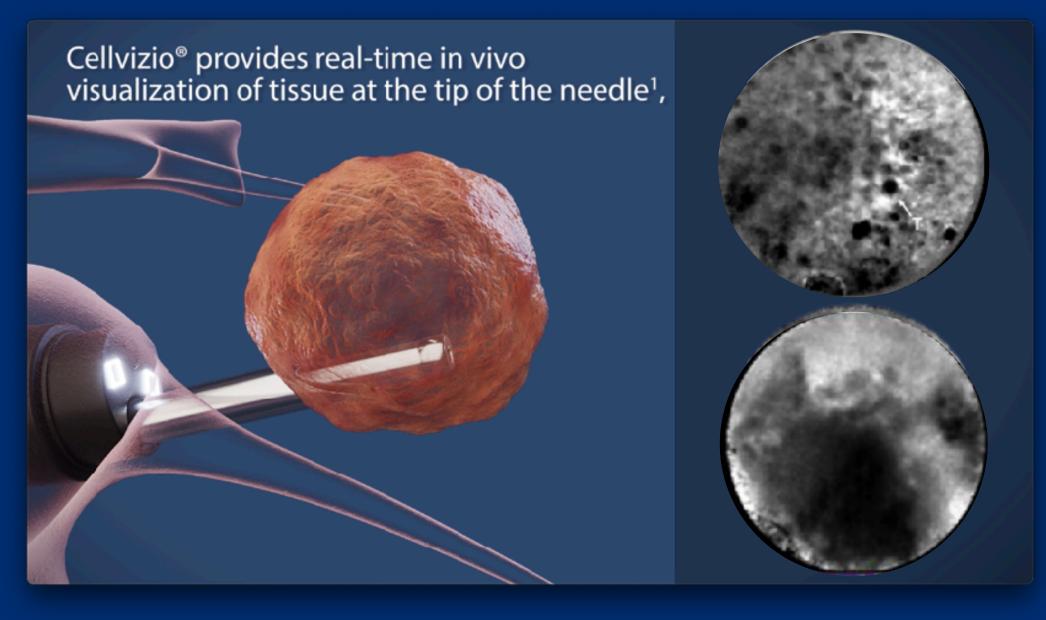
Near-miss of target nodule caused by blindly used biopsy needles





<sup>1.</sup> Heuvelmans, A. Et al. Relationship between nodule count and lung cancer probability in baseline CT lung cancer screening: the NELSON study. Lung

## The Cellvizio Solution: Giving Sight to Blind Needles



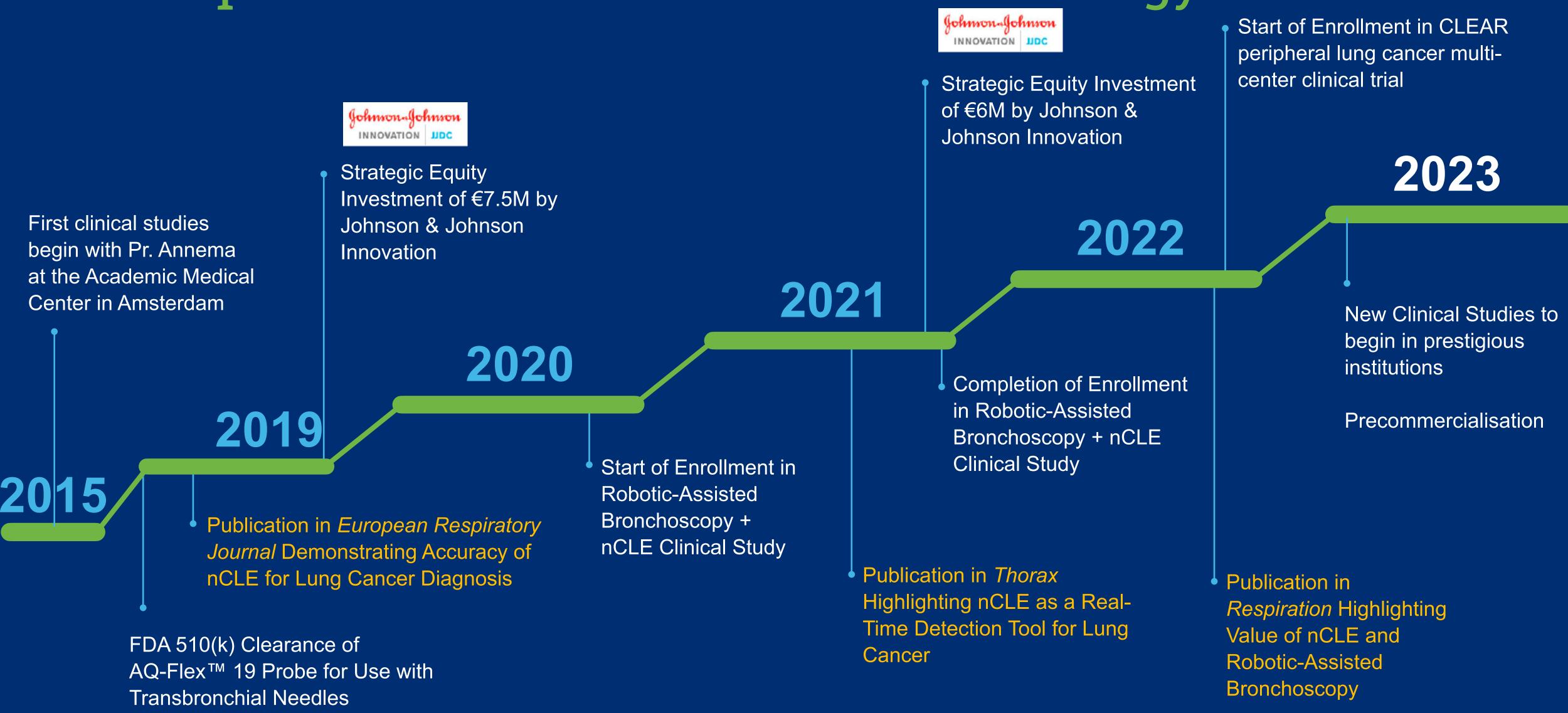
VIEW VIDEO ON YOUTUBE >

Cellvizio captures in situ images in real-time, and can provide in vivo guidance for targeted biopsy during manual and robotics-assisted bronchoscopies with the following benefits:

