Mauna Kea Technologies

Creators of Cellvizio®



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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.

Founded	2000
Office Locations	Paris, France (Headquarters)Boston, MA, USAShanghai, China
Full-Time Employees*	100

Year of IPO	2011
Exchange/ Ticker	Euronext Paris: MKEA
Number of Shares*	30,558,480



Mauna Kea Technologies - A Compelling Platform Opportunity...

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



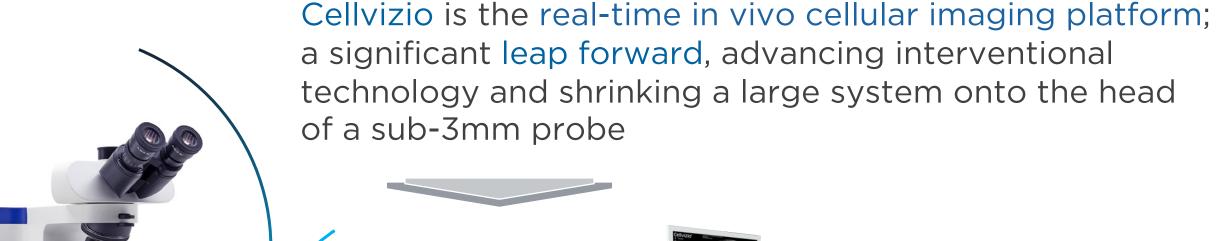
...Supported by a Focused Value Creation Strategy

U.S. commercial strategy enhanced by focused clinician targeting: Highvolume upper GI biopsy physicians and serving a high mix of Medicare patients Investing prudently in GI markets in EMEA and certain APAC markets: Strong distribution relationships and KOL support Ongoing formal evaluation process to identify and validate next commercial focus-area

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

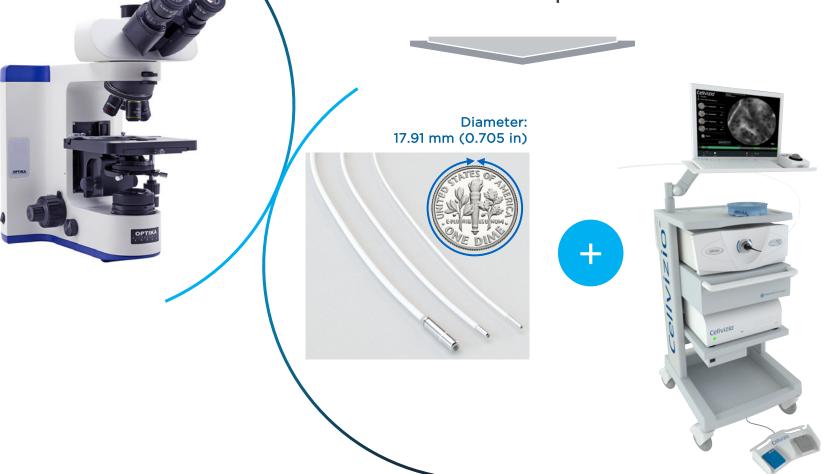
Current Standard of Care

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



Cellvizio System + Miniprobes

- Targeted biopsies
- Whole, *in situ* living tissue
- In vivo
- Unlimited number of images
- Differentiates "normal" vs. "areas of concern"
- Facilitates early detection and clinical intervention



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

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





pCLE (Probe/Catheter)

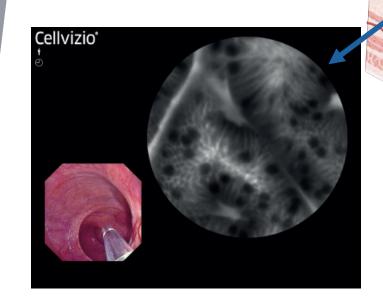


nCLE (Through the Needle)



pCLE (Laparoscopic/Robotic)

Proprietary scanning through 30,000 custom optical fibers produces microscopic images and movies in real-time during standard endoscopy procedures

