ASX: IPD

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ASX RELEASE: COMMON QUESTIONS ADDRESSED ON U.S. REIMBURSEMENT

Brisbane, Australia. – **ImpediMed Limited** (ASX: IPD) ("the **Company** or **ImpediMed"**) refers shareholders to the attached transcript and link to a Board Room Radio (BRR) address.

ImpediMed provides the opportunity to listen to an audio broadcast, or read a transcript of, nine common questions from analysts and shareholders about the subject of U.S. reimbursement and its potential significance to L-Dex® technology. The questions are addressed by Patty Telgener, Vice President of Reimbursement at Emerson Consultants. Emerson Consultants is a U.S. firm that provides US reimbursement and market development consulting to the medical device industry. The firm was recently contracted by ImpediMed to assist in building coverage for the L-Dex test in the US market.

To listen, copy the following details into your web browser:

http://www.brrmedia.com/event/98402/?popup=true

It is important to assist ImpediMed shareholders to improve understanding around the U.S. reimbursement system and its importance to the Company for physicians to be reimbursed by insurance companies, of all types, for performing L-Dex readings on their patients.

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About L-Dex

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

ImpediMed

Patty Telgener, Vice President at Emerson Consultants

BRR **Good morning; welcome to BRR. This morning ImpediMed has arranged for nine common questions from analysts and shareholders around US reimbursement and its potential significance to L-Dex to be addressed by Patty Telgener, Vice President of Reimbursement at Emerson Consultants. Emerson Consultants is a US firm that provides US reimbursement and market development consulting to the medical device industry. Core competencies at Emerson include expertise in reimbursement, clinical research, regulatory affairs and the integration of all three for medical device company strategy. Emerson Consulting was recently appointed by ImpediMed for assisting in building coverage for L-Dex in the US market. So Patty I'd like to welcome you to the call today, and very much appreciate you taking the time to talk us through a few of these points.**

PT Thank you James for this opportunity today and I hope we can be of service to other Australian medical companies looking for US assistance in reimbursement, clinical trials and/or regulatory strategies.

BRR **Patty first question we have is, what changes have occurred under the Obama administration to the United States reimbursement landscape?**

PT Well the Supreme Court is actually currently reviewing the legality of the Obama healthcare plan, which is also known as the Accountable Care Act. And everyone is expecting a ruling from the Supreme Court this summer. So although the future of the Obama healthcare plan is somewhat unknown, there are certain parts of that plan that are already in implementation today and have been in effect since the fall of 2010. So for example, uninsured people that have chronic diseases are able to access insurance through high risk pools and these high risk insurance pools are specifically created to make insurance accessible until these provisions banning all discrimination for chronic disease would be fully in place and that would come in 2014. Assuming that the Supreme Court rules that the Obama healthcare plan is legal. Another very big change that's currently in existence already today is their insurance plans can no longer have exclusions for pre-existing conditions for children. So a payer cannot avoid insuring a family strictly because they may have one child with special needs or one child with diabetes. I have about five main changes James that you're going to see that are already in effect today. Payers can no longer rescind or actually cancel policies should a patient get sick, and that actually up until this healthcare plan, payers could do that. Another big change is no lifetime limits on benefits, in the past a lot of insurance companies would actually have a lifetime benefit of a $1 million for example. And if you have a catastrophic illness that $1 million would be spent very quickly. So as of today, under the Obama plan, no lifetime limits on benefits. Another big change is young adults can stay on parents' insurance plans up to the age of 26, and what this has done is really somewhat reduced the uninsured, from those kids that graduate from college until they get a job that may offer benefits. Two more changes: one is coverage of free preventive care, this is a big change. So insurance companies now are required to pay for certain preventive care services, and are also required to do that free of co-pays and deductibles. And the last change is really out of pocket drug costs for the

Medicare beneficiaries. The Healthcare Reform Act has really done this by offering rebates and also trying to decrease what they call the donut hole. Medicare beneficiaries have seen a reduction in the amount of out of pocket for those drug costs. So again those are all in effect today, a couple other major changes should the law stay in effect they will come in the year 2014, and what will change then is payers can no longer design coverage for pre-existing conditions for either adult or children. You heard already they can't do it for children, but they will no longer be able to do that for adults. And then also no increased costs based on their health status or gender. So those are some of the very specific things that are changing under the Obama administration, but I'd also like to make one more comment that I think we're finding here in the US is the higher requirement for clinical evidence in order to obtain coverage and/or payment for new technologies. So the new term is kind of Comparative Effectiveness Research, it's known by a acronym of CER, and what that's really doing is government agencies such as NIH and Medicare are actually funding clinical studies and in the past those were all done by industry and manufacturers. So that's a big change, but right now I think everyone is kind of in a wait and see mode until that Supreme Court ruling as you said is expected this summer.