- Needle positioning for tool-in-lesion
- Assurance of lesion-in-tool
- Higher diagnostic yield of 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 Center<sup>1</sup>

# We are Building on 8 years of Product and Clinical Development in Interventional Pulmonology



# Illustrative Cellvizio cases

Cellvizio for Pancreatic Cysts

### Cellvizio Needle-based Endomicroscopy (nCLE) is a Paradigm Shift for Pancreatic Cyst Characterization

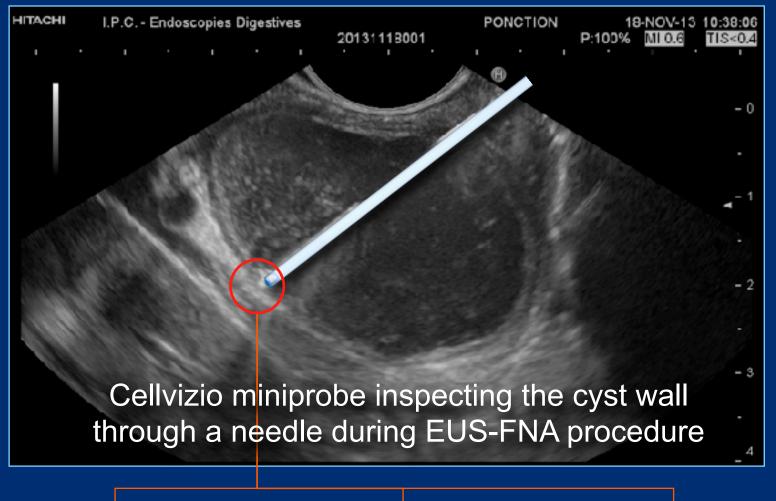
3-10%

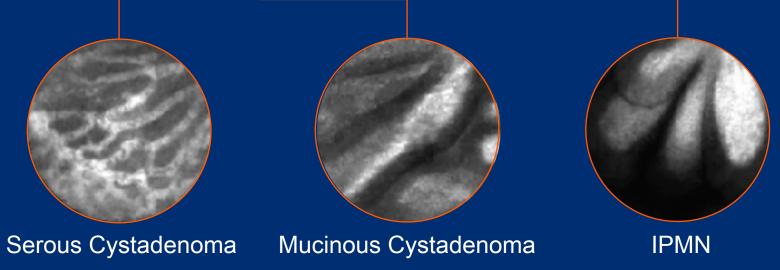
prevalence of Pancreatic Cysts, often detected incidentally during radiology

Low diagnostic yield of Radiology and Ultrasound Guided Fine Needle Aspiration (EUS-FNA)

60%

of patients with benign pancreatic cysts undergo unnecessary surgery





EUS-FNA combined with Cellvizio (nCLE)
FDA cleared in 2013 and reimbursed with category I CPT® code

