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## Seeing is Knowing

# The Power of Cellvizio<sup>®</sup> Vision

Cellvizio addresses critical unmet medical needs by providing unmatched clinical value and robust health economics that align incentives for all stakeholders.



## 100,000 patients and counting

HELPING PHYSICIANS SAVE LIVES, ONE PATIENT AT A TIME



Discovering pre-cancerous mucosal changes in the esophagus or the stomach before they become cancer can save the patient's life.



Avoiding a near-miss in a peripheral lung nodule and thus diagnosing lung cancer at an earlier stage can save the patient's life.



Characterizing a pancreatic cyst earlier and sending the patient to treatment immediately can save the patient's life.



# CELLVIZIO® THE WORLD'S SMALLEST MICROSCOPE, WITH A REVOLUTIONARY IMPACT: TRANSFORMING PATIENT LIVES EVERY DAY





ULTRA-MINIATURIZED
FIBER OPTIC MINIPROBES

#### **CELLVIZIO PLATFORM**

Proprietary cutting-edge opto-mechatronics and image processing software

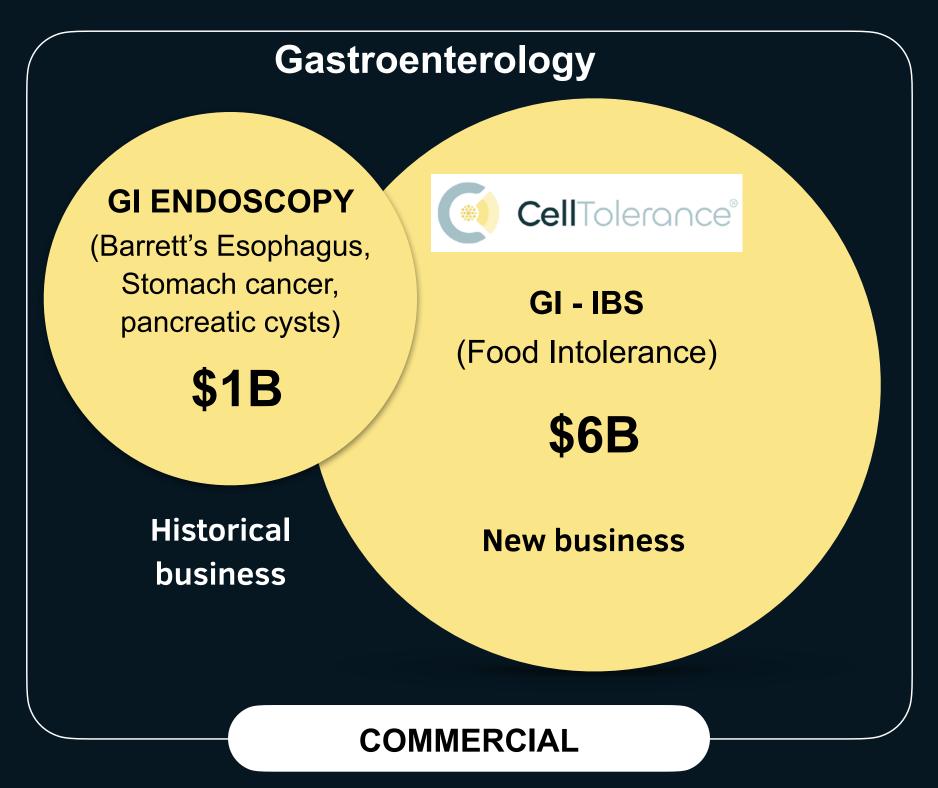
- 238 patents
- ► 1,200 clinical papers
- > **100,000** procedures
- > 20 FDA clearances
- Cat. 1 CPT Codes



REAL-TIME VISUALIZATION OF CELLS AND CELLULAR ARCHITECTURE

HUNDREDS OF LIVE MICROSCOPIC IMAGES PER MINUTE INSTEAD OF ONE RANDOM / BLIND BIOPSY

# MARKETS TECHNOLOGY USED ACROSS A WIDE RANGE OF SPECIALTIES REPRESENTING A MULTI-BILLION DOLLAR ANNUAL OPPORTUNITY





## UNIT ECONOMICS / BUSINESS MODEL

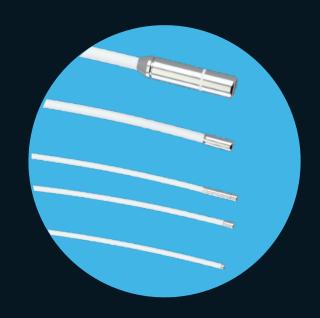
### HIGH GROSS MARGIN PROFILE

**CELLVIZIO PLATFORM** 

PORTFOLIO OF FIBER OPTIC MINIPROBES

Reusable





10 models of miniprobes designed for every application

**Gross Margin** 

CAPITAL SALE SYSTEM

90%

**PROBES** 

85%

**SERVICES** 

PAY-PER-USE<sup>1</sup>

HOSPITAL

95%

ASC

**75%** 

1. Gross margin on probes

## KEY FOCUS APPLICATION: PANCREATIC CYSTS DIAGNOSIS

### PROVEN SOLUTION TO AVOID UNNECESSARY SURGERY

3-10%

of adults have pancreatic cysts

30%

of cysts are indeterminate after endoscopic ultrasound

>50%

of cysts are indeterminate after Fine Needle Aspiration (EUS-FNA)

60%

of patients with benign cysts undergo unnecessary surgery



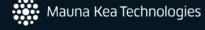
## CELLVIZIO ENABLES NEAR-PERFECT ACCURACY OF CHARACTERIZATION OF SOLITARY CYSTS

97% Accuracy

For benign vs malignant classification



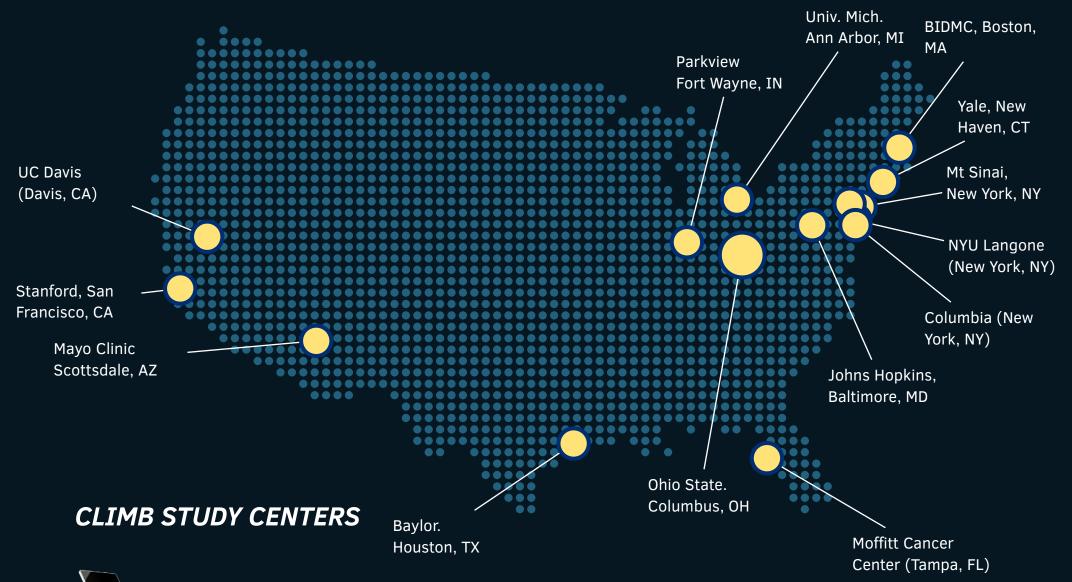
- 35% of benign cysts that won't need further surveillance
- ▶ 23% reduction in unnecessary surgeries leading to net savings of \$4,757 per patient
- 2.0x reimbursement vs GI Endoscopy with Endoscopic UltraSound Fine Needle Aspiration



