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Circadian Technologies Limited
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Toorak, Victoria 3142

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Circadian Technologies Limited (ASX: CIR) recently made two significant announcements. The first was that its partner, ImClone Systems, had demonstrated in pre-clinical animal studies that a Vascular Endothelial Growth Factor Receptor 3 (VEGFR-3) antibody, in combination with standard anti-cancer chemotherapy agents for lung, and head and neck cancers, cisplatin and docetaxel respectively, gave significantly better results in tumour inhibition than either agent alone. What implications does this pre-clinical data have for future clinical studies involving VEGFR-3?

CEO & MD Robert Klupacs
ImClone's results showed that an antibody to VEGFR-3, when combined with standard chemotherapy, not only stopped tumour growth, but actually led to a regression of tumour size in certain cancer types. This data is highly promising for the product moving forward and reinforces the potential of VEGF-C, VEGF-D and VEGFR-3 antibodies, for which we hold the key intellectual property worldwide.

ImClone's results related to animal studies so there's a caveat that what happens in animals may not happen in the human setting. However, if the data from the animal studies can be replicated in a human clinical setting, whereby patients treated with chemotherapy in combination with the antibody had significantly

improved results, it would have significant implications for the treatment of cancer patients. We'd hope these might be extended to other types of cancers.

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The second announcement was that the Chairman of Circadian's subsidiary Vegenics Scientific Advisory Board, Professor Kari Alitalo, received the InBev-Baillet Latour Health Prize 2009 with his collaborator Professor Seppo Yla-Herttuala for their research on cancer and cardiovascular disorders. What are the implications of this recognition for Circadian's drug development program?

CEO & MD Robert Klupacs
The award cited Professor Alitalo's role as the discoverer of the VEGFR-3 receptor, which is significant as we acquired the intellectual property rights around the receptor developed in Professor Alitalo's laboratory. The VEGFR-3 receptor and associated technology is a major part of our drug development program. The award doesn't directly affect the development status of any of our programs but reflects the growing international recognition of targeting the VEGFR-3 pathway as a novel and important therapeutic strategy.

The InBev-Baillet Latour prize is one of Europe's most prestigious scientific awards and is specifically dedicated to applied science, not simply to academic research. It should help to further increase the international awareness of the technology we're developing here in Australia.

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ImClone's data relates to lung and head and neck cancers. How prevalent are these cancers and what is the potential market size?

CEO & MD Robert Klupacs
With respect to lung cancer, the incidence is 13 percent of all new cancer cases, which in the US is equivalent to about 170,000 new cases per year. In terms of mortality, it represents nearly a third of all cancer deaths in the US (approximately 157,000 each year). The incidence of head and neck cancers is about 3 to 5 percent of all cancers or about 40,000 new cases per year in the US. These numbers suggest a potentially significant market for us.

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In the first half of calendar 2010 ImClone plans to file an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) to conduct clinical trials of its human VEGFR-3 antibody in the US. What else needs to be done before ImClone can file this application?

CEO & MD Robert Klupacs
The primary activities are that ImClone is undertaking scaled up manufacturing of the antibody in quantities sufficient to carry out toxicology tests over the next few months to verify that it is safe for use in humans. The results of these studies, plus the animal efficacy data which is already in hand, will be part of ImClone's submission to the FDA in support of the IND application.

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In addition to the program partnered with ImClone, you have a lead in-house program around a VEGF-C antibody designated VGX-100. Your VGX-100 development and clinical program is designed to address resistance and non-responsiveness to anti-angiogenic cancer therapies. What is the rationale for focusing on this area?

CEO & MD Robert Klupacs
Many people are aware of the significant breakthrough in cancer treatment resulting from the advent of anti-angiogenic therapies: the treatment of cancer by blocking the development of new blood vessels. However, over the last two to three years, the scientific literature has reported a subset of patients who either don't respond to anti-angiogenic therapies currently on the market, or become resistant after having initial positive results.

The literature has also indicated that those patients seem to have higher levels of other angiogenic factors, including high levels of VEGF-C or VEGF-D, in their circulation. This suggests to many experts that blocking the action of VEGF-C and VEGF-D with therapeutic antibodies, may achieve a more complete effect of anti-angiogenic therapy in the substantial percentage of patients where this recalcitrance to therapy occurs.

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You've said you intend to file an IND for VGX-100 in the first half 2011. How is this program tracking?

CEO & MD Robert Klupacs
The program is on track. We've started manufacturing for toxicology testing and further animal studies. We're on course for our IND filing within that time frame.

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You've indicated an Orphan Drug Designation (ODD) is likely for VGX-100. What would this designation mean for the development of VGX-100?

CEO & MD Robert Klupacs
ODD is helpful for three main reasons. Firstly, drugs that have ODD get market exclusivity. Secondly, for drugs with ODD, the registration and regulatory filing costs with the FDA and European Medicines Agency (EMEA) are reduced by up to 50 percent. Thirdly, an ODD can support the fast-tracking of regulatory approval for a drug. That's obviously important for getting a drug to the market sooner than would otherwise be possible.

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What has been the progress in the early-stage development of your other in-house products VGX-200 and VGX-300?

CEO & MD Robert Klupacs
Both of these products are continuing to plan. Since the completion in October 2008 of the first phase of our collaboration with Arana Therapeutics to produce

humanised antibodies of our VEGF-D candidates, we've had success in producing eight of those antibodies in enough quantities for further testing. We've now selected three of the most potent to manufacture in sufficient quantities so that we can conduct critical animal studies where we'll decide which of the antibodies to take through into clinical development. We're on track to make that designation by the end of this year.

With regard to VGX-300, we've instituted a manufacturing program with two reputable players in the US and Europe. The manufacturing results will determine how quickly we move that product into animal studies.

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As at 23 April 2009, Circadian's cash and listed investments totalled $45 million, compared with $46.8 million at the end of December. Can you describe your expected yearly cash burn leading up to the intended VGX-100 IND filing? How are you managing cash in the current financial climate?

CEO & MD Robert Klupacs
We're still expecting an annualised net cash burn of between $8 million and $12 million per annum.

I'd like to emphasise that while Circadian is in a strong financial position, we're not complacent. We're very focused on managing the cash we have prudently. In fact, in the current climate we've been able to negotiate more favourable terms from third party providers than we would have been able to in boom times. We're trying to be smart with our suppliers, putting in place very clear project development milestones and linking investment to success.

We're also looking to exploit the other opportunities of our portfolio, such as diagnostic products, so as to do deals like the ones we've done with Healthscope and Ark Therapeutics. The aim is to achieve near term on-going sources of revenue in parallel to progressing our drug development program and its related commercialisation strategy.

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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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