

Transcript of Mauna Kea Technologies 2018 Financial Results Conference Call

Introduction

Greetings and welcome to the Mauna Kea Technologies full-year 2018 financial results conference call. At this time, all participants are in a 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, Robert Gershon, CEO from Mauna Kea Technologies. Sir, please go ahead.

Robert GERSHON, CEO of Mauna Kea Technologies

Thank you, Melanie, and welcome everyone to Mauna Kea Technologies full-year 2018 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. As the recently appointed Chief Executive Officer of Mauna Kea Technologies, I will begin my remarks with a brief introduction and share a few thoughts on this great company and the compelling growth opportunity we have in front of us. After these opening remarks, Christophe will provide you with a detailed review of our full financial results along with an update on our balance sheet as of 31 December 2018. I will then share some thoughts on why we believe we are well positioned for strong performance in 2019, and where we are focussed in 2019 to drive improving growth trends in our business going forward. Then we will open the call to your questions.

As this is my first financial results call since joining Mauna Kea in October of 2018, I thought it would be helpful to share a little colour on what I have been focussed on since taking over as CEO and what I have been learning during my first 150 days on the job.

However, first I thought I would take a moment to introduce myself, share a few summary points on my experience and background. As discussed when we announced the CEO transition last fall, I was hired to guide the company through its next stage of commercial growth and success, and it was my experience directing commercial strategies and marketing executions for leading medical device companies for the past 30 years that the board felt made me the ideal candidate for this position. Unlike many new CEOs, I was very fortunate to have been engaged with Mauna Kea for more than six months in a consulting capacity leading up to my assuming the CEO position. I have to say it was incredibly exciting for me that everything I have learned in the five months since taking over as CEO has done nothing more than further validate what attracted me to this role in the first place, the opportunity to commercialise a truly innovative and disruptive technology that is advancing the current standard of care. What more can a commercial leader look for in his next challenge?

Under the leadership of the company's founder and inventor, Sacha Loiseau, and the hard work of the Mauna Kea employees around the world, the company accomplished the hardest thing there is to accomplish in the medical device space, and that is to create a truly disruptive technology that has the potential to literally change the way patients are diagnosed, treated and managed. Therefore, Cellvizio technology has the ability, unlike anything else on the market

today, to visualise the earliest disruption of tissue at the cellular level. The broad-based implications of this technology are staggering.

Now, I have observed in unfortunate reality in the many years I have been in the medical device industry, and that is there are many great products that never see the light of day, and then there are many mediocre products that are famously successful. The difference between success and failure in my opinion is creating and executing a strong commercialisation strategy. I will share more thoughts on why we are confident in both our commercial strategy and our ability to execute this strategy to drive growth.

As I said, I was very familiar with the company having worked with the team in advance of joining as CEO. This allowed me to hit the ground running and really has made my first 150 days unusually productive. I have focussed in part on building relationships with key leadership across the different teams in this global organisation and have met with virtually all of our employees, which gave me important perspectives and insights that I did not have in my consulting role.

Importantly, I have spent time with many of the key constituencies outside our organisation as well, including key customers at hospitals and academic institutions and dozens of our physician customers, many of whom are our strongest advocates of the Cellvizio technology. These discussions help me evaluate all of the primary aspects of our strategy and were instrumental in determining how best to position the company for growth going forward.

After the first 150 days as CEO I am even more energised by knowing that the potential of Cellvizio is greater than I realised before I started. I am energised by the talent level, engagement and dedication of our employees worldwide and the support I have received to date from Sacha and the rest of the board of directors.

I have emerged from this period learning with a sense of urgency to quickly instill focus and a clear direction and strategic priorities that will result in immediate and sustainable growth. We have augmented our team by attracting world-class marketing and sales talent to the organisation, and will continue to add additional members to the team as the year unfolds. We created and started to implement a very focussed strategic and operating plan that appropriately deploys our resources to the highest priority areas that will result in further unlocking the value of Mauna Kea Technologies for our investors.