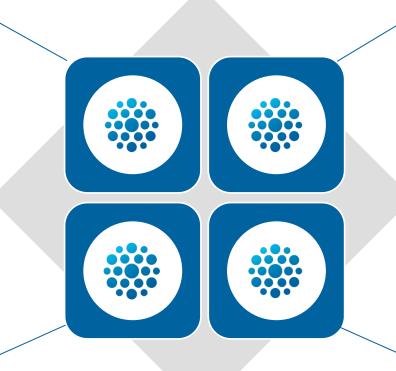




...and Enabling Better Informed Patient Management

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





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







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

\$20M
Annual Mauna Kea
Recurring Revenue
Opportunity

^{*} Definitive Healthcare 2018 procedure data; CMS.gov 2018 public data; Cellvizio annual recurring revenue opportunity based on 550,000 annual EGD with biopsy procedures multiplied by per-procedure cost; Association of American Medical Colleges physician data; Internal analysis

Established Reimbursement in Largest Patient Group in GI Market

Attractive Economics for Hospital and ASC Customers

WITHOUT Optical Endomicroscopy

Patient with EGD with GERD/BE random biopsy getting an EGD (Seattle Protocol)

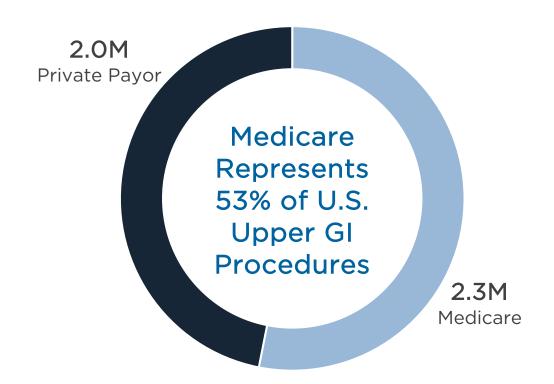
CPT 43239: **\$786 Hospital / \$397 ASC**

WITH Optical Endomicroscopy

Patient with GERD/BE getting an EGD EGD with targeted biopsy protocol with improved sensitivity



CPT 43252 + (CPT 43239)/2: \$3,392 Hospital / \$1,505 ASC Incremental reimbursement: +\$2,606 Hospital / +\$1,108 ASC



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

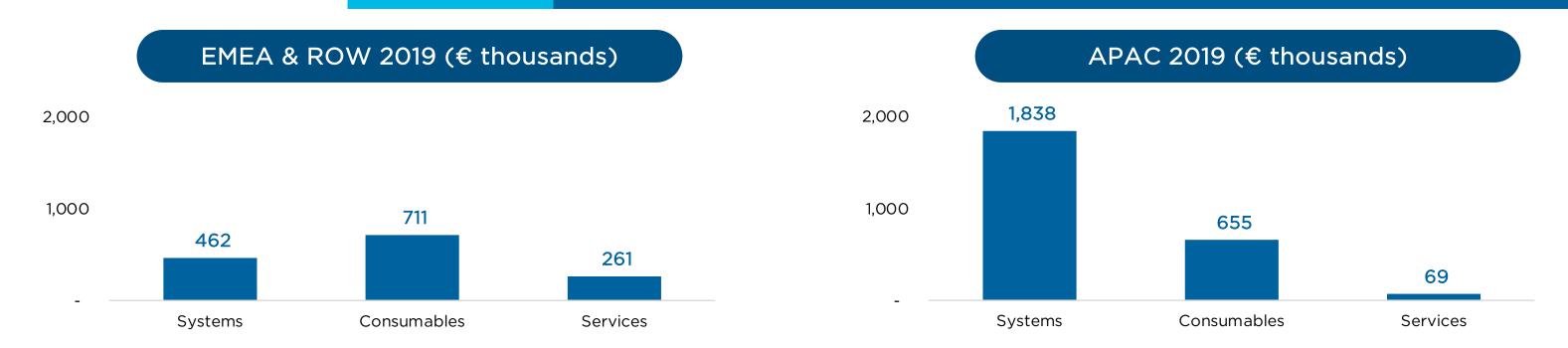
Favorable Economic Model for Cellvizio Customers = Tailwind for System Adoption and Utilization



Executing an Enhanced, Focused U.S. Commercial Strategy

- 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

ESTABLISH CRITERIA

PRELIMINARY INSIGHTS

APPLICATION HYPOTHESIS

VALIDATE

TEST AND LEARN

SCALE

- 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
- First in human study combining robotic navigational bronchoscopy and nCLE