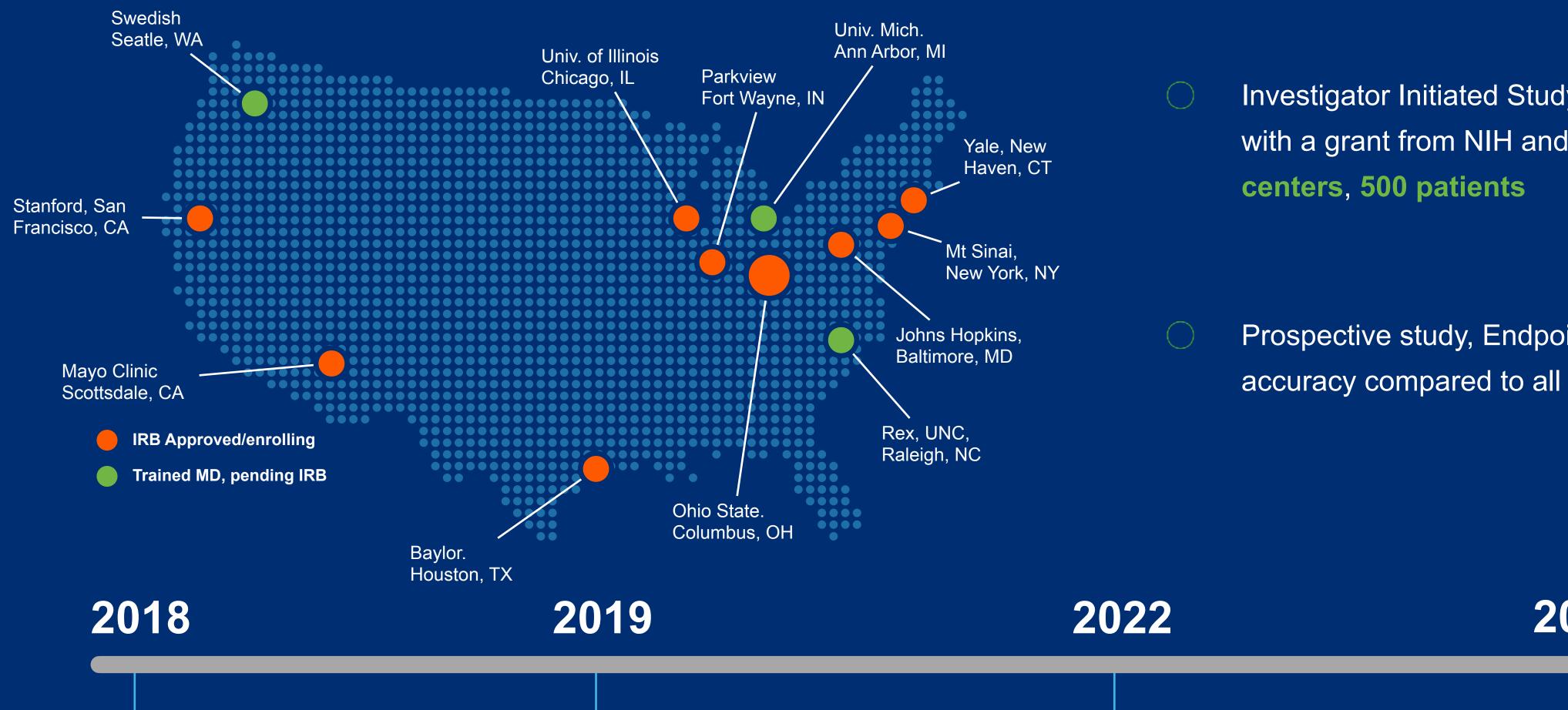
100%

specificity in characterizing Mucinous Cystic Lesions specificity in characterizing Serous Cystadenomas



### The CLIMB Pivotal Study for Cellvizio in Pancreatic Cysts

#### **CLIMB STUDY CENTERS**



Investigator Initiated Study (Ohio State University) with a grant from NIH and Mauna Kea: 10

Prospective study, Endpoint: Definitive diagnostic accuracy compared to all other techniques

2023 - 2024

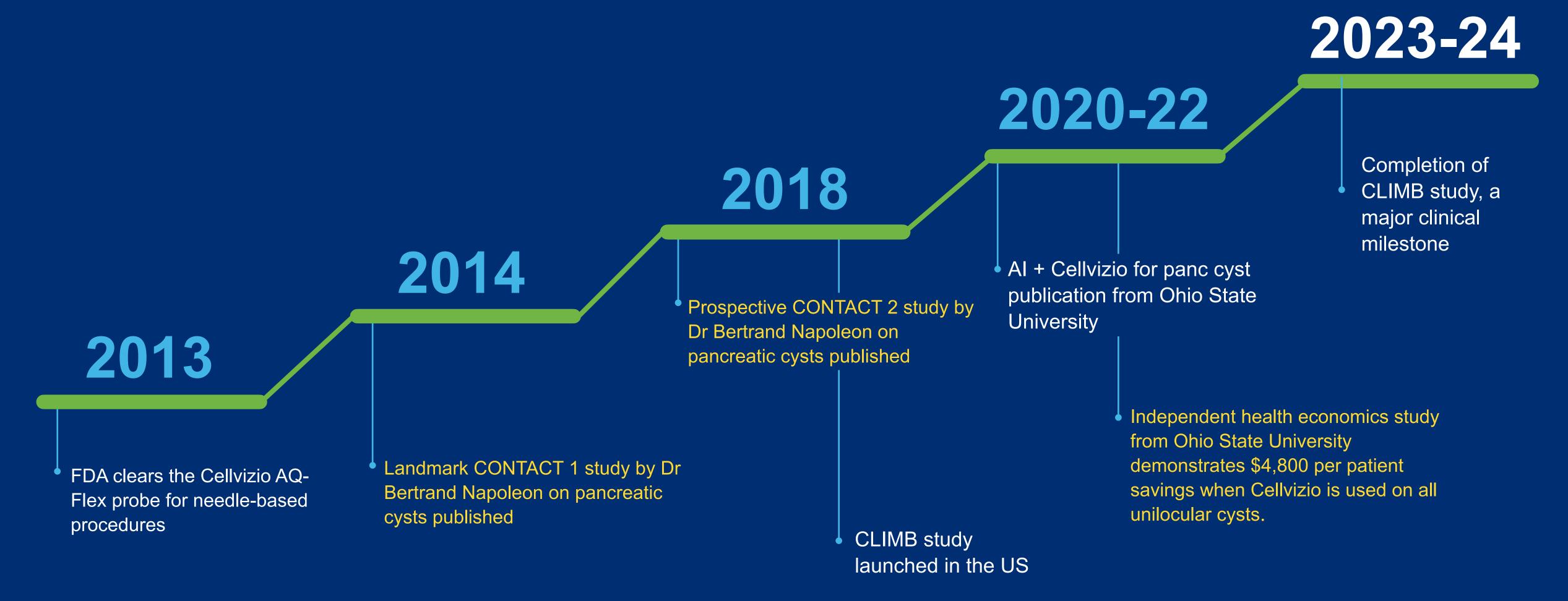
CLIMB pivotal study launched

Contracting, IRBs, training, etc.