I will share more colour on this strategic and operating plan later in this call, but first, let me turn the call over to Christophe for a detailed review of our full-year 2018 financial results. Christophe.

Christophe LAMBOEUF, CFO of Mauna Kea Technologies

Thank you Rob. As reported in our Q4 sales press release on 17 January 2019, total sales for the full-year 2018 were 6.8 million, up 1% year over year. Full-year 2018 sales growth was driving primarily by a 17% increase in consumable sales, and a 6% increase in services revenue which offset a 13% decrease in system sales in the period.

The year of year decrease in systems sales was driven by the company's strategic shift to a consignment model where units are placed compared to the price-selling model based on outright sales of systems in the prior period. The company placed 55 new Cellvizio systems under its PPU programme in 2018, up 328% year over year. New system placements in 2018 drove a 37% increase in pay-per-use consumables sales.

Total Cellvizio shipments increased 88% year over year to 81 in the full-year 2018 period compared to 43 total shipments in the prior year period. New system placements under the

company's pay-per-use programme represented 68% of total shipments in the full-year 2018 period compared to 30% in the prior period.

Total consumable probe shipments increased 9% year over year to 663 in the full-year 2018 period compared to 606 in the prior year period. Consumable probes reorders and pay-per-use orders represented 90% of total consumable probe shipments in the full-year 2018 period compared to 81% in the prior year period.

Total clinical sales for the full-year 2018 period were 5.6 million, up 3% year over year, driven by a 14% increase in sales in the Asia-Pacific region, and a 23% increase in sales in the EMEA region which offset an 88% decrease in sales in the Latin-America region.

Turning to a review of our performance across the rest of the P&L in 2018, total growth profit increased 0.1 million, or 3% year over year, to 4.7 million in 2018. Gross margins for the full-year 2018 period was 69.6% compared to a gross margin of 62.2% in the full-year 2017 period. The primary driver of the increase in gross margin was a better margin mix due to the 17% increase in consumable sales and a 6% increase in services.

Total operating expenses, excluding the cost of goods sold, in the full-year 2018 period increased 2.4 million, or 16% year over year to 17.8 million, compared with 15.4 million last year. This amount includes 1.6 million in depreciation and provisions, up to 0.5 million year over year. The primary driver of the increase in total operating expenses in the full-year 2018 period was our decision to transition our business model in the US. We anticipated that our commercial and marketing investments required to support the development of our US pay-per-use model would be reflected in our accounts. Accordingly, sales and marketing expenses, including regulatory and reimbursement, increased by 1.5 million, or 20% year over year.

Total operating expenses also increased due to higher general administrative expenses this year, which increased by 0.6 million, or 18% year over year, 3.9 million. This increase reflects unfilled positions in the finance and HR departments in 2017, as well as a recruitment cost in the United States as part of the reconstitution of our US sales team at the beginning of 2018.

Operating loss in the full-year 2018 period was 12 million, compared to 9.7 million in the prior year. Net loss in the full-year 2018 period was 12.8 million, compared to 10.2 million in the prior year period. Both operating loss and net loss were driven by the 16% increase in non-cost of goods operating expenses, offset partially with a 3% increase in gross profit compared to the prior year period.

Turning to a review of the balance sheet, as of 31 December 2018 the company had cash of 8.6 million, and long-term debt obligations of 6.5 million, compared to 17.5 million and 6.6 million respectively as of 31 December 2017.

Cash used in operating and investing activities in the full-year 2018 period totalled 12.1 million, compared to 10.5 million in the prior year period. With that, I turn the call back to Rob for a discussion of our 2019 focus area. Rob.

Robert GERSHON

Thanks Christophe. As I mentioned earlier, I spent a considerable of time learning more about the company's business, the opportunities and the challenges that commercialising our Cellvizio technology presents today. Throughout this process I have become more certain that the company's strategy in the US is not only appropriate but also best positions the company for strong growth in the years to come. There are a few key strategic factors driving the confidence that we have in our US commercial strategy.

