ASX ANNOUNCEMENT: 15 September 2011

CEO on FY12 Outlook and VGX-100 Progress

Open Briefing with CEO & MD Robert Klupacs

Circadian Technologies Limited
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Circadian Technologies Limited (ASX:CIR, OTCQX:CKDXY) is an Australian biotechnology company developing biologics-based therapies for the treatment of cancer and other serious human illnesses. Circadian owns a portfolio of products and intellectual property related to Vascular Endothelial Growth Factors (VEGFs), a class of proteins that play a critical role in regulating tumour blood supply.

Current Market Cap : $24 million

In this Open Briefing®, CEO & MD Robert Klupacs discusses

- VGX-100 has significant beneficial effects for treating Dry Eye Disease in animals
- NPAT and Royalty Revenue expected to increase substantially in FY2012
- Planned US IND filing early in the fourth quarter of 2011 for VGX-100 in cancer

Open Briefing interview:

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How does data published in the scientific journal, Archives of Ophthalmology by investigators at Harvard University's Schepens Eye Research Institute, show that Circadian Technologies Limited's (ASX: CIR, OTCQX :CKDXY) lead drug VGX-100 can significantly reduce inflammation and corneal tissue damage associated with Dry Eye Disease (DED)?

CEO & MD Robert Klupacs
We were able to show, using a mouse model with corneal eye damage very similar to Dry Eye Disease (DED) in a human being, that VGX-100 significantly reduced inflammation and significantly improved corneal integrity. To obtain this data, mice were exposed to a high air flow, dessicating environment and chemicals to induce dry eyes and treated with either the VGX-100 antibody or a control. Treatment with VGX-100 significantly reduced the area covered by lymphatics in the cornea and reduced the expression of inflammatory mediators reflective of VGX-100 reducing inflammation in DED. Damage to the cornea was monitored using a stain called fluorescein, and importantly, corneal damage was found to be markedly reduced in the group treated with VGX-100.

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What opportunities do the findings create for the use of VGX-100 as a therapeutic for DED? Why do you believe that blocking lymphangiogenic molecules will become important for the treatment of DED? How does this relate to the development of VGX-100 as a new therapeutic for diseases of the cornea or "front of the eye" disease?

CEO & MD Robert Klupacs
The findings from this world-recognised animal model show that our antibody has significant beneficial effects in treating DED. We have already found that VGX-100 works well in other diseases of the cornea. The fact that VGX-100 also works in DED creates another major opportunity.

VGX-100 works by blocking the growth of lymphatics, which is a key characteristic of DED. By blocking the growth of lymphatic vessels, the trafficking of inflammatory mediators within the eye is impaired, which reduces inflammation and therefore the severity of the disease itself. Given that VGX-100 is one of the only anti-lymphangiogenic molecules being developed in the world today, we are in an advantageous position to develop a unique drug with the potential to improve the outcome for patients with this difficult to treat condition.

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Can you outline your plans and expected timeline for additional pre-clinical and clinical development activities for the use of VGX-100 with DED?

CEO & MD Robert Klupacs
We've already invested considerably in the VGX-100 molecule in terms of manufacturing, toxicology studies and other pre-clinical activities. The ability to leverage our investment into this new indication of DED is an enormous opportunity. We are now undertaking further pre-clinical studies in larger animal models of DED. We are also undertaking additional small-scale toxicology studies in which VGX-100 is administered directly into the eye. Once these studies are complete, we will be in a position to file an investigational new drug (IND) application with the US Food and Drug Administration (FDA), with the potential to commence clinical trials in DED in early 2013.

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Circadian recently appointed Dr Ian Leitch to the newly created position of 'Director – Clinical Research'. Why has this role been created? What are Ian's immediate priorities in regards to the clinical development phase of your development in oncology and eye disease?

CEO & MD Robert Klupacs
Our activities are co-coordinated by experts in the field and we have dedicated positions for pre-clinical research, toxicology, manufacturing and intellectual property. After filing the IND, we expect to start dosing cancer patients with VGX-100 in the fourth quarter of 2011. As we have significantly progressed our development programs and are moving into the clinical phase of testing in oncology and potentially also in eye disease, we needed a dedicated position for clinical research.

Ian Leitch is an expatriate Australian with significant experience in both the eye disease and oncology disease setting, particularly with antibodies. Ian will be based in the U.S.A and his immediate priorities include managing the sites for the VGX-100 Phase 1 oncology program, co-ordinating the logistics associated with commencing trials, as well as monitoring and collecting

data so the trials move forward quickly and efficiently.

