goetzpartners SECURITIES

COMPANY NOTE

Mauna Kea Technologies SA (MKEA-FR)

Evaluating interventional pulmonology as the next value driver

OUTPERFORM
Target Price €4.10
Current Price €0.91

KEY TAKEAWAY

Earlier this year, Mauna Kea announced successful FDA clearance for the use of the Cellvizio® system in the field of interventional pulmonology ("IP"). This paves the way for entry into the large lung cancer diagnostics market and would allow Mauna Kea to leverage its existing expertise in the field of gastroenterology to maximise adoption. In our view, IP represents a promising commercial opportunity based on (1) a large market with a vast clinical need, (2) Cellvizio's® unique ability to facilitate biopsy guidance and *in vivo* characterisation, and (3) first mover advantage with a well-differentiated product that is compatible with conventional bronchoscopes, emerging endoluminal robotic platforms as well as existing advanced navigational bronchoscopy platforms. We maintain and reiterate both our OUTPERFORM recommendation and €4.10 target price ("TP"), and await further details regarding the future strategy before including the opportunity into our TP.

1. Lung cancer diagnostics market estimated to exceed $4.0bn by 2024E
With more than 2 million newly diagnosed patients per year, lung cancer is the most common as well as most deadly cancer worldwide, accounting for c.143,000 deaths annually in the US alone. The global lung cancer diagnostics market is projected to grow from $2.1bn in 2015 to $4.0bn in 2020E at a 14% CAGR, driven mainly by increasing momentum in the field of endoluminal robotics, including Auris' Monarch and Intuitive Surgical's ION system. The recent $3.4bn acquisition of Auris Health by Johnson & Johnson is testimony of the increasing traction in the space, and we anticipate an arms race between large players to create a significant commercial opportunity for Cellvizio®.

2. Using CLE to reduce the clinical and economic toll associated with lung cancer
Mauna Kea's value proposition in IP includes two key points: (1) Improving biopsy guidance by providing intralesional visualisation and (2) enabling physicians to characterise tissues *in vivo* and in real time. Several clinical initiatives are under way in order to assess how these value propositions translate into improving the diagnostic yield. We expect further details to follow in Q4/2019E.

3. First mover advantage and lack of competition facilitate market penetration
Mauna Kea's AQ-Flex 19 Confocal Miniprobe™ is the only nCLE product on the marketplace and the only technology capable of characterising tissues *in vivo*, in real time and at a cellular level. As such, the company is ideally positioned to drive accelerated market penetration following market entry. In our view, the fact that the company's AQ-Flex 19 Miniprobe, which is designed to be introduced into suspected tumours through a fine needle, is compatible with both conventional bronchoscopes as well as emerging endoluminal robotic bronchoscopes, allows Cellvizio® to integrate into the existing and future diagnostic landscape and provides a strong rationale for collaboration between Mauna Kea and larger diagnostics players active in IP.

H1/2019 financial review
Mauna Kea reported strong underlying sales growth in H1/2019 with revenues of €3.9m (+45% YoY). A 49% YoY increase in COGS was partly offset by a decline in R&D expenses (-8% YoY). Higher administrative (25% YoY) and S&M (5% YoY) expenses yielded larger than expected operating and net losses of €6.6m and €8.1m, respectively. Cash as at 3rd July 2019 was €8.8m.

We maintain and reiterate our TP of €4.10
Our TP of €4.10 per share is based on an EV/Sales multiple approach using our €25.1m revenue estimate for 2022E, a discount rate of 14% and a probability rate of 80%. We continue to believe that Mauna Kea is well positioned to enter a period of accelerated growth as the new commercial strategy and established sales infrastructure start to pay off. We expect revenues to reach €8.6m in 2019E and €14.5m in 2020E, representing 27% and 70% growth, respectively, and anticipate profitability from 2022E. Additional upside is expected from entry into new markets such as IP.

FINANCIAL SUMMARY

Net Cash/Debt (M):	1.60

MARKET DATA

Current Price:	€0.91
Target Price:	€4.10
52 Week Range:	€3.00 - €0.84
Total Enterprise Value:	30
Market Cap (M):	23
Shares Out (M):	25.2
Float (M):	24.6
Average Daily Volume:	246,620

EQUITY RESEARCH

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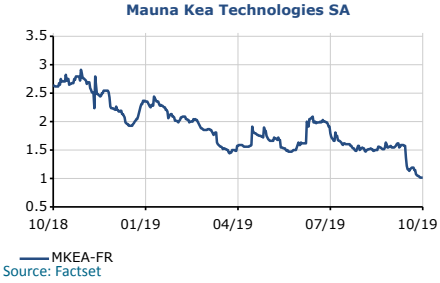
PRICE PERFORMANCE



Source: Factset

Contents

Investment summary

The AQ-Flex 19 Miniprobe™ is a needle-based confocal microscope small enough to be advanced into tumours through a 19-gauge biopsy needle

In February 2019, Mauna Kea announced that it received its 16th FDA clearance for the use of the Cellvizio® needle-based AQ-Flex 19 Confocal Miniprobe™ through existing bronchoscopes, transbronchial needles and other bronchoscopic accessories [510(k) number: K183640]. This opens the doors to the large interventional pulmonology market, allowing Mauna Kea to leverage its existing expertise in the field of gastroenterology to enter the next stage of growth. Needle-based confocal endomicroscopy ("nCLE") is complementary to Mauna Kea's existing probe-based CLE ("pCLE") portfolio and allows the real-time imaging and characterisation of benign and malignant cellular structures inside pulmonary nodules with through-the-needle visualisation. The company is currently evaluating the commercial opportunity for Cellvizio® in the interventional pulmonology market, which, in our view, represents a promising strategy and significant commercial opportunity. We maintain and reiterate both our OUTPERFORM recommendation and €4.10 target price.

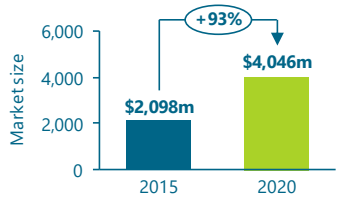
Cellvizio® extensively validated in gastroenterology

The recently 510(K) cleared Cellvizio® AQ-Flex 19 confocal Miniprobe™ opens doors to potential expansion into interventional pulmonology

Cellvizio's® existing commercial track record in gastroenterology complements the mounting evidence supporting the feasibility and safety of CLE in interventional pulmonology, and the clinical significance of CLE as a lone or complimentary method for *in-vivo* real time endomicroscopic imaging of the lungs. We expect CLE to play an increasingly prominent role in the future diagnostic landscape by enabling accurate biopsy guidance as well as reliable real-time characterisation of lung cancer and solitary pulmonary nodules *in vivo*, thus paving the way for rapid analysis of malignancy in patients with suspected lung cancer. While CLE is unlikely to replace conventional biopsies for lung cancer in the near term, the technology can provide significant clinical benefit in the existing diagnostic paradigm by increasing the accuracy and rate of representative biopsies.

Lung cancer diagnostics market to exceed $4.0bn by 2024E

CHART 1: Global lung cancer diagnostics market growth



Source: Grand View Research

With more than 2 million newly diagnosed patients per year, lung cancer is the most common as well as most deadly cancer worldwide, accounting for c.143,000 deaths annually in the US alone. As such, lung cancer represents a significant medical and economic challenge as well as a commercial opportunity for players developing innovative diagnostics solutions, such as Mauna Kea. The global lung cancer diagnostics market is projected to grow from $2.1bn in 2015 to $4.0bn in 2020E at a 14% CAGR, representing the fastest growing segment of the cancer diagnostics market (CHART 1). Continued market expansion is projected to be driven largely by (1) a growing need for precision medicine, (2) increasing pressure to reduce unnecessary intervention due to over-diagnosis and (3) a significant need to alleviate the economic burden of late-stage therapy.

First mover advantage and competitive edge

As the only FDA-cleared needle-based CLE system, Cellvizio® has a significant head start in interventional pulmonology

Mauna Kea's AQ-Flex 19 Confocal Miniprobe™ is the only nCLE product on the market and the only technology capable of characterising tissues *in vivo* and in real time. In our view, the lack of competition and unique ability to enable intralesional visualisation at a magnification of x1,000 and 12 frames per second puts Mauna Kea in an ideal position to drive accelerated penetration following market entry. Moreover, the fact that the AQ-Flex 19 Miniprobe™ is compatible with conventional bronchoscopes (including EBUS bronchoscopes), advanced navigational systems (e.g. Medtronic's superDimension) and emerging endoluminal robotic platforms (e.g. Auris' Monarch and Intuitive Surgical's ION), allows Cellvizio® to seamlessly integrate into the evolving diagnostic landscape in interventional pulmonology, paving the way for significant future sales growth on the back of accelerated adoption of emerging complementary technologies. With the recent acquisition of Auris Health by Johnson & Johnson for c.$3.4bn upfront and an additional $2.4bn in milestone payments, the interventional pulmonology space is seeing increasing momentum. We expected the arms race between J&J and Intuitive Surgical to create a significant commercial opportunity for Mauna Kea's Cellvizio® to be used in adjunct with these systems.

Valuation summary

CHART 2: Mauna Kea valuation

APPROACH	VALUATION
EV/Sales	€4.10 per share
DCF	€4.00 per share

Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations.

Our target price of €4.10/share is based on an EV/Sales multiple approach using our 2022E revenue estimate of €25.1m and the EV/Sales multiples of companies with a comparable commercial focus and maturity. Mauna Kea is well differentiated and does not have many close peers. We therefore selected a range of companies in the medical imaging and diagnostic devices space that, in our view, bear similarities to Mauna Kea, for example a focus on *in vivo* imaging and endomicroscopy and who are still relatively early stage with limited revenues. We have also performed a discounted cash flow analysis ("DCF") to capture the long-term growth potential, which yields a fair value of €4.00/share (CHART 2). Finally, we performed a sensitivity analysis to provide alternative valuation scenarios.