270+ patients enrolled across 10 centers

**Expected Completion date** 

# 10 Years of Clinical and Product Development in Pancreatic Cysts Imaging and Characterization



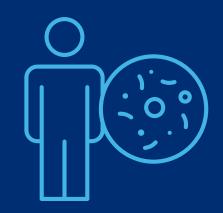
# Illustrative Cellvizio cases

Cellvizio for Inflammatory Bowel Disease (IBD)

### Inflammatory Bowel Disease: Introducing a New Key Therapeutic Endpoint with Cellvizio

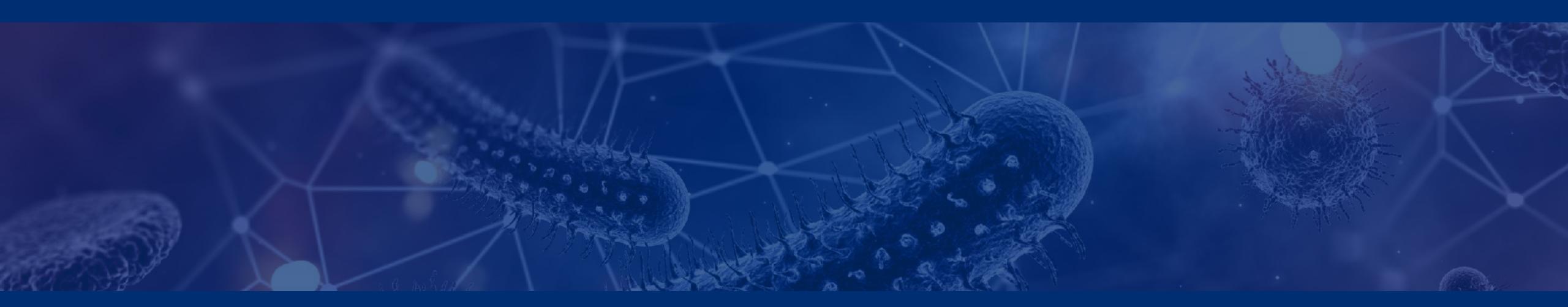
6-8 million patients suffering from IBD in the US and EU

187,000 Hospitalizations in the US per year for Crohn's disease



**Patients with Ulcerative Colitis or Crohn's Disease in remission undergo** colonoscopy every 1 to 2 years

Drug prescription every year



# Intestinal Barrier Healing, Visualized Functionally with Cellvizio, is a Far Superior Predictor

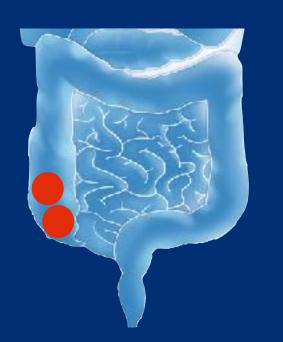
#### Gastroenterology >aga

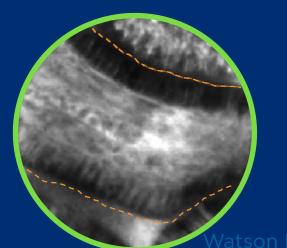
CLINICAL - ALIMENTARY TRACT I ARTICLES IN PRESS

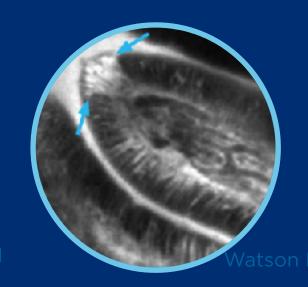
Intestinal barrier healing is superior to endoscopic and histologic remission for predicting major adverse outcomes in IBD: the prospective ERIca trial

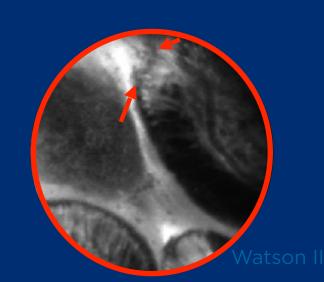
Timo Rath • Raja Atreya • Julia Bodenschatz • ... Jean-Frédéric Colombel • Arndt Hartmann • Markus F. Neurath A Marku