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Over the next 12 months, your strategic partner Healthscope Limited plans to launch the Cancer of Unknown Primary (CUP) origin diagnostic test in Australia, New Zealand, Singapore and Malaysia. In addition, sale of the VEGF-D diagnostic test for lymphangioleiomyomatosis (LAM) will be extended to territories outside of the U.S.A. What is the expected contribution of these diagnostic tests to revenue in FY12 and beyond?

CEO & MD Robert Klupacs
We expect both tests to contribute significantly to revenue but the precise amounts depend on when they are launched and when the Key Opinion Leaders (KOLs) start supporting them.

The CUP diagnostic test has a potential market of between two and ten million dollars in the territories where it will be launched by Healthscope. We receive a significant royalty payment on their sales, some of which we share with the Peter MacCallum Cancer Centre, and we expect the test to contribute significantly to revenue. Unfortunately, due to confidentiality we cannot disclose the size of the royalty percentage.

We expect royalties from the LAM test to increase in FY12 but given the time required to educate the market and expand sales to territories outside the U.S.A, a more significant increase in revenues is expected in 24 to 36 months. While the LAM test will take a little longer than the CUP test to generate royalties, anywhere between US$250,000 and US$500,000 dollars of additional royalty is possible.

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Circadian reported a net loss of $10.27 million for the year ended June 2011 on revenue of $1.39 million, compared with a net loss of $6.95 million on revenue of $1.63 million in the previous year. Royalty and licence fee income was $446,000 at June 2011, down 28 percent. What was the reason for the decline in royalty and licence fee income and what is the outlook for NPAT in FY12?

CEO & MD Robert Klupacs
Given nearly all our royalties are received in US dollars, the decline in royalties was primarily due to the appreciation of the Australian dollar compared to last year.

In 2012, both royalties and NPAT are expected to be significantly higher with Healthscope launching the CUP diagnostic test. We also expect to have at least one additional deal done in the diagnostic sector which we hope will include an upfront payment.

Sales and royalties from the LAM diagnostic test, launched in FY11 with the University of Cincinnati, are projected to increase in FY12, coupled with the expectation that the number of licensees worldwide offering the test is also likely to expand.

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Research and development (R&D) costs in FY11 were $6.57 million, up 53 percent from $4.3 million in the previous year. What factors contributed to this increase in R&D costs? Where will R&D costs trend in FY12?

CEO & MD Robert Klupacs
The major factor contributing to the increase in R&D costs was the transition over FY11 to much later stage pre-clinical work, particularly completion of toxicology studies, completion of large scale cGMP (current good manufacturing practice) manufacturing and preparation for clinical trial commencement. As we move into clinical phase work, we will have the additional expense of clinical trials but because of the significant upfront investment in manufacturing and pre-clinical development already made, a large uplift in R&D expenses over the next one to two years is not expected.

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Your cash burn for FY11 was $9.8 million, with cash in hand standing at $22.1 million at June 2011. With an expected cash burn over FY12 of $10 million to $12.5 million, and commencement of Phase 1 clinical trials of VGX-100, how are you placed to fund development of your IP portfolio in FY13 and beyond?

CEO & MD Robert Klupacs
We have at least two years of cash on hand to fund our activities at the projected cash burn rate. This timeframe does not take into consideration any additional revenues we may obtain from sources such as the new R&D tax credit scheme, any further licensing arrangements reached, and any increase in royalties.

We retain an interest in two listed biotech companies, with the potential to sell-down these interests to inject further capital into the company. While we expect to raise capital at some point, the timing of any additional capital requirements depends on various factors and we have made grant applications for non-dilutive financing. The decisions on these grants are still pending.

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What are the expected key milestones in the development of your portfolio over the next 12 months and what potential partnering opportunities will these developments present?

CEO & MD Robert Klupacs
The key milestone will be filing an IND with the FDA as it enables us to commence a clinical trial with VGX-100 in cancer in the fourth quarter of 2011. We expect to commence this trial before the end of the year and will periodically update the market on the safety and tolerability of VGX-100.

Over the next 12 months, our licensee ImClone Systems (a wholly owned subsidiary of Eli Lilly and Company) will report important results from their Phase 1 clinical trial of the antibody IMC-3C5. We also expect Healthscope to launch their CUP test and for the LAM test to expand into other territories. As we move into the eye disease setting, we will make a series of announcements regarding pre-clinical and animal model studies for both DED and other “front of the eye” diseases.

We expect to announce a strategic partnership for the development of VEGF-C diagnostics in the cancer setting. There is also the possibility of entering into partnership arrangements relating to VGX-100 over the next 12 months but ideally we would like to generate more clinical data before having those discussions.

Beyond this, we hope to start Phase 2 clinical trials of VGX -100 in early 2013. Progress towards these milestones shows we are well on the way to generating significant value for our shareholders.

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Thank you Robert

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

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