

ASX Announcement

26 February 2021

Business update call transcript

Sydney, Australia – 26 February 2021: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) is pleased to release an edited transcript from its business update call held at 4:30pm (AEDT) on Thursday, 18 February 2021.

The business update presentation which Nigel talked through on the call was released to the ASX on Thursday, 18 February 2021.

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Operator: Thank you for standing by, and welcome to the OncoSil Medical investor update. All participants are in a listen-only mode. There will be a presentation followed by a question and answer session. If you wish to ask a question you will need to press the star key, followed by the number one on your telephone keypad. I would now like to hand the conference over to Mr. Nigel Lange, CEO. Please go ahead.

Nigel Lange: Good afternoon everyone and welcome to this investor update. Thanks for being here, and I appreciate the opportunity to inform you about what has transpired over the past six months at OncoSil, and more importantly about our future plans. I will take questions at the end of the presentation. So, on slide 2, the OncoSil device, as everyone knows, is a novel therapy that represents an exciting and meaningful opportunity to make a difference to the lives of patients suffering from locally advanced pancreatic cancer. In my opinion, we're uniquely positioned to capitalise on the fact that not much advancement has occurred in this space for the past four decades. There's truly an unmet medical need for these patients as the prognosis is generally quite poor.

Over to slide 3. As for my own background, I've been in the healthcare industry for nearly 40 years, with the last 22 years in the area of medical devices and I look forward to the journey ahead at OncoSil. I have a clear understanding of what it takes to successfully launch a medical device in Europe and the United States, having successfully launched both Y-90 technologies, TheraSphere and SIR-Spheres. Furthermore, I've spent a considerable amount of time in Australia with Sirtex and am therefore familiar with the Australian market and business environment. Sirtex was indeed an exciting and fulfilling journey, and I have no doubt that this will indeed be the case at OncoSil. I am thankful to the OncoSil Board for this opportunity and look forward to building this business and creating value for all of you as shareholders.

Over to slide 4. So, what is it about OncoSil that has attracted me to accept the position of CEO? Why am I so excited to be leading this organisation? The reason is that we have a technology which offers encouraging early results for the medical community, the HDE, surgeons, medical oncologists, and gastroenterologists, not of course forgetting about our endgame, which is to provide hope for patients suffering from locally advanced pancreatic cancer. Encouragingly, there were some unexpected findings

in the PanCO study, where nearly 24% of patients were downstaged to resection. Most of you are likely aware that downstaging patients to surgical resection represents perhaps the best possible chance for an increase in survival for patients, as it is potentially curative.

OncoSil is uniquely poised, therefore, to become a market leader in pancreatic cancer therapy. I've been able to assemble an experienced commercial team in Europe and the United States. All have worked in big pharma and in medical devices with a focus on oncologic interventions. I was fortunate to be in a position to choose the best possible talent to help drive the business forward. Some are ex-colleagues, while others were former competitors, all of whom have proven track records of success. In fact, I've had the pleasure of working with most of the OncoSil team in Sydney, and I consider it to be an honour again to be working alongside them.

Moving on to slide 5. So, what has happened over the past six months? What have we accomplished? The OSPREY registry, which I'm sure you're aware is part of our labelling and has been approved by the regulator for use, and in addition has now also been approved by the central ethics committee in the UK, which means we can commence with patient treatments. We continue to prepare the data package for FDA in support of the HDE application. Furthermore, TGA had made an additional request which the team has completed and forwarded back to TGA last month.

Unfortunately, COVID has delayed our launch and impacted our ability to commercialise the OncoSil device to plan. This has not meant that there is an inactivity or complacency. The team continue to focus on targeting institutions, key opinion leaders, and thought leaders in this area. Meetings and presentations take place on a daily basis, as it is important in increasing awareness of the OncoSil device. There's no absence of interest from the medical community. In fact, in some situations we're in a bit of a pull, because the team is able to leverage the fact that they have had existing relationships with many of these thought leaders.