Palazzo, M., Sauvanet, A., Gincul, R. et al. Impact of needle-based confocal laser endomicroscopy on the therapeutic management of single pancreatic cystic lesions. Surg Endosc 34, 2532–2540 (2020). https://doi.org/10.1007/s00464-019-07062-9

## PANCREATIC CYSTS: CLIMB STUDY

## MAJOR PIVOTAL STUDY TO VALIDATE CELLVIZIO'S SUPERIORITY AND BUILD STRONG MOMENTUM



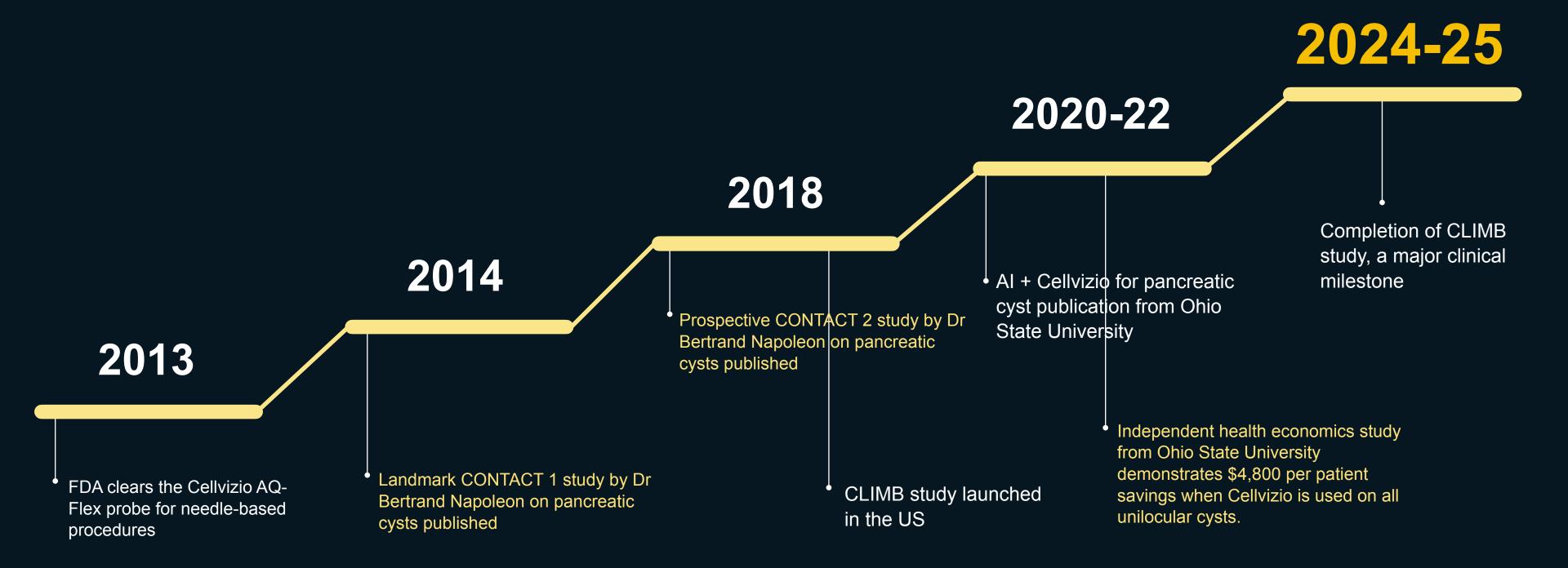
- Investigator Initiated Study (Ohio State University)
- 14 sites activated, 500 patients
- Prospective study with definitive diagnostic accuracy compared to all other techniques as endpoint
- Enrollment completed
- Presentation of results in May 2025



CELLVIZIO IS POISED TO BECOME THE STANDARD OF CARE IN PANCREATIC CYST CHARACTERIZATION

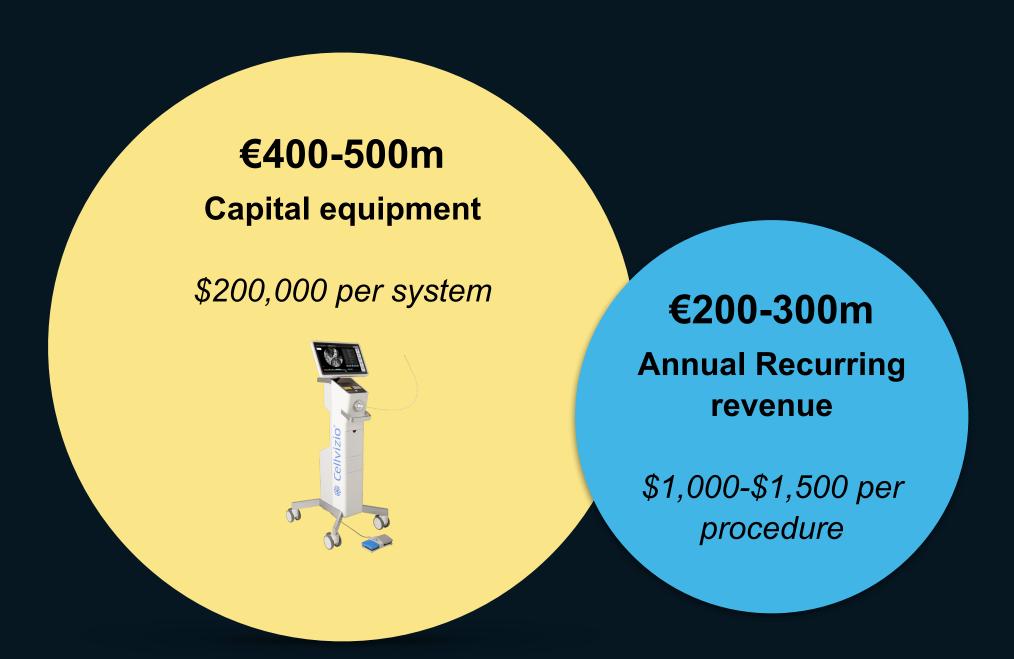
## PANCREATIC CYST CHARACTERIZATION

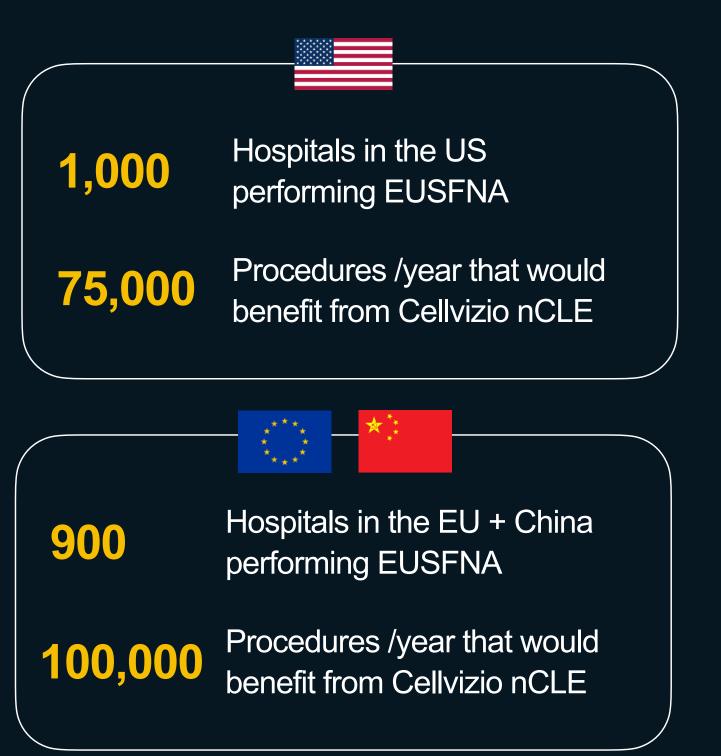
## 10 YEARS OF FAST-PACED DEVELOPMENT WITH MAJOR MILESTONES TO BE ACHIEVED IN THE COMING WEEKS AND MONTHS



