

Transcription
Mauna Kea
Technologies
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Presentation

Operator

Ladies and gentlemen, welcome to the Mauna Kea Half Year Results 2020 Conference Call. At this time, all participants are in listen-only mode. A brief question and answer session will follow the formal 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 is now my pleasure to introduce your host, Mr Rob Gershon, CEO of Mauna Kea Technologies. Sir, please go ahead.

Rob Gershon

Thank you, Greg, and welcome everyone to Mauna Kea Technologies' First Half of 2020 Financial Results and Preliminary Third Quarter 2020 Sales 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 brief summary of our sales performance for the first half of 2020. I will then discuss our preliminary sales results for the third quarter of 2020, which we elected to disclose in the interest of full transparency in light of the investment communities focused on the pace of recovery from the global pandemic.

I will also provide a brief review of our key operating highlights for the first half of 2020 period. After these opening remarks, Christophe will provide you with a detailed review of our financial results for the first half of 2020 and balance sheet condition as of 30th June, 2020, as well as the significant balance sheet enhancement activities that occurred in July. I will then provide an update on our progress with the formal evaluation process to identify new clinical areas for commercial focus, which was one of our three strategic priorities in 2020. Then we will open the call to your questions.

As reported on 20th July, our total sales for the first half of 2020 decreased 47% year-over-year to €2.1 million. First half of 2020 sales results were driven by a 7% increase in Services revenue, which partially offset declines in sales of Systems and Consumables of 59% and 52%, respectively, compared to the prior year period. The sharp decline in sales over the first half of 2020 was a direct result of the significant impact on procedure and adoption trends in our primary commercial markets around the world as a result of the global crisis caused by the coronavirus or COVID-19.

While our sales were significantly impacted by COVID-19 during April and May, we have seen a pronounced improvement in our underlying business trends as we move through the second quarter as restrictions were lifted and practices began to reopen. Specifically, we saw US procedure volume return to pre-COVID levels for the month of June, and importantly, we had seen continued improvement in US procedure volumes during the first two months of the third quarter, which I will discuss in more detail shortly.

In the face of unprecedented challenges to our business trends at the hands of COVID-19, the organisation has performed admirably, and I am very proud of the significant progress we have made over the first half of 2020 and in recent months toward our goal of enhancing our financial condition and maximising our capital resources to support the company's strategic growth initiatives.

Specifically, we have implemented a series of significant cost-cutting actions designed to tightly control operating expenses. We secured non-dilutive financing of \$0.7 million or €0.64 million and €4 million through the US Paychex Protection Programme and the French state-guaranteed loan programme, respectively. And we announced the drawdown of the €6 million second tranche of our financing agreement with the European Investment Bank. Collectively, these actions should provide sufficient liquidity to manage the business through the third quarter of 2021.

Turning to a review of our preliminary third quarter sales results, which we announced in our press release today. While not our standard disclosure and reporting practice, we elected to provide this incremental intra-quarter update in the interest of full transparency as we understand the investment community's keen focus on the pace of recovery from the global pandemic.

As I mentioned, we are very encouraged by the continued improvement in business trends in each of our primary markets around the world, though, there is understandably a varying degree of recovery depending on the market. Specifically, the recovery in

China has been faster than what we have seen in other primary markets. Procedure trends are running in excess of 90% of their pre-COVID-19 levels in recent months and we expect continued improvement in business trends in China to result in improving capital equipment demand as we move through Q4 and into 2021.

The US recovery has been encouraging overall, albeit, not entirely broad-based yet as we are seeing pockets of strength and softer trends depending upon the region of the US in question. That said, our US business trends have improved in each month since May with June procedures exceeding pre-COVID levels. July procedure trends improving further compared to June and resulting in flat procedures on a year-over-year basis for the month, and further improvement in trends during the month of August, where we saw procedure growth on a year-over-year basis, very encouraging trends indeed.

