



Company Announcement

Teleconference transcript of Investor Update held 19 March 2008

Dr Philippe Wolgen:

Good evening, good morning all participants and investors. As announced I would like to give you an update on the progress of Clinuvel and very much with an emphasis on the regulatory front. If we go back in history, we have a compound that has been used in healthy volunteers to measure pigmentation of the skin, and in 2004 the company sent a provisional note to the company's intent to file for less defined endpoints. Over the past 10 years we have demonstrated that this drug is safe to humans, well tolerated, and has photo protective properties. I keep repeating to all those interested and invested in Clinuvel, our task is foremost to demonstrate continuous safety with this novel peptide. We are now well on our way after a decade in development, however many issues will need to be ticked off to stand a reasonable chance with global regulators and the key word here is SAFETY. We have made a transition to find medical diseases which would respond to the drug CUV1647, or in other words, as of early 2006, we have found clear medical benefits to induce melanin and to find photo protection against the various skin diseases elicited by UV and sun. I would like to remind all those that in CUV1647 you have a drug that has never been put to market before, hence the classification of 'first in class' drug. Meaning a formulation, dose and delivery that needs to be optimum.

In early 2006 we came up with 3, and later added in 2007 another 2 indications and all based on the physical properties of the drug, driven by optics we are in the domain of testing this drug against the insult of light and UV on the effects on the skin. As said before, we raised in 2 rounds, monies against our plan to bring this innovative drug to market. Markets and regulators are always initially sceptical on new technology, not in the last place because no other entity has paved the way. However since the 4th of March this year, Clinuvel has obtained an official nod, granting Clinuvel 2 orphan drug statuses from the regulators in the UK, the EMEA, and this marks a historical breakthrough. If we stick by EMEA's directives and implement the EPP, the porphyria program and the CEP program, conditional upon SAFETY and efficacy, then the orphan designation granted will mean that we have a registrable drug for severe diseases. The orphan designation granted for smaller populations and by definition, orphan designations mean that this drug is targeted at smaller populations.

However, our ability to recruit approximately 8 to 10% of the populations and groups of sufferers, and our ability to show continuous safety using CUV1647 and reach the required efficacy are the requisites to pass the regulatory standards; I should stress that we need to take into account that we are dealing with living organisms, and as we all know in this industry, living biology is subject to variations at various times. So a degree of unpredictability in drug developments will always remain; this signifies the risk in R&D companies and also applies to Clinuvel, but we are continuously recording progress in time, very much decreasing the risk. With the EMEA grant of the Orphan Designations we have made a giant step forward in the development of CUV1647. I am content to date that we have shown sound safety data, and we continue to be vigilant and monitor the safe development of CUV1647. Our regulatory strategy at present is a diverse one, and it tries to address the various diseases where we deem our drug to work, and Clinuvel has the fortune to possess a drug that shields against light at a broad spectrum of wavelengths. It's our aim to prove at advanced levels where CUV1647 is best used to enter the market first.

At this occasion, I wish to answer some questions from those shown interest in the rigour that Clinuvel had to go through, signifying the difficulties in obtaining approval from the agencies like the EMEA, FDA and so forth. I would like to conclude this by saying that one of the analysts who has written on Clinuvel recently commented that 'the 4th of March 2008 marks the first time that regulators noticed that Clinuvel is on the pharmaceutical runway. It means that the regulators have accepted CUV1647 as a novel pharmaceutical entity rather than a peptide on an undefined pathway.' The next question that often arises is whether Clinuvel resembles a pattern seen in our industry and whether it is a Company actually keeping its timelines? And my answer is that we are spot on in Australia, Europe and Switzerland and given the considerable history of this company, we are thoroughly contemplating the US regulatory pathways, and when the optimum point in time is there, we will request an IND for CUV1647. I also want to recall that the company contemplated to file an IND in 2004 with the FDA, and withdrew its filing. It is heritage that we as new management carry

with us, with my new CSO, Dr Agersborg, we have set off to redesign the program in 2006. In other words, generating and collecting more clinical data to come back to the FDA to obtain an IND, a focus and clear objective. We are coming near to a point where we will be able to file, but so far I think we have not been in the position. I wish to succeed with this theme and we will file in the near future. In essence, Clinuvel is on track on the regulatory pathway as exemplified by the EMEA's grant of the 2 orphan indications, instead of the one that we hoped for, so far we exceeded expectations and more will follow on the merits of the technology.