## PANCREATIC CYSTS: A LARGE AND GROWING MARKET OPPORTUNITY

## A MIX BETWEEN CAPITAL EQUIPMENT AND RECURRING REVENUE





# KEY FOCUS APPLICATION: ESOPHAGEAL AND GASTRIC CANCERS ACCURATE DIAGNOSIS OF BARRETT'S ESOPHAGUS TO PREVENT THE DEVELOPMENT OF CANCER

18-27%

of American adults have GERD potentially leading to esophageal cancer<sup>1</sup>

**Chronic Acid Reflux (GERD)** 

50M patients

Metaplasia

THE ADJUNCT USE OF CELLVIZIO DURING ENDOSCOPY SIGNIFICANTLY INCREASES THE DETECTION RATE OF BARRETT'S ESOPHAGUS



Pre-cancerous condition than can be eradicated if detected

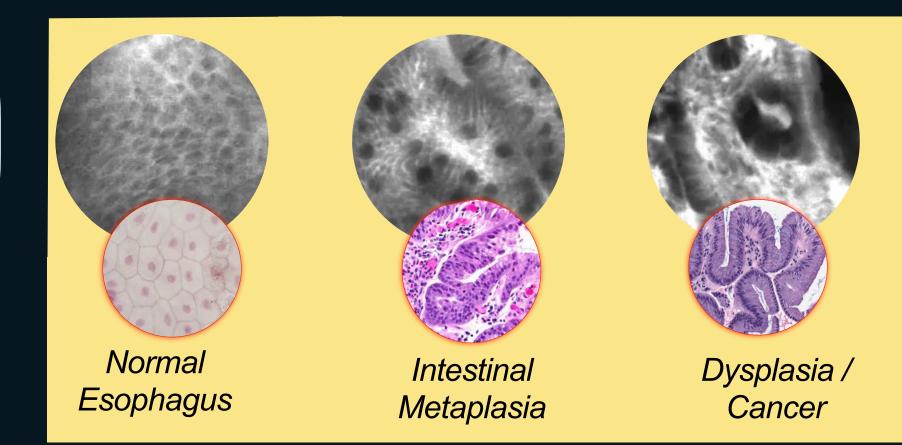
**Barrett's Esophagus** 

Dysplasia

91%

of esophageal cancer patients never received a diagnosis of Barrett's<sup>2</sup>

**Esophageal Cancer** 



<sup>1.</sup> The Changing Epidemiology of Gastroesophageal Reflux Disease: Are Patients Getting Younger? doi: 10.5056/jnm18140

<sup>2.</sup> Tan MC, Mansour N, White DL, Sisson A, El-Serag HB, Thrift AP. Systematic review with meta-analysis: prevalence of prior and concurrent Barrett's oesophagus in oesophageal adenocarcinoma patients. Aliment Pharmacol Ther. 2020 Jul;52(1):20-36. doi: 10.1111/apt.15760. Epub 2020 May 26.

### **ESOPHAGEAL CANCER**

## A META ANALYSIS¹ DEMONSTRATING THE HIGH DETECTION ACCURACY RATE OF BARRETT'S ESOPHAGUS WHEN CELLVIZIO IS USED DURING ENDOSCOPY

9 studies for a total of 688 patients and 1,299 lesions assessed the benefits of Cellvizio as an adjunct to random 4-quadrant biopsies in the surveillance of patients with Barrett's Esophagus for dysplasia and early esophageal cancer detection

96%

Sensitivity

93%

**Specificity** 

98%

**Negative Predictive Value** 

+243%

Relative detection increase compared to random biopsies

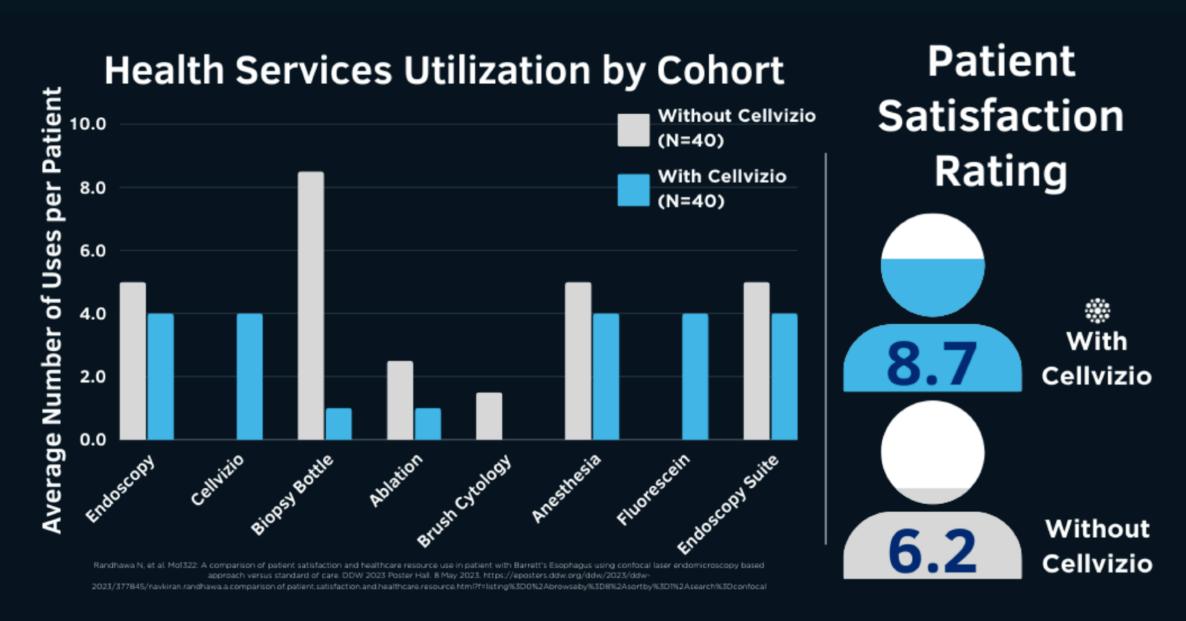


CELLVIZIO PLAYS A KEY ROLE IN SLOWING THE RAPID GROWTH OF ESOPHAGEAL CANCER

## STRONG ECONOMIC BENEFITS

## INCREASING REVENUE, OPTIMIZING HEALTHCARE RESOURCE UTILIZATION AND ENHANCING PATIENT SATISFACTION

- Proven solution with enhanced diagnostic accuracy and reimbursement with Category 1 CPT code 43252
- Used during an Upper GI Endoscopy
- Adds only a few minutes to the procedure
- 2.3x reimbursement vs Upper GI Endoscopy alone
- Improved patient satisfaction and reduction of health services
- Solid economic equation for Mauna Kea



