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Operator: Greetings and welcome to the 2019 Mauna Kea conference call. At this time, all participants are in a listen-only mode. A brief question, answer session will follow the format presentation. Please note that this conference call is being recorded and that the recording will be available on the company's website for replay shortly. It's now my pleasure to introduce your host, Mr. Rob Gershon, CEO of Mauna Kea Technologies. Please go ahead, sir.

Robert Gershon: Thank you, Mary. And welcome, everyone, to Mauna Kea Technologies first half of 2019 financial results conference call. I am joined on the call today by Christophe Lamboeuf, our chief financial officer. Let me start with a brief agenda of what we will cover during our prepared remarks. I will start with a summary of our sales performance and review of our key operating highlights over the first half of 2019. After these opening remarks, Christophe will provide you with a detailed review of our first half of 2019 financial results along with an update on our balance sheet following our enhancement activities in early July. I will then share an update on our third strategic priority, evaluating the interventional pulmonology opportunity as the next area of commercial focus for Mauna Kea. Then, we will open the call to your questions.

As previously reported, our sales for the first half of 2019 increased 45% year over year to 3.9 million euros. Total sales were driven primarily by sales of consumables, which increased 72% year over year, and sales of systems, which increased 38% year over year. The increase in sales of consumables reflects strong execution towards our primary strategic priority for 2019 driving sales of consumables, which represent utilization driven growth across our install base of Cellvizio systems. We believe the 72% increase in consumables sales in the first half of 2019 is the clearest evidence of Cellvizio customers appreciating the utility of our technology and represents a strong foundation of growth for the company in the future.

Given the fact that the US GI market is our primary commercial market, we are encouraged by the 160% increase in sales of consumables to PPU customers that we reported in the first half of 2019. This growth is a result of our strategic shift to a PPU model in late 2017, which continues to resonate in facilities specializing in digestive endoscopy, including commercial community hospitals and ambulatory surgery centers, or ASCs. Consumables sales represented more than half of our total company sales during the first half of 2019 compared to 42% of sales in 2018, a clear indication that overall utilization of our Cellvizio technology continues to grow. We continue to expect sales of consumables to be the fastest growing part of our business in 2019.

We are also performing well against our second strategic priority for 2019, driving revenue outside the US, but doing so in a targeted fashion in an effort to maximize the resources we invest in certain international markets. International sales increased 67% over the first half of 2019 led by very strong demand in the Asia Pacific region and solid growth trends in the EMEA and rest of world regions. Asia Pacific sales increased 106% year over year in the first half of 2019 fuelled by a strong and growing relationship with YOUHE, our distribution partner in China. Importantly, the demand trends we experienced from YOUHE over the first half of 2019 is a combination of both system and consumables.

EMEA and rest of world sales increased 24% year over year in the first half of 2019 driven by strong consumables growth to customers in central Europe as well as system sales to customers in Germany and Peru. Notably, the reported year over year growth performance in the EMEA and rest of world regions would have been stronger if not for our strategic shift to focus on driving adoption and utilization among clinical customers in these regions. Pre-clinical revenue declined 55% year over year and declined as a percentage of total revenue, as expected, to approximately 17% of total EMEA and rest of world sales in the first half of 2019 compared to 46% of total EMEA and rest of world sales last year.

Strong performance during the first half of 2019 was not limited to our sales results. In fact, we have made significant strides in terms of operational execution, which together will enhance the company's ability to drive growth in the years to come. Specifically, during the first half of 2019 we have enhanced our leadership in the area of sales and marketing, announced important milestones in the areas of new

product development and reimbursement, and continue to enhance our sizable portfolio of clinical validation for Cellvizio. Let me share a few thoughts on each of these progress points now.

First, we have made two notable additions to our leadership team in the areas of sales and marketing respectively. In June, Larry Weiss joined Mauna Kea as vice president of US sales. Larry brings over 24 years of sales leadership experience for both Fortune 100 and start-up organizations alike. Larry is known for building high-performing sales teams and creating a culture of success and accountability. Most recently, Larry was the vice president of US sales for Christie Medical Holdings where he was responsible for creating and driving their US commercial strategy for their vascular access business. Prior to that, Larry spent 17 years with Abbott Laboratory diagnostics division and GE Healthcare in a variety of increasing leadership roles. In addition to overseeing our growth strategy in the US this year, I've asked Larry to lead the efforts to enhance our sales training and to formalize our talent assessment process with an eye for continuing to build the optimal sales force to attack the large commercial opportunity we had in the US GI market.

