21 May 2012

ImpediMed L-Dex Clinical Experience Evening

Brisbane, Australia. – ImpediMed Limited (ASX: IPD) refers shareholders to the attached transcript which covers selected extracts of the clinical information evening held at the Australian School of Advanced Medicine, Macquarie University Hospital, on the 17th of May, 2012. The evening was designed to provide feedback on the clinical experience of L-Dex in use within the Australian health system.


This information is interesting for shareholders and potential investors to hear from medical providers about their clinical experience using L-Dex in the management of lymphoedema in breast cancer patients.

For more information:
Greg Brown
CEO & Director
T: +61(7) 3860-3700
M: +61408281127

L-Dex® is a trademark of ImpediMed Limited.

The L-Dex® scale is a tool to aid in the clinical assessment of unilateral lymphoedema of the arm and leg in women and the leg in men by a medical provider.

The L-Dex® scale is not intended to diagnose or predict lymphoedema of an extremity.

About ImpediMed
ImpediMed Limited is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed’s primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed has the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary unilateral lymphoedema of the arm and leg in women and the leg in men.

For more information, visit: [www.impedimed.com.au](http://www.impedimed.com.au)
FILE DETAILS

Audio Length: 50 minutes
Audio Quality: ☑ High ☐ Average ☐ Low

Number of Facilitators: One
Number of Interviewees: Two
Difficult Interviewee Accents: ☑ Yes ☐ No

Other Comments:

START OF TRANSCRIPT

Greg Brown, CEO: So to start off tonight I'd just like to introduce Louise. Louise is an occupational therapist with over 22 years of clinical experience in both the public and private settings, specialising in the area of breast cancer rehabilitation and lymphedema management. Louise currently is working in a research role at the Westmead Breast Cancer Institute and has a collaborative partnership with the Sydney University Breast Cancer Research Group. Professor Boyages is a Director and Professor of Breast Oncology at Macquarie University Cancer Institute. I think you were educated here at the University of Sydney, and have a fellowship from Harvard Medical School and have been an invited lecturer and educator at Oxford University at the medical school; the list goes on and on. John is the author of over 135 research and clinical articles and is committed to disseminating that research into both the general population, as well as to professional audiences.

John Boyages: Thank you very much for that kind introduction, and thank you all for coming tonight, I know it's probably a hard ask to come here on a Thursday night when we're all keen to get home or go to the pub or go out for dinner. Look, I guess ultimately products, whether they're devices or drugs or pharmaceuticals or whatever, are designed to support people. The cancer patient is scared; they often come to hospitals - and a lot of you have probably had experience of relatives who've had cancer, or friends - and you know that once you get into that medical maze it's just a nightmare and your whole life stops and you're trying to figure it all out.

What tends to happen is you go through surgery, radiotherapy, chemo and then the system leaves you in the lurch a bit and a lot of patients have fear of recurrence; a lot of patients have fear of complications. This bioimpedance spectroscopy in many ways is part of our survivorship program and offers ways of measuring
some of the complications we cause when we treat cancer, whether it's in the breast or the lower limbs or the pelvis.

In many ways it has allowed therapists who are at the cold face, like Louise, to be able to interact with those patients on a regular basis. So the MCI, the Macquarie University Cancer Institute, I've been here for about six months now and this is quite an amazing hospital and... so my job as Head of Cancer here is to - is how do you translate into personalised cancer care through screening, through treatment, research, information, diagnosis and education? I won't bore you with all our goals, but essentially it's multi-disciplinary; cancer care is very complicated so you need to work with a team of people: doctors, nurses, occupational therapists, physiotherapists and so on. We aim to translate research into practice, so how do you translate research, for example, in bioimpedance, into practice? How do you go from a pilot, as you know, into a routine business using this type of equipment?