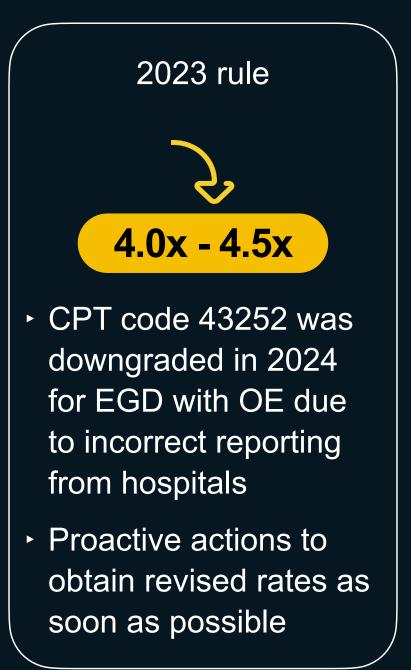
According to data presented at DDW 2023, "the use of Cellvizio is associated with lower health services utilization of endoscopy, anesthesia, biopsy, ablation and higher patient satisfaction

## U.S. CMS COVERAGE

## SIGNIFICANT FINANCIAL INCENTIVE TO USE CELLVIZIO IN BARRETT'S AND PANCREATIC CYSTS

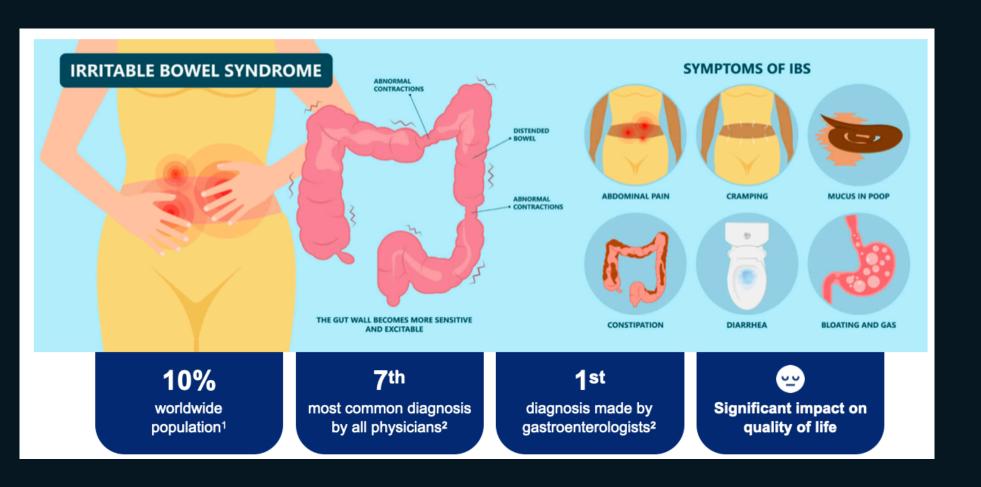
Specific CPT code 43252 to Cellvizio can be added to other CPT codes in upper GI endoscopy and EUSFNA (pancreatic cyst characterization)

	<u>ASC</u>	<u>Hospital</u>	
BARRETT'S - EGD without Cellvizio	\$470	\$865	5
BARRETT'S - EGD with Cellvizio	\$1,067	\$2,247	2.3x - 2.6x
PANC CYSTS - EUSFNA without Cellvizio		\$1,815	
PANC CYSTS - EUSFNA with Cellvizio		\$3,652	2.0x



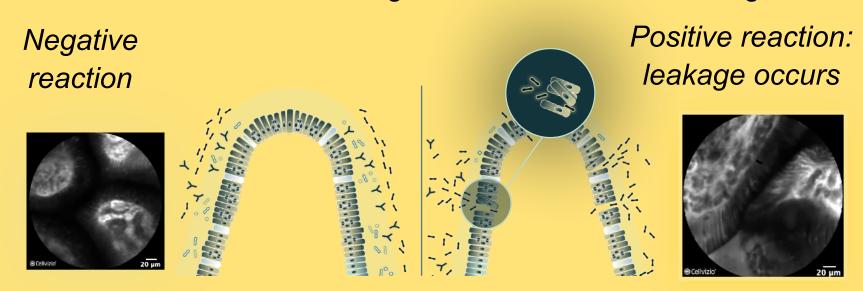
## FOOD INTOLERANCE DETECTION FOR PATIENTS WITH IBS A BREAKTHROUGH SOLUTION ENABLING BOTH DETECTION AND TREATMENT

AN UNMET NEED WITHIN A \$100B THER APEUTIC MARKET,
AS MILLIONS OF PATIENTS DESPERATELY SEEK
SOLUTIONS TO ALLEVIATE THEIR SYMPTOMS



## CELLVIZIO IS THE ONLY TECHNOLOGY ENABLING FUNCTIONAL VISUALIZATION OF THE GUT BARRIER AND FOOD INTOLERANCE DETECTION

Instantaneous reaction of the gut barrier to a food challenge



60%

of IBS patients may have an atypical food intolerance that can only be seen with Cellvizio

96%

of patients with a positive test see improvement after a CellTolerance-guided exclusion diet



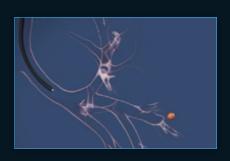
## **ENDOLUMINAL ROBOTICS FOR PULMONOLOGY**

GIVING SIGHT TO BLIND NEEDLES TO IMPROVE DIAGNOSTIC YIELD

**FOR LUNG CANCER** 

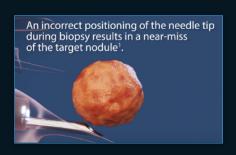
80%

of lung nodules located outside the airways with no direct visualization



38-64%

diagnostic yield caused by using biopsy needles blindly



Lack of direct visualization and CT-to-body divergence **strongly limit** advanced navigation and endoluminal robotics platforms

RESEARCH COLLABORATION

Johnson-Johnson

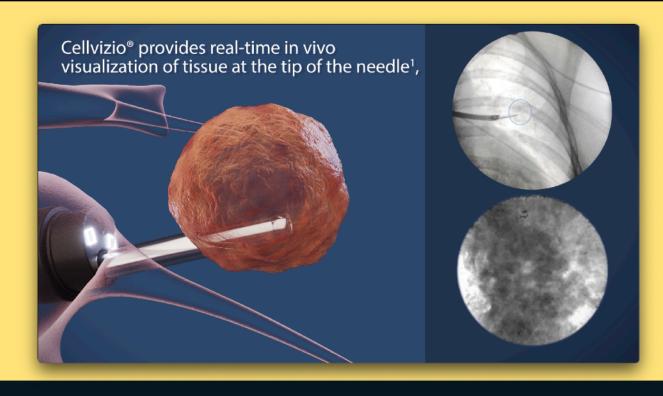
 Evaluate Cellvizio as a realtime biopsy guidance tool for use during robotic-assisted bronchoscopy.