In March, Jack McCarthy joined Mauna Kea as chief marketing officer. Jack is an accomplished senior executive with more than 20 years of success in a medical device industry, including sales and leadership roles at Covidien, now Medtronic, Z-Medica, and most recently as chief commercial officer of Bovie Medical. He has extensive experience in rapidly commercializing new technologies and products which makes him an ideal resource for our team. In his role he is responsible for global upstream and downstream marketing, business development, strategic development, and product development.

Turning to our progress in the areas of new product development and reimbursement, in February, we announced that we received US FDA 510(k) clearance for the use of the Cellvizio AQ-Flex 19 Confocal Miniprobe through existing bronchoscopes, transbronchial needles and other bronchoscopic accessories. The AQ-Flex is the 16th US FDA 510(k) clearance of the Cellvizio probe and needle-based platform. As we will discuss later on the call, the AQ-Flex may represent one of the most important clearances for the company's growth opportunity in the years to come. As discussed on our last call, we believe our Cellvizio AQ-Flex 19 Confocal Miniprobe unlocks a new era in interventional pulmonology paving the way toward more precise in situ guidance to identify the optimal area for sampling and potentially as a real-time feedback technique for diagnostic procedures in lung lesions. I'll share more on the AQ-Flex during my update on the third strategic priority in 2019 later in the call.

In June, we announced the reimbursement coverage of confocal laser endomicroscopy, specifically for Barrett's esophagus, through the creation of a new specific procedural code to be added to the common classification of medical procedures, CCAM, published in the official journal of the French Republic. We believe this decision confirms the relevance of our technology for patients at risk of esophageal cancer and we look forward to expanding our unique pro-based confocal laser endomicroscopy system, Cellvizio, to more than 300 hospitals throughout France that specialize in following patients with Barrett's esophagus.

Finally, with respect to our progress in the area of clinical validation, our Cellvizio technology continues to be recognized by leading KOLs around the world and our body of clinical evidence continues to grow. Since 2005, CLEs clinical contributions have been reported in more than 1,000 clinical publications worldwide on endomicroscopy. These include several randomized multi-center clinical trials, some funded by the company, many others done independently, in key gastroenterology and other applications. International multi-center randomized clinical trials have shown that Cellvizio enables physicians to characterize or detect early stage pathologies more precisely and make immediate therapeutic decisions.

In early May we announced an important publication in the European Respiratory Journal. The publication was a prospective study that demonstrates the potential of nCLE to aid in the diagnosis and staging of lung cancer. The article is titled, Needle-Based Laser Endomicroscopy for Real-Time Diagnosing and Staging of Lung Cancer. And according to Dr. Annema, a leading investigator in the study, "it shows that nCLE enables 89% accuracy for detecting malignancy in lung tumors and

metastatic lymph nodes with substantial intra and inter observer agreements." Dr. Annema also believes "these promising results support the fact that nCLE might qualify as an important adjunct to navigation bronchoscopy for real-time targeting and identification of lung tumors." We are very encouraged by the performance of the AQ-Flex in this study and believe is represents favorable support in our evaluation of future commercial focus areas, which we will discuss later on this call.

We were also pleased to participate in the Digestive Disease Week conference in San Diego this past May. Cellvizio was featured in 17 accepted abstracts and podium presentations demonstrating growing clinical recognition of Cellvizio as a necessary tool for real-time endomicroscopy imaging in multiple gastrointestinal indications, which we believe represents the growing awareness and appreciation for our differentiated Cellvizio technology among leading clinicians in the GI market.

So, in summary, we are pleased with our performance during the first half of 2019. We executed against our first two primary strategic priorities, which resulted in strong sales growth in both the US and in select international markets. We also made significant operating progress in the areas of enhancing leadership, new product development, reimbursement and expanding clinical validation. With that, let me turn the call over to Christophe for a detailed review of our first half of 2019 financial results. Christophe?

Christophe Lamboeuf: Thanks, Rob. As reported in our Q2 sales press release on July 17, 2019, total sales for the first half of 2019 were at 3.9 million euros, up 45% year over year. First half of 2019 sales growth was driven primarily by a 72% increase in consumable sales and a 38% increase in systems revenue, which offset a 1% decrease in services sales in the period Total consumable sales increased 0.9 million euros, or 72% year over year to 2.1 million euros in the first half of 2019. Total consumable sales were driven by 160% increase in consumable sales related to the Pay to Use program fuelled by a strong demand following the company's success in driving new system placement in this program throughout 2018.