Cancer affects 115,000 Australians every year and it's expected to rise by 2020, which is not that far away- you know, it's eight years away - to 150,000 men, women and largely due to the baby boomers coming through now as people like me are getting older. Getting to our 50s and 60s there's a higher incidence with the post-war baby boomers. In terms of which cancers, in 2020 we're talking about in pink of course breast cancer, about 17,000 patients, bowel cancer 20,000, prostate 25,000 and so on and lung cancer, and they're the most common cancers. We're looking at a survivorship program called LACE, Life After Cancer, where patients will come into our out-patient rooms, be seen by an OT, get an L-Dex measure, get a bone density measure on their heel. Get weight measurements, get exercise physiology done, look at their psychology, memory, fatigue, sexuality, menopause; a one stop shop around life after cancer.

Then from there we'll have sessions like here, maybe an education workshop that Louise runs on home therapy. We'll be doing national forums a couple of times a year and then there are Medicare and Healthcare funded one on one interventions. So if someone needs intervention for lymphedema, then they'll get an appointment for that type of thing.

Of course it's a tragedy when this happens, but it does happen, when you treat someone with breast cancer they think they're free of it. The longest case of lymphoedema I had was a lady who came to see me when she was 90 and had breast cancer when she was 50. So lymphedema can occur at any time. This lady was a fit 90 year old, went in to have a pacemaker, got an infection and then her arm blew up.
So it can happen at any time after breast cancer. Last night in my clinic I saw a cleaner who sits there all day house cleaning. When I examined her hands, nothing like that but you could tell that she had moderate lymphedema. Nobody had - she said it's been there for six months, she wasn't aware of it as a problem, she's seeing you soon Louise, but I told her about the L-Dex machine, the importance of monitoring it, that as in her work she needs to clean for an income. So it's about having a personalised approach. I was interested in this research from Sharon Kilbreath who Louise works with. When they asked a whole bunch of women about lymphedema - and this is just one of many tables, but one of the most common, unmet needs was health professionals don't know anything about it. Not having lymphedema treatment centres like the LACE program we were talking about, and this one, 30 per cent of them felt they weren't given access to early detection of lymphedema. So in the past we just wait for it to happen, we take a tape measure and say well it's bad luck, make sure you put some cream on it.

Whereas what Louise is going to talk to you about is this machine here. I'm just going to finish up by saying to be frank, I was a sceptic, so when Louise came to me, who I love dearly and I think she's a fantastic therapist, and she said John I want to get this machine, I'm going to put wires all over the patient and I want to - in the middle of your busy clinic, I want to take a measurement. I said go away Louise, do it on Friday. So we run three clinics, Monday, Wednesday and Friday. I said do the pilot on the Friday clinic and then come back to me when - I said my clinic's stressed enough as it is, I don't want this happening.

Before I knew it, 100 patients on the Friday. Then all these patients started talking to me saying, I saw Louise - and she started doing this in private practice - I saw Louise, I've had my measurements, here's my measurements, and I'm trying to work out what all these measurements mean. Oh my measurements gone down, oh and you started radiotherapy and my measurement's gone up again, I'm going okay, and it's just wonderful having someone monitor my lymphedema and monitor this for me. Also teach me how to massage my arm and teach me how to - and also give them information and support. So that's the trick here, it's not just about the machine, it's about people who are scared, who often don't have time to see these busy specialists.

Before I knew it I was saying Louise when are you going to come to the Wednesday clinic, and I think now we're doing routinely on all our patients and I'm getting the hospital to buy one here as well, which has nearly crossed the line - I don't know if you knew that but we're definitely getting one here. So I was a sceptic but I think - Louise will tell you more about it - but I think I'm pretty
excited about it and I think with the Medicare drivers and with marketing, training and so on, this is an important part of survivorship programs.