## CELLVIZIO ALLOWS SAFE AND ACCURATE DETECTION OF DIFFICULT-TO-ACCESS LUNG NODULES

90% Accuracy in detecting malignancy in tumours

Accuracy in detecting malignancy in metastatic lymph nodes

cases with needle repositioning, significantly reducing the bronchoscopic near-miss rate



## ROBOTIC SURGERY

## CELLVIZIO ENABLES PRECISE MARGIN DELINEATION DURING MINIMALLY INVASIVE ROBOTICS-ASSISTED SURGERIES

#### LIMITATIONS OF CURRENT STANDARD OF CARE

- General consensus on advanced visualization being central to minimally invasive surgery
- Currently used fluorescent agent and wide-field cameras
   poorly differentiate healthy from diseased tissue
- Ineffective pre-op tumor extension report

## CELLVIZIO ENABLES REAL TIME MICROSCOPIC EVALUATION OF SURGICAL MARGINS

- Real time evaluation of resection margins with high specificity
- Organ function and nerve sparing guidance

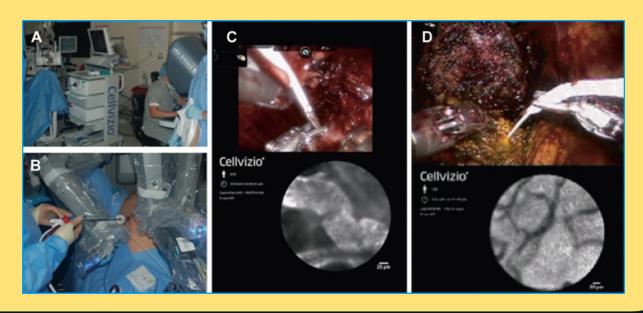
## TRANSORAL ROBOTICS SURGERY (TORS)

Preservation of larynx / pharynx function with R0 resections



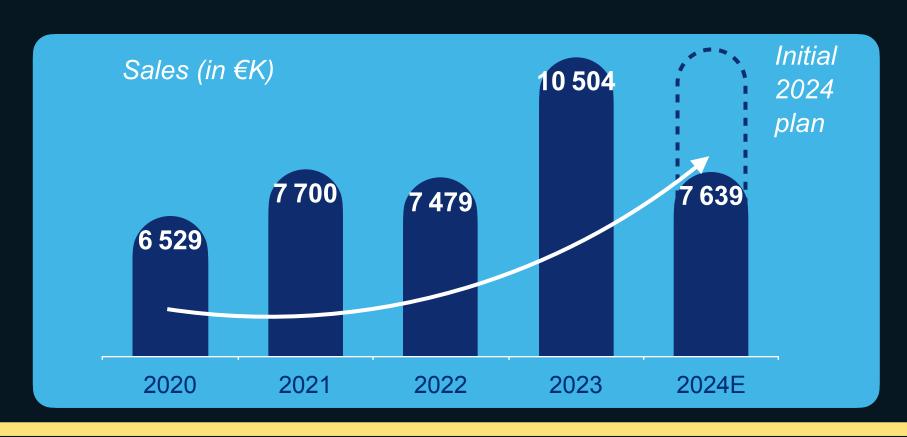
## ROBOTICS-ASSISTED LAPAROSCOPIC PROSTATECTOMY

Nerve sparing with R0 resections

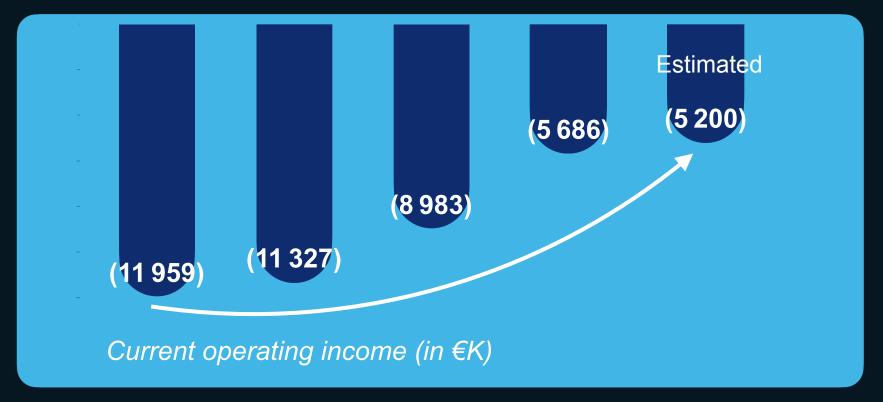


## 2024 FINANCIAL RESULTS

## CONTINUED REDUCTION IN LOSSES DESPITE LOWER SALES DUE TO SPECIFIC 2024 HEADWINDS



- Strong 2024 sales plan with a €2.5m increase in sales
- Undermined by €2m loss due to Tasly JV's failure to fullfill its contractual obligations
- Negative PPU price impact due to lower Medicare reimbursement



- Strong reduction in operating losses since 2021 with the restructuring of the U.S. team
- Significant cost reduction initiatives in 2024 more than compensating revenue losses
- Key objective to reach profitability in 2026

### 2025 - 2026 PLAN

### MAUNA KEA IS AT A STRATEGIC INFLECTION POINT

GI Endoscopy

2 CellTolerance

3 Al Platform

Pulmonology

#### **Barrett's Esophagus**

- Sustained PPU volume despite
   CMS downgrade
- Already 80% hospital data corrected, with high probability of CMS upward correction, driving a +50% price recovery

#### **Pancreatic cysts**

- Upcoming CLIMB clinical data to position Cellvizio as the gold standard for pancreatic cyst characterization
- Anticipated integration into EU clinical in 2025

#### A large and untapped market

- IBS prevalence: 10-15% of the global population
- Patients remain underserved and actively seeking effective solutions

#### A game-changing application

- The only solution enabling real-time functional visualization of gut barrier
- Delivers immediate, clear, and actionable results
- A transformative program for both patients and healthcare providers

#### Al Lab infrastructure

- Building a multi-modal image database with robust annotation capabilities
- Al-driven training models to accelerate insights for clinical and pharma applications

#### **Strategic potential**

 A scalable platform to engage pharma, medtech, and diagnostic partners

## **Excellent clinical results and progress on CLEVER study**

- Pr Renaud's results confirms
   Pr. Annema's and the onestop-shop / therapeutic
   enablement value proposition
- ▶ 65+ patients enrolled in CLEVER study, 5 top level centers in EU and 1 in NY (Montefiore)
- Extremely strong support from Pr Annema

#### **CLEAR study**

 High confidence that CLEAR study (endoluminal robotics + Cellvizio) results will be very positive

STRONG FOUNDATIONS FOR REACHING PROFITABILITY IN 2026

### 2025 - 2026 PLAN

### LEVERAGING THE STRONG UPCOMING MOMENTUM OF MATURE GI INDICATIONS

PANCREATIC CYSTS

Inclusion in EU guidelines

**Q2 2025** 

CLIMB results
Q2 2025

French reimbursement

**Q**3 2025

New capital sales

**BARRETT'S** 

CMS 2026 Rule Q3 2025 Reimbursement back to Level 3

**Q1** 2026

Opening of new ASCs 2026

Higher PPU price

Increased volume

FOOD INTOLERANCE Expansion in FR/DE/IT Q1 2025

Launch in the U.S Q2 2025

Geographic expansion 2026

New PPU revenues

Hypothetic outcome

RM GLOBAL'S STRATEGIC PROCESS IS SET TO DRIVE COMMERCIAL PARTNERSHIPS ACROSS ALL THIESE INDICATIONS

### 2025 - 2026 PLAN

### BUILDING A STRONG AND EFFICIENT COMMERCIAL TEAM

- Through our 10+ years of commercial experience, we have developed a strong understanding of the requirements,
   competencies, and needs of an optimal and efficient commercial and marketing team.
- Unfortunately, in recent years, we have lacked the financial resources to implement this effectively

#### **DIRECT COMMERCIAL TEAM**

- An experienced VP of sales
  - → Global strategy, sales execution
- Dedicated sales reps for capital sales
  - → Focus on KOL
- Dedicated sales reps for new PPU centers
  - → Provide quick training and onboarding
- Clinical specialists
  - → Drive clinical support and training