First, the US GI market is very compelling with more than 3.6 million upper GI procedures performed each year, and representing USD 2.8 billion of annual recurring revenue. There are more than 3 000 hospitals and ASCs in the US that are considered large-volume GI centres, which represents a large potential customer group for our disruptive Cellvizio technology.

Second, Cellvizio technology is well positioned to continue to disrupt, and in fact redefine the current standard of care in the US GI market. Our technology is supported by a strong body of clinical validation, regulatory clearances, established Medicare and Medicaid reimbursement at increasingly attractive reimbursement rates, and KOL support. Any one of these items can empower a sales force to help drive adoption of a new medical device technology. Together, they not only empower Mauna Kea 's sales force to help drive adoption, but they also are integral to our ability to drive improving utilisation of our technology over time.

Third, the strategic shift in our US commercial business model to focussing on pay-per-use has been validated. As discussed on calls over the last 18 months, the company transitioned the business model at the end of 2017 to offer consignment, or placement, of Cellvizio systems with pay-per-use consumable probe contracts. This new strategy enables physicians to utilise Cellvizio without the upfront capital equipment purchase which provides an attractive economic model for physicians, hospitals and ASCs.

The strategy was validated this past year with positive trends in system placements. Specifically, we placed 55 Cellvizio systems through the PPU programme in 2018, 39 of which came in the second half of the year. What is more important, and frankly more validating of the strategy overall, is that we saw very strong demand for consumable probes from GI accounts in hospitals and ASCs around the US during 2018. Specifically, we saw a 32% increase in the number of PPU cases that were used with our technology in 2018. The improving utilisation trends we experienced as we moved through the year is the clearest sign of our ability to drive growth going forward.

The fourth key strategic factor that gives us confidence in the US commercial strategy is the investment in expanding the sales force that occurred in February of 2018. We entered the year with 21 selling professionals in the US, compared to 12 at the end of 2017, and only eight in 2016. This group includes regional sales managers who lead the sales effort in their respective areas as well as clinical account managers that are integral to driving utilisation.

Looking ahead to 2019, I would like to share a few thoughts on our three strategic priorities that are guiding our organisation including one, driving consumable, that is utilisation growth in our installed base in the US GI market, our primary market for commercial focus. Two, driving revenue outside the US, but doing so in a targeted fashion in an effort to maximise the resources we invest in international markets. Three, identifying a new clinical indication for Mauna Kea 's next commercial focus area. Let me share a few thoughts on each of these now.

First, as discussed, the US GI market is extremely compelling, and we are well positioned to succeed. As such, we remain focussed on the US GI market as our primary commercial opportunity in 2019. We are focussing even further in 2019 as we have mandated that driving strong utilisation within the current installed 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, while our primary commercial focus remains on the US GI market, we have strong physician interest for our Cellvizio system in markets outside the US as well. It is important for the company to optimise the resources we have to market outside of our primary commercial focus. As such, we will be focussing in certain OUS markets where we have established KOL support and strong distribution relationships in which we can pursue growth at an attractive potential return on invested capital, which includes investments in our leadership's time as well.

I do not want to spread too thin at such an important time in our company's commercial stage of growth, so we are investing prudently outside the US in 2019.

Third, we are currently undertaking a formal process to evaluate new clinical indications to identify the company's next area of commercial focus. 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. We have several potential clinical indications that were considered in recent months, but we have identified the first one we are putting through the process, and it is interventional pulmonology.

Cellvizio is designed to be used in interventional pulmonology. In fact, in February of this year we announced receiving a 510(k) clearance for our Cellvizio AQ-Flex 19 confocal miniprobe designed to be used through existing bronchoscopes, trans-bronchial needles and other bronchoscope accessories as well as the new emerging platforms such as the Monarch from Auris.

Current navigational products provide advanced, minimally-invasive access to peripheral nodules but with limited ability to achieve direct visualisation outside the airways. The Cellvizio AQ-Flex 19 confocal miniprobe can be used through the working channel of existing navigational products to provide direct, through the needle, visualisation inside peripheral lesions. Interventional pulmonology has received a lot of popular press recently, including J&J's USD 3.4 billion acquisition of Auris, the maker of the Monarch robot that is currently being marketed for interventional pulmonology. Intuitive's recent announcement regarding the upcoming launch of their new robot for interventional pulmonology called the Ion.