The pace of recovery in our EMEA and rest of world regions has been slower than in APAC and the US, although, again the trends have varied depending on country. Within the EMEA specifically, we are seeing modest improvements in procedure trends in our commercial accounts while the recovery in business trends in our academic and research focus accounts has been much slower.

Overall, we are pleased with the improvement in business trends, which resulted in a notable recovery in our sales results for the third quarter. Specifically, as reported in our press release today, our preliminary sales for the third quarter are expected in the range of €1.8 million to €2 million, representing growth of 2% to 11% year-over-year. This reflects a meaningful improvement in sales trends when compared to the 72% decline in sales we reported for the second quarter of 2020.

Our preliminary third quarter sales results are comprised of US growth in the range of 1% to 3% year-over-year, and rest of world growth in the range of 4% to 19% year-over-year. The expected increase in third quarter sales compared to the prior year period was driven by an increase in Systems sales in the range of approximately 46% to 60% year-over-year, and an increase in Service sales in the range of 21% to 29% year-over-year, offset partially by a decrease in Consumable sales of approximately 27% to 23% year-over-year.

We are encouraged by the strong uptake in capital equipment demand during the third quarter, where we had System sales in each of our primary markets around the world. It certainly remained early days in terms of the global capital equipment recovery, but we are encouraged that our efforts to remain well positioned for the recovery, pay dividends during the third quarter. The System sale in the US was a direct result of the new commercial targeting strategy discussed on our year-end conference call in April and the System sales in the EMEA, rest of world region is a direct result of our strategic evaluation process, which I will share more colour on later in the call.

While we expect to report a year-over-year decline in Consumables sales for the third quarter, we remain encouraged by the overall improving trends in procedure demand in recent months and we expect to begin to transition from customers working through their inventory on hand in recent months to placing orders for consumables as we move through the balance of 2020.

We discussed our year-to-date operational progress in several areas on our call in late April, and we included a summary of operating progress over the first half of 2020 in our press release today. In the interest of brevity during today's call, I will call your attention to a few recent operating highlights and milestones.

Our portfolio of clinical validation had a notable addition in May with a publication in a peer-reviewed journal, Surgical Endoscopy. The publication was a review on the safety and efficacy of confocal laser endomicroscopy as a diagnostic tool for the evaluation of gastrointestinal pathologies conducted by the Technical And Value Assessment Committee, or TAVAC, of the Society of American Gastrointestinal and Endoscopic Surgeons, or SAGES. The publication and surgical endoscopy was based on the committee's systematic review of clinical studies on PubMed MEDLINE involving CLE in May 2018, as well as bibliographies of key references for relevant studies not available on PubMed.

The committee's objective was to evaluate the safety value and efficacy of CLE in the gastrointestinal tract. The results of the committee's analysis concluded that CLE offers an excellent safety profile with rare adverse events related to the use of fluorescent agents. It has been shown to increase the detection of dysplastic Barrett's esophagus gastric intraepithelial neoplasia, early gastric cancer, and dysplasia associated with inflammatory bowel disease when compared to standard screening protocols.

It also aids in the differentiation and classification of colorectal polyps, intermediate biliary strictures and pancreatic cystic lesions. We are extremely pleased by SAGES' endorsement of confocal laser endomicroscopy in the diagnosis and surveillance of gastrointestinal diseases, including GERD, Barrett's esophagus and pancreatic cysts. This peer-reviewed analysis reinforces the position of Cellvizio as an adjunct to the standard-of-care to effectively target biopsies and increase diagnostic yield, thereby improving patient outcomes and optimising clinical costs through increased diagnostic accuracy.

We made another important clinical announcement in June, though, this was regarding a clinical study of high strategic importance for Mauna Kea Technologies. On 24th June, we announced that we received authorisation from Fox Chase Cancer Centre's IRB to start a pilot clinical study combining nCLE and robotic navigational bronchoscopy, using both Cellvizio and the Monarch Platform from J&J's Auris Health, Inc. for the diagnosis of peripheral lung nodules.