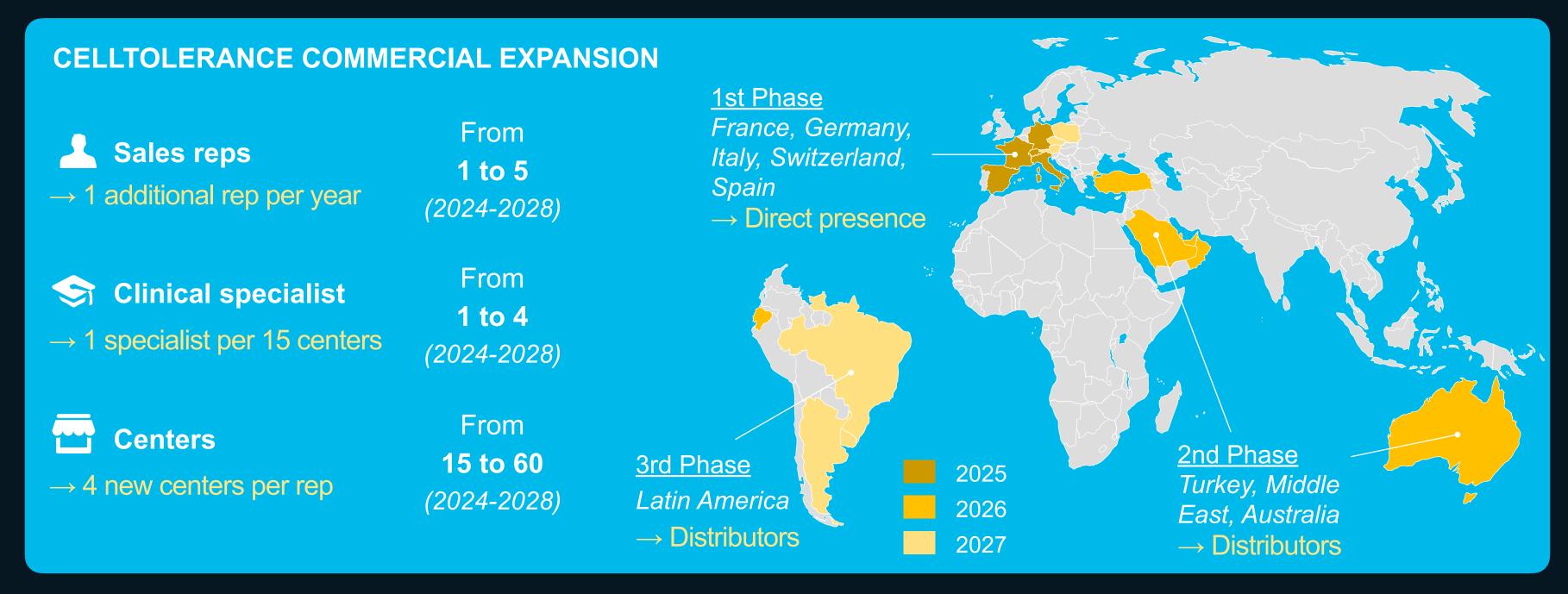
#### OTHER COMMERCIAL NETWORKS

- Commercial platforms (e.g. Eversana)
  - → Turn-key commercialization (field sales, reimbursement support, market access)
- Large swath of 1099 Sales reps
  - → Commission-based, focus on underserved states

## **EU & ROW**

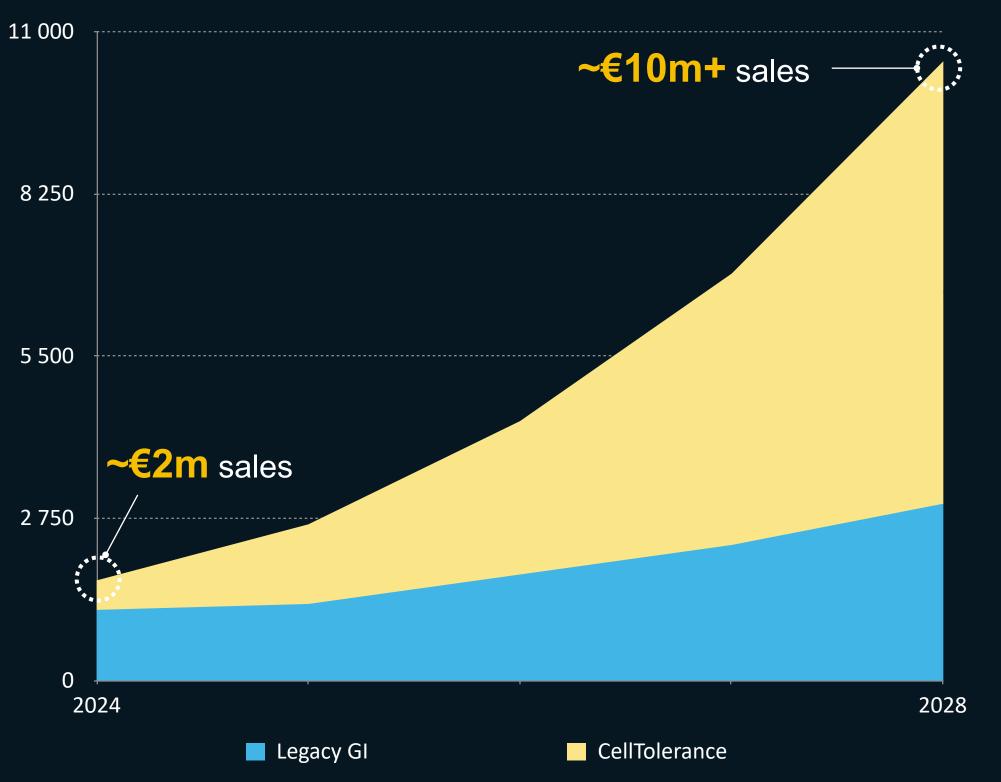
### COMMERCIAL EXPANSION DRIVEN BY CELLTOLERANCE

- EU & RoW commercial expansion driven mainly by CellTolerance's PPU business
- Some specific capital sales for pancreatic cysts through distributors
- New GTM solution to be engineered in China



## EU & ROW TOTAL SALES TO EXCEED €10M BY 2028

Total EU & RoW sales (in €K)



#### 2024

- Majority of sales in the legacy GI business
- Limited sales in food intolerance with already
   15 existing centers in Germany

#### 2025-2028

- Capital sales growth in pancreatic cysts mainly via distributors
- Strong acceleration of the food intolerance business with the expansion of CellTolerance in Europe
- CellTolerance to account for 70% of sales by 2028

## U.S.

### **COMMERCIAL EXPANSION FOCUSED ON LEGACY GI**

- ▶ Targeting of 1,000 ASCs and Community Hospitals with high volume interventional endoscopy activity for pancreatic cysts
- ▶ Partnering with with commercial platform to accelerate market penetration

#### **LEGACY GI COMMERCIAL EXPANSION**



Sales reps

 $\rightarrow$  3 additional rep per year

Clinical specialist

→ 1 specialist per 15 centers



Centers

→ 3 new PPU centers per rep

→ 3 capital sales per rep

From

3 to 12

(2024-2028)

From

2 to 5

(2024-2028)