Published: October 21, 2022 • DOI: https://doi.org/10.1053/j.gastro.2022.10.014



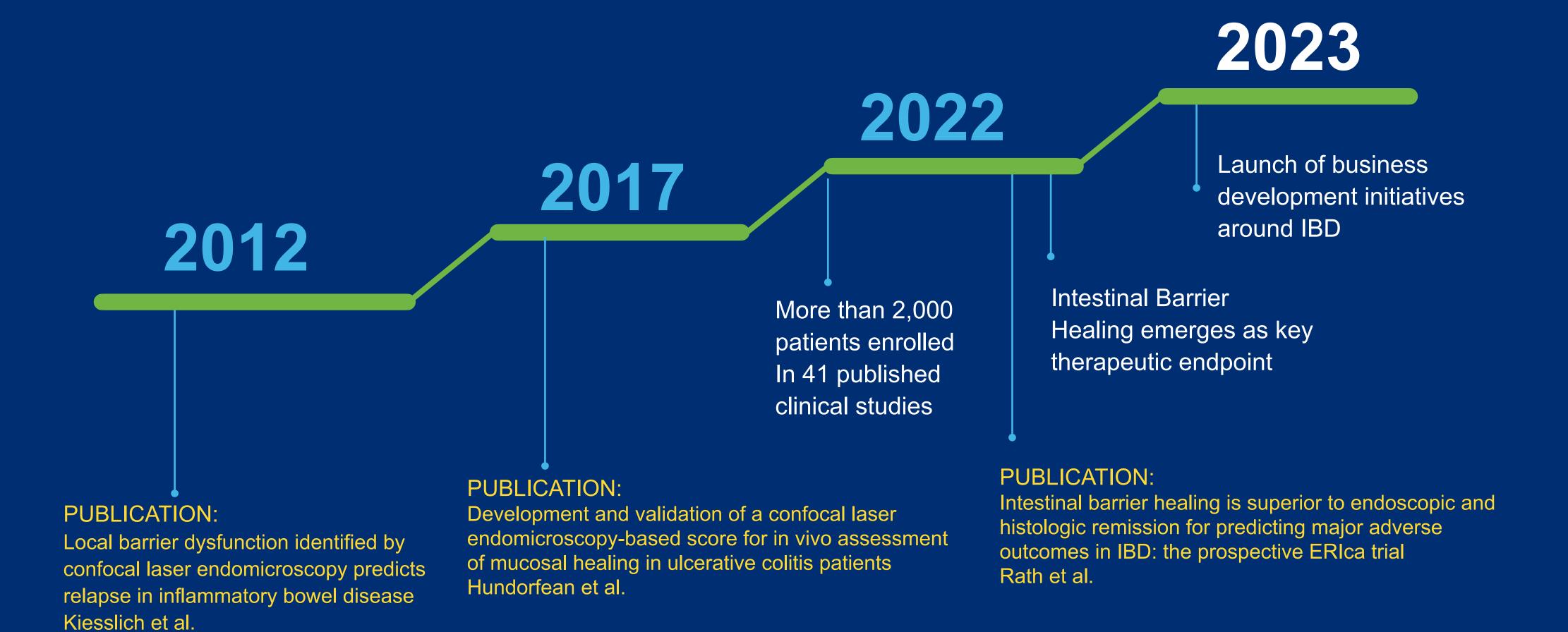






- Long term study published in Gastroenterology demonstrates that Intestinal Barrier Healing by far outcompetes all other predictors of relapse / remission
- Cellvizio is the only available imaging platform that can visualize Intestinal Barrier and characterize its state by functional and dynamic imaging

# Building on a Decade of Clinical Development in IBD with Leading Teams Around the World



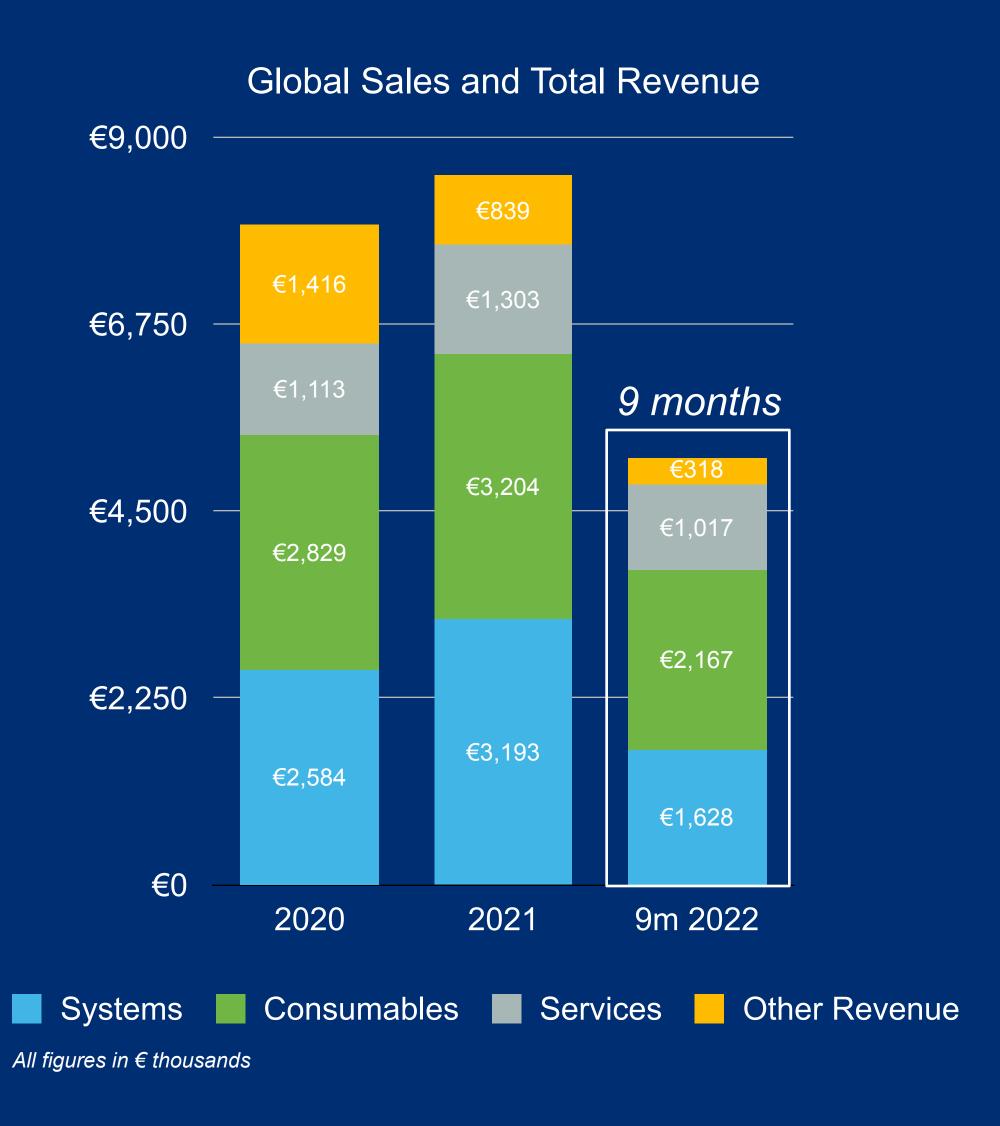
# Financial Metrics

### First 9 Months 2022 Sales and Revenue

#### Sales for the first nine months of 2022 decreased by **€275K**, or -5% year-on-year, to **€4**,812K.

Systems sales at €1,628K, -17%. Sales of consumables at €2,167K, -5%. Sales of services at 1,017 K€, +21%.