In the last telephone conference, I stated our awareness of the high rate of failure in our industry and we are trying to design and reflect on all possibilities and options to reduce risk in our company. By any stretch of imagination, it is not an easy process to develop CUV1647 to market. The coming months will see that Solar Urticaria will go into the clinic, our 4th indication and our 5th indication, photo-dynamic therapy. That means that we will have 5 indications in the clinic, all managed by one company. In the meantime we will make regulatory progress on various fronts and also markets that Clinuvel will file for registration in 2009 and I sincerely believe that we are on track to do this. If this drug continues to demonstrate the same safety profile as the past years, then I am confident that we stand a more than reasonable chance of bringing this drug to market.

I would like to thank all of you that are sticking by Clinuvel, we as management are fully aware of the uncertain times in the markets, and of your patience which has been tested by the development of CUV1647 to become a known entity, drug, into the market. As management we very much appreciate and are aware of your confidence to date and I would like to open the phone and the lines for the questions.

Mike *[surname], US:

Yes, Dr Wolgen I have a question about the IND filing. I am wondering why, I understand there's some delays with it, but I wondered why you keep telling the shareholders publicly that it will be filed by a certain date and then it's never filed by that date? I can go back to October 2nd 2007, you said in a corporate file interview that it would be filed by December of 2007 and since then there have been a couple more instances when you have said that it would be filed by a certain date when it hasn't been, and the latest is that it still says on your website that it will be filed in the first quarter of this year. So I am not sure why investors are told over and over it will be filed by a certain time, and that deadline is never reached.

Dr Philippe Wolgen:

Thank you Michael. The point of filing an IND hinges very much on the confidence that you have and the reasonable certainty that you will actually obtain with IND, and what we at Clinuvel take into consideration is the unsuccessful attempt in 2004. To put the company in the best possible position from a data point of view and to decrease the risk of not obtaining an IND, we continue to prepare for lodgement. So what we are doing is we are assessing at every given point in time, that is more or less on a weekly basis, whether the chances of obtaining an IND with the current dossier answers every question that has been posed 4 years ago, all the issues that have been met; at Clinuvel we are very much approaching a position to get a green light from all different parties involved in this filing process, I want to make absolutely sure that we as executional team, in the interest of the Company and shareholders, will be granted this IND. Given the lengthy history of this company, the risk of rejection has to be minimised. While we prepare the lodgement to detail, we are filing in 3 other jurisdictions in the world. So the delay that is incurred is solely due to the fact that this company has to be in an optimum point, almost over-compensating on the data and the evidence provided to the FDA, and the delay incurred is for me very much acceptable as long as we remain confident we have a drug that can be filed and tested in the US.

Mike *[surname]:

Ok. Do you anticipate that you will file in 2008 still?

Dr Philippe Wolgen:

Yes, absolutely.

Mike *[surname]:

Ok, could I follow up with another quick question?

Dr Philippe Wolgen:

Sure.

Mike *[surname]:

Can you tell me the status of the start of SU Phase 2?

Dr Philippe Wolgen:

Yes solar urticaria is a very interesting phenomenon. It is an entity that is seen in a very small population in the world and what we have done is we have selected the very centres that have a sub-population of those SU patients who are therapy resistant. In other words, the very little therapy that is there for those solar urticaria sub-populations do not seem to work and that's the population that we will provide the drug CUV1647 for. Again, we anticipate that we are very near to file for commencement of these trials and that will be a Phase 2 open label trial in those patients.

Mike *[surname]:

Ok. Thank you.

Dr Philippe Wolgen:

You are welcome. Next question please. Is there any discussion, any comments, any information required or needed?

Philip *[surname], Australia:

Thank you. I was just reading an article that said Dr Aston said a typical, a successful Phase 3 drug got a royalty between 25 and 60%. With the indications going with orphan status, are you guys thinking more along the registration and how you will distribute and what sort of royalties would be acceptable for this drug?

Dr Philippe Wolgen:

Thank you Philip. The question harbours many elements Phil, the momentum is almost there were you start looking at distribution and marketing, sales of this drug, always conditional upon safety and efficacy and having the approvals. Orphan designations, orphan diseases are by definition smaller populations. If this company were to distribute this drug, then it would probably be able to cater for these smaller populations. For larger populations you need a distribution machinery, and whether the company will build it itself or seek assistance in the form of partnerships, that's a decision to be made at Board level, but royalties only come into play if licensing deals are being signed. At the moment we have been in a reasonably comfortable position not having to think and seek those licensing agreements, but the further we come along the development pathway the more opportune these discussions will become.

Philip *[surname]:

Ok. Thank you. I just have one other quick question and it's again to do with finances, with the problems we have been having in the banking sector, sorry I came in a little bit late to the meeting, but with the banking problems that we have had, have the 60 odd million in assets been stable? We haven't seen a capital loss or anything silly like that there?