Louise:

Well thanks John and good evening everyone. Thanks for your attention, I'm the second speaker so I'll have to get you up and doing exercise because I'm a therapist that gets women doing exercise, but I won't just now. I'm going to hopefully follow on from John in talking about my experiences of using L-Dex, or bioimpedance technology, with women with breast cancer, and other patients who have lymphedema. So John was very specialised and focussed in breast cancer related lymphedema, but as a lymphedema therapist I also see other lymphedema caused by other types of cancers that John's eluded to, which we also see lymphedema and I use L-Dex for that as well. I can certainly say that my practice as an occupational therapist in lymphedema therapy has changed significantly over the last five years, since becoming aware of this technology and very much - at Westmead Hospital we set up a lymphedema clinic with John's support about 16 years ago. Westmead Hospital is a large teaching hospital in Sydney, and we set up the service and we had the same staffing levels there in the lymphedema clinic as we did 15 years ago, and yet we get 200 new referrals per year.

So the demand and the resources for lymphedema continually grow. So we really got to a point where we had to say what can we do to change our practice here, because we can't keep up with treating the significant cases of lymphedema that we're getting. So you can see there the National Breast and Ovarian Cancer Centre did a review of the literature in 2008 and breast cancer, we say the estimates for lymphedema are about 20 per cent, and the other cancers are there. So varying amounts and the other cancers we don't really have good figures there because we don't measure it very well, and we certainly don't see those patients often before surgery. So there's a huge scope for work in this area.

Now the big point on this side is really this one, that early detection and effective management can reduce symptom severity and really improve quality of life. That's really the key to success in gaining long term control. This isn't just something that's happening here in Australia, the National Lymphedema Network in the US has developed this position statement, because people are really agitating for better lymphedema services, better access to regular monitoring for this. They've developed this position statement on screening and measurement for early detection of breast cancer related lymphedema.

So in the past we would wait for lymphedema. We would sit in our clinics and be inundated by people coming with obvious signs of swelling in their arm. We'd use our regular little tape measure and we'd measure the difference and compare the
difference in their affected arm versus the unaffected arm. We'd know that your affected arm, your dominant arm, is usually bigger than your non-dominant arm, and we would take into account for that. When you're measuring the arm, you're actually measuring three main things. You're measuring fat, fluid and muscle. So that's where L-Dex comes into our real age here, in monitoring women by specifically measuring extra cellular changes which we know are a pre-requisite, or pre-indicator, for lymphedema. So instead of waiting at this end to see visible signs of lymphedema, we're aiming to get down to this side, where we actually educate women and educate them appropriately to their risk. Whether they've had a few lymph nodes removed or whether they've had a significant number removed, we want to tailor our education to try to reduce the anxiety and the stress associated with lymphedema.

Often we have patients come into us and say they're concerned about their breast cancer, and rightly so, but often one question is, I don't want to get that lymphedema because my grandmother had a really swollen arm and she looked awful with that arm and she couldn't do things because of it. So we're trying to really encourage people to try to prevent it.

There's increasing evidence internationally for this early detection and management of lymphedema. Really I've been saying for a number of years that L-Dex is really the gold standard for monitoring and detection of early lymphedema. It's a very non-invasive method, and we did have lots of resistance and lots of hesitation in the Westmead Breast Clinic. We have these three multi-disciplinary clinics. There's about probably 20 team members in a clinic three days a week.

The woman comes into the BCI at Westmead and if she's just been diagnosed with breast cancer, she comes into her consulting room and that's her consulting room for the morning. So she's often there two to four hours, so she might be seeing someone to have a biopsy. She'll see a surgeon, often a surgical registrar. If they're thinking she's going to need radiotherapy, she'll see a radiation oncologist. The breast care nurse will come and see them. Because we're a teaching hospital, they'll see a research nurse. Then the little OT said, John we want to come into that clinic and take a measurement and there was lots of resistance. This is back in 2007 we started this, and John said do a proposal, to get rid of me for a while, write up a proposal and do it like you said to me, on the Friday clinic, and we have really good results. It is now routine practice. So this is the device that we have. We actually have two of these at Westmead, which we're very fortunate and very appreciative of because John, although he may not be using this machine on a day to day basis, he, as the director, funded the purchase of these devices. We now
have one that's situated in the breast cancer clinic where all of our new patients come in for their breast cancer management, and follow-up. Then we also have one machine in the lymphedema clinic, which is situated in another department in the hospital.