The pilot clinical study is being conducted by Dr Christopher Manley, Director of Interventional Pulmonology and Assistant Professor of Medicine at Fox Chase Cancer Centre in Philadelphia and Prof Jouke Annema, Prof of Pulmonology Endoscopy at Amsterdam University Medical Centre. The main objective of this study is to assess feasibility and safety of Mauna Kea's AQ-Flex 19 Confocal Miniproboscopes during robotic navigational bronchoscopy in the analysis of peripheral lung lesions.

As discussed on prior calls, the AQ-Flex 19 Confocal Miniproboscopes is designed to be introduced into suspected lesions through a fine needle and is compatible with both conventional bronchoscopes and emerging endoluminal robotic bronchoscopes, such as the Monarch platform. It is the only cleared nCLE technology capable of imaging tissue microstructures in vivo in real-time and at the cellular level.

This study will include 25 patients with peripheral nodules and enrolment is underway and progressing favourably to-date. This pilot clinical study is being co-funded by the Lung Cancer Initiative at Johnson & Johnson and Mauna Kea Technologies, and represents a key milestone towards the third strategic priority that we have discussed throughout 2019 and 2020, which is focused on identifying the next area of commercial focus for the company. I will share a broader update on our progress towards this strategic objective later on the call, but we are understandably pleased with the beginning enrolment in this important clinical study and look forward to sharing updates on our progress in the coming months.

Finally, we made another important announcement in recent months, which is the appointment of Claire Biot, PhD, as an Independent Director to our Board. Dr Biot brings impressive leadership experience in the field of medical technologies from a commercial and market access perspective. Her current role as Vice President Life Sciences Industry at Dassault Systèmes, gives her a unique and very interesting vantage point on Mauna Kea's commercial growth opportunities.

So in summary, we are very pleased with the material improvement and business trends beginning in June and continuing in each month of the third quarter. We are encouraged that these improving business trends, combined with our strong execution toward our primary strategic priorities, focused on driving growth in the US and in select international markets, has resulted in a return to growth as evidenced by our preliminary third quarter sales results, which reflect total revenue growth in the range of 2% to 11% year-over-year.

We also made significant operating progress during 2020, which we believe enhances our ability to drive growth in the years to come. Most importantly, we have executed well in terms of controlling costs and improving our balance sheet. And we are proud to be in arguably the strongest financial condition we have been in at any point in the last few years, despite the challenging operating environment over the last six-plus months due to COVID-19 pandemic.

With that, let me turn the call over to Christophe for a detailed review of our financial results for the first half of 2020. Christophe?

Christophe Lamboeuf

Thanks, Rob. Given the detailed disclosure of our sales results in our second quarter and first half of 2020 sales recent press release on 20th July, my commentary today will focus on our full financial results for the first half of 2020.

Total revenue for the first half of 2020 decreased €1.3 million or 30% year-over-year to €3.2 million compared to €4.5 million last year. By way of reminder, in addition to our sales results, total revenue on our income statement includes other income comprised of research tax credit and a US PPP grant for a total of 1.1 million compared to 576,000 in the prior year period.

Gross profit for the first half of 2020 decreased €1.1 million or 43% year-over-year to €1.4 million compared to €2.5 million last year. Gross margin over the first half 2020 period was 67.2% compared to 62.7% in the first half of 2019.

Total operating expenses for the first half 2020 period decreased €1 million or 10% year-over-year to €8.7 million compared to €9.7 million in the first half of 2019. The decrease in total operating expenses was primarily driven by a decrease of €0.6 million or 29% year-over-year in research and development expenses, a €0.4 million decrease or 9% year-over-year in sales and marketing

expenses, and €0.2 million decrease or 57% year-over-year in share-based payment. All of these decreases were partially offset by a €0.3 million increase or 11% year-over-year in administration expenses compared the first half of 2019.