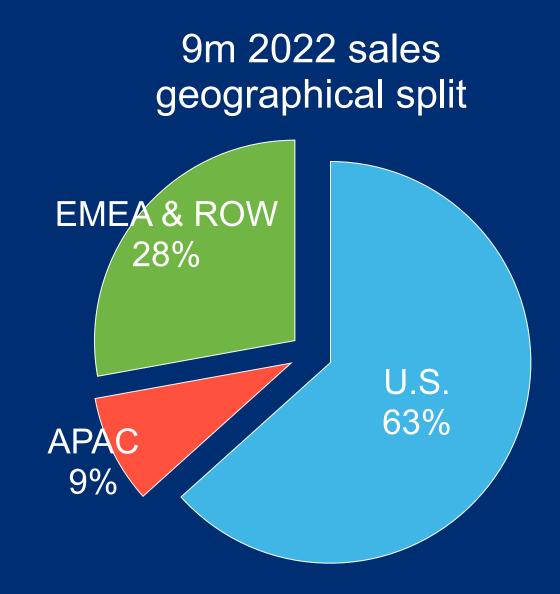
Stability of sales revenue in spite of downsizing was a key corporate goal announced during the strategic repositioning in December 2021 and demonstrates adoption in target markets.

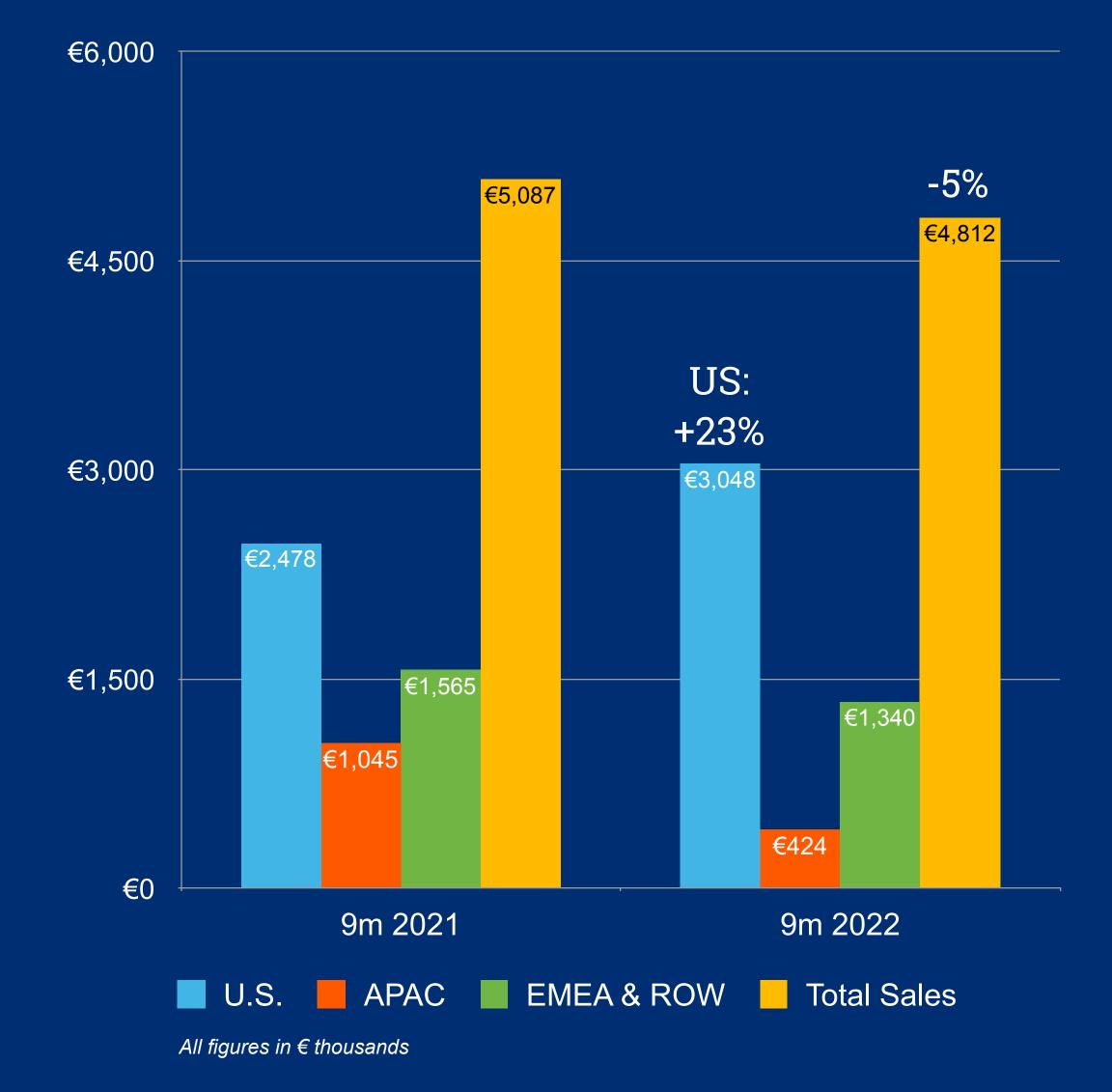




## 9m 2022 Sales by Geography Show Solid US Progress

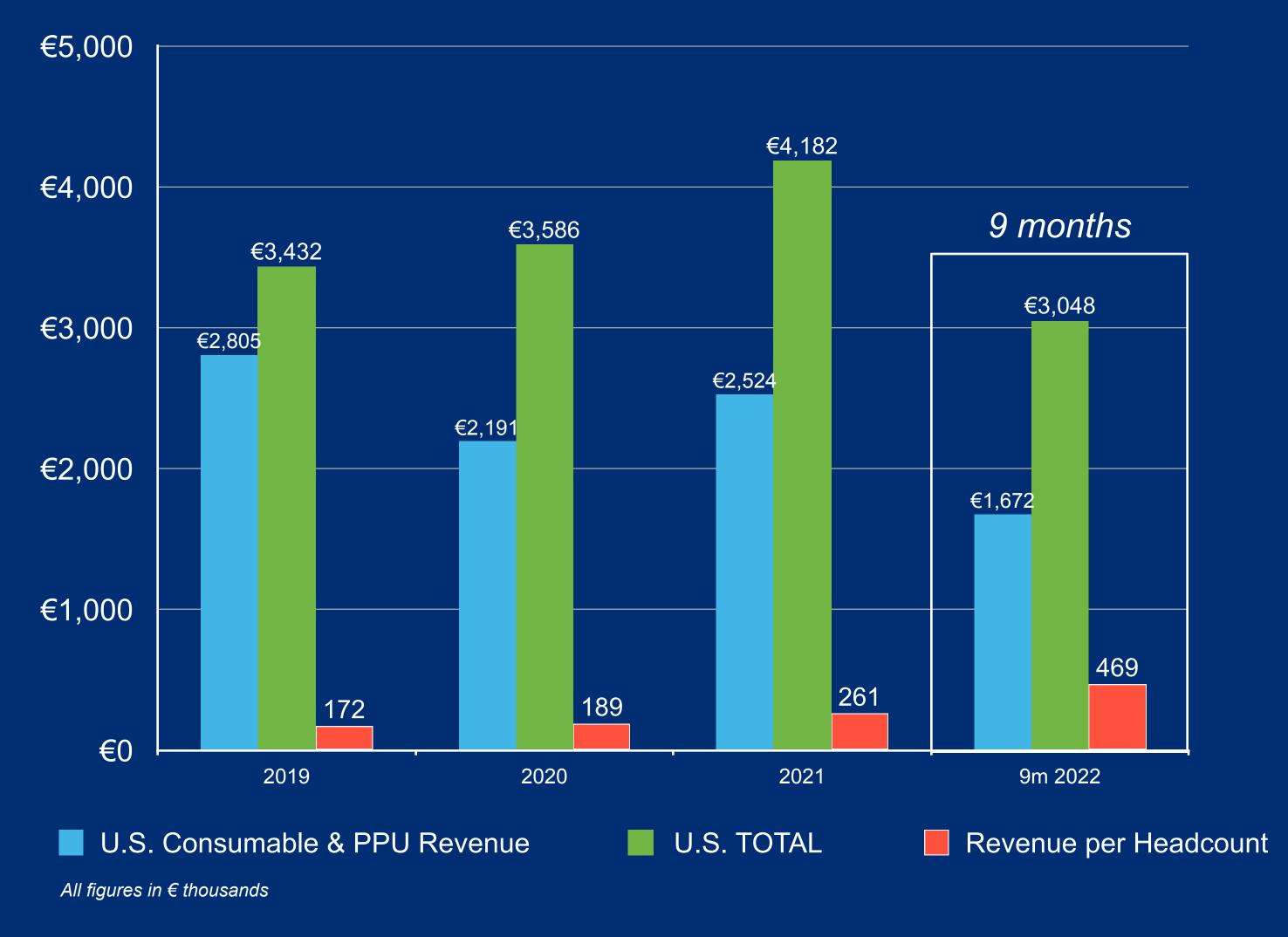
- Solid 23% growth in the US
- Impact of COVID-19 and Tasly deal in China
- Overall, relative stability of sales revenue according to plan





### Cellvizio U.S. Revenue per Headcount is Showing Significant Growth

- U.S. consumable (probe) and PPU revenue demonstrate adoption of Cellvizio in the targeted market segment
- Launch of next-generation Cellvizio has rekindled capital sales initiatives
- 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
- 28% CAGR in revenue per sales person in the U.S. since 2019
- Demonstration of product market fit and scalability



#### H1 2022 Income Statement

In €k - IFRS Standards	30/06/2022	30/06/2021	Variation	%
Sales	3 391	3 314	77	2%
