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Circadian Technologies Limited (ASX: CIR) recently announced that its licensee (through its wholly owned subsidiary Vegenics), Ark Therapeutics Limited (LSE: ARK) has received clearance by the US Food and Drug Administration (FDA) to commence Phase III human trials of Trinam® which is based on your Vascular Endothelial Growth Factor (VEGF) intellectual property. Can you comment on the value implications of this trial for Circadian?

CEO & MD Robert Klupacs

This is a milestone valuation event for us. The fact that Circadian's technology is in Phase III, with the potential to generate royalty income for us in two to three years time, should give investors some valuation markers around our technology.

Trinam® is a novel treatment that prevents blood vessels blocking in kidney dialysis patients who've had vascular access graft surgery. It will improve quality of care and quality of life for these patients. Importantly Trinam® is just one aspect of our VEGF-D portfolio. We ourselves are developing other aspects of VEGF-D including VEGF-D antibodies (the VGX-200 series) as potential anti-cancer agents, and are currently evaluating recombinant VEGF-D protein in a number of disease models including wound healing. The fact that Trinam® is now entering late stage clinical development can only add value to the other applications we're developing, and it's non-competitive with these other projects.

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The Special Protocol Assessment (SPA) for Trinam[®] and the updated Investigational New Drug (IND) for the trial has been approved by the FDA. Ark now intends to apply for Fast Track Designation and submit a rolling Biologic License Application (BLA) for sale and marketing approval. What does this mean for the timeline of the Phase III trials and the eventual commercialisation of Trinam[®]?

CEO & MD Robert Klupacs

An SPA is effectively a collaboration between a company and the FDA. It enables a company to pre-agree the efficacy measures of the clinical study which if met, can get rapid approval.

In the case of Trinam[®], Ark has previously indicated that the Phase III studies will take approximately 18 months to complete. If the results of these studies are positive for the measures agreed with the FDA, it's possible the product could be approved within a year or so after completion of the clinical studies. Most drug approvals take two or more years after completion of clinical studies.

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What level of milestone payment will you receive as a result of Trinam[®] entering Phase III and when will it be recognised in your accounts?

CEO & MD Robert Klupacs

We'll receive a number of milestone payments on the later stage development of Trinam[®]. The commencement of the Phase III trial doesn't trigger a milestone payment but payments will be due if it's successful. We also continue to receive ongoing annual payments from Ark and will receive royalties on sales of the product.

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What is the potential market for Trinam[®]?

CEO & MD Robert Klupacs

At this point in time, there's no competing product, so it's very hard to do a comparable analysis seeing that current market estimates could potentially be an underestimate. Ark has previously published an estimate of up to US\$500 million sales per annum as its goal for Trinam[®].

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Part of your strategy is to develop at least one therapeutic to proof of efficacy in Phase II trials and subsequently partner the clinical development. Can you comment on the partnering prospects for Circadian's pipeline? Have the partnering prospects been impacted by the recent economic slowdown?

CEO & MD Robert Klupacs

Over the last six to nine months, we've been approached by a number of companies, particularly as it's become better known that we control the VEGF intellectual property and what we're doing with it. We're actively negotiating with some of those companies.

In respect of the effects of the current economic climate, industry news announcements indicate that deal levels seem to be similar to those of the last two or three years. From our perspective, given whom we're dealing with and the discussions that are on-going, it appears that the wider economy has had no impact.

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You indicated that your cash burn objective is between \$10 million and \$12 million a year. Is this still a realistic target considering the recent market turmoil?

CEO & MD Robert Klupacs

It's realistic for a couple of reasons. Firstly, it's an average figure – some years' cash burn will be more, some years' less. Secondly, our key differentiating factor in the biotech space is that we have very strong cash reserves. At the end of December we had cash of about \$40 million, equivalent to three and a half to four years worth of cash burn. We're very comfortable maintaining our cash burn at those levels.

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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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