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Pacific Edge Limited
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Half Yearly Announcement

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Start of Transcript

Moderator: This is PGI, please stand by we are about to begin. Good day everyone and welcome to the Pacific Edge conference call. Today's call is being recorded. At this time I would like to turn the conference over to the Pacific Edge CEO, David Darling. Please go ahead.

David Darling: Thank you moderator. Welcome to the 2014/2015 Pacific Edge half year results conference call. Joining me today is a new member of our team at Pacific Edge, Kate Rankin, our Chief Financial Officer. Welcome Kate.

Pacific Edge has entered its first full year of trading in the US and we are seeing a strong start to the first two quarters of both the New Zealand and US markets. Our revenue has grown in the first half to provide us with a total revenue of \$1.5 million, which is up 773% on last year.

\$500, 000 of this is interest and FX gains and \$1 million is our trading revenue. The trading revenue consists of \$714, 000 of our commercial and user program tests and we're very pleased with our performance in this half.

This year we have seen a combined laboratories throughput grow by 93% from last quarter of 2014 to the first quarter of 2015 and by 154% from Q1

to Q2 of 2015. This metric of our growth is designed to provide a yardstick of our performance and consists of both user study tests and commercial sales.

As we progress through this year we will have more extensive laboratory performance information to share with you at year end.

As you all know the US is our key market and will drive the majority of our revenue as we go forward. In the US, our sales executive team expanded from four at the end of the last financial year through to 12 on the ground in August and September of this year. The sales team are focused on 11 of the 19 sales regions.

During the year we have achieved some of our key objectives, firstly with the signing of Multiplan, the last of the big four national provider networks, or as we call them, NPNs. Whilst we will continue to add NPNs and regional provider networks, RPNs, our focus over this first half has been our large target customers - the large urology group practices or as we call them, LUGs and other large urology practices, the integrated healthcare providers and the veteran's administration.

Another of our key objectives was the signing of Kaiser Permanente to a user program. This in itself is a major achievement as Kaiser has many suitors that vie for their internal research and development resources and of course they will select those that have the greatest potential to add value to their business. It was great to have been able to achieve this outcome.

Kaiser is expected to start recruitment of approximately 2,000 patients within the next few months in their user program. We'd expect a conclusion of this user program in 2015. An expected successful outcome of this user program will be a prerequisite to moving this relationship into a full commercial program. At this stage we have no specifics on what the shape of this commercial relationship will be. Obviously we'll be working on that over the next six months or so.

In the last six months we have successfully completed two independent validation studies with the Waimate and Canterbury district health boards, both returning results that support the clinical study findings.

We have launched our Cxbladder e-commerce site - a radical move in the normally quite staid medical community, so very much a first both for the company and for the medical community. We sold our first test within an hour of the launch, which was great to see.

Sales are progressing but numbers are quite small to date. We expect to see urologists and other physicians purchasing Cxbladder tests online for their practices using this platform.

The e-commerce platform will become one of the resources available to patients through the patient community which is being developed for bladder cancer patients. Pacific Edge is the cornerstone sponsor of this site and we expect to see other key organisations coming on board next year to support and sponsor this site.

Pull from patients is seen by us as a key element in building the market penetration, particularly in the US where patients have considerable say and considerable ability to draw through.

Looking forward we'll be concentrating on growing our revenue base in all of our markets, in particular the US. We expect to be working closely with the Center for Medicare and Medicaid Services to obtain approval for their reimbursement program.

We'll continue to grow the market awareness with attendance at the urologist's conferences and expand the provider network base into the regional networks and add more large urology practices ex core customers.

We would also expect our partner in Spain to start their business and our Australian customer base to grow. We will continue to progress the valuation of South East Asia as our next target markets for the Cxbladder family.

For this first half, our balance sheet and cash flows reflect the growth of our business. They are as planned and are indicative of the attainment of our goals. We continue to achieve our expansion goals whilst keeping firm control of our cash burn. We are a lean growth company.

Adding new tests to the Cxbladder family is one of the key opportunities to grow our business. We will add a new test in December this year as

Cxbladder triage, a product that is sought by a number of customers in New Zealand and the US. This product is of particular value to integrated healthcare providers such as Kaiser, hospitals, clinics and payers and all those that take a holistic view of cancer detection and management costs.