With more than 240 000 annual lung biopsy procedures in the US alone, interventional pulmonology represents a compelling market opportunity for Mauna Kea's next clinical indication for commercial focus. Our evaluation process will be rigorous and disciplined. The evaluation includes a six-step process that starts with screening criteria and includes phases of validation, commercial test and learns, and it ends with scaling the new indication. This process will be led by marketing, and will involve our field sales team, our clinical affairs and regulatory teams and customers.

We expect the evaluation process to take the better part of 2019, and we plan to report on our progress as we achieve key milestones along the way. For now, we are sharing that the recent regulatory clearance of our Cellvizio AQ-Flex 19 confocal miniprobe helped confirm that making interventional pulmonology the first candidate for our new evaluation process was the appropriate choice.

We are excited to have begun the formal evaluation process and believe that our AQ-Flex is paving the way toward more precise guidance to identify the optimal area for sampling, and potentially as a real-time feedback technique for diagnostic, staging and treatment procedures for lung lesions. If successful, we believe this could be an incredibly exciting commercial opportunity that will drive growth for the company in the years to come.

In closing, we are pleased with the strong performance we had in 2018, and are seeing that progress continue in 2019. We are a focussed organisation with three key strategic priorities in 2019, led by our efforts to drive consumable growth in our installed base in the US GI market. We expect to maximise our resources in key markets outside the US to continue to drive adoption of our disruptive Cellvizio system internationally, and we are pursuing a formal evaluation process to identify the company's next clinical indication for commercial focus. We expect 2019 to be a year of significant progress for Mauna Kea Technologies.

I want to recognise and thank our incredibly engaged, hardworking and dedicated employees for their efforts in 2018 and for bringing the year to a strong close in the fourth

quarter. I would also like to thank our board of directors and our shareholders for their support, and everyone on this call for their interest in Mauna Kea Technologies.

Melanie, we would now like to open the call to questions.

Melanie

Thank you. Ladies and gentlemen, if you wish to ask a question please press zero and one on your telephone keypad.

The first question comes from Martin Brunniger, from Goetz Partners Securities. Sir, please go ahead.

Martin BRUNNINGER, Goetz Partners Securities

Hello, this is Martin Brunniger here actually from Goetz Partners Securities. Thank you, Rob and Christophe, for the 2018 review and 2019 outlook. I just had three quick questions regarding year 2019's strategic pillars. The first one would be driving consumables and utilisation. I was wondering, in terms of utilisation, do you have any guidance on how many procedures are being carried out on average per hospital, or ASC, and the split between the two in the US at the moment?

My second question-

Robert GERSHON

Okay.

Martin BRUNNINGER

-regarding driving revenue outside the US, with pay-per-use now being validated in the US, do you consider moving to that business model outside the US as well, or is it going to stay in the US for now until it gains that attraction?

The third question would be in terms of identifying new indications and particularly regarding the recent announcement with Cook Medical, do you still plan to follow urology at the moment, or is it more focussed on pulmonology? Thank you.

Robert GERSHON

Okay. Well, thank you so much for your questions. I will take them one at a time. With respect to driving, you know, consumables and utilisation, that is, as I indicated in our prepared remarks, that is our number one strategy, and we fully expect, as indicated in the prepared remarks, that this will be the largest contributor to our growth in 2019. It will be the biggest area of growth for us in 2019, utilisation and consumables. Having said that, we do not provide, you know, specific financial guidance.

On your second question, in terms of our PPU programme and whether we are clearly gaining traction, and whether or not we are going to expand that programme outside of the US, the answer to that is at the moment, this is a US-only programme, and most of our sales OUS goes through distribution, and it is a different model. Therefore, at the moment we do not offer a PPU programme outside the US, and we will continuously evaluate different programmes that resonate with customers outside the US, but at the moment, it does not fit our plan, but we will, you know, continuously evaluate what is best for customers.