Total consumable sales represented 52% of total sales in the first half of 2019 compared to prior year period. Importantly, the mix of consumable sales to customers in the Pay perUse program continues to expand rapidly and represented 39% of total consumable sales in the first half of 2019 compared to 26% in the prior year period.
Total system sales increased 0.4 million euros, or 38% year over year to 1.3 million euros in the first half of 2019. System sales to clinical customers increased 101% year over year, which offset a 73% decline in system sales to pre-clinical customers in the period. The largest contributors to the year over year increase in system sales for the first half of 2019 was the APAC region, which increased 185% year over year in the first half of 2019.

System sales to the EMEA and rest of world regions increased 53% year over year, which helped offset a decline in system sales to the US as a result of our strategic focus on driving the PPU model in the US GI market this year. Total Cellvizio system shipments increased 67% year over year to 15 in the first half 2019 period compared to nine total shipments in the prior year period. We had ten new system placements under the company's Pay per Use program in the first half of 2019 period, compared to 16 in the prior year period. Total consumable probe shipments increased 71% year over year to 461 units in the first half of 2019 compared to 269 units in 2018.

Turning to a review of our performance across the rest of the P&L: Gross profit in the first half 2019 increased 0.7 million euros, or 43.5 year over year, to 2.5 million euros compared to 1.7 million euros last year. Gross margin in the first half of 2019 was 62.7% compared to 63.5% in the first half of 2018. The primary driver of a decrease in gross margin in the first half of 2019 was an unfavourable margin mix related to the 106% growth in sales to the APAC region in the first half of 2019 period.

Total operating expenses in the first half of 2019 increased 0.9 million euros, or 10.3% year over year, to 9.6 million euros compared to 8.7 million last year. The increase in total operating expenses was primarily driven by an increase in administration expenses of 0.5 million euros, or 24% year over year,

to 2.6 million euros driven by investments made in the second half of 2018 to strengthen the management team. An increasing share base payment of 0.4 million euros, or 107% year over year, to 0.4 million.
An increase in shared-based payment of 0.4 million euros, or 904,6% year-over-year, to 0.4 million euros.
An increase in sales and marketing expenses of 0.2 million euros, or 5.1% year-over-year, to 4.6 million euros driven by commercial and marketing investments required to support the deployment of the PPU model in the US.
The increase in total operating expenses in the first half of 2019 was partially offset by lower depreciation provisions, which were 0.7 million compared to 0.9 million euros last year. Research and development expenses were 2 million euros compared to 2.2 million euros last year. The decrease in R&D expenses was driven by higher capitalized costs. Compared to last year, the company's investments in R&D projects remained constant in the first half of 2019.

Operating loss in the first half of 2019 period was 6.6 million euros compared to 6.5 million euros last year. The increase in operating loss was driven by the 0.7 million increase in gross profit offset by 0.9 million euros increase in operating expenses compared to the prior year period.
Net loss in the first half of 2019 period was 8 million euros compared to 6.8 million in the prior year period. The increase in net loss was primarily driven by non-recurring financial costs of 1.7 million euros associated to the early repayment of the IPF Partners bond financing.

Turning to review of the balance sheet:
On June 28, 2019, the company redeemed all non-dilutive bond financing with IPF Partners for a total amount of 10.7 million euros. The financing with IPF Partners was comprised of two bond tranches of 4 million euros and 5 million euros issued in February 2017 and May 2019 respectively. As of June 30, 2019, the company had a cash balance of zero and total debt obligations of 6.4 million euros including 2.7 million of bank overdraft, compared to 8.6 million euros of cash and 7.1 million euros of total debt obligations as of December 2018.
Pursuant to the new loan agreement for 22.5 million with EIB, which we announced on June 20th, on July 3rd, the company announced we had received the first tranche of 11.5 million euros.

We are very pleased to have a European investment bank as our new financial partner. This new loan agreement provides us with a requisite capital to execute our growth plans and does so at more attractive borrowings terms. Specifically, the new loan agreement carries an interest rate of 5% and the first tranche accrues interest until the bond matures in five years, which significantly improves our cash flow profile over this period.
As of July 3, 2019, and following the restructuring of its staff, the company had 8.8 million euros of cash available. Cash used in operating and investing activities in the first half 2019 period totalled 4.8 million euros compared to 5.9 million euros in the prior year period.

With that, I'll turn the call back to Rob for a discussion of our progress toward our third strategic priority for 2019. Rob?