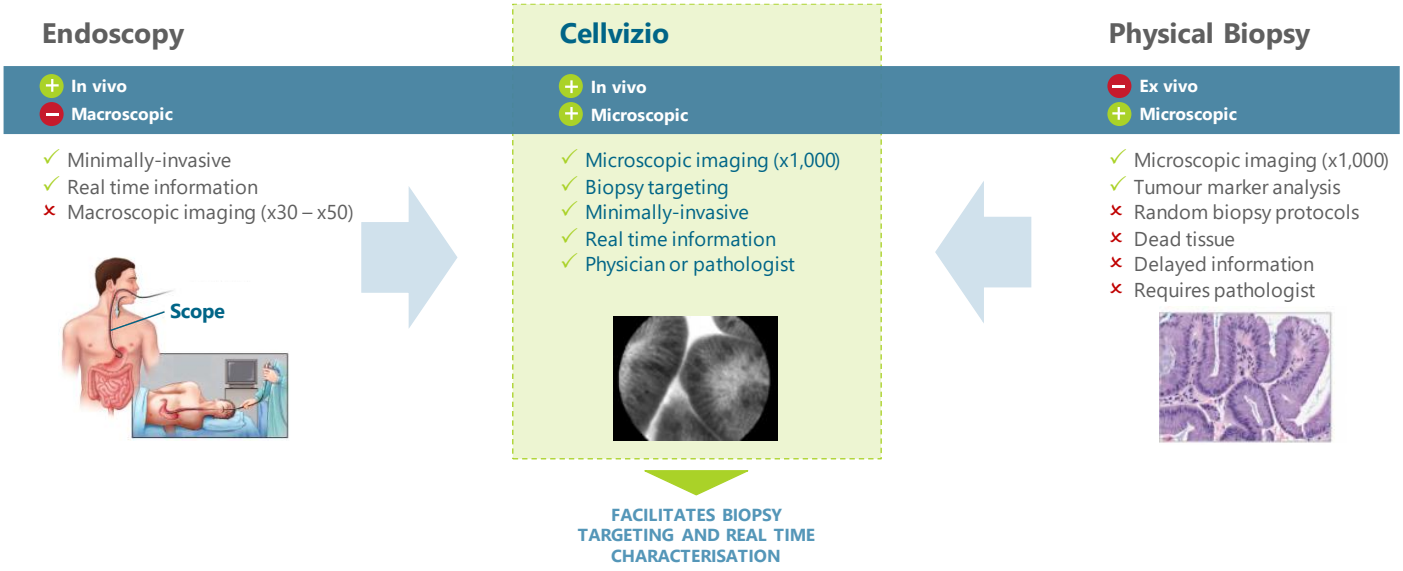
Fundamentals in GI underpin future growth

Cellvizio's® value proposition:

1. *Biopsy needle guidance to the right location*
2. *Intralesional visualisation enabling real time in vivo tissue characterisation*

With Cellvizio®, Mauna Kea have shrunk the microscope into the head of a small probe, enabling it to be inserted into the patient via an endoscope for microscopic *in vivo* visualisation and characterisation. This has profound implications for the diagnostic paradigm and streamlines patient management by allowing the identification of precancerous tissues and morphological changes during early stages of cancerous growth (CHART 3). With global cancer treatment shifting to more targeted intervention, early detection is paramount to a successful treatment outcome. The larger the target becomes, the more heterogenous and complex the surgical and / or pharmacological intervention will need to be. This means that the chances of a positive treatment outcome diminish with progression, requiring radical intervention with less specific drugs, with a broader side effects profile.

CHART 3: Cellvizio® enhances the standard of care



Source: Company data, goetzpartners Research

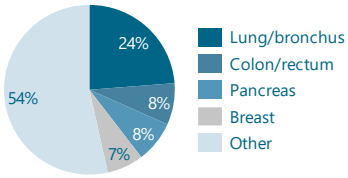
CLE clinical rationale – Improving clinical outcomes

Cellvizio® can help to reduce false negatives as well as false positives, streamlining the diagnostic process and thus creating substantial social and economic savings

Research suggest that up to 96% of peripheral pulmonary nodules discovered during screening are false positives. Current imaging modalities commonly fail to detect abnormalities in some instances ("false negatives"), while wrongly identifying healthy tissue as abnormal in other instances ("false positives"). Due to superior magnification and resolution, Cellvizio® can be used to visualise abnormalities on a cellular level which can be leveraged to (1) improve biopsy targeting on a microscopic level, and (2) aid in the characterisation of tissue *in situ*. This could improve diagnostic rates while minimising overdiagnosis. As a result, abnormalities can therefore be identified earlier, when they are just developing, paving the way for earlier intervention and more successful treatment outcomes, while at the same time minimising the economic burden.

Expanding into interventional pulmonology

CHART 4: Estimated distribution of cancer deaths (2019)



Source: NIH – SEER Program, goetzpartners Research

Mauna Kea in the past repeatedly communicated its intentions to evaluate the interventional pulmonology market as the next big value driver for the company. Interventional pulmonology is a sub-segment of pulmonology medicine and specifically deals with the minimally invasive endoscopic and percutaneous procedures used for the diagnosis and treatment of a number of respiratory disorders, with lung cancer representing the largest segment. Lung cancer is the leading cause of cancer deaths, accounting for c.1.8 million deaths in 2018[1]. Age is one of the main risk factors for developing respiratory cancer and other upper airway disorders, and future demographic shifts will increase demand in this field, making interventional pulmonology one of the fastest growing endoscopy segments. Mauna Kea has had an increased focus on applications of Cellvizio® in the gastroenterology segment in the past, but with the FDA approval of the AQ-Flex 19 Miniprobe™ for interventional pulmonology announced earlier this year, Mauna Kea is ideally positioned to leverage its existing expertise in CLE technology and commercialisation in the vast pulmonology market, which is characterised by a significant clinical need (CHART 4). As such, interventional pulmonology may represent the next value driver for the company.

CHART 5: Cancers with the lowest 5-year survival rate in the US

	ESTIMATED NEW CASES[1]	ESTIMATED DEATHS[1]	5-YEAR SURVIVAL[2]
PANCREAS	56,770	45,750	9.3%
LIVER	42,030	31,780	18.4%
LUNG AND BRONCHUS	228,150	142,670	19.4%
OESOPHAGUS	17,650	16,080	19.9%
STOMACH	27,510	11,140	31.5%
BRAIN / CNS	23,820	17,760	32.9%
OVARY	22,530	13,980	47.6%
MYELOMA	32,110	12,960	52.2%
LARYNX	12,410	3,760	60.3%
LEUKAEMIA	61,780	22,840	62.7%

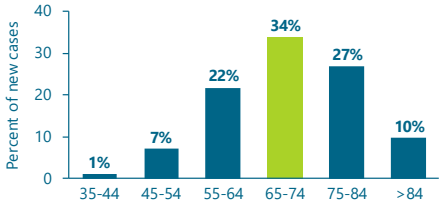
[1] Estimates for 2019, [2] 2009 - 2015 average
Source: National Institute of Health – SEER Program, goetzpartners Research

Lung cancer epidemiology

Lung cancer accounts for 12.9% of new cases, but for 23.5% of all cancer deaths, killing a disproportionate number of patients

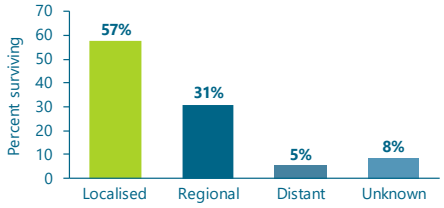
Lung cancer is the leading cause of cancer death, accounting for 12.9% of all new cancer cases. The average age at diagnosis for lung cancer is 70 years old (CHART 6), limiting the use of systemic treatment as well as surgical resection due to an increased risk of adverse events and complications. This makes lung cancer particularly difficult to treat, which is in part reason for the high level of disease recurrence characteristic for lung cancer, thus further emphasising the need for effective, minimally invasive diagnostic methods that can characterise tumours earlier. At present, only 19.4% of patients survive for more than 5 years (CHART 7). While the vast majority of patients are currently diagnosed at the symptomatic stage (CHART 8), improvements in diagnostics are expected to increase the proportion of patients that are diagnosed at earlier stages, increasing the chance for potentially curative treatment. In turn, improvements in lung cancer treatment are expected to increase the demand for better diagnosis.

CHART 6: Percent of new cases by age group



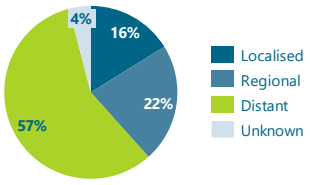
Source: National Institute of Health – SEER Program, goetzpartners Research

CHART 7: 5-year relative survival



Localised: confined to primary site; Regional: spread to regional lymph nodes; Distant: metastasised; Unknown: unstaged
Source: National Institute of Health – SEER Program, goetzpartners Research

CHART 8: Percent of cases by stage

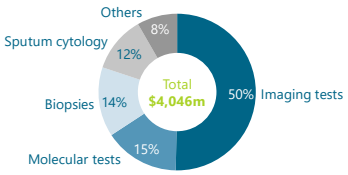


Localised: confined to primary site; Regional: spread to regional lymph nodes; Distant: metastasised; Unknown: unstaged
Source: National Institute of Health – SEER Program, goetzpartners Research

[1] World Health Organization – www.who.int

Lung cancer diagnostics market to exceed $4.0bn by 2024E

CHART 9: Global Lung cancer market by test (2020)

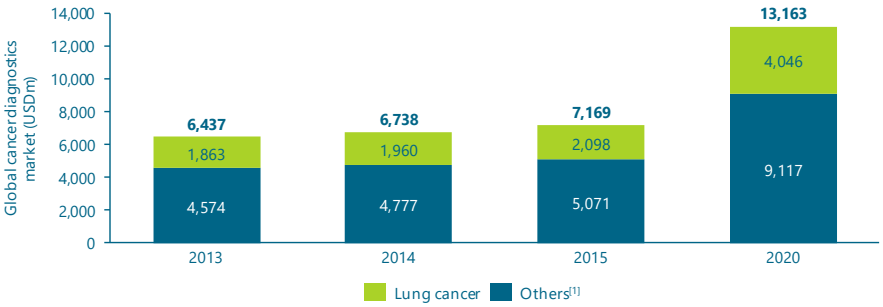


Source: Grand View Research, goetzpartners Research

With more than 2 million newly diagnosed patients per year, lung cancer is the most common as well as most deadly cancer worldwide, accounting for c.143,000 deaths annually in the US alone. As such, lung cancer represents a significant medical challenge as well as a commercial opportunity for new entrants developing effective therapies and innovative diagnostics solutions. The global lung cancer diagnostics market is projected to grow from $2.1bn in 2015 to $4.0bn in 2020E at a 14% CAGR, representing the fastest growing area of cancer diagnostics (CHART 10). Lung cancer is expected to remain the second largest segment of the $13.2bn cancer diagnostics market following breast cancer, accounting for 31% of the total market. Within this segment, imaging tests represent the vast majority of the market (CHART 9). North America accounts for the largest share of the global market (35%), followed by Europe (30%) and Asia (15%), respectively.