<b>Gross Profit</b>	2 480	2 343	137	6%
% Gross Margin	73%	71%		
Other Income	318	548	(230)	-42%
R&D Expenses	(337)	(306)	(31)	10%
M&S Expenses	(775)	(822)	47	-6%
G&A Expenses	(1 494)	(1 597)	103	-6%
Total Expenses	(2 606)	(2 726)	<b>120</b>	-4%
R&D Payroli	(1 286)	(1 149)	(137)	12%
M&S Payroli	(1 945)	(2 824)	879	-31%
G&A Payroli	(938)	(1 553)	615	-40%
Total Payroll	(4 170)	<i>(5 527)</i>	<i>1 357</i>	<b>-25</b> %
EBITDA	(3 977)	(5 361)	1 384	-26%
D&A	(824)	(379)	(446)	118%
Shared-based Payment	(155)	(359)	204	-57%
EBIT	(4 957)	(6 099)	1 142	-19%
Non-current operating	(05)	0	(05)	N1/A
income	(85)	0	(85)	N/A
Financial Result	(1 170)	(592)	(578)	98%
Net Profit/ (loss)	(6 212)	(6 691)	479	-7%

- Increase in the gross margin of €0.1m or 2%
- EBITDA improved by €1.3m following the company's reorganization or -26%
- The net result is -€6.2m (+€0.5m vs 2021) after taking into account a financial result of -€1.2m, which is €0.6m lower than the financial result for 2021 due to in particular unfavorable exchange rate effects (-€0.5m).