We will launch another Cxbladder test during 2015 to continue to build our one stop shop offering to urologists, healthcare providers and payers. This will be the third product in our family of Cxbladder products.

So the remainder of 2014/2015 looks to be a strong year for us and we certainly look forward to growing Pacific Edge's revenue in 2015 and 2016 as a follow on.

Thank you for all those who have joined the call. Moderator could you please open to the floor for questions?

Moderator: Thank you, if you would like to ask a question, please press star, followed by the number one on your telephone keypad and wait for your name to be announced.

Your first question comes from the line of Simon Hartley from Otago Daily Times. Your line is open please go ahead.

Simon Hartley: (Otago Daily Times, Reporter) Hi David, congratulations on the result.

David Darling: Thanks Simon, that's great.

Simon Hartley: (Otago Daily Times, Reporter) Very goodly, hey you're talking about - like you said, keep the cash burn firmly under control, but you had cash for the medium term in one of the releases earlier this morning. When you talk about medium term, how far out is that - cash available for how long?

David Darling: As at the end of the half year we had \$14.7 million in cash and we are expected burn is of the same order as last year and similarly for the following year. There's more than enough cash in there as planned for the - over that planned horizon.

Simon Hartley: (Otago Daily Times, Reporter) Yeah, what date is that horizon though - you want to work that out, that could be 2.5 years?

David Darling: Yeah, no that's for the remainder of this year and all of next year.

Simon Hartley: (Otago Daily Times, Reporter) Okay, [unclear]. Any full year guidance available today?

David Darling: No, we don't. We won't be providing any full year guidance at this point Simon.

Simon Hartley: (Otago Daily Times, Reporter) Okay, would you like to repeat this first half or better it?

David Darling: We would. That would be great. We're on track to meet our expectations, so.

Simon Hartley: (Otago Daily Times, Reporter) Any thoughts yet on when you could be booking a profit - what financial year you'd be going into there - two or three years away?

David Darling: No we can't make a call on that at this point in time Simon.

Simon Hartley: (Otago Daily Times, Reporter) Okay and just lastly, where does China fit in with the expectations of focusing on the South East Asian market at the moment?

David Darling: Sorry could you repeat that question?

Simon Hartley: (Otago Daily Times, Reporter) Where does China fit in the scheme of focusing on South East Asian market in the future?

David Darling: Yes, well I mean China is really central Asia and so it's kind of outside the rim that we've given ourselves at the moment, but China is a very big and difficult to deal with country. It's got a lot of promise and a lot of potential.

One of the ways that you can gain access to China is through Taiwan. Taiwan has a new economic relationship that enables closer economic relationships

to occur with China and if we start to build our business into Taiwan well that will open up China in years to come.

Simon Hartley: (Otago Daily Times, Reporter) Okay, very good and this will be the last question, you were talking about your sales group going from four to 12, can we expect there to be 24 at the end of the year?

David Darling: No, we've targeted 12 for this year and then we will reevaluate our progress with these people. Obviously we have 19 sales regions and our goal will be to progress to having sales representatives in those 19 sales regions.

Simon Hartley: (Otago Daily Times, Reporter) Excellent, that's great. Thank you David and thanks Kate.

David Darling: Thanks Simon.

Moderator: Your next question comes from the line of Chelsea Leadbetter of Forsyth Barr. Your line is open please go ahead.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Thanks moderator, morning Dave, just a couple of questions from me. Firstly, you mentioned in the release or the presentation about potentially working towards being accepted into the standards of care in New Zealand, what do you sort of need to get to, to be able to achieve that?

David Darling: Thanks Chelsea, a standard of care is - we're working with the National Health Council to build an understanding - a dossier of the performance of Cxbladder to the standard that the National Health Council would see as providing the level of support and evidence necessary to go forward.

We're not quite sure what that will end up being, but we've been working with them now steadily for about a year. Our goal to get onto the standard of care is of course to remove the [user pays] problem that you often come across when you deal with the government funded institutions.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Am I right in assuming that won't happen in the next year or so then?