CHART 10: Cancer diagnostics market forecast to 2020E

MARKET SIZE



MARKET GROWTH

TYPE	CAGR% (2015-2020)
Lung cancer	**14.0%**
Breast cancer	**12.5%**
Colorectal cancer	**12.4%**
Melanoma	**11.6%**
Others	**12.7%**

[1] Includes breast cancer, colorectal cancer, melanoma and others
Source: MarketsandMarkets, goetzpartners Research estimates

CHART 11: The Monarch platform

Source: Auris Health

Emerging endoluminal robotic platforms are expected to drive market growth

The lung cancer diagnostics market is expected to expand rapidly over the coming years, driven mainly by the development of new technologies in the field of endoluminal robotics, including Auris' (Johnson & Johnson) Monarch and Intuitive Surgical's ION system (CHART 12). These systems are being developed with the aim to improve clinical outcomes by more accurately identifying smaller lesions, reaching peripheral areas of the lung and increasing the notoriously low diagnostic yield associated with lung cancer historically. Early results of Auris' ongoing BENEFIT study indicated encouraging results earlier this year by demonstrating improved reach beyond a conventional thin bronchoscope. However, beyond improving navigation, the systems have yet to deliver evidence for being able to translate into meaningful clinical outcomes. The fact that these systems are limited to the visualisation of lesions within the airways – rather than the parenchyma, where 85% of lesions are located – could provide a large opportunity for Mauna Kea, which can empower these systems to drive biopsy targeting, and thus improve diagnostic yield beyond what is possible without Cellvizio®.

CHART 12: Drivers & Challenges

	DRIVERS	CHALLENGES
CLINICAL	▪ Increasing focus on interventional pulmonology by large medtech and diagnostics players ▪ Increasing emergence of endoluminal robotics ▪ Clinical validation of improvements in diagnostic yield ▪ Growing need for precision medicine ▪ Potential to reduce metastatic disease and mortality ▪ Need for less invasive tests to improve patient experience ▪ Incentive to reduce unnecessary intervention due to over-diagnosis	▪ Identification of biomarkers suitable for non- or minimally invasive analysis ▪ Development of markers for both cancer detection and risk profiling ▪ Need for extended large-scale longitudinal studies
ECONOMIC	▪ Need to alleviate the economic burden of late stage therapy ▪ Global shift towards value-based payment models ▪ Increasing number of early detection companies entering the market	▪ Need for more flexible payment structures ▪ Building a strong economic rationale ▪ Competitive pressure of major providers
SCIENTIFIC	▪ Proliferation of specific disease and prognostic biomarkers ▪ Increasing number of cutting-edge genome sequencing technologies	▪ Need for more sensitive and precise diagnostic technology ▪ Need for more powerful and flexible data analysis techniques
OTHER	▪ Raising awareness of early diagnosis benefits ▪ Growing influence of healthcare lobbies ▪ Population aging	▪ High fragmentation of the global healthcare landscape ▪ Numerous ethical questions surrounding early diagnosis ▪ Substantial regulatory barriers

Source: goetzpartners Research

In our view, advances in the development of liquid biopsies provide a great growth opportunity for Mauna Kea, as liquid biopsies can detect but not locate malicious lesions

Smaller nodules increase the need for accurate biopsy targeting systems

The routine uses of minimally invasive cancer screens such as liquid biopsy tests, which can detect cancer, but at the same time avoid over-diagnosis, is still some time away. However, given the enormous benefits of early diagnosis both in terms of saving lives and reducing the proportion of cancer patients requiring expensive and frequently unpleasant late stage therapy, the movement towards early diagnosis is inevitable and strongly depends on the development and implementation of the appropriate technology. In our view, *in vivo* imaging that facilitates biopsy targeting will play an increasingly important role in the future, in order to meet the demand for earlier characterisation without fuelling overdiagnosis. Technologically advanced robotic guidance systems, as compared to manual systems, offer multiple additional benefits including improved navigation to difficult-to-reach locations. We expect Cellvizio® to be well positioned to penetrate the market as a routinely used adjunct to existing and future robotic systems.

Large unmet clinical need

The increasing demand for improved and more efficient lung cancer diagnostics is strongly driven by the fact that only 16% of all lung cancer cases in the US get diagnosed at a localised stage, while the remaining cases develop into more aggressive forms before detection, which reduces the 5-year survival rate to only 5% in the most advanced patient group (CHART 8). The benefits of early diagnosis in cancer are well-established and evidence has shown that early diagnosis provides a compelling case for improving cancer survival, as shown by the National Lung Screening Trial ("NLST"), which demonstrated that screening high risk patients with low dose chest computed tomography ("CT") reduced mortality from lung cancer by 20%[2]. However, lung cancer has historically been characterised by a notoriously low diagnostic yield, with 96% of the positive screens subsequently being found to be non-malignant. This highlights the urgent need for accurate diagnostic tools with high specificity as this minimises overdiagnosis and reduces the clinical burden associated with lung cancer.

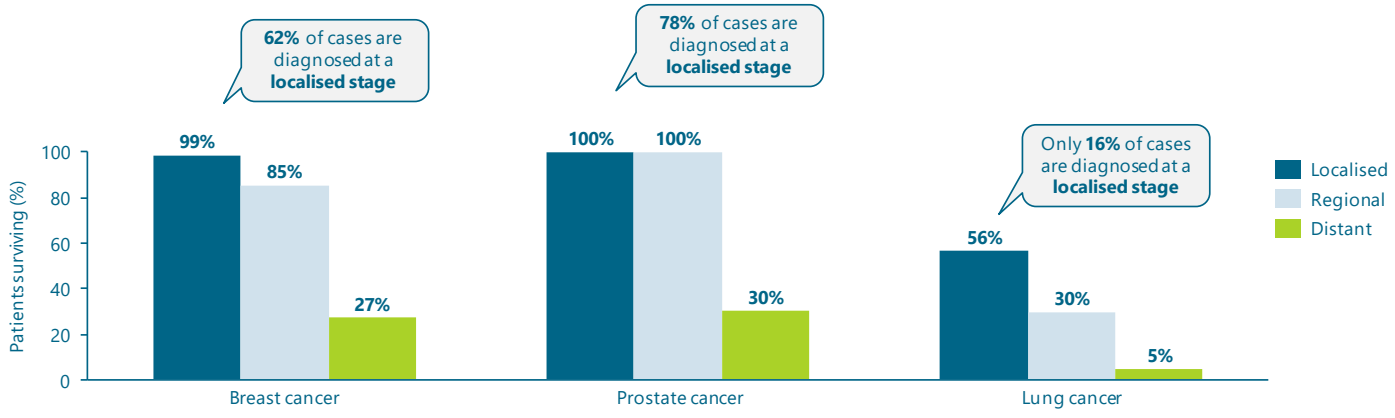
Advantages of early characterisation for treatment:

- *Easier resection due to smaller tumour size*
- *Less heterogenous cancer*
- *Immune system still intact*
- *Body more resilient to aggressive treatment*

Early detection: the key to improved treatment outcomes and survival

Early detection enables earlier, more effective, less complex, and more affordable treatment, thereby reducing the incidence of metastatic disease and decreasing mortality at a reduced cost. While early diagnosis can drastically improve survival rates (CHART 8), some cancers are more prone to be diagnosed early than others: 62% and 78% of patients diagnosed with breast and prostate cancer, respectively, are diagnosed at a stage when the cancer is still highly localised, while only 16% of lung cancer cases are diagnosed with localised disease. This has a direct impact on survival rates: 90% of patients diagnosed with breast cancer will now survive longer than 5 years, compared with only 19% for lung cancer - figures that have remained relatively stable for decades. The fact that lung cancer detected at the earliest stage (Stage I) can be cured with surgery or radiation more than 80% of the time, emphasises the strong case for early detection in improving lung cancer survival by shifting patients from late to earlier, more curable stages. Cellvizio® may play an important clinical role by enabling easier, faster and safer tissue characterisation *in vivo*.

CHART 13: Breast, prostate & lung cancer 5-year survival by stage at diagnosis



Source: National Institute of Health – SEER Program, goetzpartners Research

[2] The NLST Research Team. Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med 2011; 365: 395–409

Growing cancer prevalence creates a large economic toll

Indirect costs, like morbidity and informal care, represent 60% of total cancer costs to societies

The economic impact of cancer is significant and increasing. The total annual economic cost of cancer in 2010 was estimated at approximately $1.2 trillion, and rising prevalence and subsequent productivity loss are expected to exacerbate this economic burden. According to estimates, lung cancer is associated with the highest economic cost (15% of overall cancer costs), followed by breast cancer (12%), colorectal cancer (10%), and prostate cancer (7%). This is largely due to the significant morbidity associated with lung cancer as compared to other cancers, such as persistent breathlessness, chronic cough and chest infections. Increasing implementation of large-scale screening is only expected to increase this cost further.

Pancreatic cysts as a proxy for cost benefit

Use of needle-based CLE in addition to gold standard endoscopy in pancreatic cysts can reduce the number of surgical interventions by 23%

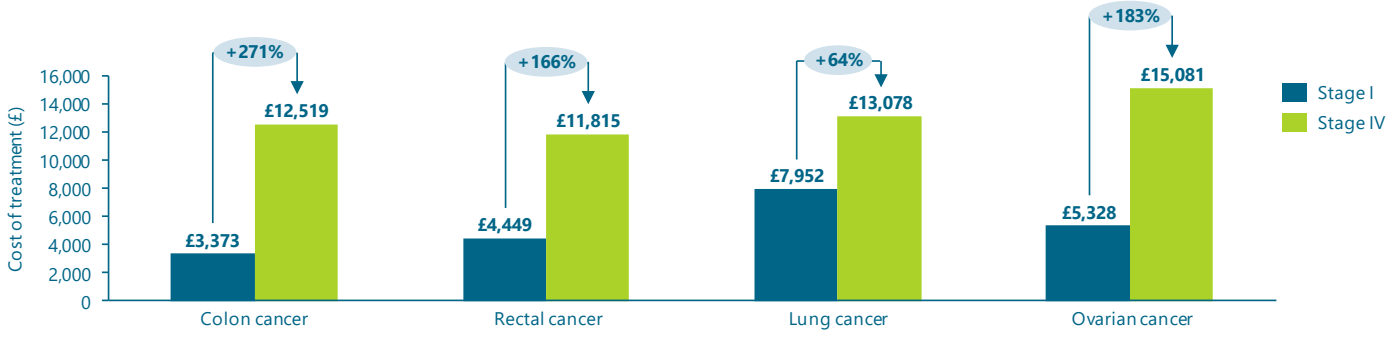
While limited data is available for the cost effectiveness of nCLE in lung cancer, the analysis of pancreatic cysts can be used as a proxy. A study by Le Pen *et al.* (2017) investigated the economic benefit associated with needle-based CLE ("nCLE") for the diagnosis of pancreatic cysts in France. The study reports that the use of nCLE in addition to conventional endoscopic ultrasound-guided fine-needle aspiration ("EUS-FNA") led to a 23% overall reduction in the number of surgical interventions. The cost-savings were reported to exceed the additional cost of the diagnostic technique, translating into overall cost-savings of 14% and 13% in the private and public sectors, respectively. Moreover, according to the study the additional use of nCLE would save the lives of 4 in 1000 patients by eliminating mortality associated with unnecessary intervention, which further highlights the medico-economic benefits associated with CLE.

