

ASX ANNOUNCEMENT: 20 February 2012



# **Half Year Results and Outlook**

Open Briefing with CEO & MD Robert Klupacs

Circadian Technologies Limited Level 1, 10 Wallace Avenue Toorak, Victoria 3142

Circadian Technologies Limited (ASX: CIR, OTCQX: CKDXY) is an Australian biotechnology company developing diagnostics and biologic 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 blood supply.

Current Market Cap: \$24 million

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

- Half year results and outlook
- Update on Phase 1 VGX-100 trials
- Outlook for royalties and IP portfolio

# **Open Briefing interview:**

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Circadian Technologies Limited (ASX: CIR) reported net operating cash outflow of \$3.9 million for the first half ended 31 December 2011, compared with outflow of \$5.7 million in the previous corresponding period. This reflected \$1.9 million fall in cash costs to \$4.6 million, offset by a \$0.1 million drop in income. What is the outlook for cash burn for the current year ending 30 June 2012?

#### **CEO & MD Robert Klupacs**

We previously indicated our projected cash burn for the full year would be between \$8 million to \$10 million. We are still budgeting for this range.

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First half R&D costs were \$1.3 million, down from \$3.9 million in the previous corresponding period. Given the ongoing Phase I clinical trial of VGX-100 in oncology and IND enabling studies with VGX-100 in "front of eye" disease models, what is the outlook for R&D costs in the near term?

## **CEO & MD Robert Klupacs**

In the second half of the current financial year, our R&D costs won't significantly increase.





However, we'll see higher R&D costs as we move into FY2013 because we'll be expanding our clinical trial program, beginning to manufacture further material for later stage Phase II studies and starting to ramp up our ocular program.

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In October, Circadian received clearance by the US Food and Drug Administration (FDA) to commence clinical trials of VGX-100 in the oncology setting and the first patient was dosed in early January 2012. What has been the progress of the trial to date? What is the expected timeline of the trial and what is the primary endpoint?

## **CEO & MD Robert Klupacs**

The trial is progressing very well with excellent recruitment at our two US sites. We expect to complete the trial towards the end of 2012, enrolling between 36 and 54 patients at varying doses of our drug, either alone or administered with Avastin®.

The primary end point is safety as well as the identification of a dose we can take into Phase II. The patients eligible for this Phase I trial are people in the later stage of the disease who generally have no other available therapy. While Phase I studies are designed to test safety, we are also monitoring the affect of VGX-100 on their tumours.

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You expect initial data from further pre-clinical studies of VGX-100 as a treatment for front of the eye disease in the current half, and have indicated you will also commence formal development of VGX-100 in this setting. What are the potential investment/return metrics of this setting versus the oncology setting?

#### **CEO & MD Robert Klupacs**

We believe the return on investment would be similar. While the likely market size for a drug in the ocular disease setting is less than in the oncology setting, the investment level required and time taken to bring the drug to registration is also likely to be less.

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You've indicated that Healthscope will launch your cancer of unknown primary (CUP) diagnostic test in its licensed territories in March or April. How is the launch expected to impact your royalty and licence income in FY2012 and beyond?

## **CEO & MD Robert Klupacs**

We're excited about the potential launch but it won't have a significant financial impact on FY2012. The test needs to be launched and the supply chain stocked. After that, in FY2013 and beyond, we hope to generate significant royalties from Healthscope sales and generate income from partnering deals for marketing the test in the major territories of North America, Europe and Japan.

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The combined value of your interests in Antisense Therapeutics Limited and Optiscan Imaging Limited stood at \$3.4 million as at 31 December 2011, up from \$1.3 million at 30 June 2011. What are your intentions regarding these holdings and to what extent is their divestment part of your strategy to fund Circadian's development pipeline?





#### **CEO & MD Robert Klupacs**

We've held both these assets for a significant time and are delighted with their progress in the recent period. Optiscan has fantastic technology, a very strong management team and is a refocused business. Antisense has recently had a positive announcement regarding successful completion of Phase 1 studies with their lead drug and imminent commencement of Phase 2 and that a major pharmaceutical company is performing due diligence As part of possible partnering discussions.

When we changed Circadian's business model from incubator to drug-development company, we understood that these assets could be converted to cash. We're not in a rush to divest either stock: we believe both have significant value upside and we'll seek to maximise our return. However, if we see the right opportunity to release a portion of our investment to help fund our own drug development activity, we'll do so at the right time.

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Circadian had cash reserves of \$18.3 million as at 31 December 2011, down from \$22.1 million six months earlier. Given your stated objective of generating value by undertaking pre-clinical and early human clinical development and partnering with pharmaceutical companies, are you adequately funded in the short to medium term?

### **CEO & MD Robert Klupacs**

We're adequately funded to implement our business plan in the short term and at least get to Phase IIa studies. Apart from our cash reserves of \$18.3 million, we also expect to be eligible to receive future refundable tax offsets under the new R&D tax incentive. We also hope to secure grants from a number of applications we have pending around the world. We also have the potential to release some value from our Antisense and Optiscan holdings, as I mentioned earlier.

We're also focusing on generating recurring income. We're receiving royalties from our VEGF-D diagnostic test for the lung disease lymphangioleiomyomatosis (LAM), which was launched in the US in the first half of this financial year, and we'll soon start receiving royalties from the Healthscope diagnostic kit, so revenue should be enhanced. This, combined with the ability to do smaller deals for the CUP test in markets outside Healthscope's licensed markets of Australia, New Zealand, Singapore and Malaysia, puts us in a good position.

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Circadian has licensing agreements with ImClone Systems (owned by Eli Lilly) for the development of a VEGFR-3 antibody and with Ark Therapeutics for the development of VEGF-D gene therapy products. Both licensees are expected to complete Phase I trials in the second half of calendar 2012. What are the potential implications of these trials for any future licensing deals for Circadian's IP and for the value of your IP portfolio?

## **CEO & MD Robert Klupacs**

While Ark Therapeutics is in the niche of gene therapy applications, a lot of the data it's generating is proving the role of VEGF-D in cardiovascular disease and helping to add value to our portfolio.

With ImClone completing Phase I clinical trials of VEGFR-3 and moving into Phase II, there's a growing awareness in the industry of our compounds being viable therapeutic development targets. We expect this to have benefits for industry awareness of our other assets, particularly





VEGF-C and VEGF-D. While VEGFR-3 is the first of our compounds to reach this stage of development, it also creates a lot of perceived value for the rest of our portfolio.

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Thank you Robert.

For more information about Circadian Technologies, visit <a href="www.circadian.com.au">www.circadian.com.au</a> or call Robert Klupacs on +61 3 9826 0399.

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