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CEO on FY11 Outlook and Strategic Focus

Open Briefing with CEO & MD Robert Klupacs

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

- **Outlook for cash flow, R&D spend**
- **Strategic focus and milestones over next 12 months**

Open Briefing interview:

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Circadian Technologies Limited (ASX:CIR) reported net operating cash outflow of $7.5 million for the year ended 30 June 2010, compared with outflow of $6.6 million in the previous year. The outflow was less than your cash burn projection of $8 million to $12 million per annum. What was behind the lower than expected outflow and what is the outlook for cash burn in the current year?

CEO & MD Robert Klupacs
The lower than expected cash outflow was due primarily to three reasons. Firstly, much of our R&D is spent offshore and we benefited significantly from a favourable foreign exchange rate. Secondly, many of our projects are done through third party providers, for example preclinical studies and manufacturing, and our experienced staff negotiated much better terms than budgeted. Thirdly, some of these production processes we developed achieved higher yields than originally projected which meant the cost of materials was lower than expected.

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Royalty and licence fee income was $622,000 in 2010, down from $722,000 in the previous year. How is this expected to trend given progress by your partners such as ImClone Inc., which is developing a VEGFR-3 antibody and Healthscope Limited, which is developing a diagnostic for cancers of unknown primaries (CUP)?

CEO & MD Robert Klupacs
The slight reduction in royalty and licence fee income was mainly due to the negative effect of foreign exchange movements on our offshore receipts. We expect an increase in royalty and licence fee income in the next 12 months, flowing from expected increases in partner sales of

research reagents and the potential for royalties to flow from other diagnostic applications in our portfolio.

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R&D costs, excluding personnel costs, were $4.3 million in 2010, down 4.2 percent from the previous year, but total investment in R&D (including personnel and R&D support costs) was $6.2 million up 3.3 percent. Given your plan to file an investigational new drug (IND) application with the US Food and Drug Administration (FDA) for VGX-100 in 2011, what is your expected R&D spending for the 2011 financial year?

CEO & MD Robert Klupacs
Our R&D spend in 2010 was a little more than expected, and higher than previous years. For 2011 we expect R&D spending to be in the $8 million to $12 million range.

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Circadian had cash in hand of $31.9 million as at 30 June 2010, down from $38.8 million a year earlier. What is the expected R&D spend on your VGX-100, VGX-200, VGX-300 and VEGF programs as they move forward and how are you positioned to fund them?

CEO & MD Robert Klupacs
As I mentioned earlier our expected cash burn is between $8 million to $12 million annually. This will mostly be associated with R&D and IP expenses. Last year, R&D expenses were about 60 percent of our total costs, with IP and administration costs making up the remainder. This year, we expect R&D spending to account for approximately 70 to 75 percent of outgoings.

The $31.9 million cash on our balance sheet positions us strongly to move forward over the next 12 to 24 months. At the same time, we're also looking to potentially partner some of our programs over that time so we're well placed to fund ongoing R&D activities.

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How does data collected to date reinforce a case for clinical evaluation of VGX-100? Which indications look most promising for VGX-100 and what are the long term market opportunities for the drug?

CEO & MD Robert Klupacs
We presented data on VGX-100 at the American Association for Cancer Research (AACR) conference in April. The oncology community was excited that VGX-100, when combined with chemotherapy and other anti-angiogenic agents, could have a significantly enhanced response in various tumour types compared with those agents alone.

The data generated to date, particularly for VGX-100 as part of chemotherapeutic "cocktails", has enhanced the possibilities for the drug compared with 12 months ago. Feedback from the industry has reinforced this view, and we've seen activity in many different tumour types. While a number of indications look promising, we haven't decided which solid tumour type to focus on as yet. We are continuing to evaluate this with our clinical advisors. However colorectal cancer, breast cancer, lung cancer and smaller diseases such as gastric cancer and brain cancers such as glioblastoma are currently the most likely tumours we'll initially focus on.

In the long term, the main market opportunities for VGX-100 are around its uses in combination with existing chemotherapy. While we don't expect it to be a US$7 billion drug like Avastin, it

has wide potential across a number of tumour types and potentially outside of cancers. We're positive about the future possibilities and believe the market size for VGX-100 will be directly proportional to the clinical benefit it provides.

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In 2010, Circadian demonstrated the ability to manufacture cancer drug candidate VGX-300 in commercial quantities. How will this affect anticipated timelines and costs for the pre-clinical development of VGX-300 in 2011?

CEO & MD Robert Klupacs
VGX-300 is a unique biological drug and the ability to manufacture it in commercial quantities was a major milestone for us. The next stage is to develop a formulation of the drug so that its pharmacokinetic profile, or how long it stays in the body after delivery, can be adjusted to the levels required. We don't expect large expenditures on VGX-300 over the next three to six months as there are still a few remaining early phase activities we need to complete. Assuming success, VGX-300 could be confirmed as our second drug candidate some time in late 2011. We'd then likely increase our R& D spending on it accordingly.

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What is your current strategy for securing licensing agreements for the key compounds in your development pipeline? How will you seek to optimise value for shareholders?

CEO & MD Robert Klupacs
Our strategy of taking lead molecules to clinical proof-of-principle before partnering them with major pharmaceutical companies remains unchanged. However a number of companies have expressed interest in our molecules and it is possible that we may be offered the opportunity to partner earlier than proof-of-principle. A key consideration for us in any partnership will be the ability to maintain significant involvement in the development of the molecules through the clinical development process.

We believe the more data we can generate on VGX-100, VGX-200 and VGX-300 demonstrating their significant potential in the treatment of cancer, the more we'll increase shareholder value. We're also focused on monetising other aspects of our portfolio to drive revenue: for example we are seeking partnership deals for other parts of our portfolio and other IP assets. We are confident that this strategy will generate significant value over the next 12 to 24 months.

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What will be the strategic focus for Circadian in the current financial year and what milestones do you expect to achieve?

CEO & MD Robert Klupacs
We continue to aggressively push forward with our VGX-100, VGX-200 and VGX-300 programs. VGX-100 in a cancer setting remains our core activity and we are also aggressively seeking partnerships for other assets within our IP portfolio.

In the current financial year, we expect our partner ImClone to file an IND in relation to the VEGFR-3 antibody. We also hope to commence clinical studies with at least one of our compounds and progress other non-therapeutic opportunities in our IP portfolio, particularly diagnostic tests that utilise the measurement of VEGF-C or VEGF-D. We recently announced that our subsidiary company, Vegenics Limited, had been granted a US patent for diagnostic kits

for detection of VEGF-D as a biomarker in human samples, adding to our already considerable VEGF IP portfolio.

Late this year or early next year, we look forward to our partnership with Healthscope leading to the launch of a test for cancers of Unknown Primary Origin (CUP). And towards the end of the year we expect to complete the arbitration process with Ark Therapeutics, and that should allow us to provide further clarity on the way forward.

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Thank you Robert.

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

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