## Simplified Balance Sheet

ASSETS (€k - IFRS)	06/30/2022	12/31/2021
Non-current Assets		
Intangible assets	3 033	3 371
Property, plant and equipment	1 070	1 233
Right of use	943	1 124
Non-current financial assets	357	355
Total of non-current assets	5 405	6 083
Current assets		
Inventories & Work in progress	3 313	3 013
Trade receivables	1 271	1 532
Other current assets	1 850	2 228
Current financial assets	31	29
Cash and cash equivalents	5 306	11 866
Total of current assets	11 771	18 667
TOTAL OF ASSETS	17 175	24 751

EQUITY AND LIABILITIES (€k - IFRS)	06/30/2022	12/31/2021
Equity		
Issued capital	1 784	1 784
Share premium	6	111 920
Reserves	(12 107)	(110 759)
Foreign currency translation on reserve	718	168
Profit / (Loss)	(6 212)	(13 445)
Total of equity	(15 811)	(10 333)
Non-current Liabilities		
Long-term loans	26 413	26 890
Non-current provisions	174	855
Total of non-current liabilities	26 587	27 745
Short-term loans and borrowings	2 022	1 807
Trade payables	1 202	1 667
Other current liabilities	3 174	3 865
Total of current liabilities	6 398	7 339
TOTAL OF EQUITY AND LIABILITIES	17 175	24 751

- Trade receivables decreased in line with sales volume.
- Other current asssets including R&D tax credit €0,3m
- Non-current provisions decreased with payments linked to restructuring.
- Long-term debt remained stable, mainly including EIB loan: €19m and Guaranteed loan by State: €4m

#### Cash Flow Statement

In K€ - IFRS	June-22	June-21
Profit / (Loss)	(6 212)	(6 691)
Eliminations	1 051	1 603
Δ in working capital	(1 016)	(575)
Net cash flows from operating activities (A)	(6 176)	(5 663)
Сарех	(137)	(896)
Net cash flows from Investing activities (B)	(137)	(896)
Capital increase	6	933
Δ in financial debt - IPF		
Reimbursment of debt on leases (IFRS 16)	(283)	(271)
Net financial interest paid	(37)	0
IPF penalties and others		
Financing of Tax Research Credit	0	711
Other	(4)	2
Cash flow from financing activies ( C )	(318)	1 375
Net FX differences	71	8
Cash end of period	11 866	8 606
Cash beginning of period	5 306	3 428
Change in Cash	(6 560)	(5 178)

- R&D tax credit and equity line were activated during the second half of the year
- Capex decreased as the commercialization of next-generation platform started in Q3 2021 and lower capitalization of R&D expenses in 2022
- Cash at the end of June 2022 was 5.3M€
- Cash position is expected to be strengthened by payments related to the partnership with Tasly

## Stock and Shareholding Information

#### Stock Market Data

- Listed on Euronext Paris regulated market, Compartment C
- Initial listing:July 6, 2011
- Number of outstanding shares: 44,584,335
- Market cap:€25M

#### Identification Codes

• ISIN: FR0010609263

Ticker: MKEA

Bloomberg: MKEA.FP

Reuters: MKEA.PA

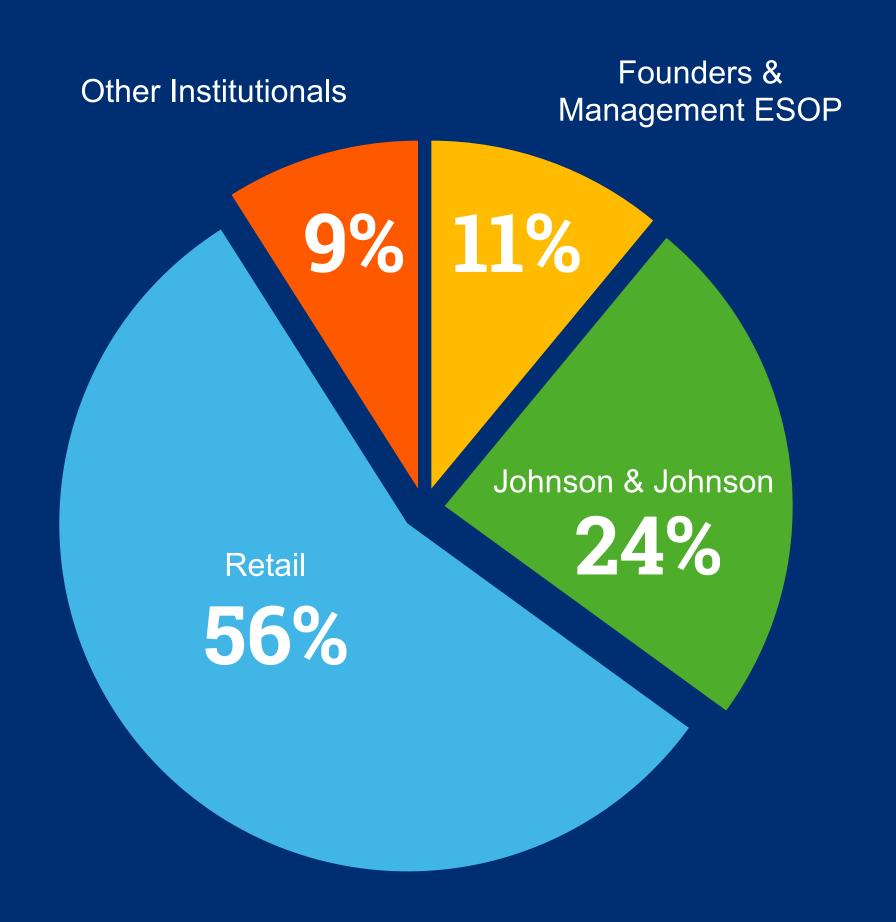
#### Analyst Coverage

**GILBERT DUPONT Guillaume Cuvillier** 

**Damien Chaplain** 

ODDO BHF

#### Shareholders Structure





# Investment Summary

- 2021 new strategy validated with recent Tasly Pharmaceutical partnership
- Multi-billion market opportunities addressed by proprietary Cellvizio platform
- ✓ Strong pipeline of strategic partners to address large additional markets based on portfolio of regulatory / clinical / product assets
- Clinical collaboration with the Lung Cancer Initiative at Johnson & Johnson in the field of robotic-assisted bronchoscopies