Limiting the economic burden of late stage disease

Cellvizio's core value proposition of increasing diagnostic yield would not only help to limit the clinical, but also the large economic burden associated with lung cancer

Early detection not only improves patient outcomes but can also provide significant cost savings by avoiding the high treatment costs associated with life-threatening metastatic disease. CHART 14 outlines the stage-specific costs of treatment for several cancers in the UK. Overall, treatment for Stage III and Stage IV cancers costs the NHS more than two times the amount spent on treatment for Stage I and Stage II cancers. More accessible diseases, such as colon cancer, can be treated at a relatively low-cost if detected early but treatments costs tend to rise sharply as the disease progresses. However, for less accessible cancers such as those in the lung, which involve complex resection of localised disease, the cost difference between early and late-stage treatment appears relatively low compared to other cancers, implying lower potential cost-savings from earlier diagnosis on a patient-basis. However, on a population-wide basis, this trend quickly reverses due to the much higher incidence of lung cancer.

CHART 14: Treatment costs significantly less at earlier stages of disease



Source: Cancer Research UK, goetzpartners Research

1. Using CLE to improve biopsy targeting

Cellvizio® addresses two key barriers in the diagnosis of lung cancer:

1. *Obtaining quality tissue*
2. *Characterising relevant tissue sooner*

The current gold standard for lung cancer diagnosis leaves significant room for improvement. At present, transthoracic needle aspiration ("TTNA") is the preferred option for sampling peripheral pulmonary nodules, due to its high diagnostic yield of 80% to 90%[3]. However, this method carries a 25% risk of causing pneumothorax (collapsed lung). Alternatively, other less invasive options, such as flexible bronchoscopy in combination with brushing and washing, as well as transbronchial biopsy ("TBB") under guidance using electromagnetic navigational bronchoscopy ("ENB"), virtual bronchoscopy ("VB") or radial-probe ultrasound ("r-EBUS") provide a significantly lower diagnostic yield between 50% and 65%[4,5]. With large diagnostics and medtech players increasingly turning their attention to interventional pulmonology, improvements in clinical utility of emerging advanced guidance systems and endoluminal robotic systems have yet to be delivered. While these systems address the shortfall of conventional bronchoscopy in terms of navigating to peripheral regions of the lung, their diagnostic utility is reduced by the fact that visualisation is limited to the airways, proving less helpful in assisting the targeting of nodules in the parenchyma, where most of the lesions are located. Overcoming this limitation is the first of two key value propositions of Mauna Kea's nCLE platform.

CHART 15: Current lung biopsy modalities

PPROCEDURES	DESCRIPTION	PROS	CONS
TRANS-THORACIC NEEDLE ASPIRATION (TTNA)	Percutaneous insertion of needle into tumour through chest wall	Accurate	High complication rates
ENDOBRONCHIAL ULTRASOUND (EBUS)	Visual exploration of pulmonary bronchi using a flexible tubular ultrasound probe, often associated with biopsy	Low complication rates	Hard to obtain biopsy due to manual navigation
ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY (ENB)	A virtual, 3D bronchial map is created from a patient's CT scan and used in conjunction with electromagnetic technology to see and guide the bronchoscope in real time	Easy to navigate	Costly, added time and training required
VIDEO-ASSISTED THORACOSCOPIC SURGERY (VATS)	A small camera, inserted into the patient's chest via small incisions, transmits images from inside the chest to aid in guiding the physician during the procedure	High complication rates	Invasive and costly
ROBOTIC BRONCHOSCOPY	A hand-held controller allows physician to navigate a small endoscope into the lung	Robotic precision, better reproducibility and access	Costly and limited visualisation capabilities outside of airways

Source: goetzpartners Research

Restrictions in visualisation limit biopsy targeting at present

85% of lesions are found outside the airways and cannot be visualised accurately using existing modalities. This impedes biopsy targeting and reduces diagnostic yield

In order to take a biopsy, first a CT scan is taken, then physicians use a thin bronchoscope to navigate to the lesion under real time fluoroscopy. Using EBUS, physicians can visualise the nodule to be able to position the scope. Once in the vicinity of the nodule, the EBUS probe will have to be removed in order to introduce an endobronchial needle, thereby losing visual guidance, which significantly decreases the likelihood of acquiring a meaningful sample. Commonly, an on-site pathologist will assess the cells in real time to verify sample quality, and it often requires more than 8 passes to reach a meaningful volume. Importantly, while emerging endoluminal robotics platforms do not address this key challenge of guiding biopsy needles, Mauna Kea's through the needle visualisation holds great promise in unlocking the full potential of these emerging systems as well as existing bronchoscopes by significantly improving the targeting of relevant biopsy sites.

Imaging and sampling challenges in lung cancer using EBUS

Conventional technologies allowing real time macroscopic inspection and biopsy targeting lack power to support the increasing need for characterisation of smaller nodules

The use of EBUS leaves significant room for improvement since it cannot characterise nodules. As a result, a biopsy is required in order to be able to assess malignancy in a laboratory *ex vivo*. However, tissue sampling is particularly challenging using EBUS guidance, as it lacks intralesional visualisation to guide biopsies. Additionally, primary tumours in the lung often show much lower tumour cellularity than other tumour types, with tumour purity often being less than 20% due to a high proportion of stromal cells, lymphocytic infiltration, and necrosis[6]. This emphasises the clear need for technologies that offer intralesional visualisation, such as nCLE, to improve biopsy quality and optimise patient management by

[3] Hiraki *et al.* (2010)
[4] Rivera & Mehta (2007)
[5] Gex *et al.* (2014)
[6] Hiley *et al.* (2016)

maximising diagnostic yield. Importantly, biopsy targeting will play an increasingly prominent role in the future, as advancements in screening and liquid biopsy technologies drive a need for reliable imaging techniques that can accurately characterise smaller nodules.

CHART 16: Technical, logistical and biological challenges in lung cancer diagnosis

TECHNICAL	LOGISTICAL	TUMOUR BIOLOGY
▪ Low diagnostic yield due to limitations in current imaging modalities in navigating the needle to the right location ▪ Multiple tests with the potential for discordant results (e.g. immunohistochemistry vs. fluorescence in-situ hybridisation for anaplastic lymphoma kinase mutation) ▪ Technology-specific failures due to differences in sensitivity	▪ Return of test results to clinicians in a clinically relevant timeframe ▪ Desirability of local, real time testing approaches ▪ Education and training of laboratory and clinical staff in new technology ▪ Standardisation of assessment criteria usable by clinicians	▪ Diversity of molecular subgroups within lung cancers and interpatient heterogeneity ▪ Significant intra-tumour heterogeneity ▪ Treatment evolution and resistance in response to treatments ▪ Evolving treatment paradigms and biomarkers ▪ Increasing complexity of detectable genomic changes in cancer

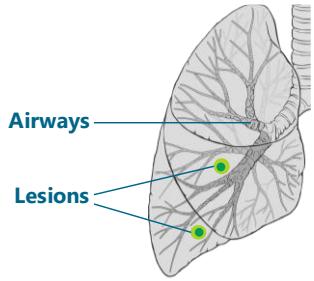
Source: Hiley *et al.* (2016)

Advantages of using nCLE as an adjunct to current modalities

Mauna Kea have developed a needle-based CLE that can be introduced through a 19-gauge needle and used to visualise malignancy on a cellular level from inside the tumour in real time

CLE lends itself to the accurate and rapid onsite pathologic evaluation of suspected malignancies, but with a significantly higher magnification and a much higher diagnostic resolution than EBUS. This has widespread implications for improving the overall outcome of the diagnostic process and allows doctors to look beyond the tissue's surface morphology. As a result, doctors can examine biopsy samples as they are obtained and request additional samples to be taken immediately if needed, thereby increasing sample quality and reducing waiting times for patients.

CHART 17: 85% of lesions are located outside the airways

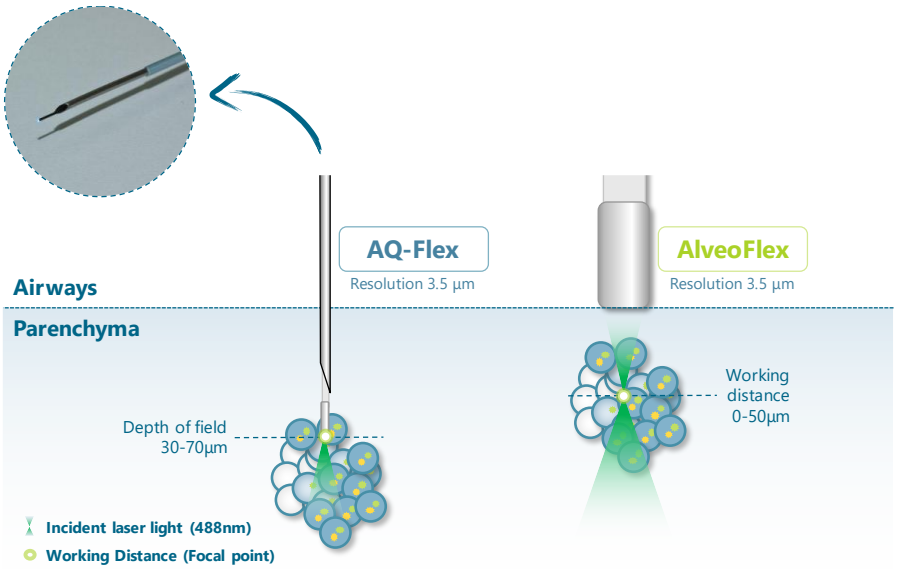


Source: Adapted from wikipedia.com

Mauna Kea's AlveoFlex and AQ-Flex

Since pCLE, where the probe is inserted through the operating channel of a conventional endoscope, is limited to scanning the surface of lung tumours, Mauna Kea have developed the needle-based AQ-Flex 19 CLE, which is small enough to be introduced into tissue through a 19-gauge biopsy needle. This creates the possibility for real time microscopic visualisation within the parenchyma to (1) guide biopies and (2) characterise tissues *in situ*. The AQ-Flex 19 Miniprobe™ is preloaded into a 19-gauge FNA ("fine-needle aspiration") needle, which is inserted into the lung tumour / lymph node under real-time ultrasound guidance (CHART 18). The nCLE is then advanced into the tissue, whereafter video sequences from within the tumour are transmitted and recorded while moving the nCLE under EUS guidance. It only takes a few minutes to image a lymph node over the full diameter in a single plane using nCLE, representing minimal added effort to doctors. Following image acquisition, the nCLE is removed and the needle is passed back and forth in the same plane as the previous miniprobe, allowing sampling of the most relevant tumour regions as identified by nCLE. FNA samples are then processed on glass slides and analysed with conventional staining and immunohistochemistry techniques.