Operating loss for the first half of 2020 period was €6.2 million compared to an operating loss of €6.6 million for the first half of 2019 period. The decrease in operating loss was driven by the €1.1 million decrease in gross profit offset by the €1 million decrease in operating expenses and by the €0.5 million increase in other income compared to 2019.

Net loss for the first half of 2020 period was €6.7 million compared to a net loss of €8.1 million for the first half of 2019 period. The decrease in net loss was primarily driven by the decrease in operating loss compared to the prior year period, as well as a decrease in interest expense net, driven primarily by non-recurring financial cost of €1.7 million in 2019 associated to the early repayment of the IPF Partners bond financing.

Turning to review of the balance sheet. As of 30th June 2020, the company had a cash balance of €4.2 million and total long-term debt obligations of €16.1 million compared to €10 million of cash and €15.5 million of long-term debt obligations as of 31st December, 2019. The change in cash during first half of 2020 period was driven by €4 million of cash used in operating activities, including a positive impact of €0.6 million of a grant through the Paycheque Protection Programme, PPP, under the US CARES Act, €0.9 million of cash used in investing activities and €0.9 million of cash from financing activities.

As Rob mention earlier, we announced significant developments post 30th June that had enhanced our balance sheet and financial condition. In July, we announced the drawdown of the €6 million second tranche of our financing agreement with the European Investment Bank. Also in July, we secured non-dilutive financing of €4 million through French state-guaranteed loans programme, PGE. Together, these balance sheet activities, along with strong execution of our cost-cutting strategies, provide sufficient liquidity to manage the business through the third quarter of 2021.

With that, I'll turn the call back to Rob. Rob?

Rob Gershon

Thanks, Christophe. Turning to an update on our progress with the formal evaluation process to identify new clinical indications for commercial focus, which was introduced as one of our three strategic priorities in 2019 and identified as a key priority again for 2020.

As discussed on our recent calls, 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 it will result in us uncovering the next application for commercial focus that will serve as the future growth engine of the company. In March 2019, we identified interventional pulmonology as the first potential clinical application that we put through this process. As a reminder, 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 the company.

As we moved through each stage of this formal process, we have been increasingly encouraged by the potential opportunity in the interventional pulmonology market, given the very large incidence rate of lung cancer, the highest mortality rate among all cancer types and the fact that we have a unique solution to help improve the current lung biopsy standard of care.

The development of Cellvizio's needle-based probe allows the physician to penetrate and visualise inside the nodule in real-time and in vivo. We also believe that the AQ-Flex could improve diagnostic yield and reduce the need for unnecessary invasive procedures for diagnosing and/or staging lung cancer. We continue to believe one of the most compelling aspects of the interventional pulmonology opportunity for Mauna Kea is that Cellvizio, when used in combination with robotic and advanced navigational platforms, has the promise of improving targeting in situ tissue characterisation and increased diagnostic yield.

To that end, in December 2019, we announced the collaboration with the Lung Cancer Initiative at Johnson & Johnson, which is working to develop new diagnostic and therapeutic approaches for this disease with significant unmet need. This is an exciting collaboration for Mauna Kea. We have been working hard in 2020, and as discussed earlier, the recent start of enrolment in a pilot clinical study represents the achievement of an exciting milestone.

While we are proud of the progress we have made since we started the formal evaluation of interventional pulmonology, not the least of which is the collaboration with J&J's LCI team on potential applications for technology in the endoluminal robotic space, but as discussed on our call in April, the strategic evaluation is not limited to our efforts in endoluminal robotic space. In fact, we

have multiple other interesting potential new clinical applications for Cellvizio that we are taking through the formal evaluation process.

First, our evaluation of the large potential market opportunities in manual bronchoscopy. Recall, that while endoluminal application of robotic and navigation-assisted technologies is incredibly compelling, it remains in the early days of adoption. The substantial majority of procedures today are done with manual bronchoscopy and we are evaluating how our current Cellvizio technologies may improve diagnostic performances, impacting patient management decisions, and in turn, patient outcomes in this space or how we may focus our R&D efforts to create innovative new solutions by enhancing our current technologies.