David Darling: No it could well happen sooner than that, but we don't know for sure and as we're being used as the guinea pig for this system - the New Zealand system, to I guess take and adopt new medical technology at a rapid rate. We're first up, so it could be a little longer than they would expect the process to normally take, but everybody's feeling their way.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Thank you. Other question around some of the user programs that are currently underway in some of the markets, could you give us an idea on perhaps the average length of how long these have - are taking or expected to take?

David Darling: Sure, can do. The user programs take two main forms, a user program evaluation, which can be 25 tests. That's usually an opportunity for the urologist to understand how the technology can fit within their program.

They often have made a commitment to adopt this technology and they want to see how it fits in before they make their final decision, so 25 tests can be relatively short. Depending on what size of practice they have and which particular value proposition they would like to target with the technology.

Once again, it's a variable amount of time, but it could be as short as three months, but it could be as long as nine months even to recruit the 25 patients that they would wish to evaluate this test on. It's very dependent on the type of patients.

Then it travels through to the user programs that are what we call user program studies and these are much more formal user programs. They are often the user programs that are associated with the larger groups, such as the LUGs. These LUGs can often have their own research groups and as such it will involve a formal protocol development and IRB ethics approval before we start the test.

They can run out to 12 months to even 15 months to get those completed before they embark on their adoption process.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Thank you and final question from me really, if I think about triage as the next product in the line. If I'm thinking about the US market in particular, are you expecting it to take a

similar timeframe to what you've seen with Detect or should this one be a little bit quicker as you've already got some relationships with urologists in that market?

David Darling: Yeah very good question. We asked that question ourselves and we - some of our customers are expected to transition across to Cxbladdertriage because that's the value proposition that they would like to see the test being - the technology being used on.

Others, if it's a large organisation, they are going to want to run their own user program to see how this technology fits and I think the classic case there would be Kaiser Permanente. Obviously Kaiser are a customer for Cxbladdertriage, that's where they see it adding most value to their business.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Thanks for that Dave and congratulations on the result.

David Darling: Thanks Chelsea, thank you very much.

Moderator: Just as a final reminder, if you would like to ask a question, please press star one.

Your next question comes from the line of Andrew Bolland of Salts Funds Management Limited. Your line is open please go ahead.

Andrew Bolland: (Salts Funds Management Limited, Analyst) Thank you, good day David. Hey I was just interested in your commentary around the commercial partnerships in Spain, expected to start sooner. I know we've spoken about this in the past and sort of around some of the difficulties you've encountered there.

So just interested in what's changed and how that's looking around that partnership.

David Darling: Sure, pretty much the same drivers there Andrew. They have chosen a value proposition that requires a specific data set to be collected. So we're working with those guys to get that done.

Ideally we would have liked to have seen them to lead out with Cxbladder Detect and a conventional application, because Cxbladder Detect can provide a very good outcome for a number of those value propositions.

They've identified a particular value proposition that the key opinion leader, a urologist in Spain, would like to lead with. So, it's taken quite some time to get that data together and get that underway.

Just recently, that organisation has split itself into two. They've split their therapeutic business out from their diagnostic business and that's created a little bit of dissonance in terms of time and getting those transitions completed. So there's a little bit of a delay there as well.

They remain very, very good partners. They have all the capability to transition onto this test and we are looking forward to having them start.

Andrew Bolland: (Salts Funds Management Limited, Analyst) Cheers and just in terms of your mentioning of South East Asia today and obviously following on from the European patent yesterday, understanding that these are sort of medium to long term things. South East Asia is ahead of the European expansion to your mind?

David Darling: Yes it is. South East Asia offers us a great opportunity. They are generally - we would regard them as quick adopters. We also enter the South East Asian arena with a product that is a lot more advanced from a regulatory perspective and a commercial extension perspective.

They can relate to it in a lot more complete framework. We're finding that our market is very strong. It's very interested. Obviously South East Asia have set themselves up to be a big cornerstone provider to medical tourists.

As such that's in a particularly attractive opportunity for all people who would like to get into South East Asia. So, a very live and very real opportunity for the company and it certainly is streaks ahead of any roll out into Europe.