All relevant functions, as you've noted from the presentation, have been resourced, including key account managers, country managers. We've brought on a chief medical officer, global head of medical affairs, and somebody who is taking care of market access and reimbursement. In addition, we have also recruited the training function.

So, moving on to slide 6. What are the strategic priorities for OncoSil in EMEA and APAC? Our immediate focus is on short-term revenue growth and generating cash flow. The UK team will continue to support those centres in and around London who are active in treating self-paying, private patients. Similarly, the team in Australia will provide the necessary support to ensure a continuum of patients having access to the treatment in New Zealand.

Public reimbursement is one of the critical success factors for the EU business. Overall, the public sector represents over 90% of the total market. Priority will be given to the markets of Germany, the UK, Netherlands, Belgium, and Switzerland, where the second wave of activity around public reimbursement will focus on France, Italy, and Spain. The primary aim of this activity is to ensure the inclusion into regional and national treatment guidelines, which require a higher level of evidence and tend to satisfy the requirements of various payers such as NICE, which is the National Institute for Clinical Excellence in the

UK, HAS in France, and IQWiG in Germany. We can only achieve this through a clinical development pathway ensuring that studies we conduct in the future provide a basis for comparison, as this is what payers expect.

Lastly, there are downstream benefits to having a CE mark. It provides us with additional leverage as it serves as a basis for obtaining regulatory approval in markets that recognise the validity of CE marking. So, these are markets that would exist in the Middle East, for example, where they will accept the fact that we have a CE marking approval, and we can use this as a basis to obtain regulatory approval in those markets.

Moving on to slide 7. What are the strategic priorities for OncoSil in the United States? Filing for the humanitarian device exemption, or HDE, perhaps represents the most expeditious route to market in the US for a medical device provided that annual patient numbers do not exceed 8000. Filing for distal cholangial or bile duct carcinoma made strategic sense for OncoSil. This patient population is approximately 1500 per year in the United States. For the HDE, there is a requirement to demonstrate the safety of the device. However, it is exempt from effectiveness requirements but must be intended to benefit patients. The HDE approval will also mean that the product will be reimbursed from CMS, which is the Centre for Medicare and Medicaid Services, once the product has been approved by FDA.

Third-party payers, I would like to inform you, generally follow the lead of CMS, and provide subsequent reimbursement coverage to their patient subscribers.

In addition, I am pleased to inform you that we have engaged the services of a highly respected former colleague in the United States to proactively pave the way for the application of a dedicated HCPCS code, which is a product specific code in addition to associated procedural codes that cover the procedure and ensure that it is reimbursed.

Lastly, in terms of the PMA, or pre-market approval, obviously we'll capitalise on the breakthrough device designation. This allows for consultation with FDA on matters such as clinical trial design to ensure that all parameters are met in an effort to support the PMA in locally advanced pancreatic cancer. It is important to note here that the recent CMS final rule has afforded to devices a minimum reimbursement pathway of four years once approval is obtained.

Over to slide 8. So, as a wrap up, I would like to draw your attention to the recent additions to the team who, in my opinion, are vital to the success of OncoSil. That is, Dr Ralph Peters, who has joined as Chief Medical Officer, Mr David Turner, who is Head of Medical Affairs, and Mr Olaf Michaelsen, who is the Director of Access, Reimbursement, Economics, and Assessment. As you have seen, all have considerable experience and are recognised experts in the oncology space. I am delighted to have them on board and firmly believe in their abilities to help drive the business forward.

The success of this business won't be measured on first sales, but rather on month-on-month and year-on-year growth. It's about building a sustainable business model, but more importantly it's also about our people and their dedication to serving the needs of patients. Thanks for your attention, and I will now take questions.

Operator: Thank you. If you wish to ask a question, please press *1 on your telephone and wait for your name to be announced. If you wish to cancel your request, please press *2. If you're on a speakerphone, please pick up the handset to ask your question. Your first question comes from Shane Storey from Wilsons. Please go ahead.