There are two specific areas in the broader manual bronchoscopy that we are evaluating currently: peripheral lung nodules and acute respiratory failure in the ICU, including acute respiratory distress syndrome, or ARDS.

First, on the acute respiratory failure. We believe there maybe applications for Cellvizio to help those patients suffering acute respiratory failure, commonly caused by acute respiratory distress syndrome, ARDS, congestive heart failure and pneumonia. These patients are typically on respirators in the ICU. Determining the cause of acute respiratory failure is critical for the treatment decision-making process. Indeed, the detection of early fibrosis in these patients is potentially beneficial to determining appropriate treatment. Current standard of care methods such as chest CT and ultrasound imaging are unable to differentiate lung infection present in pneumonia, from fibrosis triggered by sustained inflammation in ARDS patients.

And while lung biopsy can differentiate fibrosis from infection, it is associated with significant risks such as pneumothorax, lung collapse and bleeding. Clinicians are further challenged by the fact that steroids are a viable option for treatment of fibrosis in ARDS patients, but can cause serious complications, including death, in patients with lung infection.

In a recent study, Prof Jouke Annema and all, reported that Cellvizio could safely be used to differentiate between important causes of acute respiratory failure without the need for lung biopsy, differentiating early fibrosis from lung infection and could lead to critical changes in patient management and treatment going forward.

The clinical work completed by the team from the Department of Pulmonology at Amsterdam University Medical Centre continues to lead the discussion on acute respiratory failure causes and the assessment of lung fibrosis. Importantly, there were multiple presentations on the subject from this team and another team led by Dr Silbernagel from the Department of Pneumology, Asklepios Lung Centre, Gauting in Munich, Germany, at the recent 2020 ERS International Conference Virtual Meeting. ERS is the world's largest meeting for respiratory physicians, scientists, allied health professionals in all areas of respiratory medicine. We are in the early days in our evaluation of this specific opportunity, but one that appears to be very compelling.

With respect to peripheral lung nodules, building upon the recent published studies on the use of Cellvizio during manual bronchoscopy for peripheral lung nodules, we continue to work with interventional pulmonology KOLs in the US and Europe, who are evaluating the potential contributions Cellvizio could make to increasing diagnostic yield. Results of a new study on the evaluation of peripheral lung nodules with Cellvizio were also presented at the recent 2020 ERS International Congress Virtual Meeting by the team from Amsterdam University Medical Centre.

The study shows nCLE diagnostic accuracy with 95.3%, impressive performance versus standard of care. Additionally, we are encouraged by the clinical validation, which points to the potential opportunity for Cellvizio to enable more accurate targeting of lung nodules and increasing diagnostic yield of transbronchial needle aspiration.

Another area we are taking through the formal evaluation process is an interesting potential new application within GI in the area of irritable bowel syndrome, or IBS, with a specific focus on food allergies. There is a real clinical problem to address as there are no reliable biomarkers available and the current diagnostic methods are unreliable, which means that many patients continue to suffer without clear treatment.

We are continuing our work with KOLs wells in Germany and we're happy to have delivered a new system in the third quarter to Vilshofen[?] Hospital as they see value in using Cellvizio for real-time observation of mucosal response to food antigen, which may provide certainty compared to the current testing methodologies, which are lacking. We look forward to adding more clinician accounts in Germany as part of the evaluation of the IBS opportunities in the coming months.

Finally, we have another area of clinical interest we are exploring, fluorescent-guided surgery, tissue characterisation to eliminate false positives. This is a drug-device combination opportunity that offers access to a rapidly developing field of medicine.

Pharmaceutical and other companies are creating molecules that attach to targeted cancer cells. Currently near-infrared cameras are used to excite and visualise these molecules.