- Second indication under early 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



(Johnson allohuson innovation) JDC

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

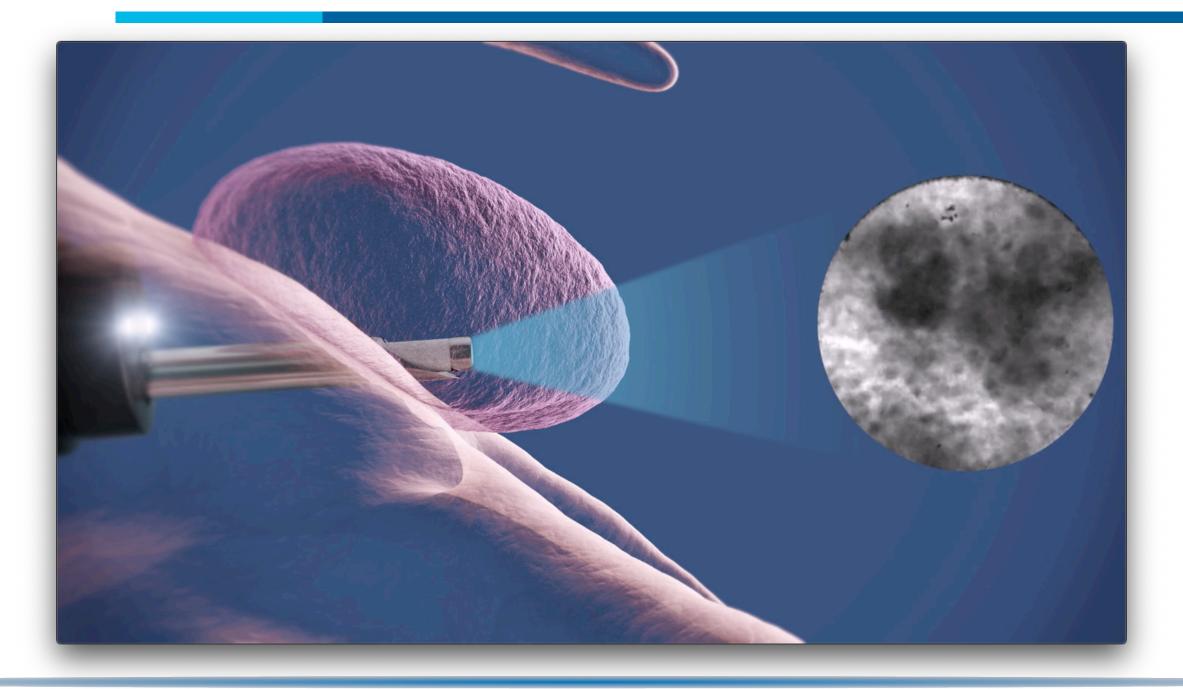
Strategic investment will advance the collaboration of Mauna Kea with the Lung Cancer Initiative at J&J, which is working to develop new diagnostic and therapeutic approaches for lung cancer with significant unmet need

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 Lesions¹



Cellvizio can diagnose and stage lung nodules with 90% accuracy¹, leading to better informed patient management



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

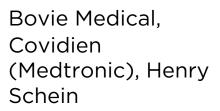
"...workshop panelists agreed that in the hands of endoscopists who have met the preservation and incorporation of valuable endoscopic innovation thresholds (diagnostic accuracy) with enhanced imaging techniques (specific technologies), use of the technique in Barrett's esophagus patients is appropriate."

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.

Robert L. Gershon
Chief Executive Officer



Management Team & Board of Directors



Christophe Lamboeuf, CPA
Chief Financial Officer

Intrasense, General Electric, Ricoh, CS Telecom, Toshiba



Team

Management

François Lacombe, Ph.D. Chief Scientific Officer

Astrophysics programs: ISOCAM, ADONIS, NAOS



Jack McCarthy
Chief Marketing Officer

Bovie Medical, Z-Medica, Covidien (Medtronic)



Aline Criton, Ph.D.

Chief Clinical and

Regulatory Affairs Officer

SuperSonic Imagine, Philips Healthcare, ATL Ultrasound



Bruno Villaret
VP, International Sales

Tyco, Saint-Gobain



Cameron Lee VP, U.S. Sales

Pentax Medical, Trinity Western Univ.