BRR **And Patty given the complexity of US reimbursement, how much of a competitive advantage do companies have once reimbursement is in place for a new technology?**

PT Before I can answer the question I might just say due to the structure of our current reimbursement system, you know, it is not unusual for new technologies to experience a delay between market release and to the time that they actually achieve coverage coding and/or payment for their new technology. So for example FDA approval is required before you can apply for any codes and/or coverage but that process to get a new code or get coverage can easily take 18 to 24 months. But yes to answer your question. There are certainly competitive advantages when a new technology such as L-Dex is successful in getting, for example, a specific CPT code for their technology. Getting a specific CPT code can really create a barrier to entering for other technologies that although they may be similar they are different enough that they must get their own CPT code, which as you heard can be anywhere from 18 to 24 months at a minimum. So market acceptance of a new technology in my opinion can be significantly impacted, depending on whether or not reimbursement is in place. Hospitals and physicians they're under cost pressure so they need to make sure that they're getting reimbursement before they can adopt new technology and also patients are becoming much more involved with the purchasing decisions of healthcare dollars, as they're paying more and more out of pocket. So yes, I would say that there is a competitive advantage as companies establish reimbursement.

BRR **And Patty how much pressure are the US Government and US private insurers under to control costs? And how much additional pressure can be placed on the public to pay?**

PT I would say we are definitely seeing an increased and cost pressure from all interested parties. For example hospitals and physicians continue to see their reimbursement levels declining. Patients are also being asked to pay more out of pocket expenses, either through increased premiums on the front end, or through increased co-payments and/or deductibles. In addition, in order to control the costs of premiums, patients now are actually participating in what they may call a health savings plan, and this is a situation where they may have a deductible of up $5000 and this would mean that that patient, or that patient's family, is responsible for the first $5000 of their healthcare spending. So hence we're

really seeing patients becoming more educated consumers, because they are getting more pressure to pay for their healthcare. But when we look at Medicare, Medicare is certainly facing cost pressure, due to the increasing Government budget crisis. However interesting enough Medicare, by law, cannot make coverage or non-coverage decisions based on cost effectiveness. Those decisions by Medicare must be based on clinical effectiveness, not cost effectiveness. Medicare has also made some other changes in response to what I would call the budget crisis. For example, Medicare now has what they call a tiered system, where premiums for Medicare beneficiaries are now based on income. In the past once you became 65 and became a Medicare beneficiary everyone used to pay the same monthly premium. That has changed and now it is set based on income. So wealthier Medicare beneficiaries are now paying higher premiums, compared to beneficiaries that may have a lower income. We talked about patients. We talked about Medicare. I would also say commercial payers continue to be under pressure to reduce cost and as a result they are requiring a higher level of clinical evidence from new technologies in order to provide coverage and reimbursement. However, I would say that with strong clinical data that shows improved outcomes payers in the US both Government and commercial are still open and are providing coverage for new technology.

BRR **And what type of overall saving is needed for a US private payer to sit up and take notice of a new technology's benefit; is it .03 cents per member per month saving to an insurer significant?**

PT That is a good question James. That's a tough one, because as you heard Medicare by law is not allowed to make coverage decisions based on cost effectiveness. But as we know health economics are part of any discussion with payers on reimbursement for a new technology. However, unlike payers and government bodies outside the US, most commercial plans do not base coverage decisions strictly on per member per month cost or savings. I would summarise it by saying that it really comes down to the total value equation that payers are analysing, not just direct cost savings. But most importantly any economic story clearly must start with the clinical benefits which L-Dex delivers and then they can talk about economic savings. So in this context the economic benefit really is upside on present practice. On its own .03 cents per member per month saving for a large payer, say $10 million, would really only reflect a savings in direct cost of $3.6 million in a year. Under the assumption of L-Dex reimbursements, that's an assumption at $600 a reading; you know what this may or may not be compelling when you consider the overall cost for treating those 10 million members. However, being able to show cost savings along with the improved clinical outcomes does demonstrate that the total value equation of a new technology such as L-Dex would likely be compelling to payer.

BRR **Is insurance policy, either payment policy or medical policy, a requirement for coverage by an insurer; and does policy guarantee payment on a test?**

PT Medicare and commercial plans do not have to, per se, have a written coverage policy in order to consider that product or that service covered. Many times coverage is on a case by case basis and that's based on medical necessity for that individual patient. Frequently and especially with Medicare coverage decisions are frequently only written if payers want to actually initiate non-coverage, or if they feel there is potential for over utilisation they may ask you write a coverage policy to limit that service to only certain diagnosis, but may times we see payers not necessarily write coverage, but continue to pay that on a case by case basis. You asked about the guarantee of payment, and I would say that medical policy is never a guarantee of payment but certainly having positive written coverage can minimise the risks of non-payment, and that is assuming

that that patient met the medical necessity criteria outlined in the coverage policy.