We have a 510(k) cleared and CE-marked near-infrared version of Cellvizio that has been used to similarly excite and visualise certain molecules. This is an important area of development for us and we are encouraged by the progress we have made in recent months. We hope to have something to announce in this area later this year.

In summary, we are executing well toward our third strategic priority, which is 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, in the endoluminal robotics area. And we are also continuing to take other new potential indications through the formal evaluation process. And we look forward to updating investors as things develop this year.

With that, Greg, we will now open the call for questions.

Q&A Session

Operator

Thank you. Ladies and gentlemen, if you wish to ask a question, please press 01. It's 0 and 1 on your telephone keypad. To ask a question, you have to press 01 on your telephone keypad. 01 on your telephone keypad. We don't have any questions for the moment. Let's wait a few moments for a few question. Ladies and gentlemen, if you wish to ask your question, you have to press 01. It's 0 and 1 on your telephone keypad. We have a first question from Kieron Banerjee from Goetzpartners Securities. Please go ahead.

Kieron Banerjee

Good evening, gentlemen. Thank you for taking my questions. Just three quick questions for me today. Firstly, I wanted to touch on the Q3 estimates of original numbers. To what extent you think this will carry over to Q4, this growth we're seeing year-on-year? And also to what extent you think this is a rebound from Q1 – so mainly the second quarter? And how do you think that will impact your Q4 numbers also for the full year? Secondly, if we could just touch quickly, Christophe, on where the gross margin improvement came from? And finally, could we – could you give us any indication as to the timelines of first data from the ongoing MARK[?] trial? Thank you.

Rob Gershon

Okay. Yeah. Thank you for your question. With respect to Q3 estimates and whether we expect it to continue in Q4, certainly we are encouraged by the improvement trends that we've seen. April was our low point. In May and June, we began to see a recovery and then further improvements in Q3.

Certainly, barring an unexpected setback with respect to COVID-19, it's pretty reasonable to expect that we will continue on the pace that we are. And we'll see the trends continue in Q4. As much as how much of this was a rebound from Q2, certainly there were pent-up cases that were not done during the lockdown period throughout the different markets throughout the world, that were done in Q3. So we know – we expect that some of it was the pent-up demand and others was just new demand.

So some of it is pent up demand. Some of the demand does go away as procedures just didn't occur. But we are encouraged by the uptick, by the very pronounced uptick in procedures since.

With respect to gross margin, I'll turn it over to Christophe to comment on gross margin improvement.

Christophe Lamboeuf

Yes. Our gross margin was significantly up this year during the first half compared to last year. And this is mainly driven by the sales mix. We had very, very strong sales to our distributors and specifically in China last year, where the upfront gross margin is significantly lower than in our direct sales channels, like in the US or in France and Germany. And so it really depends on the sales mix, and the sales mix was more favourable at least looking at the gross margin level this year.

Rob Gershon

And with respect to your third question, which was on the Fox Chase Cancer Centre study and when we expect to see the first data. Right now, enrolment has begun. Our next announcement will be when enrolment is completed. And that is targeted to complete in mid-2021. And as indicated on clinicaltrials.gov, it is progressing nicely, and as soon as enrolment is completed, we'll make that announcement.

And then data, really it's uncertain when the data will come out from there, but it'll certainly be several months after the completion of enrolment.

Kieron Banerjee

Perfect. Thank you.

Rob Gershon

You're welcome. Thank you.

Operator

Thank you. We don't have any question at the moment. Ladies and gentlemen, if you wish to ask a question, please press 01 on your telephone keypad. 0 and 1 on your telephone keypad. Ladies and gentlemen, if you wish to ask a question, please press 01 on your telephone keypad. Looks like we don't have any further question. Last call, if you have a question please press 01 on your telephone keypad. And there are no more question. I give the floor back to you for the conclusion.

Rob Gershon

Okay. Well, thank you everyone for participating. And we certainly wish you and your families to be healthy and safe during these very uncertain times. So thank you very much.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you all for your participation. You may now disconnect your lines.