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 President, Hospitals & Health Systems, Teladoc Health



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



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



Sales and Financial Performance Full Year 2019 and First Nine Months 2020



2020 First Nine Months Sales: Significant Improvement in Sales Trends

2020 First Nine Months Sales

	Actual	Last Year	V LY%
Systems	1,447	1,911	-24%
Consumables	1,854	3,097	-40%
Services	843	732	15%
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Total	4,144	5,739	-28%

	Actual	Last Year	V LY%
APAC	1,106	2,058	-46%
EMEA & ROW	728	1,132	-36%
U.S. & Canada	2,310	2,549	-9%
Total	4,144	5,739	-28%

All figures in € thousands

- First nine months total sales were down 28% versus last year, a significant improvement compared to the 47% decrease year-overyear in 1H 2020
- Consumables sales down 40%
- U.S. sales down 9% vs last year, driven by a pronounced slowdown related to COVID-19 beginning in March
- Pronounced improvement in underlying U.S. business trends beginning in late Q2 and continuing through Q3
- APAC sales down 46% mainly driven by low consumables
- Strong impact of COVID-19 on ROW activity throughout H1, recovering significantly in Q3



2020 Q3 Sales: Notable Recovery vs. 1H 2020

2020 Q3 Sales

	Actual	Last Year	V LY%
Systems	000	560	50 0/
Systems	889	562	58%
Consumables	871	1,034	-16%
Services	283	207	37%
Total	2,044	1,803	13%

	Actual	Last Year	V LY%
APAC	587	561	5%
EMEA & ROW	468	322	45%
U.S. & Canada	989	920	7%
Total	2,044	1,803	13%

All figures in € thousands

- Total sales for the third quarter of 2020 increased €0.2 million, or 13% year-over-year, to €2.0 million
- U.S. & Canada sales increased 7%, APAC sales increased 5%, and EMEA & ROW sales increased 48% year-over-year
- Consumables sales decreased €0.2 million, or 16% year-over-year, to €0.9 million
- Systems sales increased €0.3 million, or 58% year-over-year, to €0.9 million
- Services sales increased €0.1 million, or 37% year-over-year, to €0.3 million



Mauna Kea Technologies - A Compelling Platform Opportunity

- 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
- Enhanced management depth of expertise across multiple indications and market segments