Dr Philippe Wolgen:

We have various investments in the hands of our reputable bankers. We have the large proportion of the money available in cash and we do not anticipate or foresee any issues, no.

Philip *[surname]:

Excellent. Thank you.

Dr Philippe Wolgen:

Next questions, comments, discussions this is the forum to do it please.

John D *[surname], Australia:

Good evening Dr Wolgen. I have a question in relation to your relationship with Absolute Capital Management? I was wondering, they used to be the largest shareholder, I understand that funds are still distressed, have you had contact with them recently?

Dr Philippe Wolgen:

Well, we speak to all our larger shareholders and Absolute Capital has been more than commendable in their holdings. Since they announced the restructuring of their funds in September '07, they have held very steady in the position of Clinuvel and I must say in these markets that's not an easy feature. So, I am pretty happy with the position of ACMH as major shareholders, and all of our larger equity holders to date, a) they have borne the patience in the development of this company, and b) I also understand that Absolute Capital has been able to restructure its funds. Yes, we are in regular contact with Absolute Capital and I sincerely wish to see them stay in this company.

John D *[surname]:

Excellent, thank you Dr Wolgen.

Adrian *[surname], Switzerland:

Good evening Philippe, I have seen, you were appearing recently on a TV interview in Switzerland, Cash-TV, where you were asked about the idea of having a listing in Switzerland, how far has this idea developed?

Dr Philippe Wolgen:

Thank you Adrian. The interview mentioned 2 things, what was asked to me or the question posed to me was whether this company was seeking any other listing in Europe, and I don't exclude that. At the moment we have got a shadow listing on Xetra Dax in Germany where we have reasonable but not impressive volume, and the question was 'would you consider any other listing?' And standing in front of Swiss cameras I would say to you that Switzerland is not a bad market for pharmaceutical companies in general. We have not activated a process to list anywhere in the world or Switzerland; but Australia remains our primary market, and so far we haven't had any impetus or any reason to change our current strategy. Switzerland is a very good market that understands biotech and pharma, that's all.

Adrian *[surname]:

Thank you.

John R *[surname], Australia:

Dr Wolgen I was just following up on that question about Absolute Capital, since the shares dropped from the \$1.20 to the 35, 36 cents arena, I was just wondering if there's been any significant change in the major shareholders? Has there been any sort of redistribution there at all?

Dr Philippe Wolgen:

No I don't see any redistribution on our share register and when you say major changes, we haven't seen any changes over and above the 2% requiring reporting by shareholders; and on your specific question, Absolute Capital, I reiterate that I find it reasonable and commendable in these times that a hedge fund is maintaining its holding of 20% stake in a small biotech company; this gives me confidence a) that they have stabilised their position, and b) that they have confidence in the chosen pathway to bring this drug to market.

John R *[surname]:

So they have still held their position even though the shares have dropped in value?

Dr Philippe Wolgen:

That's correct, and that is over time, and time often gives you the answers. These major shareholders have borne the patience and hence have the liquidity to ride out the lengthy development of new drugs. Yes, we as management are pretty confident and happy with it, but we are constantly in discussion with our major shareholders to understand what their position is in bear markets.

John R *[surname]:

Thank you.

Dr Philippe Wolgen:

You are welcome. If there are no further questions, I close the discussion for tonight. I thank you for your patience and your attendance in the early or late hours and you will see the transcript on our website. Please keep with us for the next 12 months. Thank you.

END OF TRANSCRIPT

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX:**CUV**, XETRA/DAX:**UR9**, ADR:**CUVLY**) is an Australian biopharmaceutical company developing its photo-protective drug CUV1647 as a preventative treatment for a range of UV-related skin disorders as well as in cancer related treatments.

The five indications are:

| Indication | Description | Clinical Trial Status |
|---|---|---|
| Polymorphic Light Eruption (PLE / PMLE) | Severe sun poisoning | Phase III trials started May 2007 |
| Erythropoietic Protoporphyrria (EPP) | Absolute sun intolerance | Phase III trials started April 2007 |
| Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Patients (OTP) | Precursor to skin cancer / non-melanoma skin cancer | Phase II trials started October 2007 |
| Solar Urticaria (SU) | Acute anaphylactic reaction to sun | Phase II trials planned to begin 1 st quarter 2008 |
| Phototoxicity associated with Photodynamic Therapy (PDT) | Photo-sensitivity associated with cancer treatment | Phase II trials planned to begin 1 st half 2008 |

Phase I and II human clinical trials using CUV1647 have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date.

Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of CUV1647.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its leading drug candidate, CUV1647, for a range of UV-related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks. Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward-looking statements), investors should note the following:

- actual results may and often will differ materially from these forward-looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development programme for CUV1647 can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for CUV1647 is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place

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