Shane Storey: Good afternoon, Nigel. Thanks for taking my questions and thank you for the presentation. Could you please provide an update on where OncoSil sits today with respect to manufacturing, logistics, and the ability to supply into both commercial and clinical sites?

Nigel Lange: Manufacturing takes place here in Germany. The targets are irradiated down at Lucas Heights in Australia. The supply chain is robust enough to enable us to serve markets in Europe, APAC and the United States. Of course, there are challenges during these times of COVID, namely around transportation routes and not as many flights obviously being available, but the team are on top of that. We have a team that takes care of this on a daily basis, so we're well equipped. We have been able to get doses down under, as I've said, and within Europe there is no issue in terms of moving our product. Our product flies as dangerous goods, but there have been no restrictions placed on that.

In terms of manufacturing capability, yes, we've got capacity to be able to supply as we ramp up over the next three years. We don't believe there's any risk in that at all. I hope that answers your question.

Shane Storey: Yes, it does. I guess my second question, Nigel, just given your background at Sirtex, and as an incoming CEO it's always interesting to get a new perspective, I guess, of a piece of technology that a lot of us on the call will have covered for some years, so at Sirtex your challenge, I guess, was - you had a salvage therapy that was being pushed up into higher lines of treatment. How do you mentally position OncoSil's device in your mind, as maybe a device that possibly deserves to be offered sooner rather than later to patients, and how do you think you'll go about influencing physicians, particularly medical oncology, and the way they think about this device? That's all, thank you.

Nigel Lange: Okay. Well, look, these patients have a much poorer prognosis than patients that we were treating at Sirtex. So, yes, we will endeavour to treat patients much earlier, so let's remember that we're after a segment of this patient population that represents roughly 40% of the total patient population. The difficulty with pancreatic cancer is that patients present rather late. However, we believe that we're not competing with existing standard of care chemotherapy. In fact, we're synergistic, so there's the combinatorial effect that we've got, and I believe that the data that we've got supporting the downstaging to resection is strong enough to convince medical oncologists that they should be using this as early as possible.

So, the PanCO results bear that out. Again, that was an unexpected finding, but we are comparing to the existing published studies that are out there in terms of phase II and phase III. So, I'm confident that we will be able to position this in the minds of oncologists and gastroenterologists, and particularly the surgeons, that this has a much greater benefit when we can use it earlier in the treatment pathway of the patient.

Shane Storey: Thanks. That's really helpful. Thanks, Nigel.

Nigel Lange: Thanks, Shane.

Operator: Your next question comes from Melissa Benson from Wilsons. Please go ahead.

Melissa Benson: Good afternoon, Nigel. Thanks for taking my questions. I just wondered around the priorities you noted being short-term revenues, particularly in the UK. I was just wondering if you're able to give us some more colour around those nine UK hospitals. You mentioned supporting them to facilitate increased patients. Just how you're going about that.

Nigel Lange: Okay. So, the team is engaged particularly at those institutions that have the ability to treat private patients. The activity around that is designed to inform the catchment area, so specialists in the catchment area that have patients, that have the ability to pay for the therapy, can be referred into these hospitals. So, we're also working with the marketing teams at the private institutions so that they can go out and promote this. In addition, we're also working with patient advocacy groups to inform them that the therapy is available. So, the team remains very, very active in supporting not only patient advocacy groups but the marketing arm of these private institutions as well.

Melissa Benson: That's great, thank you. Just one other question, more around the HDE approval for the US. Just if you were able to give us any - we noted that you're preparing the data package. Is there any kind of information around timelines or what's still required that might be delaying anything?