So really what L-Dex does, and I agree with these statements wholeheartedly, it really can pick up early lymphedema. It highlights the need for taking these pre-operative measures. So rather than waiting until someone develops lymphedema, we want to know what their true base line is before they have any interference via surgery or any cancer treatment. L-Dex also shows how different interventions can be tracked and also shows the effect of some medical and surgical interventions, and I'm going to show you some of those through some case studies. Rather than me talking about it, let's perhaps show some patients. So as I say, we said, well how can we improve our service? We couldn't keep up seeing the patients who develop lymphedema who at one stage in 2007, we had a 12 month waiting time for someone to do our intensive bandaging programme to reduce their arm size. We just couldn't keep up. This intensive treatment takes two hours to complete, which is very hands-on, massage, bandaging the arm and then getting it into a plateaued state of reduction, then we put them into a compression sleeve. I may have alluded to a few of you before, that these compression garments that people wear, you're meant to wear them all day long, every day, to really control and contain the swelling. They cost $450 per garment and they're mean to have two garments at a time, so they've got one on and washing one, and then they need to be replaced every six months. So that's $2000 a year just for someone to maintain compression garments, and that excludes the costs of going and having any type of therapy or massage and monitoring. So lymphedema is a high-cost condition.

I'd like to share with you how we use L-Dex in our clinic, and these are patients in the BCI and in my private practice. So this is someone that I guess is ideal, it's a journey that I hope most of our women could go on. So this is Carol, aged 52. She came to me for a pre-operative measurement where I was able to give her really tailored education in what are the risks, according to her surgery, for lymphedema, and what are the things she could do to try to prevent lymphedema? So I saw her before her surgery and you'll see here that the green area between minus 10 and plus 10 is the normal range of where this L-Dex value should fit into. Carol fitted in beautifully, her pre-op level was 1.6. This was a reading the patients actually take home and know, so were not saying that it's some highfalutin number, they know what their reading is and we give them a record of their reading that they take home and they bring back their little pamphlet every time they come for a measurement.
So they're feeling empowered. They're feeling in control of monitoring their symptoms. After surgery she came back to me and her reading had gone up to 8.9, and I reassured her that that's very normal. Often when women have surgery, you get post-surgical swelling, and that's normal. If you go and have a knee operation, your knee is going to swell. So very reassured by education there.

Then Carol went and had some radiotherapy, I won't say it was from John, but anyway. After her radiotherapy she had quite a significant sunburn type of reaction, her skin started to peel and was very red and very painful, which meant she couldn't lift her arm very much because if you could imagine having a sunburn across your chest, you're not really going to want to put clothes on the line or do things around the house because it's painful. This pain of discomfort can be two to four week sometimes depending on the severity of it. So during that two to four weeks when it's so sore and painful, she's not doing activities so her shoulder movement actually gets restricted.

So because she's not moving and her arm's not functioning as well, she starts to retain a little bit of fluid there, and you'll see that the reading went up, and she wasn't able to move after radiotherapy. After her skin recovered from the radiotherapy, she was back to her normal level of exercise. Twelve months down the track, she wanted to be reassured that her reading was okay, which it was, it was a point different from where she started and two years down the track she came and it was also perfectly normal, with no problems. She's back now dancing, she's riding a bike, she's walking, she's back doing - living her normal life, being through chemotherapy, radiotherapy and very happy to regained her sort of survivorship mode. Very reassured, and it was really her initiating to be followed up and monitored with that.