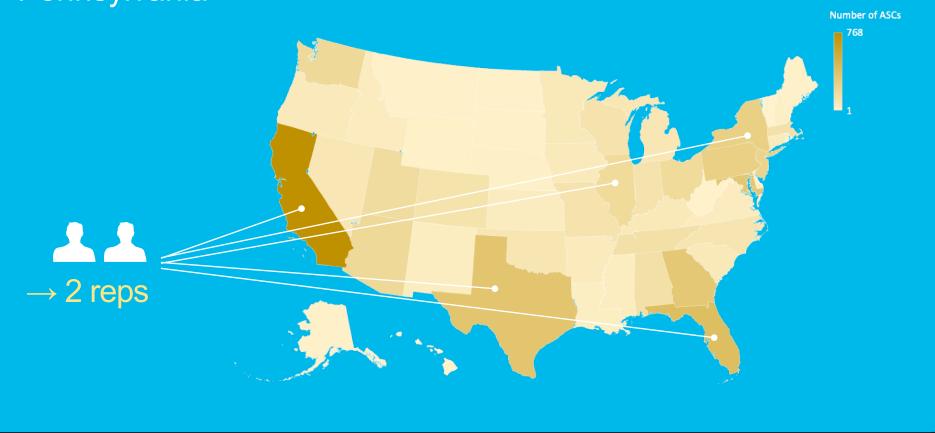
From

35 to 100

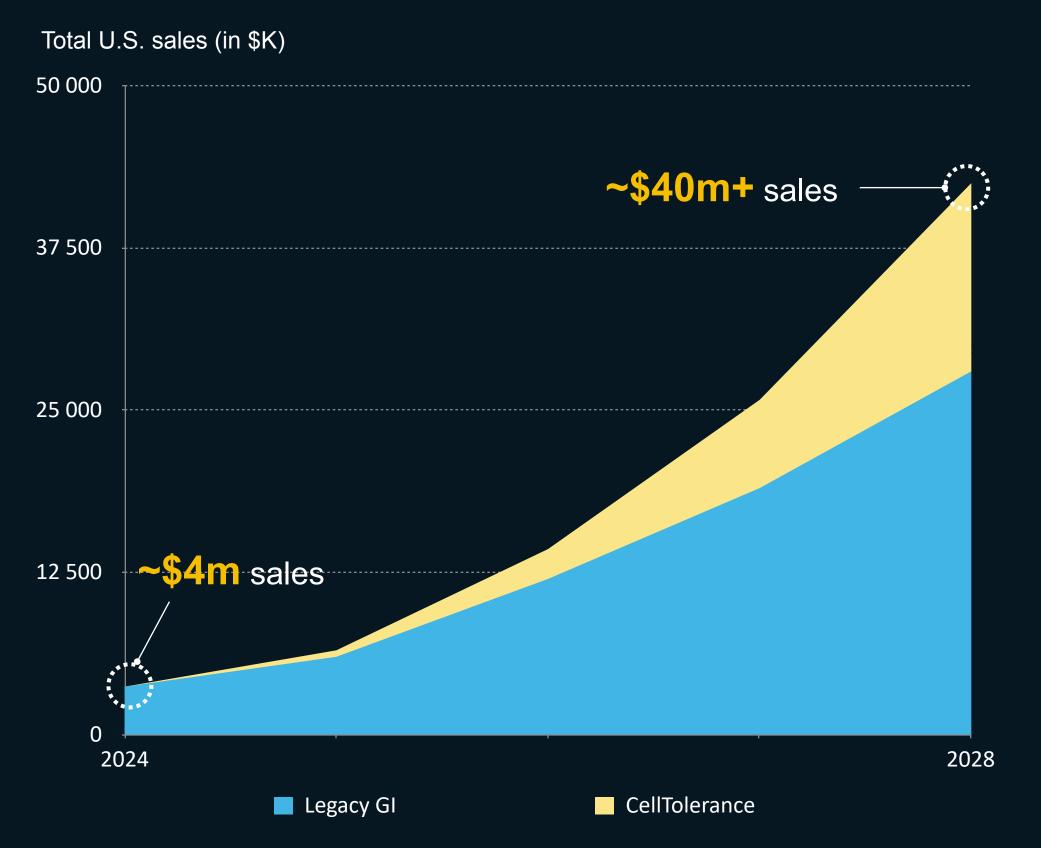
(2024-2028)

#### Density of ASCs by U.S. state

- ▶ High density in California, Texas, Florida, New York, Illinois
- Other growth regions: Arizona, North Carolina, Georgia, Pennsylvania



## U.S. TOTAL SALES TO EXCEED €40M BY 2028



#### 2024

- All sales in the legacy GI business
- 40% of sales in PPU with 4,000 annual procedures

#### 2025-2028

- New momentum in capital sales for pancreatic cysts
- Acceleration of PPU sales with increasing number of procedures to 20,000 by 2028 and price (+50%)
- Launch of CellTolerance in 2025 on a PPU business model for a cost of 1,000 per procedure

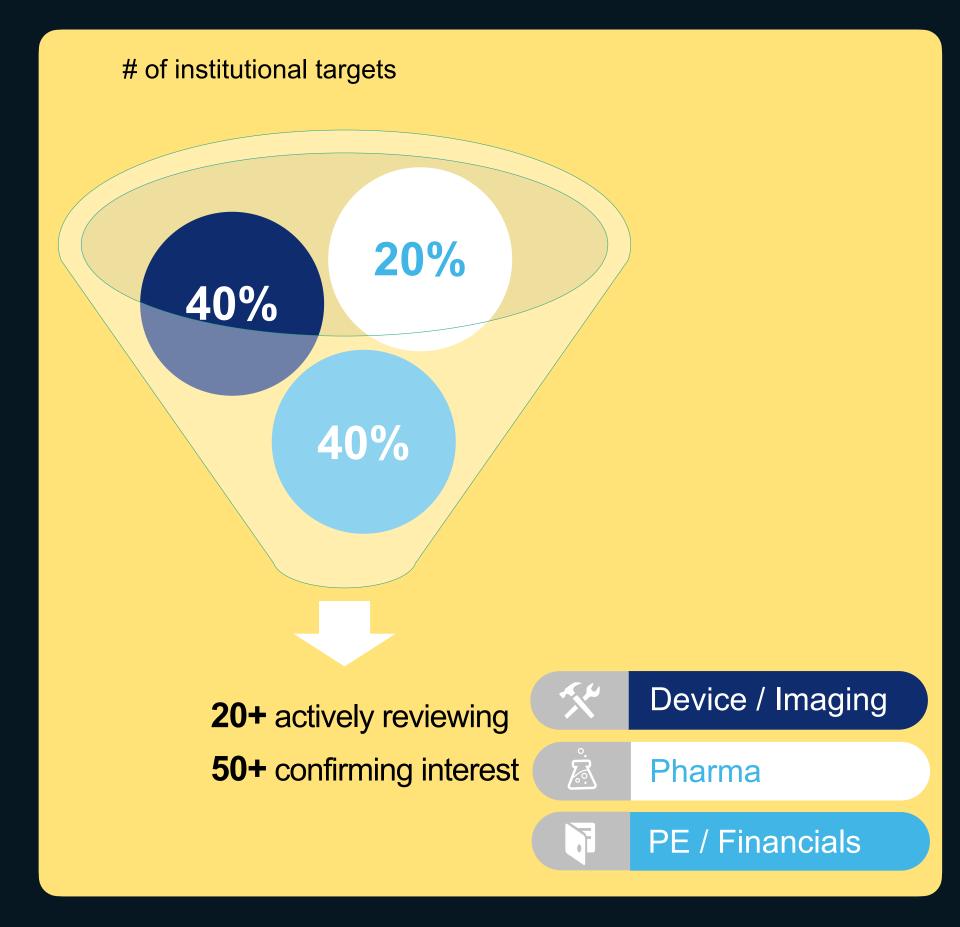
## A STRATEGIC PROCESS WITH ACTIVE DISCUSSIONS UNDERWAY

### **TARGETING FINALIZATION OF ONE OR MORE OPTIONS BY MID-2025**





- Process started end-2024
- Strong traction since mid-January post JPM Conference
- All options including M&A, PE-backed take private, licensing
- Moving to potential positioning for formal indications of interest in March