Robert Gershon: Thanks, Christophe. As discussed on our last call, we are currently undertaking a formal process to evaluate new clinical indications to identify the company's next commercial focus area. To the extent this process is successful, we believe this will result in us uncovering the next application for commercial focus that we believe will serve as the future growth engine of the company. In March, we identified interventional pulmonology as the first potential application that we are putting through this process. The evaluation has been rigorous and disciplined and we have made progress in moving through the six-step process that starts with screening criteria and includes phases of validation, commercial test and learn, and ends with scaling the new indication. The process has been led by Jack McCarthy and has involved teams throughout our organization.

By way of background, Cellvizio is designed to be used in interventional pulmonology. In fact, as stated earlier, our AQ-Flex 19 is designed to be used through existing bronchoscopes, transbronchial needles,

and other bronchoscopic accessories, which makes it a perfect option for use with new emerging robotic and existing advanced navigation platforms. Robotic and advanced navigation products provide minimally invasive access to peripheral nodules, but with limited ability to achieve direct visualization outside the airway. The Cellvizio AQ-Flex 19 Confocal Miniprobe can be used through the working channel of existing navigation products to provide direct through the needle visualization inside peripheral lesions.

The primary goal of our formal process is to evaluate the commercial opportunity interventional pulmonology presents in terms of market potential, clinical value, product feasibility and overall strategic value for our company. Based upon our progress to date, we are increasingly encouraged by the potential opportunity in the interventional pulmonology market. Let me share a little color on some of our learnings thus far in the evaluation process. First, the market is very large given the incidence rate in excess of two million cases a year in the United States alone. Lung cancer is the number one cause of death among oral cancer types. There were approximately 240,000 lung biopsies in the United States in 2018, a number that is estimated to grow to more than 400,000 by 2025. Of the 240,000 lung biopsies in the US last year, roughly 160,000 were peripheral nodules, which reside outside the bronchus airways. The AQ-Flex could offer a unique solution in characterizing these nodules and potentially avoiding unnecessary surgeries.

In terms of the unmet clinical need today, I would like to highlight two specific challenges. First, needle biopsy through parenchyma and airways happens without direct visualization and comes with clinical risks including pneumothorax and bleeding. Until the development of the robotic and advanced navigation platforms, those nodules were difficult to access. They could be reached by more invasive techniques such as transthoracic needle aspiration and video-assisted thoracic surgery, which are associated with higher rates of complication and comorbidity. The AQ-Flex 19, in contrast, can be used in conjunction with robotic and advanced navigation platforms. The development of Cellvizio's needle-based probe allows the physician to penetrate and visualize inside the nodule in real-time an in vivo.

Second, historically, endoluminal access suffers from a low diagnostic yield of approximately 50%. This is an area of focus for robotic and advanced navigation technologies, many of which have goals of increasing diagnostic yield to 85 to 90% over time. Improving diagnostic yield to these levels would reduce the need for unnecessary invasive procedures for diagnosing or staging lung cancer. What appears to be the most compelling about the interventional pulmonology opportunity for Mauna Kea is that Cellvizio, when used in combination with these robotic and advanced navigation platforms, has the promise of improved targeting, in situ tissue characterization and increased diagnostic yield. Our AQ-Flex 19 Confocal Miniprobe has already received 510(k) clearance, which means no significant R&D investment or regulatory risk.

In fact, Cellvizio's needle-based confocal laser endomicroscopy, nCLE, has been validated in characterizing pancreatic cysts by two Mauna Kea sponsored clinical studies called Contact One, Contact Two, and one investigator-initiated study called Index. The outcomes from these studies demonstrated significant improvement in pancreatic cyst characterization and reduction in unnecessary surveillance or surgery. Our formal interventional pulmonology evaluation process to date has identified the need for new nCLE clinical studies with AQ-Flex 19 demonstrating efficacy in both detecting and characterizing lung nodules. We expect to announce the first of these studies in the fourth quarter of 2019.

In summary, the formal evaluation process is progressing nicely and we are increasingly encouraged by the potential prospects as we move through each stage. The interest level is high among key constituents in the market, most importantly, KOLs and high-volume physicians that see the benefits our technology may provide as they endeavour to improve the diagnosis and treatment of patients suffering from lung cancer. Before we open the call for questions, I want to briefly review our three strategic priorities for 2019 to remind investors where our organization is focused on driving execution and results.