This is Donna, another one of my patients who, as you'll see by the number of readings there, was probably very anxious about getting lymphedema. One of the things she came to me and said, she's a mum of two teenage boys, she said, I don't want to get lymphedema, and that was almost more in her face as her main concern, than recovering from the cancer. So again, we took a pre-op measurement with Donna which was four, which was very normal, within the normal range. Her reading after surgery also went up to 14, 15, which again, I reassured her was normal for post-surgical swelling. You'll see there that the readings then came down and she had quite significant and extensive surgery. She had a mastectomy and reconstruction so she had quite a lot of restricted movement. She came to me several times to have mobilisation and exercises for her movement, but each time she saw me we took a measurement. She was very keen for this reading to go down and that's why we did take it regularly. Her
reading came back down to her normal range, and even below. You'll see she took on this new faith of surviving after breast cancer, she wanted to do anything and everything that I told her would help prevent getting lymphedema. So she was doing regular exercises, massage, all sorts of things.

Then she had a chemotherapy drug called Taxol, that we know and through research it's quite well known these days that Taxol can increase fluid retention, and unfortunately for Donna, her reading went up because she was on this drug. Again, because we know it, we can say it's okay, we're going to monitor you, we're monitoring closely, because she was a bit anxious, she was wanting to be monitored. Her reading when the effects of Taxol came out of her system came back again to normal. She was going along quite well with no symptoms and then all of a sudden she had some heaviness and pain in her arm. She had what we call Axillary Web Syndrome, or some cording that occurred. Then she had a burn on her thumb which developed an infection. That infection probably triggered this increase in her L-Dex reading. She needed to be on antibiotics, and we got her very quickly into a compression garment, also doing some massage and exercises. You'll see there that her reading has come right down, actually lower than her starting point and she is very diligent with exercise and massage. She wears a compression sleeve on occasion but she certainly prevented long-term lymphedema. She's so focused in herself not to get it, that she's determined to continue this sort of management. She just feels really empowered and in control because she's being monitored. So that's Donna.

Christine is another patient of ours who unfortunately has developed lymphedema. She's 59, she started at a minus four L-Dex reading, had initially some postsurgical swelling and she was also a lady very focused on exercise. Up here this was actually back in 2009 and she got this reading of 15 and 14, where she didn't have any of this swelling in her arms, like when I took measurements with the tape measure, there was no difference between her arms and I was racking my brain - why has the reading come up? I now know it was this chemotherapy drug Taxol, but at the time, it wasn't as obvious that this was drug related. We got it down once the effects of the drugs came out of her system and she completed treatment and she was down at about three. Unfortunately for Christine, she had a reconstruction after her mastectomy and she had an infection in that that actually meant that her reconstruction failed, so the reconstruction had to be removed surgically, and that really triggered her lymphedema. We know that the lymphatic system's major role in the body is to fight infection, so when our ladies develop an infection in their arm or the chest area, that puts a lot of extra strain on the lymphatic system. For Christine, unfortunately that was really the main point for her, that we couldn't afford this surgery of removing the implant that she had,
but it meant then that she's been left with lymphedema. You'll see her reading went up to in the 30s, but it's now down very well controlled lymphedema at 19. Again, what I really like about using this L-Dex is that it tells the story, and usually most of the time when readings go up or down, that it's treatment related in the early stages, or that when someone's developed lymphedema, we can often see if they've done something in their lifestyle, that the reading's gone up, or that they're being really diligent in self-management and the reading comes down. So I find it useful as a clinician but my patients also find it useful. I have a couple of patients who come in and they want to guess what their L-Dex reading is, depending on how good they've been or how diligent they've been with their self-management.

So I said I'm focused on breast cancer and that's certainly the largest part of my case load, but I do see some other lymphedemas. This one's a lady who had secondary lymphedema of the leg following a traumatic injury. So she's 69 years old and when I saw her for the first time, she already had lymphedema in her leg, and I did an L-Dex and her reading was 9.5 initially, which is right up at the upper end of the normal and because I hadn't seen her before, I don't know how far out of the normal range she might have started. Months after we had her controlled, she came to me with a reading of 34, and she informed me that she'd been to a local club for a bingo match, a bingo game, she fell over walking outside of the club facilities, hurt her knee and her leg blew up. Then, with some diligent management and compression and therapy, her reading is actually now down at minus nine, which shows that we've actually done better than when she first came to me. We did bandaging and compression therapy to really get that leg down. So again, we can look at it as a story of the woman's journey of lymphedema.