CHART 18: Mauna Kea's interventional pulmonology probes: AlveoFlex and AQ-Flex



Source: Company data, goetzpartners Research

Overcoming challenges seen in conventional EBUS: CLE can analyse tumour cross sections and better target the 20% of cancerous cells in a tumour that will support a meaningful diagnosis

nCLE improves biopsy guidance and may improve diagnostic yield

Identifying the optimal area for tissue sampling increases the accuracy while reducing the overall number of biopsies required as well as the frequency of false negatives. With lung biopsies being costly procedures and considering the high percentage of false negatives, better targeting of tissue biopsies can lead to more meaningful biopsies and has wide implications on overall costs and cost effectiveness. Moreover, by being able to visualise malignancy on a cellular level within tumours, the core can be analysed more carefully thus increasing the chance of capturing a sample of the 20% of malignant tissue normally present in lung tumours. This provides valuable location-specific information necessary to reach a clinically meaningful diagnosis. Having insight into the tumour at 12 frames per second also provides an advantage for moving targets, as is the case with nodules in the lung.

2. CLE for early *in vivo* tumour characterisation

nCLE provides real-time information regarding the malignancy status of lung tumors and mediastinal nodes and could improve bronchoscopic diagnostics and thus:

- *Improve diagnostic rates*
- *Reduce the number of surgical diagnostic procedures required*
- *Shorten the time-before-treatment interval*
- *Reduce costs*

At present, patients – whether at high risk and outwardly healthy or symptomatic – undergo a series of steps to first confirm the presence of lung cancer, followed by further testing to determine whether the disease is life-threatening and eligible for aggressive treatment, too advanced for disease-modifying intervention, or benign. The second key value proposition of Mauna Kea's nCLE probe is to streamline this process, by providing doctors with real-time information on pathology during the initial steps of the diagnostic pathway. This helps to (1) reduce the number of false positives as well as false negatives, and (2) provides accurate insights into disease stage and progression in case of cancer presence, allowing earlier and better treatment planning. This not only saves time but also minimises overtreatment and the need for repeated invasive tissue biopsies to rule out disease. Providing endoscopists with real time feedback is especially critical in lung cancer, as over 50% of cases of carcinoma *in situ* are estimated to progress to an invasive cancer within a 6-month time period, highlighting the importance of reaching a diagnostic conclusion at the earliest time possible.

The importance of characterising tissue in vivo

The profound advantages from being able to characterise the malignancy status *in vivo* are directly linked to the current clinical paradigm: At present, pulmonary lesion assessed *in vivo* must meet 8 different diagnostic criteria in order to be defined as benign. In c.50% of cases not all 8 of these criteria are met, which means the test is considered inconclusive and the lesion is subsequentially surgically removed. However, nearly a third of these resections are found to be benign following *ex vivo* assessment, highlighting the large need for modalities such as nCLE, which can differentiate if a nodule is clearly cancerous or not cancerous at all.

The more we understand about tumour biology and related patient segmentation, the more precisely health technologies will have to be to characterise cancer subtypes and stages

nCLE suitability for early characterisation and more accurate disease staging

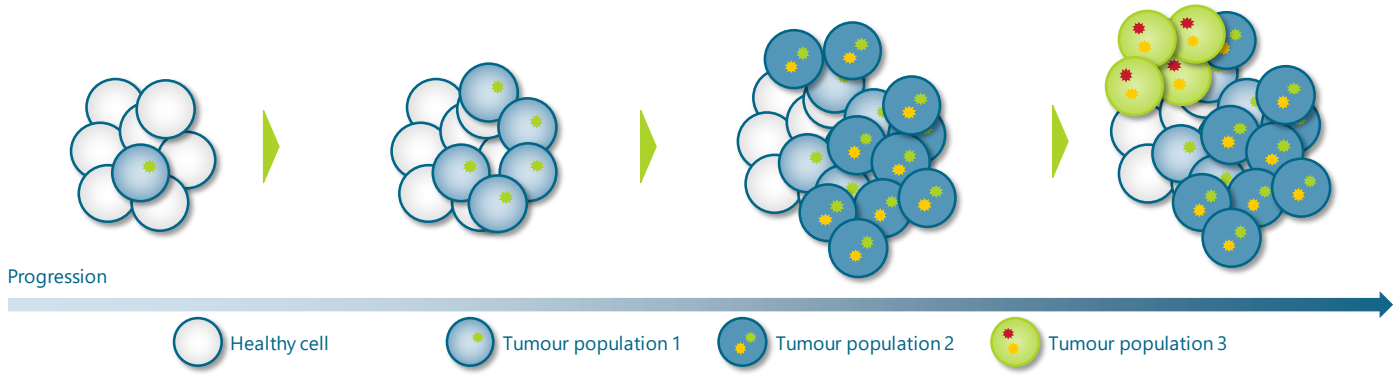
Pathologists are increasingly front and centre in cancer care. Rapid advances in our molecular understanding of cancer are allowing earlier diagnosis and better targeting and personalisation of cancer therapies, driving the need for diagnostic methods that support the identification of earlier tumours and smaller nodules. While the diagnostic yield of all conventional *in vivo* imaging technologies decreases as nodule size decreases, imaging with Cellvizio® is agnostic to changes in tumour size as it allows analysis from within the tumour at a cellular level. This can improve diagnosis as well as disease management. Based on its established clinical validity and ability to seamlessly integrate into existing diagnostic workflows, Cellvizio® looks ideally placed to play an increasingly important role in the personalisation of cancer therapy by facilitating the differentiation between aggressive and benign pathology, allowing patients to receive the most effective treatment for their specific cancer and to avoid the discomfort and expense of unnecessary, ineffective and / or highly invasive surgeries.

Precision medicine:
Using genetic and biologic information to classify patients into subpopulations with different therapy needs and to predict response to treatment

Paving the way for precision medicine…

Substantial advances in the characterisation of the human genome have led to a much better understanding of the genetic mechanisms underlying different types of cancer. A key observation is the fact that cancer cells within the same tumour can display different genotypic, phenotypic and morphological profiles (tumour heterogeneity), driven by their underlying genetic make-up (CHART 19). On one hand, tumour heterogeneity represents a significant challenge in designing effective treatment, however, an increased understanding and characterisation of tumour biology forms the basis of more accurate molecular profiling of individual patients, enabling better stratification and prognosis, thus paving the way for tailored therapeutic regimens utilising more refined treatment strategies with higher therapeutic yield and reduced risk of adverse events. Since precision medicine in oncology is currently still largely dependent on the analysis of tissue biopsies taken from the tumour, Cellvizio® could help in capturing more tumour cells with all clinically relevant markers present.

CHART 19: Tumour heterogeneity impedes accurate diagnosis



Source: goetzpartners Research (adapted from PC Nowell (1976) – The clonal evolution of tumour cell population)

CLE allows identification of residual disease following surgical resection as well as treatment response surveillance, providing easier follow ups and faster readouts than conventional physical biopsies

…and accurate treatment response monitoring

Real time *in vivo* assessment of tumour morphology following treatment onset enables longitudinal monitoring of patient-specific treatment response and assessment of the tumour's susceptibility to particular drugs. This information can be used to detect resistance and to determine the right targeted therapy as early as possible, thus improving long term outcomes and extending survival. Furthermore, cellular visualisation using CLE in combination with fluorescent immunohistochemical markers could facilitate optimal stapling of the parenchyma around the nodule prior to surgical resection, thus allowing for as much healthy tissue to be spared as possible while reducing the risk of adverse effects.

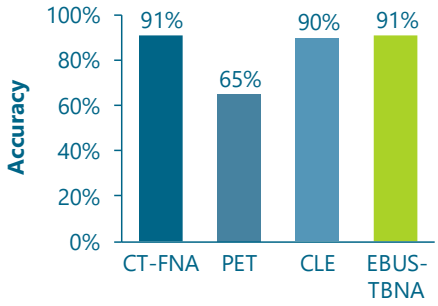
nCLE for real time diagnosis and staging of lung cancer

Needle-based endomicroscopic imaging has been shown to provide accurate results on the nature of pulmonary lesions and metastatic lymph nodes, by enabling a 90% accuracy for detecting malignancy, with substantial intra- and inter-observer agreements. These findings support the fact that nCLE might serve as an important adjunct to navigation bronchoscopy for real-time targeting and identification of lung tumours. The below clinical data illustrates Cellvizio's® ability to support precise guidance to identify the optimal area for sampling as a real-time feedback technique for diagnostic, staging and treatment procedures in lung tumours.

NPV as the key clinical parameter

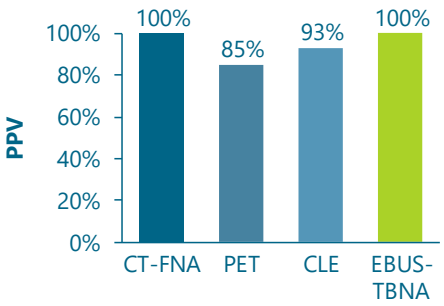
The charts below illustrate the accuracy (CHART 20), positive predictive value ("PPV", CHART 21) and negative predictive value ("NPV", CHART 22) of conventional diagnostic methods and nCLE. While PPV of a CT-guided biopsy in diagnosing malignancy is assumed to be close to 100%, the NPV is often considered the more critical clinical parameter as it captures the probability that subjects with a negative screening test truly do not have the disease. As illustrated below, nCLE has comparable sensitivity and specificity to other methods, however nCLE is better at excluding malignancy as highlighted by its superior NPV. Moreover, NPV estimates for CT-FNA of lung nodules as low as 59% have been reported[7], further increasing the potential upside that can be achieved using nCLE, especially in light of the growing need for diagnostics that can identify smaller tumours in the future. It is of note that in addition to a higher NPV, nCLE offers the added benefit of providing physicians with a breath of qualitative data on a microscopic level.

CHART 20: Diagnostic accuracy



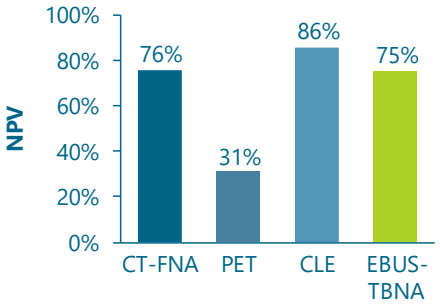
Source: Wijmans *et al.* (2019), Barta *et al.* (2017), Divisi *et al.* (2018)

CHART 21: Positive predictive value



PPV: positive predictive value
Source: Wijmans *et al.* (2019), Barta *et al.* (2017), Divisi *et al.* (2018)

CHART 22: Negative predictive value



NPV: negative predictive value
Source: Wijmans *et al.* (2019), Barta *et al.* (2017), Divisi *et al.* (2018)

As the only FDA-cleared needle-based CLE system, Cellvizio® has a significant head start in interventional pulmonology

Competitive landscape & Mauna Kea competitive edge

Mauna Kea's AQ-Flex 19 Confocal Miniprobe™ is the only nCLE product on the marketplace and the only technology capable of characterising tissues *in vivo* and in real time. In our view, the lack of competition and unique ability to enable intralesional visualisation at a magnification of x1,000 and 12 frames per second puts Mauna Kea in an ideal position to drive accelerated penetration following market entry. Moreover, the fact that the company's AQ-Flex 19 Miniprobe™ is compatible with conventional bronchoscopes (including EBUS bronchoscopes), advanced navigational systems (e.g. Medtronic's superDimension) and emerging endoluminal robotic platforms (e.g. Auris' Monarch and Intuitive Surgical's ION), allows Cellvizio® to seamlessly integrate into the evolving diagnostic landscape in interventional pulmonology, paving the way for significant future sales growth on the back of accelerated adoption of emerging complementary technologies.