First, we are intently focused on driving consumable growth in our PPU install based in the US GI market. The US GI market is extremely compelling and we are well positioned to succeed. As such, we remain focused on the US GI market as our primary commercial opportunity in 2019. We are focusing even further in 2019 as we have mandated that driving strong utilization within the current install base of systems in the US GI market is our highest strategic priority this year. We expect that our success in this area will evidence itself in our ability to drive consumable sales faster than any other area in our business this year.

Second, we expect to drive revenue outside the US by doing so in a targeted fashion in an effort to maximize the resources we invest in international markets. We will continue to focus in certain OUS markets where we have established KOL support and a strong distribution relationship where we can pursue growth at an attractive potential return on invested capital.

Third, continuing our formal evaluation process for identifying a new clinical indication for Mauna Kea's next commercial focus area. We are encouraged by the work we have done thus far in interventional pulmonology, specifically in validating the potential market opportunity, the fact that we have cleared technology for lung nodule characterization, and that there is strong interest from key constituents to understand how AQ-Flex 19 may improve their ability to increase diagnostic yield and in turn improve patient outcomes. Mary, we would now like to open the call for questions.

Operator: Yes, ladies and gentlemen, if you wish to ask a question, please press zero one on your telephone keypad. We have our first question from [inaudible]. Sir, please go ahead.

Speaker: Hello, Rob. Thank you for walking us through the results and your strategy for 2019. Very insightful. You mentioned a six-step process to evaluate the pulmonology opportunity. Could you share a bit more detail on where you currently are and what step you're in and what you're planning to do over the next step? And also, when we could expect the potential decision to be made on this.

Robert Gershon: Yes, okay. Thank you very much for the questions, I do appreciate it. I will answer it a little bit in reverse order. So, we indicated back in March that we expect the process, which is quite rigorous and disciplined, to take all of 2019. We are certainly on pace for this process to be completed in 2019. So, to date, we have gone through a lot of the steps and we are toward the end of the process where we're specifically validating some of the early hypotheses that we have had and then we are starting to do what we call test and learn in terms of the commercial application in some of our sales and marketing strategies. So, we're toward the end of the process and expect to complete the process by the end of the year.

Speaker: Great. Is pulmonology the only opportunity that you're evaluating at the moment?

Robert Gershon: Yeah, so great question. It's the only opportunity that we've commented on publicly, but it is important to know it's not the only opportunity that we have put through this process. We have put several others through the process, but interventional pulmonology has clearly emerged as the frontrunner and the one that we have commented on publicly. But this process was not limited to interventional pulmonology, it's just where we have landed as a result of taking several other applications through the process.

Speaker: Great. Thank you.

Operator: Thank you. We haven't any questions for the moment. Ladies and gentlemen, I remind you that if you wish to ask a question, please press zero one on your telephone keypad. We have next questions from [inaudible]. Sir, please go ahead. Sir, your microphone is open, you can ask your question.

Speaker: Sorry. Hi, good evening. I would like to know if you could give some more information on the growth margin and why it's decreased?

Christophe Lamboeuf: Yes. Thank you, Thomas. As we explained, yes, the main driver for the change in growth margin is the sales mix that we had knowing that we had an increase of 106% of our sales to APAC this quarter. And the APAC sales represent 38% of our total sales compared to 21% last year. So, this is really a channel mix combination.

Speaker: Okay. And with regards to interventional pulmonology, do you already know how you're going to commercialize it in the US? Will you agree to do it by yourself, would you have an additional safety? Could you give more information on this?

Robert Gershon: Yes. Thanks for the question. It is too early to determine exactly what our commercial strategy will be. Whether we do it ourselves or do it through a partnership, so that is to be determined. What is quite clear is the market seems ripe for the type of solution that we provide as evidenced by the large amount of interest that has been expressed for the use of our recently cleared probe, the AQ-Flex 19 that we discussed during the prepared remarks. It has clearly captured the attention of the market from every perspective, including from other manufacturers, and as indicated in the prepared remarks, certainly by the clinician community.

Speaker: Okay. Thank you.

Operator: Thank you. We haven't any questions for the moment. Ladies and gentlemen, if you wish to ask a question, please press zero one on your telephone keypad. Ladies and gentlemen, I remind you that if you wish to ask a question, please press zero one on your telephone keypad. Sir, we haven't any questions for the moment.

Robert Gershon: Okay. Then in closing, we just thank you for your interest in Mauna Kea and we do look forward to keeping you apprised of our progress as we continue. The next release of sales numbers is scheduled per the financial calendar on October 17th. That would be for Q3. So, thank you very much.

Christophe Lamboeuf: Thank you.

Operator: Ladies and gentlemen, thank you all for your participation. You may now disconnect.