Nigel Lange: I can't give you anything specific to timelines but the FDA have asked that we update the data, and that's exactly what the regulatory team is doing now. We've been asked to provide updated data from the PanCO study, together with data from OncoPac-1, which was a study that took place in the United States. Both studies have closed and the study reports are now being written. The 75-day clock reset will occur once we submit the clinical study reports. So, the reason for the major delay, I want to just inform you and everybody else, was related to COVID as the access to hospitals is not permitted, so we couldn't get in there to close out the study.

Fortunately, OncoPac-1 is closed and it closed at the end of November, so that gives you an idea around timing. But needless to say that the study reports are now being written, and these will be submitted, but I can't give you a specific time. It's in the not-too-distant future.

Melissa Benson: Thank you, that's very helpful. That's all my questions, thanks.

Nigel Lange: Thanks, Melissa.

Operator: Your next question comes from Jim Mac, a private investor. Please go ahead.

Jim Mac: Hello, Nigel.

Nigel Lange: Hello, Jim.

Jim Mac: I have two questions regarding the regulatory approval in Australia. Firstly, have you had any indication from the TGA as to a timeline of a reply after the request for further data last month? Secondly,

if or when that is approved in Australia, are there physicians and hospitals ready to go to use the product here in Australia?

Nigel Lange: Well, I can tell you that, as you know, with the PanCO study, we had participation from Australian sites, so the good news is that those sites have already been up and running, because they've participated in the trial. So, as far as training and that is concerned, that's actually a major benefit because they're already positioned to be able to start the treatment once we do obtain an approval, but I can't unfortunately give you anything specific on the timeline back from TGA at the moment.

Jim Mac: Okay, thank you.

Nigel Lange: You're welcome.

Operator: Your next question comes from Tony Ciro. Please go ahead.

Tony Ciro: Thank you, Nigel, for taking my call. You've mentioned that really the key, the key for OncoSil's commercial success, must be to obtain public reimbursement. Are you able to clarify what type of strategies you're looking at in achieving that objective, because all we've heard so far is that you're looking at getting some private payers to pay for it, which is obviously a very expensive amount of money for the device. You mentioned that you're going to be looking at some clinical studies. Could you elaborate on that, please?

Nigel Lange: Absolutely. As I stated, we're going to build this business based on when we are able to achieve reimbursement in the public sector, right, because it represents the majority of the European market. To put this in context for you, we're currently sitting with results from a single-arm trial, which is the PanCO study. Reimbursement from the public sector requires a hard endpoint but that endpoint also has to have a comparator i.e., the OncoSil device versus something else. Subsequently, we need to be able to go down a clinical development pathway, which will mean that we will need to conduct a randomised trial.

We need to be able to increase the level of evidence that we have so that this can be reflected in regional and national guidelines. For example, in Europe, that would be the ESMO guidelines, which is the European Society of Medical Oncology, and then further to that we will also be looking at national guidelines, so that could be, for example, the S3 guidelines in Germany. In the United States, the national guideline would be the NCCN guidelines. But this can only be effected once we have the results of a randomised clinical trial.

In addition, there are opportunities in specific European markets which offer OncoSil the possibility to conduct nationally sponsored studies, and these are fully funded by the government. They will be in a position to meet the requirements of the payer community. An example of this would be a sponsored study by the GBA in Germany, because the device now shows that we have possible or probable benefit, but it requires further investigation. That is recognised, so that's one pathway.

There's another pathway in the Netherlands, for example, where there is something called potentially promising care, and the ZiN, who are the body that is responsible for reimbursement in the Netherlands,

this is another possible pathway that we can take where a locally conducted trial will be performed, and it will be done as an IIT through a sponsor institution, but that is something that OncoSil ticks all the boxes, where we can participate in that. So, I hope that answers your question.

Tony Ciro: I just want to follow up on that. You're talking about a randomised trial in order to support the data and the evidence for public reimbursement. How long will this take?