[7] Quint *et al.* (2006)

Future growth drivers

While we believe Cellvizio® is ideally positioned to penetrate the existing interventional pulmonology market given its unique selling propositions when it comes to improving existing diagnostic paradigms, we also believe that technological progress of complementary technologies will further drive the need for Cellvizio® in the future. The future opportunity can broadly be divided into (1) intrinsic factors, including the potential to combine CLE with *in vivo* immunohistochemistry, and (2) extrinsic factors, such as advances in complementary diagnostic as well as therapeutic modalities, such as liquid biopsies and targeted therapies. As the line between diagnosis and therapy is becoming increasingly fluid, technologies that can facilitate treatment planning as well as execution based on underlying pathology subtype, such as Cellvizio®, will become increasingly important. As such, Mauna Kea could help to shape the future diagnostic paradigm of lung cancer and other cancers.

Intrinsic factors – expanding the use of CLE

Endoscopic and laparoscopic intraoperative image- and molecular guided cancer surgery

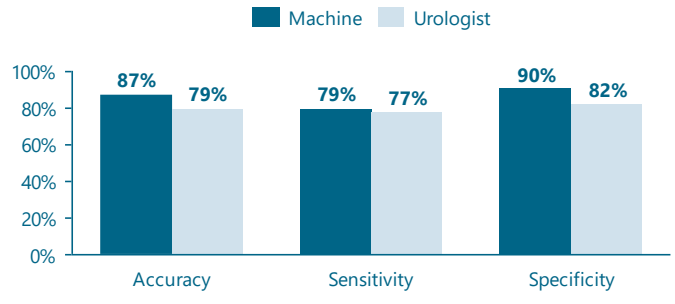
Surgery remains the cornerstone and first-line treatment for many solid tumours. While a wide variety of imaging modalities are available for staging prior to surgery, surgeons still rely primarily on visual and haptic cues in the operating environment. Image and molecular guidance might improve surgical resection outcomes through enhanced tumour definition and margin detection *in situ*. Intraoperative image- and molecular-guided cancer surgery involves injection of a fluorophore, which is excited at a specific wavelength and the emitted fluorescent photons are detected, allowing surgeons to identify tissue properties and differentiate between tumours and healthy tissue. To date, Cellvizio® is the only system that provides this optionality at a microscopic level while being small enough to fit within a needle). New fluorophores could be developed to stain some pathophysiological processes, therapeutic targets, or enzyme activities, providing surgeons with additional insights. It should be noted, that nCLE in its current form cannot be used as a substitute for pathology, as nCLE with fluorescein does not allow for tumour marker analysis, which is important in determining lung cancer subtypes and the optimal treatment strategy. Using CLE in combination with antigen-specific probes, as has been done in gastroenterology before, may be a promising future strategy, enabling real-time confirmation of malignancy status of the nodule under investigation, paving the way for immediate bronchoscopic treatment.

Due to technical superiority of Cellvizio® compared with related technologies, Cellvizio® is the most likely to find widespread application in the AI market

CLE image standardisation catalyses development of AI-supported diagnostics

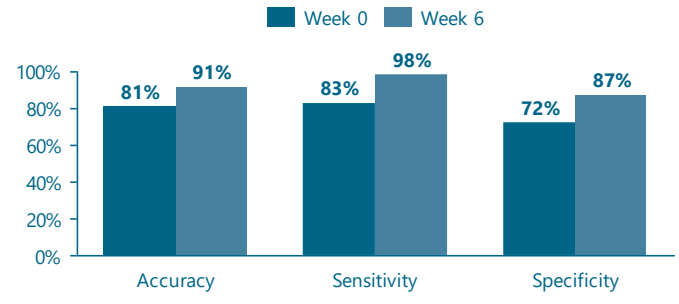
Due to an acceleration in the development and application of robot-assisted surgery and artificial intelligence ("AI") in the field of healthcare, it comes as no surprise that Mauna Kea is actively pursuing ways to harness the full power of the latest AI techniques to optimise its diagnostic platform in line with rapid technological advances in AI and data-driven surgery. The primary focus for Mauna Kea lies in the AI-assisted interpretation of medical images (CHART 23). As the outcome of image interpretation is highly dependent on the resolution and quality of the data input, Cellvizio® has a clear competitive advantage in this quickly advancing field. Furthermore, improvements in technology as well as increasing CLE imaging standardisation can be harnessed to train algorithms to identify lesions more accurately in the future. More transparent regulatory pathways, increasing recognition of AI-mediated benefits in the field of medical technology and a steep learning curve (CHART 24) will, in our view, continue to boost adoption of Cellvizio® over the long term.

CHART 23: Diagnosis of bladder cancer by AI and urologists



Source: Mauna Kea, Joe Liao *et al.*

CHART 24: CLE learning curve in diagnosing GI cancer



Source: Rapat Pittayanon *et al.* (2012)

Paving the way for partnerships in robot-assisted surgery

Cellvizio's® integrability with current technologies in robot-assisted surgery suggest large opportunity for strategic partnerships

Data-driven surgery helps surgeons to identify margins and to determine what action to take. With FDA clearance and CE marking for use of Cellvizio® in conjunction with surgical robotic systems now in place [510(k) number: K172844], and with increasing integrability of Cellvizio® into other platforms, Mauna Kea is well-positioned to enter potential strategic alliances with major players in the field of robotic surgery, such as Intuitive Surgical, the largest manufacturer of surgical robots with a global installed base of more than 4,000 systems. Improved identification of resection margins and nerve sparing are key drivers for increased application in this field. The steep learning curve associated with Cellvizio® and lack of need for extensive specialist training mean faster clinical benefits, further driving adoption.

Extrinsic factors – growth of complementary technologies

Improvements in diagnostic modalities drive the need for CLE

Liquid biopsies are being developed to detect epigenetic changes, circulating tumour cells, or other molecular markers characteristic for cancerous/pre-cancerous growth

There is a clear need for modalities that can shift diagnostic rates from later stages of lung cancer to earlier stages in order to reduce the socio-economic burden. Continuous improvements in diagnostics mean that more cancers will be detected at an earlier stage, when nodules are smaller and more difficult to locate, identify and analyse, thus increasing the clinical need for Cellvizio® as well as market size. Importantly, while lung cancer screening has already been implemented in the US, it is still under consideration in Europe. However, widespread routine screening is expected to be implemented in Europe in the near future, which would significantly increase the number of lung nodules being diagnosed. Furthermore, with the development of liquid biopsies and screening tools progressing rapidly, macroscopic imaging using CT, PET or other imaging modalities will become increasingly insufficient and increase the frequency of false positives and inconclusive results. As such, Cellvizio® can be used to maximise the benefits of advancements in screening and liquid biopsies, by allowing navigation to and targeting of smaller nodules without a loss in sensitivity and accuracy compared with other conventional modalities that, in contrast to CLE, lose diagnostic accuracy as tumour size decreases, calling for more sophisticated *in vivo* diagnostics.

The importance of phenotypic information for diagnosis and treatment planning

While liquid biopsies may in the near future be able to reliably detect the presence of cancer, CLE will allow them to be localised and characterised beyond genotype

Tumour genotyping and genetic sequencing enable the identification of genetic abnormalities that drive particular tumours. Despite rapid improvements in both cost and speed of sequencing an entire genome over the last decades, sequencing remains expensive for routine application. While leveraging genome sequencing will improve cancer diagnosis and guide pathologists towards the optimal choice of therapy, Cellvizio®, in our view, will remain a tool that can provide phenotypic context about the genetic data, allowing pathologists to form a comprehensive diagnostic view by providing detailed morphological context that aids accurate classification and identification of tumour subtypes. Furthermore, the combined use of Cellvizio® and fluorescent imaging to visualise molecular cancer markers holds vast promise for the future of both cancer diagnostics as well as care.

Cellvizio® aids patient stratification and facilitates targeted therapy

Clinical evidence supports the use for PT in lung cancer, Cellvizio® can be used to navigate treatment by enabling accurate placement of fiducial markers

As cancer therapies are becoming increasingly targeted, the pressure to get the right treatment to the right patient increases. Technological improvements in the field of proton therapy, for example, enable better targeting of smaller tumours, and Cellvizio® could play a key role in the placement of fiducial markers to optimise tumour targeting prior to radiotherapy. Targeted proton therapy has been shown to improve survival in NSCLC compared with photon therapy, while simultaneously reducing the risk of side effects such as inflammation of the lungs and oesophagus. As illustrated in CHART 8, c.38% of patients are currently diagnosed at a regional or localised stage, representing a large patient population suitable for PT, which is only expected to expand as diagnostic and screening modalities further improve, creating large demand for modalities such as Cellvizio®, which can support the image-guided placement of fiducial markers (small metal objects that are placed within the tumour to help pinpoint tumour location with great accuracy). This allows maximisation of the radiation dose to the tumour while sparing surrounding healthy tissue.

Valuation suggests fair value of €4.10 per share

Our target price of €4.10/share is based on an EV/Sales multiple approach using our 2022E revenue estimate of €25.1m and the EV/Sales multiples of companies with a comparable commercial focus and maturity. We have also performed a discounted cash flow analysis ("DCF") to capture the long-term growth potential (CHART 25). Finally, we performed a sensitivity analysis (CHART 26, CHART 27) to provide alternative valuation scenarios.

CHART 25: Mauna Kea valuation

APPROACH	VALUATION
EV/Sales	€4.10 per share
DCF	€4.00 per share

Source: goetzpartners Research estimates

CHART 26: Sensitivity analysis for EV/Sales valuation

Probability of success	EV/Sales multiple 5.1x	6.1x	7.1x	8.1x	9.1x
70%	68	79	91	102	114
75%	72	84	96	109	121
80%	76	89	102	115	128
85%	80	94	108	122	136
90%	84	99	114	129	143

Source: goetzpartners Research estimates
Warning Note: Forecasts are not a reliable indicator of future performance. The return may increase or decrease as a result of currency fluctuations.