Then your third, regarding new indications, and our recent announcement with respect to Cook Medical, Cook, and whether or not we are going to focus on urology. Just to level set,

make sure everyone is on the same page, just to discuss Cook for a moment. As you might know, in the fall of 2015, the prior management team set up an initiative to pursue strategic partnerships, and the first one of those partnerships was Cook, in the area of urology. At that time, we agreed to develop a private label version of Cellvizio for Cook, and Cook agreed to market and sell it globally.

As we indicated not too long ago, we were quite disappointed with the lack of commercial progress in the urology market to-date, and thus we made the decision to terminate that agreement. Now, per our comments, our prepared remarks this afternoon, we are really focused on the three strategies that we just mentioned, and with respect to the new indications, our focus right now is on interventional pulmonology. Therefore, we are not seeking to replace that relationship right now. There will be more to come as we continue to evaluate different opportunities, but our focus right now is interventional pulmonology.

Martin BRUNNINGER

Brilliant, thank you very much.

Melanie

We do not have any further questions. Ladies and gentlemen, I would like to remind you that if you wish to ask a question, please press zero and one on your telephone keypad. We have a new question from Arsene Guekam from Kepler Chevreux. Sir, please go ahead.

Arsène GUEKAM, Kepler Chevreux

Hello gentlemen. I well understood that you give no guidance about utilisation of your system, however, could you give us just a flavour about, on average, how often the system is used in hospitals? It could be very interesting to see what can be the potential. That is the first question.

The second question is about the increase of sales and marketing in 2018, the increase was around 20%. I would like to know if at this time you consider that you have enough staff, or are you going to make some new recruitment in 2019.

The last question is about cash. I understand that you have enough cash until the end of the year. What are you going to do in order to strengthen this cash position? Thanks a lot.

Robert GERSHON

Okay, yes, thank you for your question. I will take the first two, and then invite Christophe to discuss the cash question.

You are exactly right, we are not providing, you know, guidance, and we are not-, speaking very specifically on, you know, the number of cases per unit. However, what I would like to reiterate is the way to think about and measure the success of our strategy is through our first strategic priority, which is to drive utilisation. We have given a flavour, you know, historically, what the consumables look like, and as we indicated in the prepared remarks, given our focus on utilisation and consumables, as our number one strategy, we do expect that to be the largest area of growth for the company.

On your second question, with respect to sales and marketing, yes, on the sales side, you know, we clearly increased the sales organisation quite significantly over the last few years. In 2017, we had 12 sales professionals, and as we mentioned, in 2018 we had 21. The size of the organisation and the composition of our organisation, which was just put in place in February of 2018, is really optimal for executing on our strategy at the moment. Therefore, while we

might modestly add to sales, the thought right now is it is a good sized organisation. Therefore, we are going to keep it where it is at for the foreseeable future.

With respect to marketing, we have added some really world-class talent, and our view is we are going to continue to add talent onto the marketing team as we continue going forward. Therefore, we have several active recruiting engagements at the moment. I will turn it over to Christophe to comment on cash.

Christophe LAMBOEUF

Yes, just on expenses and as Rob mentioned, we will have, in 2019, the full effect of the investment we made in 2018, and some other investments as well that Rob just mentioned. Therefore, yes, we expect our expenses globally to increase, no more than 10%.

Now, back to the cash, we had 8.6 million cash, and five million borrowing facility at the moment, which means we have cash to fuel our growth initiatives this year. We will be evaluating all potential options to enhance our balance sheet, including debt and equity.

Arsène GUEKAM

Okay, thank you, gentlemen.

Melanie

We do not have any further questions. Ladies and gentlemen, I would like to remind you that if you wish to ask a question, please press zero one on your telephone keypad.

Ladies and gentlemen, if you wish to ask a question, please press zero and one on your telephone keypad.

We do not have any further question.

Robert GERSHON

Okay, so once again, we thank everyone for your engagement on this call, and we look forward to updating on our progress in our next earnings release and subsequent earnings calls. Thank you.

Christophe LAMBOEUF

Thank you.

Melanie

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