Nigel Lange: I can't give you an exact timeline on that, Tony. I appreciate the question and understand your frustration. One of the things that I'm very conscious of having lived through this at Sirtex was a trial that took years to complete, and also, once it did report out, the space had moved out from underneath us. So, in designing trials here, we need to design trials that have the ability to meet the requirements of the payers, have a hard endpoint, but are not trials that are going to take years to recruit. We are in a position to take advantage of the fact that we have this breakthrough designation. We don't need large patient numbers. Let's remember that the PanCO trial was conducted in a few centres in Australia and a couple of centres in Europe. We now have the ability to be able to go out and do these trials at centres that are very specialised in this area.

So, I firmly believe that we have the ability to accelerate the recruitment into any randomised clinical trial, much more so than in the early going when we were involved in the PanCO study.

Operator: Your next question comes from John Hester from Bell Potter. Please go ahead.

John Hester: Hi Nigel, just a follow-up question to Tony's from a minute ago. You talked about the public reimbursement being subject to a randomised trial, and we all understand that. What about the retrospective literature study that was conducted for the purposes of the approval? Is that of no merit in getting that public reimbursement moving?

Nigel Lange: In order to satisfy the likes of NICE and HAS an IQWiG, as I mentioned during the presentation, they will not take a naïve, indirect comparison. However, we have the ability to do an adjusted naïve indirect comparison which will potentially satisfy their requirements. That's something that we have started now. That's something that Olaf Michaelsen has started. So, that is currently being worked on, and it's being worked on with the statisticians as well.

So, there is the possibility that we can use that, yes.

John Hester: Then just a follow-up from me. The approval came through in March, and COVID hit and all these sorts of other delays have happened. I'm just interested to know the state of play in the UK as we stand here today. Are there further regulatory barriers to the use of the product, and are they currently screening for patients, and if so, can you paint a picture for us as to when can we expect some revenues here?

Nigel Lange: Thanks for that question, John. I'm confident that we will get first patient dose sales in the first half of 2021 in Europe, and of course this is going to be in the UK. From a regulatory point of view there are no restrictions. For the OSPREY registry, the only thing that is left to be done now are some contractual obligations. Firstly, you get two passes. Everyone understands it's part of our labelling.

Unfortunately, when we submitted the OSPREY registry for ethics approval in the UK it got knocked back because they considered it to be unethical that the regulator mandated that patients agree to consent in order to get treated. We went back to the regulator and convinced them that we are not going to get this through an ethics committee. You need to change the requirement here to say that it's not mandatory for a patient to consent in order to get treated.

So, that resulted in about a four-month delay. We resubmitted to ethics. It's through ethics now and it's approved. All of the radiation licences at the institutions that we're targeting are approved. They can certainly move ahead. So, as I mentioned, there are only some contractual obligations left because obviously their legal teams need to review this as well, and I think that's quite imminent. So, I think we're very confident that we're going to get revenue in the first half of this year.

John Hester: So on the regulatory side, you're on the precipice there. What about with the two key other groups, patients and also the treating physicians? Where are they now? The trial was a couple of years ago now. Where are they positioned and have you primed them up ready to go?

Nigel Lange: Oh, absolutely. Just because there's COVID, it doesn't mean to say that anybody has stopped. I can tell you that the team are very active in all markets that we've targeted, not just in the UK. But look, there is no absence of interest in the technology, from the medical oncology side and I can tell you surgeons in particular are very excited about the resection data from the PanCO trial. Surgeons are going to be one of the primary drivers of this technology too.

John Hester: Yes, excellent. Well, thank you very much for that update.

Nigel Lange: You're welcome.

Operator: Your next question comes from Shane Storey from Wilsons. Please go ahead.

Shane Storey: Hi, Nigel. Regarding the comparative evidence, I understand that you're thinking randomised control studies there, but should I think of that separate to the PMA-directed clinical activities you might have planned in the US? Is there a scenario where you could recruit a trial across jurisdictions with the same intent?

Nigel Lange: Shane, that's absolutely correct, and that is our intent. We aim to kill two birds with one stone. Not only will it satisfy the payer community in Europe, that's our intent, is to design a trial where obviously we can cross borders here. That trial can also serve as a basis for the PMA submission in the US.