## STRATEGIC PRODUCT DEVELOPMENT ROADMAP

### **ALIGNED TO VALUE CREATION MANDATE**

#### **CELLVIZIO IMAGING DATASETS**





Advanced prototype

applications in GI

development

Other applications in

developed for various

- In situ / In vivo endomicroscopic imaging data for multimodal datasets
- Development of foundation models, including IBD / IBS





In vivo endoscopic

targeted cancer cells

► 1st FDA clearance in

visualization of

2022

Integrated navigation

**ROBOTIC ASSISTED IMAGING** 

- Smart needle probe localisation
- Agnostic exploration
- and data capture
- tools







## LEADERSHIP TEAM

### SEASONED, CONNECTED AND BATTLE-TESTED



Sacha Loiseau, Ph.D. Chairman and CEO, Founder













Nathalie Lecoq Chief Operating Officer





Côme de La Tour du Pin Chief Financial Officer



FIPSEN Styscogene



**Bruno Villaret** VP, International Sales







François Lacombe, Ph.D. Chief Scientific Officer









**Daryl Donatelli** VP, Global Marketing & U.S. Sales

BAUSCH+LOMB

Scientific



**Olivier Coeffic** VP of R&D

**PHILIPS** capsul





**Christopher McFadden** Director Managing Director, Apollo Global Management



Jacquelien ten Dam Director **CFO Mimetas** 



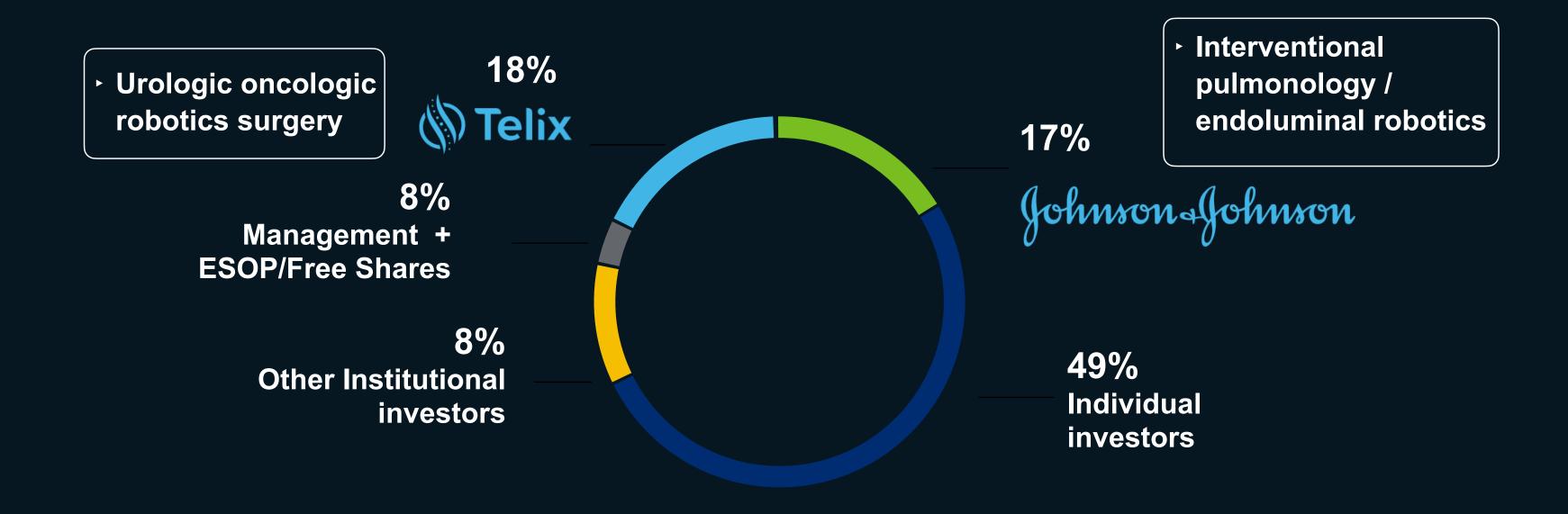
**Molly O'Neill** Director Chief Strategic Partnerships Officer, Aegis Ventures



**Claire Biot** Director VP Life Sciences. Dassault Systèmes

## **SHAREHOLDING**

### TWO MAJOR STRATEGIC SHAREHOLDERS WITH STRONG INTEREST IN THE TECHNOLOGY



#### **3 MAJOR EQUITY INVESTMENTS SINCE 2019**



**Johnson & Johnson** invested twice in 2019 and 2021 for a total of €15 million



**Telix Pharmaceuticals** invested €6 million in 2023

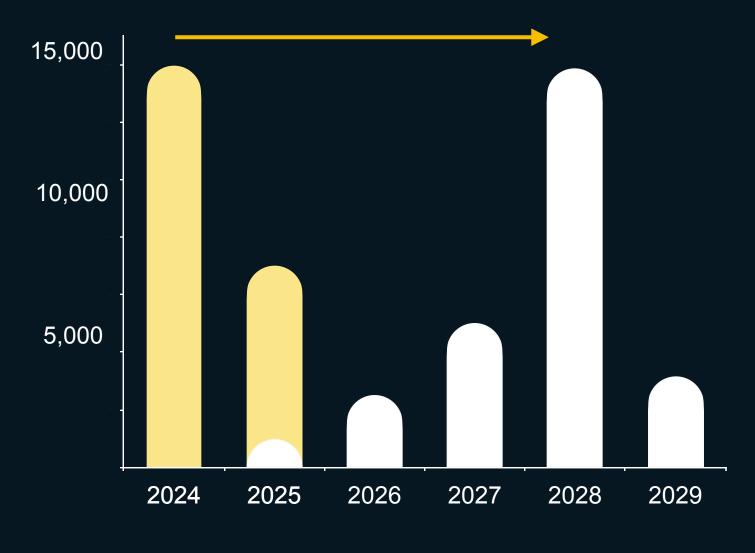


## **BALANCE SHEET**

### A €21.7M EIB LOAN RESTRUCTURED IN 20241

- Total of €17.5m split into 2 tranches with maturities of July 2024 and July 2025
- Interests of 5% (Tranche A, PIK) and 7% (Tranche B, PIK and cash)
- Restructuring in April 2024 including postponement of 70% of maturities by 4 years
- Initial repayments in July 2025 onwards of €1m in 2025,
   €2.5m in 2026, €5m in 2027
- Royalties on sales (2%) included as part of the restructuring applicable over 6 year capped at a maximum €10m

### **EIB loan maturities¹** (in €K)



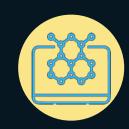


## WHY MAUNA KEA?

## A UNIQUE AND UNPARALLELED TECHNOLOGY POISED FOR STRONG SHORT TERM MOMENTUM AND GROWTH



DIFFERENTIATED TECHNOLOGY



- Cellvizio® proven proprietary cutting-edge opto-mechatronics and image processing software
- Leading the global adoption of real-time cellular imaging

UNIQUE IP COMPLEX



- 200+ issued patients including 13 on Al + endomicroscopy
- ► Category 1 CPT codes in the US. 20+ FDA clearances, CE mark, NMPA clearance

MULTI-BILLION MARKET OPPORTUNITY



- Current markets represent \$7B opportunity in GI endoscopy / food intolerance
- An additional \$1.3B potential through strategic partnerships

STRATEGIC INTEREST



- Ongoing strategic review process driven by 2 investment banks gaining significant traction including with shareholders JNJ and Telix Pharmaceuticals
- Positive newsflow with key milestones supporting the opportunity

EXPERIENCED TEAM



- Leadership with 100+ years of experience in all fields of Medtech
- Battle-tested and highly connected