CHART 27: Sensitivity analysis for DCF valuation

Probability of success	WACC 16%	15%	14%	13%	12%
70%	72	81	90	100	112
75%	77	86	96	107	119
80%	81	91	101	113	127
85%	86	96	107	120	134
90%	90	101	113	126	141

Source: goetzpartners Research estimates
Warning Note: Forecasts are not a reliable indicator of future performance. The return may increase or decrease as a result of currency fluctuations.

EV/Sales multiple analysis based on 2022E revenues

Mauna Kea is well-differentiated and does not have many close peers. We therefore selected a range of companies in the medical imaging and diagnostic devices space that, in our view, bear similarities to Mauna Kea (CHART 28), for example a focus on *in vivo* imaging and endomicroscopy and who are still relatively early-stage with limited revenues. We then calculated the median LTM EV/Sales trading multiple, which we applied to our 2022E sales forecast for Mauna Kea. We discounted this value back using our estimate for Mauna Kea's WACC of 14% and applied a probability of success rate of 80% to capture the commercial risk associated with Mauna Kea achieving our forecasts. This yields a fair value of €4.10 per share (CHART 25).

CHART 28: Companies with a comparable focus area as Mauna Kea

EURm

Company Name	Country	Period	Market cap	Enterprise value	Sales (LTM)	EV/Sales
Mauna Kea	**FR**	**06/30/2019**	**24**	**30**	**8**	**3.8x**
Intuitive Surgical	US	06/30/2019	55,200	52,891	3,539	14.9x
FUJIFILM Holdings	JP	06/30/2019	20,014	20,912	18,933	1.1x
Olympus	JP	06/30/2019	16,847	17,410	6,269	2.8x
Carl Zeiss Meditec	DE	03/31/2019	9,731	9,912	1,334	7.4x
Ambu B	DK	06/30/2019	3,746	3,895	394	9.9x
SuperSonic Imagine	FR	06/30/2019	35	59	25	2.4x
Optiscan Imaging	AU	06/30/2019	14	13	1	19.7x
BioView Ltd	IL	12/31/2018	10	6	6	1.1x
SciBase Holding	SE	06/30/2019	8	3	1	4.2x
Average						**7.1x**

Source: FactSet, goetzpartners Research
Market data as at COB 8th October 2019
Warning Note: Past performance and forecasts are not a reliable indicator of future performance. The return may increase or decrease as a result of currency fluctuations.

10-year DCF analysis captures long-term value

Our DCF analysis for Mauna Kea is shown in CHART 29. We forecasted Mauna Kea's financial performance for 15 years to 2033E and applied a terminal value using a 4.0x exit multiple. Free cash flows ("FCF") are discounted and risk-adjusted using the same parameters as in the EV/Sales valuation above, i.e. a WACC of 14% and probability of success of 80%. This yields an equity value of €101m and a fair value of €4.00/share.

CHART 29: Mauna Kea discounted cash flow analysis

Discounted cash flow	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Dec YE (GBPm)	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-23	31-Dec-24	31-Dec-25	31-Dec-26	31-Dec-27	31-Dec-28	31-Dec-29	31-Dec-30	31-Dec-31	31-Dec-32	31-Dec-33
EBITDA	**(9.5)**	**(5.2)**	**(1.9)**	**3.2**	**8.1**	**14.0**	**21.2**	**29.1**	**39.3**	**51.6**	**66.2**	**83.6**	**104.0**	**128.2**	**156.5**
Tax	-	-	-	(0.4)	(1.0)	(3.5)	(6.0)	(9.1)	(12.6)	(16.8)	(21.8)	(27.7)	(34.7)	(43.0)	(52.7)
tax rate	0.0%	0.0%	0.0%	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)	(35.0%)
CapEx	(0.7)	(1.2)	(1.5)	(2.0)	(2.5)	(3.1)	(3.9)	(4.7)	(5.7)	(7.0)	(8.4)	(10.2)	(12.2)	(14.6)	(17.4)
% sales	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)	(8.0%)
ΔWC	(0.7)	(1.5)	(0.6)	(1.0)	(0.6)	0.0	(1.5)	(0.0)	(1.7)	(2.0)	(2.4)	(2.8)	(1.5)	(3.5)	(4.1)
% growth	2613.0%	123.4%	(63.3%)	75.8%	(40.0%)	(102.0%)	(12358.1%)	(97.2%)	4068.6%	18.8%	17.1%	17.8%	(45.5%)	129.8%	16.7%
FCF	**(10.9)**	**(8.0)**	**(3.9)**	**(0.2)**	**3.9**	**7.3**	**9.8**	**15.2**	**19.2**	**25.8**	**33.6**	**42.9**	**55.6**	**67.1**	**82.3**

PV free cash flows	64
PV terminal value	50
Net present value	**91**
Net debt YE2019E	9.5
Equity value	**101**
Shares in issue (m)	25.2
FV per share (€)	**4.00**

Source: goetzpartners Research estimates. Warning Note: Forecasts are not a reliable indicator of future performance. The return may increase or decrease as a result of currency fluctuations.

Financials

H1/2019 financial review

Mauna Kea reported strong underlying sales growth in H1/2019 with revenues of €3.9m (+45% YoY). A 49% YoY increase in COGS was partly offset by a decline in R&D expenses (-8% YoY). Higher administrative (25% YoY) and S&M (5% YoY) expenses yielded larger than expected operating and net losses of €6.6m and €8.1m, respectively.

CHART 30: H1/2019 results below our estimates (in 000s)

P&L items	H1/2018A	H1/2019A	YoY	GPS H1/2019E	Δ vs. GPS
Revenue	**2,707**	**3,937**	45%	**n.a.**	n.a.
Cost of sales	(987)	(1,468)	49%	(1,033)	42%
Gross profit/(loss)	**1,720**	**2,469**	44%	**2,903**	(15%)
R&D expenses	(2,235)	(2,050)	(8%)	(2,373)	(14%)
Administrative expenses	(2,069)	(2,578)	25%	(2,016)	28%
S&M	(4,376)	(4,597)	5%	(4,639)	(1%)
Operating profit/(loss)	**(6,479)**	**(6,614)**	2%	**(5,596)**	18%
Profit/(loss) for the period	**(6,834)**	**(8,096)**	18%	**(5,989)**	35%

Source: Company data, goetzpartners Research estimates
Warning Note: Past performance and forecasts are not a reliable indicator of future results or performance. The return may increase or decrease as a result of currency fluctuations

Financial Models

CHART 31: Mauna Kea profit and loss model

Profit & Loss Statement		2017A	2018A	H1 2019A	H2 2019E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Dec YE (EURk except EPS)	units	31-Dec-17	31-Dec-18	30-Jun-19	31-Dec-19	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-23	31-Dec-24	31-Dec-25
Revenue	**EURk**	**6,687**	**6,760**	**3,937**	**4,632**	**8,568**	**14,548**	**18,489**	**25,103**	**31,463**	**39,180**	**48,432**
COGS	**EURk**	**(2,129)**	**(2,058)**	**(1,468)**	**(781)**	**(2,249)**	**(4,120)**	**(4,492)**	**(5,826)**	**(7,192)**	**(8,815)**	**(10,736)**
% revenue	%	(32%)	(30%)	(37%)	(17%)	(26%)	(28%)	(24%)	(23%)	(23%)	(22%)	(22%)
Gross profit	**EURk**	**4,558**	**4,702**	**2,469**	**3,851**	**6,320**	**10,428**	**13,997**	**19,277**	**24,272**	**30,365**	**37,696**
% revenue	%	68%	70%			74%	72%	76%	77%	77%	78%	78%
R&D expenses	EURk	(4,265)	(4,653)	(2,050)	(2,696)	(4,746)	(4,841)	(4,938)	(5,037)	(5,137)	(5,240)	(5,345)
% revenue	%	64%	69%	52%	58%	55%	33%	27%	20%	16%	13%	11%
S&M expenses	EURk	(7,586)	(9,097)	(4,597)	(4,682)	(9,279)	(9,465)	(9,654)	(9,847)	(10,044)	(10,245)	(10,450)
% revenue	%	113%	135%	117%	101%	108%	65%	52%	39%	32%	26%	22%
Administrative expenses	EURk	(3,350)	(3,953)	(2,578)	(1,454)	(4,032)	(4,113)	(4,195)	(4,279)	(4,364)	(4,452)	(4,541)
% revenue	%	50%	58%	65%	31%	47%	28%	23%	17%	14%	11%	9%
Other operating expenses/income	EURk	-	-	-	-	-	-	-	-	-	-	-
% revenue	%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total operating expenses		**(15,202)**	**(17,703)**	**(9,226)**	**(8,831)**	**(18,057)**	**(18,418)**	**(18,787)**	**(19,162)**	**(19,546)**	**(19,936)**	**(20,335)**
Other expenses	EURk	(210)	(138)	(432)	294	(138)	(138)	(138)	(138)	(138)	(138)	(138)
Other income	EURk	1,144	1,141	576	566	1,141	1,141	1,141	1,141	1,141	1,141	1,141
Operating profit/(loss)	**EURk**	**(9,710)**	**(11,998)**	**(6,614)**	**(4,121)**	**(10,734)**	**(6,988)**	**(3,786)**	**1,118**	**5,729**	**11,432**	**18,364**
% revenue	%	(145%)	(177%)	(168%)	(89%)	(125%)	(48%)	(20%)	4%	18%	29%	38%
D&A expense		(1,074)	(1,130)	(630)	(570)	(1,200)	(1,746)	(1,920)	(2,112)	(2,324)	(2,556)	(2,812)
% revenue	%	16%	17%	16%	12%	14%	12%	10%	8%	7%	7%	6%
EBITDA	**EURk**	**(8,636)**	**(10,868)**	**(5,984)**	**(3,551)**	**(9,535)**	**(5,242)**	**(1,866)**	**3,230**	**8,053**	**13,987**	**21,175**
Financial revenues		205	116	58	58	116	116	116	116	116	116	116
Financial expenses		(740)	(902)	(451)	-	(451)	-	-	-	(2,875)	(1,500)	(1,250)
Profit/(loss) before tax	**EURk**	**(10,245)**	**(12,785)**	**(7,007)**	**(4,063)**	**(11,070)**	**(6,872)**	**(3,671)**	**1,234**	**2,970**	**10,047**	**17,229**
growth	%	5%	25%	3%	(32%)	(13%)	(38%)	(47%)	(134%)	141%	238%	71%
Income tax		-	-	-	-	-	-	-	(432)	(1,039)	(3,516)	(6,030)
Tax rate		0%	0%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Net income/(loss)	**EURk**	**(10,245)**	**(12,785)**	**(8,096)**	**(4,063)**	**(11,070)**	**(6,872)**	**(3,671)**	**802**	**1,930**	**6,531**	**11,199**