Annette at 65 years has secondary lymphedema of the leg following vulvar cancer where they're removed lymph nodes in the groin, and you'll see there that she came to me, this time not before surgery, but up at 21 and the reading then came down following treatment, and intensive treatment, down to eight, which was back in this normal range.

A 27 year old, I've had some older ladies but I've seen some younger ladies, we've had quite a few young people with breast cancer. Kylie at 27 years had secondary lymphedema following no specific surgery to her lymph nodes. She went in for groin surgery, totally unrelated to any type of cancer, totally not planning for anything to be done or problems to her lymphatic system. So there was a complication in her surgery, but the she developed a swollen leg. For a 27 year old who's actually a fashion designer, having one leg bigger than the other is not what she wants.
She's obviously very self-conscious of this. She's very conscious, she has to wear stockings to maintain this leg. We've had to do a lot of psycho-social support with her because she's at a stage in life that she wants to develop relationships, she wants to have children in the future, she's got her life ahead of her, and to be faced with having to wear compression stockings on your leg for the rest of your life has been very distressing for her. So her leg has come down and is very stable. She's actually off travelling in New York at the moment, working in fashion, and has got a job for when she comes back as an editor for a fashion section in a magazine, but for her lymphedema is an issue. When there's days that she's on the floor doing fit-outs for the magazine, and she's on her feet, probably on a concrete floor, she knows, she ups her level of compression to reduce her symptoms.

So I guess just in summary, a few summary comments about us using this at Westmead Hospital and in private practice, that we know that pre-operative assessment and regular ongoing monitoring using L-Dex has shown to be really feasible and successful in detecting early lymphedema in a busy, multi-disciplinary clinic. So as John said, we've had this running across our three clinics, and as therapists, we're actually just considered part of the team now. We get a lot more referrals for early lymphedema from the team, they know how we are, they know who to refer to, and now, four years on, it's just routine.

We're just there and bioimpedance is just something routine that the breast surgeon says, I want you to have your blood done and your weight and your height done before surgery, fill in the hospital admission form, see our psychologist, see our occupational therapist, we'll measure your arm. Then the person comes to me, still probably overwhelmed with being told they have breast cancer, but able to sit down with me four an hour, that I can go through tailored education about lymphedema, about the risk of lymphedema and how we're going to monitor you to prevent lymphedema.

My philosophy is really empowering women so that they can feel in control and they're not just going to sit around and wait for lymphedema, we're going to actually do something. If you tell someone that if you get out there and exercise, then that's going to help prevent lymphedema, they're going to be on board to want to do it.

Just finally before I finish, I would just allude to that we're involved in research too in this area, at Westmead. We were fortunate to receive a $650,000 grant through Cancer Research Australia with the National Breast Cancer Foundation, and this is the work I do with Professor Sharon Kilbreath at Sydney University. It's a multi-centre study. There's six hospitals, Westmead, Royal Prince Alfred,
Royal North Shore, Liverpool, Campbell Town and Royal Brisbane Women's Hospital. The aim of the study is to determine the factors that predict the development of lymphedema following surgical treatment for early stage breast cancer. It's a prospective study and our actual recruitment for this study has closed. We've got 540 women involved in this study. We are also using tape measures.

The big thing that we're using is a self-report and observation from the woman herself. What we're finding is women are just really, really happy to feel like they're being monitored. So that if we see any change when they come for the study and are monitored at six months or 12 months, if there's an increase in their L-Dex reading, they get referred to go and see a therapist to have it more investigated or treated. So they're very empowered to be on this journey. So really, pre-operative assessment, regular ongoing monitoring using L-Dex is now standard best practice. It is at the BCI at Westmead at my private practice and we're setting it up here at Macquarie as well. We're really looking at early shoulder work, giving tailored education and participating in research. We've got other projects that are evolving in this whole area as well, to really look at the outcomes for these women. So thank you.

[Applause]

END OF TRANSCRIPT