Andrew Bolland: (Salts Funds Management Limited, Analyst) Thanks Dave.

David Darling: Thanks.

Moderator: It appears as though that we have no further questions.

David Darling: Alright, thank you.

Moderator: Okay, just let you know we've now got two late questions. One of them is from Adrian Vance from Forsyth Barr. Your line is open please go ahead.

Adrian Vance: (Forsyth Barr, Investment Advisor) Hi, morning David. Well done, David just quickly could you just give us a little bit more detail around the CMS timing and approvals in your mind and also regarding the published or journals that are required in order to support something like this.

Do you feel that you're still on track with the application on that?

David Darling: Yeah thanks Adrian, good questions. Yes, the CMS - it's not a - I think it's probably good to point out here that this is not a piece of paper that you fill out like you might have to do for a Federal supply schedule.

You have to interact with these people and walk with them on a path that they prescribe. That path is additive, so they can change up the path as they see fit. They require you to put together a dossier and engage with them. When they are happy that they have all the answers they require then they will give you a pass on your driver licence and you'll move ahead.

As everybody should know, the approval for CMS, Center for Medicare and Medicaid Services is the public insurer. The public insurer - we are unable to provide GSM technology to people who are insured under the CMS, that's all people in the United States who are over the age of 65 would be eligible for CMS, not necessarily all take that opportunity up.

However we can provide this technology to those people and we can keep those invoices and submit them at a later stage when we have attained our coverage the CMS.

We've engaged with the CMS. We're working with them. We're preparing all of the bits and pieces for them and we're on track and very happy. They are happy.

Adrian Vance: (Forsyth Barr, Investment Advisor) So is the KP trial, is that going to form basis for that application or is there supporting evidence already in relation to the Cxbladder?

David Darling: No, we won't need the KP user program data for that purpose.

Adrian Vance: (Forsyth Barr, Investment Advisor) Right and then final question from me, obviously just looking to reaffirm the five year plan that has been talked about. I take it you're still on track for \$100 million revenue within that five year period?

David Darling: Yes, we are thanks Adrian. We firmly believe that that's a very doable target and we'll be pushing very hard to ensure that we attain it.

Adrian Vance: (Forsyth Barr, Investment Advisor) Good luck. Thank you.

David Darling: Thanks Adrian, cheers.

Moderator: We have a follow up question from Chelsea Leadbetter from Forsyth Barr. Your line is open please go ahead.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Thank you, just a follow up question from me Dave, after Andrew's question around Spain. Would you be able to provide us with a bit more colour around the Australian market and how that's progressing?

David Darling: Sure, the Australian market we have a co-exclusive relationship with Healthscope. We particularly wanted a relationship in Australia because we needed to have a large pathologist to help us with gaining access to the public purse.

It was always a long term strategic relationship with a pathologist in Australia. We chose Healthscope particularly because they were the largest healthcare provider. They were the second largest path company and they had a very strong appetite for micro-diagnostics.

They've been through an inordinate number of changes from being de-listed and held privately to being relisted - several changes and swaps of various sales components out of their business. They've struggled to get what we would have thought was a progressive rate into the Australian market.

We have the opportunity under our co-exclusive to supplement or directly engage in that market and we're going through right now a process of identifying other partners to take our technology into Australia. We're actively working ourselves.

We've just signed up two large user programs in Australia and we're looking for a third shortly.

Chelsea Leadbetter: (Forsyth Barr, Analyst) Congrats, thank you very much for that Dave.

David Darling: Thanks Chelsea.

Moderator: It appears as though we have no further questions. I'd like to hand the call back to David for any additional or closing remarks.

David Darling: Thank you moderator. Yes, I'd just like to reiterate that last point that we are very excited about the rest of this year and looking forward to growing out our revenue in 2015/2016.

It's an exciting time for us and particularly as I've commented to a number of you, it's challenging for a company to build a product of this nature and take it into the market. They are quite revolutionary products, but it is outstanding to put two products into the market. By the end of next year we will have three.

We're very delighted by the progress of the company. That ends the commentary from my perspective. Thank you moderator.

Moderator: That concludes today's conference. Thank you all for your participation. You may all disconnect.

END OF TRANSCRIPT