Source: goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

CHART 32: Mauna Kea balance sheet model

Balance Sheet	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Dec YE (EURk)	31-Dec-17	31-Dec-18	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-23	31-Dec-24	31-Dec-25
ASSETS									
CURRENT ASSETS	**24,043**	**15,806**	**11,562**	**13,736**	**15,697**	**17,385**	**19,779**	**14,879**	**19,632**
Cash and cash equivalents	17,453	8,623	3,913	3,215	4,557	4,605	5,883	485	3,279
Trade receivables	2,034	1,643	2,348	3,587	4,052	4,814	5,172	5,367	6,635
Inventories & Work in progress	1,969	2,456	2,156	3,725	3,815	4,629	5,320	5,555	6,177
Other current assets	2,587	3,083	3,145	3,208	3,272	3,338	3,404	3,472	3,542
NON-CURRENT ASSETS	**3,704**	**3,956**	**3,442**	**2,860**	**2,419**	**2,315**	**2,508**	**3,087**	**4,150**
Tangible assets, net	1,466	1,985	1,934	1,875	1,831	1,821	1,840	1,898	2,004
Intangible assets, net	2,100	1,838	1,375	852	455	361	535	1,056	2,012
Non-current financial assets	138	133	133	133	133	133	133	133	133
TOTAL ASSETS	**27,747**	**19,762**	**15,004**	**16,596**	**18,116**	**19,700**	**22,287**	**17,966**	**23,782**
LIABILITIES									
CURRENT LIABILITIES	**4,153**	**4,904**	**4,078**	**5,404**	**5,456**	**6,101**	**18,120**	**13,130**	**14,566**
Trade payables	1,663	2,087	1,848	3,161	3,200	3,831	4,335	4,830	5,295
Short-term loans and borrowings	386	600	-	-	-	-	11,500	6,000	6,957
Staff and social security payable	1,438	1,554	1,554	1,554	1,554	1,554	1,554	1,554	1,554
Other current liabilities	666	662	675	689	703	717	731	746	760
NON-CURRENT LIABILITIES	**6,850**	**6,879**	**13,879**	**19,879**	**24,879**	**24,879**	**13,379**	**7,379**	**422**
Long-term loans and borrowings	6,567	6,457	13,457	19,457	24,457	24,457	12,957	6,957	-
Non-current provisions	283	422	422	422	422	422	422	422	422
TOTAL LIABILITIES	**11,003**	**11,783**	**17,957**	**25,283**	**30,335**	**30,980**	**31,499**	**20,509**	**14,988**
EQUITY									
SHAREHOLDERS' EQUITY	**16,744**	**7,979**	**(2,953)**	**(8,687)**	**(12,220)**	**(11,280)**	**(9,212)**	**(2,543)**	**8,794**
Issued capital	974	1,008	1,008	1,008	1,008	1,008	1,008	1,008	1,008
Share premium	87,973	91,753	91,753	92,753	92,753	92,753	92,753	92,753	92,753
Reserves	(61,957)	(71,998)	(84,645)	(95,577)	(102,311)	(105,844)	(104,904)	(102,836)	(96,167)
Profit/(loss)	(10,245)	(12,785)	(11,070)	(6,872)	(3,671)	802	1,930	6,531	11,199
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**27,747**	**19,762**	**15,004**	**16,596**	**18,116**	**19,700**	**22,287**	**17,966**	**23,782**

Source: goetzpartners Research estimates.
Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

CHART 33: Mauna Kea cash flow model

Cash Flow Statement	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Dec YE (EURk)	31-Dec-17	31-Dec-18	31-Dec-19	31-Dec-20	31-Dec-21	31-Dec-22	31-Dec-23	31-Dec-24	31-Dec-25
OPERATING CASH FLOW									
Profit/ (loss)	(10,245)	(12,785)	(11,070)	(6,872)	(3,671)	802	1,930	6,531	11,199
D&A expense	1,074	1,130	1,200	1,746	1,920	2,112	2,324	2,556	2,812
Share-based transaction expense and revenue	210	138	138	138	138	138	138	138	138
Other	354	643	-	-	-	-	-	-	-
Change in Working Capital	**(1,136)**	**(26)**	**(692)**	**(1,545)**	**(567)**	**(996)**	**(597)**	**12**	**(1,480)**
Inventories & Work in progress	(255)	(313)	300	(1,569)	(90)	(813)	(691)	(235)	(622)
Trade receivables	(25)	433	(704)	(1,240)	(465)	(762)	(358)	(195)	(1,267)
Trade payables	(1,176)	419	(239)	1,312	39	631	504	496	464
Other current assets	291	(557)	(62)	(63)	(64)	(65)	(67)	(68)	(69)
Other current liabilities	29	(8)	13	14	14	14	14	15	15
NET CASH USED IN OPERATING ACTIVITIES	**(9,743)**	**(10,900)**	**(10,424)**	**(6,534)**	**(2,179)**	**2,056**	**3,795**	**9,237**	**12,669**
CASH FLOW FROM INVESTING									
Payments for current financial assets	-	-	-	-	-	-	-	-	-
Proceeds from current financial assets	-	-	-	-	-	-	-	-	-
Payments for PP&E and intangibles	(727)	(1,254)	(685)	(1,164)	(1,479)	(2,008)	(2,517)	(3,134)	(3,875)
% revenue	11%	19%	8%	8%	8%	8%	8%	8%	8%
Proceeds from disposal of PP&E and intangibles	2	1	-	-	-	-	-	-	-
Other	(10)	7	-	-	-	-	-	-	-
Net cash provided by investing activities	**(735)**	**(1,246)**	**(685)**	**(1,164)**	**(1,479)**	**(2,008)**	**(2,517)**	**(3,134)**	**(3,875)**
CASH FLOW FROM FINANCING									
Proceeds from issue of shares	-	10	-	-	-	-	-	-	-
Proceeds from exercise of share options	15,496	3,804	-	1,000	-	-	-	-	-
Repurchases/ resales of treasury shares	31	-	-	-	-	-	-	-	-
Other	3,386	(515)	6,400	6,000	5,000	-	-	(11,500)	(6,000)
Net cash provided by financing activities	**18,913**	**3,299**	**6,400**	**7,000**	**5,000**	**-**	**-**	**(11,500)**	**(6,000)**
Net change in cash and cash equivalents	8,435	(8,846)	(4,710)	(697)	1,342	48	1,277	(5,398)	2,794
Effect of exchange rate on cash and cash equivalents	(35)	16	-	-	-	-	-	-	-
Cash and cash equivalents, beginning of period	9,053	17,453	8,623	3,913	3,215	4,557	4,605	5,883	485
Cash and cash equivalents, end of period	**17,453**	**8,623**	**3,913**	**3,215**	**4,557**	**4,605**	**5,883**	**485**	**3,279**

Source: goetzpartners Research estimates.

Warning Note: Past performance and forecasts are not a reliable indicator of future performance or results. The return may increase or decrease as a result of currency fluctuations.

Charts

FINANCIAL CALENDAR

17-Oct-2019: Q3/2019 Sales

COMPANY DESCRIPTION

Mauna Kea Technologies SA, a medical device company, develops and sells endomicroscopy and optical biopsy for the diagnosis and treatment of cancer and other diseases. Its flagship product is Cellvizio, a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues, including the identification of cells and vessels and their organization or architecture. The company was founded in 2000 and is headquartered in Paris, France.

SCENARIOS

Base Case - GP Investment Case

Mauna Kea may enjoy widespread adoption of Cellvizio in the US, followed by further expansion into Asian markets. Mauna Kea finds global distribution partners for Cellvizio and existing partnerships will start bearing fruits.

Bluesky Scenario

The new consignment business model allows Mauna Kea to quickly establish a large installed base in the US, facilitating the uptake in the GI market and expansion into other applications including robot-assisted surgery and neurology. Cellvizio becomes imaging standard for its approved applications given its attractive profile compared with other imaging technologies.

Downside risk

Uptake of new technologies by healthcare providers can be slow and the development of alternative imaging methods pose the main risk to Mauna Kea in the field of GI.

Peer Group Analysis

SWOT

Strengths - Established technological superiority and increasing reimbursement rates. Large patent portfolio and good potential to expand into further indications

Weaknesses - Sales growth in China dependent on collaboration with YouHe Medical Technologies

Opportunities - Provide technologically superior imaging solutions for medical conditions associated with inadequate options for early diagnosis

Threats - Market entry by competitors and alternative technologies could erode sales

Important Disclosures: Non-Independent Research

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Companies Mentioned in this report

- (MEDTRONIC PLC (MDT US))
- (JOHNSON & JOHNSON (JNJ US))
- (INTUITIVE SURGICAL INC (ISRG US))
- Mauna Kea Technologies SA (MKEA-FR)
- Medical Technology (MT)

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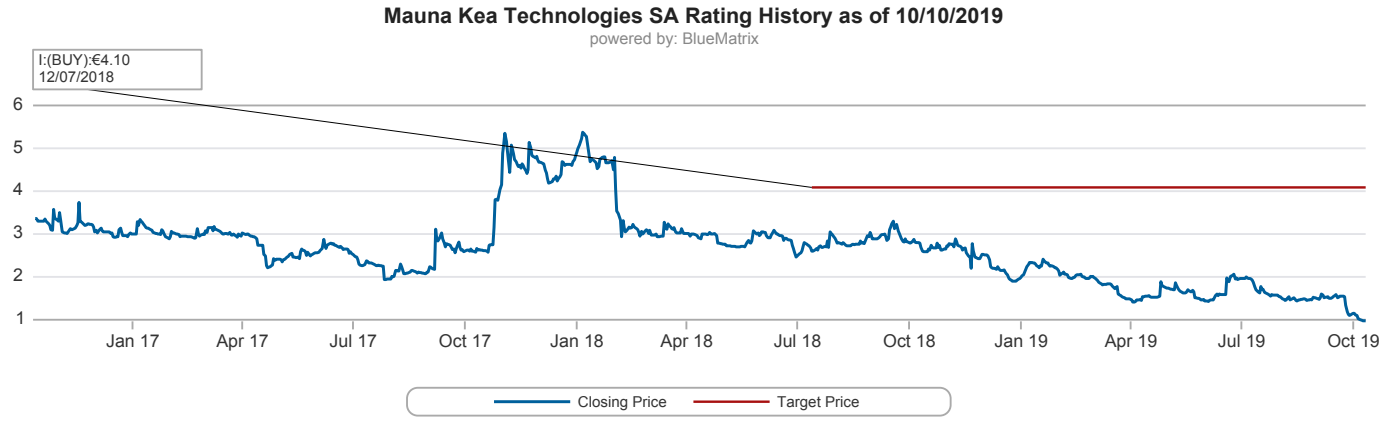

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Compensation

GPSL has received compensation from Mauna Kea Technologies SA for the provision of research and advisory services within the previous twelve months.

MKEA-FR
€4.10 | Company Update
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