Shane Storey: That answers my question.

Operator: Your next question comes from Jean-Marc Muller from JMS Invest AG. Please go ahead.

Jean-Marc Muller: Yes, good morning Nigel, can you hear me?

Nigel Lange: I can hear you, thank you.

Jean-Marc Muller: That's great, thank you. Thank you for taking my questions. It seems that the public reimbursement is a bit further down the road, given what you just explained about additional studies. So, I would like to focus a bit on the private payer market for now. Can you give us some numbers? How big is this market? I understand that the whole population is maybe 50,000 patients, 10% is private payer, so that will be 5000 patients, and that - if that is correct, how long would it take you to really bite into this market? Can we expect that you'll treat in your next fiscal year 1,000 patients plus or so? Is this how the plan goes? How fast can you ramp it up now in the UK, in Germany, and in the other jurisdictions where you have the approval? Thank you.

Nigel Lange: Well, I want to be perfectly candid with you. A lot of the private patient business is going to be in the UK, in greater London and in and around Manchester. There is not much private market business in continental Europe. It's less than 10%. The raft of private patients across the United Kingdom will not be quite the same as continental Europe. So, the only possible exception to that would be in Switzerland, and potentially in Luxembourg, which are smaller markets.

However, in other markets such as Italy, for example, where the reimbursement system is a little bit different, we're able to focus on hospitals that have carve-out budgets within specific departments, and that's potentially where we see the low-hanging fruit as well. There is some potential for private market business in Germany. It's limited. Germany is the biggest market, and that obviously is going to be a big focus for us, but to generically say that there's 10% of the patients that are private market across Europe is a little bit challenging, I think, because it varies from country to country again.

However, what I think is important to recognise is the situation in the US. Once the HDE is approved in the United States, then the CMS, which is the Centre for Medicaid and Medicare Services, has no choice but to reimburse the product. That's why we've proactively started now to ensure that we have a dedicated code and associated procedural codes for the OncoSil device, so that once this approval is obtained, we can hit the road running there, because that is an easier road to obtaining reimbursement.

Jean-Marc Muller: Given the cost structure as it is now, how many commercial patients do you need to actually break even?

Nigel Lange: I can't give you that number off the top of my head.

Karl Pechmann: It's probably a little bit early for us to be talking about patient numbers to get to break-even, because there are efficiency gains that come with increased patient doses. So, it's a little bit too early in our commercialisation to go into that level of precision.

Jean-Marc Muller: Okay. But is it fair to say that there will be most likely another financing round eventually, probably in next fiscal year, given how things are progressing and given the cash burn at the company?

Nigel Lange: As you know, as at 31 December 2020, we had a cash balance of roughly \$18 million and based on our current burn rate we've got roughly six quarters of runway, but of course this doesn't account for any impending sales and our flexibility to ramp up or down cost while we commercialise.

Jean-Marc Muller: Okay, cool. Thank you very much.

Nigel Lange: You're welcome.

Operator: Your next question comes from George Larcos. Please go ahead.

George Larcos: Nigel, good afternoon. Thank you very much for the presentation. An RCT with 190 patients is probably going to take at least a couple of years before you can get the data out to the wider medical community. When one looks at authoritative medical reviews on pancreatic cancer, particularly locally advanced pancreatic cancer, OncoSil, despite its appeal, scarcely gets mentioned, which is a real problem, I think, because the device seems to work and yet authoritative reviews scarcely mention it.

So, I think this could be a major problem for the company in terms of getting it out to the wider medical community. So, let's say you've got about 24 months before an RCT dataset becomes available to the wider community. What are you going to do in those 24 months to try and get a little bit more traction in the oncologic community so that people are more aware that it's available beyond the participating institutions?