BRR **At what level of insurance coverage does the doctor need to see to adopt regular L-Dex testing in their practice? Does the doctor need 30%, 50%, 80% of patients covered to adopt?**

PT In my experience it is not necessarily what percentage of patients have coverage for a new technology, but it is more the overall amount of reimbursement and level of payment that that physician receives. In general, doctors are prepared to introduce a new technology when it is somewhat at a breakeven point, if he or she were to run the L-Dex test for example on all patients. For example, if the commercial plans are covering a new technology but Medicare may not yet adopt this coverage, that physician may still utilise that technology and consider it profitable because the payment rates for those commercial plans are sufficient. In some regions, such as California or Florida, which have a very high Medicare population, that breakeven point might come from having payment and coverage from Medicare alone rather than the commercial payers. So again I would not say it comes down to a certain percentage. Another change I referenced in the previous question is really how more and more patients now have what they call high deductible insurance plans. In that case the patients are the decision maker as to which treatments and procedures they want to undergo and hence pay out of pocket. Patients that are candidates for L-Dex may be very likely to pay out of pockets since they would be occurring the high out of pocket expenses should they develop lymphedema. So it is really important to kind of look at the total picture when understanding the physician's rate of adoption for a new technology.

BRR **Patty when effective coverage does occur will it happen US wide all at once or will it happen locally and regionally?**

PT For Medicare I believe that coverage will most likely occur regionally with individual decisions being made by what we call the 15 Medicare Administrator Contracts, that's acronym is MACS, and each of those 15 MACS have a medical director and they can make coverage decisions independent of the other MACS. I believe Medicare most likely will occur regionally and that's usually what I recommend a manufacturer do, and then go to CMS at a national level. However, some of the commercial plans such as Humana, Aetna, Cigna, and Anthem for example, are what we would consider national plans and once they make coverage decisions that would be on a national level. Then we also have many Blue Cross/Blue Shield plans that would be regional or local, like Blue Cross/Blue Shield in Alabama would only cover that state. Other Blue Cross/Blue Shield plans may cover several states and so I would consider that kind of a combination of regional and/or local.

BRR **With respect to accountable care, what is it? And how long will it take to roll out into the US system?**

PT Well first of all, let me explain "accountable care". Accountable care organisations really are a network of providers such as primary care physicians, physician specialists, hospitals and/or home care agencies that actually share responsibility for a given subset of patients. The intent of the Accountable Care Organisations or ACOs as you may hear it referred to here in the US their intent is really to give doctors and hospitals financial incentives to provide quality care yet keeping down cost. However, conversely, these same providers may actually see financial losses if they don't meet those benchmarks in patient outcomes and care co-ordination. And this is very different because historically our doctors and hospitals have been paid on a fee for service where providers are paid literally per test or procedure. But the move to Accountable Care Organisations would

reward providers with a share of the cost saving, so they would no longer be paid per test or per procedure but actually overall taking care of that patient. As far as the timing, actually Medicare has some ACO demonstration projects already underway. On the commercial side we have organisations such Kaiser, Cleveland Clinic, Mayo Clinic, are already set up similar to an ACO. In my opinion L-Dex is very well suited for the ACO model, because in that model really all financial incentives are aligned both physician, hospital and payer, to provide the best patient care on the front end, to avoid the long term complications. And this is really evident by the early adoption of L-Dex by several you know large healthcare systems similar to an ACO.

BRR **Patty a final point, do you see lymphedema becoming a quality metric in breast cancer care for clinical outcomes?**

PT In my opinion, yes. Lymphedema as a quality metric would very much align with other quality and performance metrics already implemented. As you know complications of lymphedema can be very costly. Quality metrics would incentivise physicians in hospitals to provide the best care so they could actually avoid lymphedema. But in order to do this, in order to really have it become a quality metric, speciality societies will need to be the driver on lymphedema treatment detection guidelines. They would need to push for quality measurement around breast cancer that would increase awareness and proactive detection of lymphedema and really make that the standard of care, rather than just treating the lymphedema --be more aware and proactive to actually prevent lymphedema. And I think that could be done and measured well in the quality metric.

BRR **Well Patty we really appreciate you taking the time to talk us through these questions, I'm sure that investors and shareholders will find it of great value, and once again appreciate your time this morning.**

PT You are welcome, James. Thank you for the opportunity.