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VGX-100 Inhibits Tumour Growth

Open Briefing with CEO & MD Robert Klupacs

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

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

- significance of VGX-100 animal tumour model data
- partnering strategy and next steps of VGX-100 development
- next 12 months potential milestones

Open Briefing interview:

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Circadian Technologies Limited (ASX: CIR) recently announced VGX-100 either alone or combined with other drugs showed significant anti-tumour activity in mouse models of prostate, pancreatic and brain cancers. To what extent does the data complete your animal tumour model evaluation of VGX-100?

CEO & MD Robert Klupacs
We're very excited by the data we've generated so far in the animal models. It's been important for us to show that the VEGF-C (VGX-100) molecule blockade adds to the blockade achieved with a VEGF-A anti-cancer molecule (such as the drug Avastin). This means VGX-100 may have significant clinical applications in cancer. We believe it is important for us to continue undertaking animal model studies in a range of different tumour types using combinations of our molecule with other anti-cancer drugs as part of our evaluation of VGX-100's mechanism of action and to identify further clinical opportunities.

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Does the data provide any insight into the cancer indications which VGX-100 may be used for in clinical trials? What will be your main considerations in deciding which cancers to conduct the clinical trials on?

CEO & MD Robert Klupacs
It certainly does. As stated earlier, although we are going to conduct further animal model cancer studies, what we've seen in the studies conducted to date is that by adding our molecule to other cancer treatment(s) there may be a significant clinical opportunity. For example, in the data for brain cancer we saw an additive effect where VGX-100 was used in

combination with Avastin. This is quite exciting given Avastin has just been approved by the FDA for single use in that particular cancer indication.

Our decision for the ultimate indication(s) to be used in clinical trials will be based on animal data we obtain from all cancer model studies that we undertake. However other factors will also be considered in making this decision. This includes the relative ease of patient recruitment and the relative unmet clinical need.

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What are the next steps in developing VGX-100?

CEO & MD Robert Klupacs
The next step is to undertake toxicology studies to evaluate what doses of VGX-100 will be safe to be studied in humans. These studies, which will be commencing soon, will be undertaken by a specialised pre-clinical services company.

In parallel, we will commence the bulk manufacture of clinical grade material (drug compound) to Good Manufacturing Practice (GMP) levels so that drug compound is available in time for our first clinical trial scheduled for the first half of 2011.

We will also be interacting with the US Food and Drug Administration (FDA) during the toxicology studies phase. The purpose of these interactions is to seek input and guidance with respect to the design of our first clinical trial and to seek feedback on interim results of our toxicology studies. These are prudent and important steps leading up to the filing of our Investigational New Drug (IND) application – a precursor to conducting clinical trials.

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With respect to the toxicology studies you plan to commence before the end of FY10, what are their estimated costs and can you provide a timeline for their completion?

CEO & MD Robert Klupacs
The specific costs of toxicology are commercially confidential. In terms of the timeline we expect the studies to be completed by the end of this calendar year.

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What is your current strategy in terms of developing VGX-100? Do you have any intentions to take on partners?

CEO & MD Robert Klupacs
We're focused on taking VGX-100 to the clinical proof of principal stage (end of Phase 2a trials). However, we recognise that clinical development activities can be expanded with a partner, and we'll continue to engage with interested parties. This may lead to a partnership before that point.

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You intend to file an IND application with the US FDA in the first half of 2011 in order to begin human clinical trials of VGX-100. Why have you chosen to file the application in the US?

CEO & MD Robert Klupacs
The major reason is that the US FDA is recognised as the most rigorous regulatory authority in the world. So we've taken a deliberate strategy to try and make sure that we fit the higher standard in one of the world's largest markets. We also recognise that pursuing an FDA drug approval path is universally recognised and respected and this is important for potential partnering of our project with international companies.

Although the IND will be filed with the US FDA we have also built into our strategy engaging with the European Medicines Agency (EMEA) during the early stages of our drug development program as we also recognise their importance. It is fair to say that the FDA and then the EMEA are the gold standards and so we are aiming for that standard.

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You reported cash reserves of $34.8 million at end of December 2009 and net cash outflows for the half year period of $3.9 million. Will you have enough funds to take VGX-100, VGX-200 and VGX-300 to further development?

CEO & MD Robert Klupacs
We've said over the past 12 months, that our plan has been to partner one or more of our programs at the pre-clinical stage and take one to clinical proof principal (i.e. the end of Phase 2a). We've identified VGX-100 as the lead program which we would like to take to clinical proof of principal. However, as I said earlier, we may enter into a partnering arrangement for VGX-100 at an earlier stage of its development if the benefits – both monetary and from a clinical development perspective are compelling enough. We believe our existing cash resources will be sufficient to fund our current programs for over two and a half years even assuming no licensing or partnering income.

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What material milestones are you aiming to achieve over the next 12 to 14 months?

CEO & MD Robert Klupacs
The key milestones relate to the drug development activities associated with VGX-100:

- commencement and completion of toxicology studies to assess safety,
- completion of the bulk manufacture of GMP clinical grade drug compound for use in human trials;
- interactions with the FDA and filing of the IND with the FDA; and
- if the above precursor milestones are successfully completed, the commencement of the Phase 1 trial in the first half of 2011.

In addition, assuming successful development validation by our partner Healthscope, the launch of our cancers of unknown primary diagnostic tests is expected to occur by the end of the calendar year.

We also expect our partner Eli Lilly/ImClone to have commenced clinical trials of the VEGFR-3 antibody, which they've licensed through us, by around the end of 2010.

Overall, by the first half of 2011 our goal is to have two cancer drugs in clinical development, a new diagnostic test launched by Healthscope, and continuing advancement of our product development pipeline from research to pre-clinical phase.

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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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