Nigel Lange: In my own experience, and I've seen this with Sirtex as well, the trial is actually a catalyst to generate interest by the medical community. It creates the awareness that we need in order for us to disperse the technology to a wider range of clinicians. So, I see potential spin-off here, because we've got the ability to reach wider with participating clinical sites, and then those sites that are participating in a trial will have other sites referring into with potential patients. So, I don't envision that we're going to be in this position for too much longer. As a matter of fact, I think the team has only really just gotten started from the commercial side of things.

For example, in Germany, we have 30 centres, all of whom are recognised in this area for treating and conducting complex procedures related to locally advanced pancreatic cancer. That's just one example. So all of these are targeted institutions for us. We've had meetings with the majority of them. There is interest out there now, it's just a matter of us developing this pathway forward in terms of how we're going to handle this clinically.

George Larcos: Thank you. My second question is this. With cholangiocarcinoma, it's fundamentally a different disease than locally advanced pancreatic cancer. You don't really have a mass to inject into endoscopically. So, what is the technology that you're going to employ? Are you going to coat a stent with P32 and insert it up a bile duct? What is the proposed mechanism for treating bile duct cancer? You can't see it endoscopically. You might be able to see it with an ERCP or something like that, but it's a fundamentally different type of disorder. So, it presents challenges, at least to my perspective, in terms of how you're going to get the P32 into it. That's what I'm asking.

Nigel Lange: Well, it's interesting that you say that, because I've just had this discussion with a very prominent surgeon. He was intrigued that we filed for bile duct, and his comment to me was, well, if you can show me anybody right now that can distinguish between bile duct and locally advanced pancreatic cancer, he said, I'd like to meet them, because it really doesn't exist.

We've worked with FDA on this as well, and they recognise that there is the potential here in terms of being able to treat these patients, so they've accepted the fact that we can do this effectively. I can certainly get back to you if you're asking a more medically related question and I can have my Medical Director get back to you if you like. If you want to reach out to me, we can go over that specific question with you at a later point in time.

George Larcos: Thank you.

Operator: Your next question comes from Vicky Grove. Please go ahead.

Vicky Grove: Yes, thanks for taking my question. Getting back to the PanCO study, I reckon it's huge that almost a quarter of the patients were downstaged to surgical resection. Can you tell us what has happened to those patients since? Are some still alive, and what has the follow-ups been?

Nigel Lange: Yes, indeed, some of those patients are still alive. This study is closed but we'll certainly hear about how those patients are doing. Yes, 24% was the actual downstaging to resection. There's been another paper recently by one of the participants in the study who was also treating patients outside of the study, and I'm happy to report that the results of this particular paper are running at 42% resection rate. So, again, that's very encouraging because the majority of the patients are truly R0 resections, which as you know is the best possible outcome that we can have from a surgical intervention.

Vicky Grove: So, why is there no follow-up of those patients? Because surely, if some of them are actually achieving cure, that would be huge.

Nigel Lange: There is follow-up on those patients. The study has closed, but those patients, some of those patients, are still alive today. The patients are still being followed.

Vicky Grove: Okay. Thank you.

Nigel Lange: You're welcome.

Operator: Your next question comes from Otto Buttula from Webinvest. Please go ahead.

Otto Buttula: Hi Nigel. The previous CEO mentioned liver many times. We haven't heard much about liver for quite a while now. Obviously you've got other rivers to row down at the moment, but is that still part of the company's plan?

Nigel Lange: We've got, obviously, limited resources, and we need to focus our resources where we have or are targeting regulatory approvals in the short-term, so in the area of locally advanced pancreatic and distal bile duct in the United States. That's the immediate plan. I'm not suggesting to you that we won't look at liver in the future, but for now, in the short-to-medium term, we're not going to be entertaining anything to do with liver during this initial period. But I won't discount it to say that we will never look at it.

Otto Buttula: Thank you.

Operator: Thank you. There are no further questions. That does conclude our conference for today. Thank you for participating, you may now disconnect.

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Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable bile duct cancer. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$3b.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial

results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.