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Circadian Technologies Limited (ASX: CIR) recently announced that it has signed an agreement with Healthscope Limited (ASX: HSP) to commercialise a novel diagnostic technology for Cancers of Unknown Primaries (CUP). What is significant about this deal?

CEO & MD Robert Klupacs

This deal is significant in two ways. Firstly, it will bring to hospitals a major advancement in diagnostics for an important cancer class. Patients with CUP will be able to be diagnosed more effectively, so they can receive more appropriate treatment. Secondly, for us, it's an important first step in the commercialisation of the CUP diagnostic technology. We expect to receive revenues from sales domestically, but we also retain all commercialisation rights in the major markets. In this respect, the present deal is an important stepping stone to larger commercial opportunities for the product.

We're hoping to have this test available in the next 12 to 18 months.

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Dr. Bowtell, you are a co-inventor of the technology licensed to Healthscope. What is CUP and what is the benefit of this new technology to cancer patients?

David Bowtell, Director of Research, Peter MacCallum Cancer Centre

CUP is cancer found in one part or organ of the body, but originates from another unknown part of the body. This scenario involves patients with metastatic cancer

in whom the cancer may have spread throughout the body but the organ the cancer has originated from is uncertain.

The benefit of this new technology to cancer patients is that it will allow oncologists to have a better idea of what the primary cancer is, even if in an advanced stage, in order to choose appropriate therapy for the particular type of tumour and hopefully yield better results.

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How prevalent are CUP? Are they a common form of cancer?

David Bowtell, Director of Research, Peter MacCallum Cancer Centre

CUP is ranked the seventh most common cancer in Australia. This makes it more common than leukemia. And it's the fourth most common cause of cancer deaths based on Cancer Statistics Australia 2007. It's a condition that has a low level of awareness relative to other diseases partly because it's difficult to categorise. It's also a significant health problem and particularly important as CUP is typically difficult to treat because of uncertainty about the optimal treatment.

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Can you explain how this technology differs from the standard diagnostic techniques currently used?

David Bowtell, Director of Research, Peter MacCallum Cancer Centre

The standard techniques currently used to identify the site of origin of cancers are a mixture of pathology and imaging such as positron emission tomography (PET) or CAT scans. Unfortunately, in the case of CUP, these tests do not reveal the primary tumour.

The potential advantage of this new technology is that, instead of relying on a single marker for identifying the site of origin, this test employs hundreds of markers and utilises patterns of gene expression within a tumour to identify its organ of origin. By taking a biopsy of the tumour, the diagnostic method can be applied immediately using quantitative methods to identify the tumour type. We believe that this will shorten the diagnosis time and lead to use of the most appropriate treatment.

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Can you describe the deal structure and how Circadian will benefit from commercialisation of the test?

CEO & MD Robert Klupacs

Healthscope is one of the largest diagnostics providers in the Asia Pacific region. They're a leader in providing breakthrough technologies such as the CUP tests to patients. We are pleased to be partnering with such a respected company. Healthscope will clinically validate and market the test throughout Australia, New Zealand, Malaysia and Singapore and will be responsible for all costs associated with this activity.

Circadian will receive upfront and milestone fees. Financially, the most significant part of the deal is the royalty we will receive on sales of the test, and

we've also negotiated guaranteed minimum royalties. Based on published deals throughout the world, the percentage royalties we'll receive are very much toward the upper end of the range one would see in the diagnostics industry for a licensing deal. I believe that this is reflective of the novelty and value of this technology.

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Circadian will retain rights to market the test to the remainder of the world. What are your plans to market the test globally?

CEO & MD Robert Klupacs

We'll retain rights not only to the tests but also to any improvements that may be developed by Healthscope. This represents an enormous commercial opportunity for us to take the technology overseas with a partner or one of the major national or international diagnostics firms.

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What is the potential market for CUP diagnosis globally?

CEO & MD Robert Klupacs

In the US alone, CUP represents about 4 percent of all cancers or around 60,000 cases per year. Typically, the market for a diagnostic test is larger than the number of people who have the condition. The sales price for a test of this type would be between US\$1,000 and US\$2,000 per test. Based upon these factors, it's reasonable to expect that the worldwide market may be well in excess of US\$100 million.

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The CUP diagnostic test was developed in collaboration with the Peter MacCallum Cancer Centre. How will Peter MacCallum benefit financially from the agreement?

CEO & MD Robert Klupacs

Our deal with Peter MacCallum is structured as a partnership. We funded the majority of the earlier research at Peter MacCallum and will pass on 40 percent of the net revenues we receive. In addition, we've negotiated with Healthscope that Peter Mac will pay a substantially reduced fee for the test. So we've been able to ensure that Peter Mac will have more economical access to this important new technology.

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Beyond CUP, are there other cancer types where this technology may be useful?

David Bowtell, Director of Research, Peter MacCallum Cancer Centre

Yes, the same technology could be applicable to virtually *any* cancer type. Used in a different setting clinically, for example by identifying tumour types based on their pattern of gene expression, it may be possible in the future to identify a particular chemotherapeutic agent to which the tumour would be more responsive. This is one aspect of the new diagnostic technology that clinicians are excited about - the potential to use more targeted treatments based upon the specific nature of a given tumour.

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Can you describe how the availability of this test may change clinical practice?

David Bowtell, Director of Research, Peter MacCallum Cancer Centre

Firstly, confirming the origin of the cancer should lead to more appropriate treatment for an individual with cancer. Secondly, the process to identify the origin of a particular cancer is expensive and may be uncomfortable. A test that rapidly diagnoses the site of origin should mean that patients are receiving appropriate treatments, and costs and patient morbidity are reduced due to fewer investigations to find the site of origin.

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Since you took over as CEO last year, Circadian has undergone a significant transformation from a broad-based technology incubator to a specialised developer of cancer treatments. How does this agreement with Healthscope fit into your strategy? How will it add value for shareholders?

CEO & MD Robert Klupacs

We are now highly focused on the development of antibody drugs to treat cancer. We have a very promising pipeline of three pre-clinical drugs (VGX-100, VGX-200 and VGX-300) whose development is advancing rapidly, and two partnered programs (Trinam[®] with Ark Therapeutics, which is in Phase 3 trials, and a VEGFR-3 antibody designated for product development with Imclone Systems). We consider this one of the best pipelines in Australian biotechnology.

While pushing these programs forward, we've also been divesting and monetising a number of the legacy assets from our earlier technology incubator model. The CUP diagnostic is one that we intend to continue to develop and exploit due to the strategic alignment between cancer diagnostics and cancer treatment. This deal should provide us with cash flows to further strengthen our financial position. The technology itself may also allow us to accelerate our therapeutics programs, for example by improved patient selection for clinical trials. Lastly, it may spawn new diagnostics opportunities as well. These are major advances in the value of our technology assets.

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Thank you Robert and David.

For more information about Circadian Technologies, visit www.circadian.com.au or call Robert Klupacs on +61 3 9826 0399

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