FY2012 Results and Outlook

Open Briefing interview with CEO and MD Robert Klupacs

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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.

In this Open Briefing®, Robert discusses:

- Results and FY2013 outlook
- Outlook for royalties and portfolio commercialisation
- Strategy for VGX-100, VGX-300 and VEGF-D development

Record of interview:

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Circadian Technologies Limited (ASX:CIR, OTCQX:CKDXY) booked net cash outflow of $5.8 million in FY2012, and R&D expenditure (excluding personnel costs) was $3.6 million. What is your expected cash burn over FY2013 and how will you allocate expected R&D expenditure across your various programs?

MD & CEO Robert Klupacs
We expect net cash outflow in FY2013 of between $8 million to $10 million, with a significant proportion allocated to the ongoing development of VGX-100 in the oncology setting. Expenditure on our ophthalmology development program will increase and we also expect to ramp up our development work in clinical diagnostics.

R&D expenses are expected to increase as we move in to later clinical development and incur necessary clinical material manufacturing costs this year.

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Circadian's royalty and licence fee income was $510,000 in FY2012, up 14.4 percent. What is the outlook for royalty and licence income in FY2013 given the launch in July of your cancer of unknown primary (CUP) test by licensee Healthscope?

MD & CEO Robert Klupacs
We expect FY2013 royalty income will be significantly higher, but just how much higher will be dependent on exchange rates. We generate most of our royalties in US dollars so our income will be affected by the exchange rate. In constant currency terms, royalties should increase significantly over the $510,000 we generated in FY2012.

We don't expect the Healthscope deal will have a major impact on royalties in FY2013 as there will be the usual lag in sales following the launch as Key Opinion Leaders become educated about the product. We expect royalties from Healthscope sales will start to accelerate from early 2013 onward. We expect to do more reagent deals this year so our

royalties from reagent providers should increase. We also expect royalties from our VEGF-D kit to increase with ongoing sales through the Cincinnati Children's Hospital Medical Center.

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In June 2012, you made a share placement of $1.02 million to international and Australian based institutional and sophisticated investors at an issue price of $0.49 per share. As at the end of June, cash and equivalents stood at $16.4 million, down from $22.1 million a year earlier. Do you have adequate funding for your planned programs over FY2013?

MD & CEO Robert Klupacs
We definitely have enough money to support our activities until the next major value accretion points. Although we have $16.4 million available, we know that markets are tight and we're closely looking at how the money is invested and utilised.

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You expect initial Phase I clinical data relating to VGX-100 in oncology indications to be available in the current half. To what extent might this early trial data add to the value of your VGX-100 program and what are the licensing opportunities for the drug?

MD & CEO Robert Klupacs
Apart from establishing clinical proof of principle, a key issue raised by prospective partners has been the potential for additive toxicity when our drug is combined with other anti-angiogenic drugs. The Phase I study isn't designed to measure efficacy, rather it's designed to assess the safety and tolerability of our drug either alone or when combined with the drug Avastin.

We believe the successful completion of the Phase I trial will be a value point for prospective partners, as it will de-risk an important component of the program. Regardless of whether we can get a deal just on this trial data alone, de-risking the combination of VGX-100 and anti-angiogenic agents by showing it's safe and well tolerated, will be a key driver for ongoing development. We believe that once we can show our prospective partners the Phase I data, the discussions we've had to date will go to the next level.

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Over FY2013 you expect to continue to generate proof of efficacy for VGX-100 and VGX-300 in animal models of eye disease. When do you expect to file an investigational new drug (IND) application for VGX-100 or VGX-300 to enable clinical trials in age related macular degeneration (AMD) patients?

MD & CEO Robert Klupacs
We're looking at both molecules in parallel and if we decide to move on VGX-100, the IND filing will likely be in the second half of calendar 2013. If it's VGX-300, the filing would likely be in the first half of 2014.

We're developing VGX-100 for oncology and while we can leverage that, there is some commercial sense in developing one drug for cancer and another for eye disease. We're currently running various experiments comparing VGX-100 and VGX-300, but we haven't as yet formally designated which will be the lead compound for eye disease development, particularly for back of the eye disease.

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Can you update us on the development of VEGF-D as a clinical diagnostic test in disease settings? What are your plans for this program in FY2013?

MD & CEO Robert Klupacs
The VEGF-D clinical diagnostic is being sold through the Cincinnati Children's Hospital Medical Center as an aid to diagnosis of the lung disease lymphangioleiomyomatosis (LAM). It's been on the market now for two years and the number of tests conducted has doubled in

both years. While it's a relatively small market, we're seeing significantly more uptake by key opinion leaders and sales continue to increase.

We've also identified additional opportunities for the VEGF-D test in various clinical settings and disease states. We're looking at potentially investing more into the program so we can market an FDA approved VEGF-D kit. This would allow us to seek greater levels of reimbursement and to break into additional settings. The kit is currently marketed as a laboratory developed kit sold under CLIA waiver conditions. If we can register it through the FDA, we believe the test would be used as an aid in diagnosis for a larger number of disease states, increasing the potential number of tests in the USA to 50-100,000 tests per annum.

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Your stated plan includes "selectively commercialising" aspects of your portfolio, particularly therapeutics outside the oncology area, and clinical diagnostics and reagents for potential early revenues. What progress do you expect to make in this strategy in the coming year?

MD & CEO Robert Klupacs
We've identified opportunities that weren't there 12 months ago. The question now for the company is working out the correct allocation of investment and pushing forward with commercialisation.

We see clinical diagnostics as a significant opportunity for us and are assessing whether to invest more aggressively in the VEGF-D diagnostic. We also see a significant opportunity to use VEGF-C as a biomarker of various drugs' responses and may further invest in developing a clinical, as opposed to research grade, diagnostic in that area. We've looked at partnering with a major player for this and have had good discussions over recent months.

We also have a number of reagents we've developed in-house that are significantly better than what is currently available in the research reagents market. There's an opportunity for us to market these directly - they're already in our inventory and could generate sales over the next one or two years.

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At 30 June 2012, Circadian's listed investments were valued at $3.7 million, up from $1.3 million the previous year. What is your strategy in relation to these investments?

MD & CEO Robert Klupacs
We continue to be holders of both Antisense and Optiscan. Both companies have flagged the likelihood of major developments over the next six to 12 months which we hope will be value generating. We will continue to review when to sell some or all of those investments based on market conditions, the prospects of each company and Circadian's funding needs.

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Circadian is involved in oncology, ophthalmology and diagnostics development. What is the rationale for maintaining a diversified portfolio? Would you see value in greater focus?

MD & CEO Robert Klupacs
We recognise that some investors like part but not all of our assets. We're in the process of reviewing our current structure and our options to maximise shareholder value. We're evaluating the best ways to give investors transparency around our assets and assessing options like creating vehicles to invest specifically in oncology or ophthalmology. We hope to finalise a strategic plan in the next few months.

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Thank you Robert.

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

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