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Clinuvel Pharmaceuticals Limited
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Clinuvel Pharmaceuticals Limited recently raised A$35.2 million in new equity to fund the development program of CUV1647. The company's financial position is now transformed. What advances in clinical development and strategy have been achieved?

CEO Philippe Wolgen
The company's prospects have evolved very substantially in the last 12 months.

Firstly, I think it is important to note that the last twelve months of clinical development have been built on a significant safety profile in the patients treated. Since I joined Clinuvel we have redirected the clinical strategy of the company, to become entirely focused on demonstrating efficacy for CUV1647 in a "registrable' clinical indication. A key component of the changes was the appointment of Dr Helmer Agersborg as Chief Scientific Officer. We revisited the biochemical properties of CUV1647 and made the decision to apply CUV1647 where the clinical demand was most evident. Also, I have worked intensely with the existing Board for the company to benefit from their experience in the industry.

Secondly, we've built a cohesive management and clinical team around our lead drug candidate CUV1647, which takes responsibility for the program and executes it accordingly. This team is pivotal in the continuous development of CUV1647. I believe we have made significant progress by recruiting physicians and opinion leaders in their field worldwide.

Thirdly, through careful clinical trial design we have attained our milestones in demonstrating the efficacy of CUV1647 in key indications such as polymorphous light eruption (PLE) Phase IIb trials in Melbourne, the start of erythropoietic protoporphyria (EPP) trials in Switzerland and the protocols rewritten for the forthcoming trials.

Fourthly, we have ensured that we have communicated our strategy and objectives consistently to investors in Australia and internationally.

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What has been the value driver? Why have prospects improved?

CEO Philippe Wolgen
Unpredictably, a change in paradigm occurred where least expected during our investigations into photobiology of skin cancer we learnt that the incidence of skin cancer (SCC) and actinic keratosis (AK; pre-malignant sunspots) in fair-skinned organ transplant patients was significant. Research demonstrates that organ transplant patients with skin type I and II (according to the Fitzpatrick classification), have 65 to 100 times increased risk of developing skin cancer following the organ transplant.

We believe that CUV1647 could play a role in reducing the rate of AK development in organ transplant patients. We will commence clinical trials in 2007 with these patients.

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In your address to shareholders at last week's AGM you mentioned the clinical funding requirement of A$54 million for the CUV1647 development program. What is included in this estimate?

CEO Philippe Wolgen
Our latest prospectus contains an estimate of A$54 million to fund the clinical program, including the program for continuous product development, costs of clinical trials in PLE Phase II/III, AK Phase II, EPP Phase II/III, and other clinical costs.

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At the AGM you also highlighted the significant progress made towards first registration of CUV1647 in the last financial year. What trials are planned to progress the development of CUV1647 during the 2007 financial year?

CEO Philippe Wolgen
At this stage our clinical program contains five activities for the foreseeable future. However, I reiterate that in this business there are risks, which are typical to the dynamic process of drug development. I believe that we have a team with the right mindset to adapt to these dynamics and successfully achieve our objectives.

Having said this, clearly the upside of taking a new drug to market must be attractive from an investor's perspective. As it currently stands, our immediate targets are:

1. PLE trials planned in Q1/Q2 2007 in Europe;

2. EPP trials planned in Q1/Q2 2007 in Europe and Australia;
3. Solar Urticaria (SU) trials planned in Q1/Q2 2007 in the UK and Europe;
4. AK in immuno-compromised organ transplant patients, trials planned mid 2007 in Europe and Australia; and
5. Obtaining an Investigational New Drug (IND) status in preparation for our US clinical program.

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In the first fiscal quarter ended 30 September 2006, Clinuvel recorded a net cash burn of A$2.9 million. What is the likely rate of cash burn for the remainder of fiscal 2007?

CEO Philippe Wolgen
The A$2.9 million is a direct result of running a tight fiscal policy, but includes the costs of disposing of the pharmaceutical distribution business EpiPharm. The cash burn rate for the second and third quarters is projected to be close to the figure in the first quarter. It is important to note, that our spend is focussed on the clinical development of CUV1647.

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What is the relevance of the recent patent filings for specific clinical applications of CUV1647? Why has it been necessary to file new patents for the use of CUV1647?

CEO Philippe Wolgen
Continuous patent filing is very much the norm in pharmaceutical development. As discoveries in the application of CUV1647 are made, we will expand and fortify the intellectual property position of Clinuvel to continue to build the value of the company.

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In your address to shareholders, you also mentioned a US presence with the establishment of Clinuvel Inc. in San Francisco. What part will this presence play in Clinuvel's continuing development program?

CEO Philippe Wolgen
Our US office will position us closer to the US Food and Drug Administration (FDA) and will facilitate the coordination of the US trials. It is essential to have a presence on the ground in the US and this will also enhance the strength of our clinical team headquartered in Melbourne.

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What are the key milestone achievements marking continued progress towards first registration of CUV1647, which are being targeted during the 2007 financial year?

CEO Philippe Wolgen
Our key milestones, which we can be reasonably confident of achieving include: interim results for the EPP trial currently being conducted in Europe; commencement of Phase II/III trials in PLE subject to regulatory approval; commencement of trials in organ transplant patients in Australia and most likely in Europe.

Above all, I see the thoughtful and continuous monitoring of the safety profile for CUV1647 in human subjects a major milestone. Unlike the building of any other business, I keep reminding my team that we are working with and on humans. Safety of our lead peptide is a permanent focus. We've adopted the mindset to look at each safely tested patient as a corporate milestone.

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Can you provide on overview of the prospect of taking CUV1647 to market?

CEO Philippe Wolgen
Uniquely, we have identified four clinical indications for CUV1647. Past this I do not want to raise expectations, but we will announce a more specific regulatory timeline once more clinical results start coming in.

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Thank you Philippe.

For more information about Clinuvel Pharmaceuticals Limited, view www.clinuvel.com or contact CEO Dr Philippe Wolgen on +61 3 9660 4900.

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