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

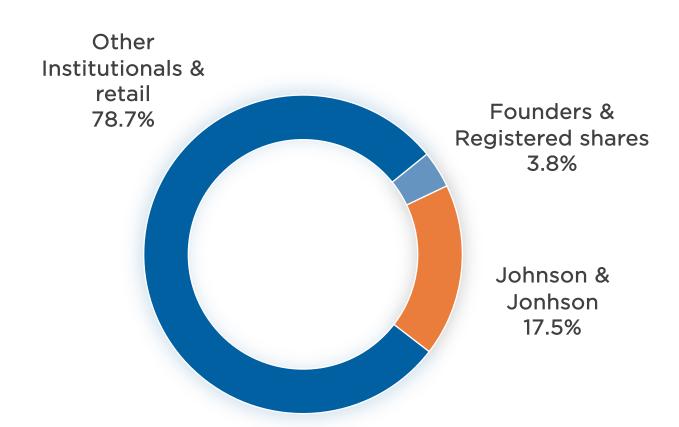
GILBERT DUPONT

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



Tight Control of OpEx Decreases EBITDA Loss

P&L STATEMENT (K€)	2020 A	2019 A	Δ vs. N-1 (k€)	Δ vs. N-1 (%)
Sales	2,100	3,937	(1,837)	(47)%
Gross Margin	1,412	2,468	(1,056)	(43)%
Other revenues	1,064	576	488	85%
R&D Expenses	(373)	(583)	210	(36)%
M&S Expenses	(970)	(1,264)	294	(23)%
G&A Expenses	(1,415)	(925)	(490)	53%
Total Expenses	(2,758)	(2,772)	14	(1)%
R&D Payroll	(977)	(1,271)	294	(23)%
M&S Payroll	(3,014)	(3,060)	46	(2)%
G&A Payroll	(1,098)	(1,403)	305	(22)%
Total Payroll	(5,089)	(5,734)	645	(11)%
EBITDA	(5,371)	(5,463)	92	(2)%
R&D Depreciation	(110)	(196)	86	(44)%
M&S Depreciation	(215)	(272)	57	(21)%
G&A Depreciation	(339)	(250)	(89)	36%
Depreciation	(664)	(719)	55	(8)%
Share based payment	(184)	(432)	248	(57)%
EBIT	(6,219)	(6,614)	395	(6)%
R&D total expenses	(1,460)	(2,050)		
M&S total expenses	(4,199)	(4,596)		
G&A total expenses	(2,852)	(2,578)		
Total expenses	(8,695)	(9,656)		
GM rate	67.2%	62.7%		
Opex W/O Dep & SBP	(7,847)	(8,506)		
7 @2020 Mayraa Kaa Ta	alasa alla asta a			

- Total revenue for the first half of 2020 decreased €1.3 million, or 30% year-over-year, to €3.2 million
- Total revenue for the first half of 2020 was significantly impacted by the global crisis caused by the coronavirus, or COVID-19
- Gross margin was 67.2% in the first half of 2020 period, compared to 62.7% in the first half of 2019 period
- Total operating expenses (w/o COGS)
 decreased €1.0 million, or 10% year-over-year, to
 €8.7 million
- EBITDA loss decreased by 2% year-over-year, to €5.4 million

Balance Sheet

ASSETS	Jun-20	Dec-19
Non-current Assets		
Intangible assets	2,788	2,343
Property, plant and equipment	1,993	1,696
Right of use	1,627	1,630
Non-current financial assets	319	173
Total of non-current assets	6,727	5,842
Current assets		
Inventories & Work in progress	2,828	2,592
Trade receivables	1,672	2,444
Other current assets	2,083	2,701
Current financial assets	89	59
Cash and cash equivalents	4,212	9,982
Total of current assets	10,884	17,778
TOTAL OF ASSETS	17,611	23,621

- Trade Receivables reduction in line with sales decrease
- Inventories up slightly due to sales shortfall during COVID-19 period
- Other current assets included R&D tax credit for 2019 and H1 2020

EQUITY AND LIABILITIES	Jun-20	Dec-19
Equity		
Issued capital	1,223	1,223
Share premium	98,265	98,257
Reserves	(99,047)	(84,130)
Foreign currency translation on	178	176
reserve		
Profit / (Loss)	(6,712)	(15,272)
Total of equity	(6,093)	253
Non-current Liabilities		
Long-term loans	16,094	15,499
Non-current provisions	308	299
Total of non-current liabilities	16,402	15,798
Short-term loans and borrowings	1,620	474
Trade payables	1,938	2,275
Other current liabilities	3,744	4,821
Total of current liabilities	7,302	7,570
TOTAL OF EQUITY AND LIABILITIES	17,611	23,621

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



Cash Flow Statement

In K€	June 2020	June 2019
Profit / (Loss) Eliminations	(6,712) 1,321	(8,097) 3,149
Δ in working capital	1,380	820
Net cash flows from operating activities (A)	(4,011)	(4,128)
СарЕх	(892)	(720)
Net cash flows from Investing activities (B)	(892)	(720)
Capital increase		20
Δ in financial debt - IPF		(4,000)
Reimbursment of debt on leases (IFRS 16)	(276)	
Net financial interest paid	(21)	(503)
IPF penalties and others		(1,789)
Financing of Tax Research Credit	(565)	0
Other	(16)	(192)
Cash flow from financing activities (C)	(878)	(6,464)
Net FX differences	9	6
Change in Cash	(5,771)	(11,306)
Cash BoP	9,982	8,623
Cash EoP	4,211	-2,683

- Decrease in negative EBITDA primarily drove the slight improvement of net cash from operating activities
- CapEx comprised of systems placed in pay-peruse in the US and capitalization of R&D expenses of €585K
- 2019 financing reflected IPF debt prepayment
- Cash used in operating and investing activities totaled €4.9M, including €0.6M of US PPP
- Cash at the end June 2020 was €4.2M and further strengthened in July with €10M of new debts (€6M from EIB T2 and €4M of PGE)

Thank You

