Clinuvel communique

MARKET ACCESS

I look back at a turbulent period, as CLINUVEL has brought the 'negotiations' with GKV-Spitzenverband (National Association of Statutory Health Insurance Funds in Germany) to a successful end. Key observations from this procedure are that insurers are coordinating efforts internationally to cull healthcare costs, and will come up with any conceivable argument to lower prices of pharmaceuticals irrespective of prior investments, manufacturing and distribution costs, post-marketing expenses, company's structure, and obligatory ongoing research for children. The GKV-Spitzenverband is leading European insurers in curtailing the position of pharmaceutical companies, appeared very well prepared, and left no stone unturned in its attempt to end the existence of CLINUVEL. From our perspective there was only going to be one outcome for CLINUVEL to survive and continue to serve European EPP patients. The outcome is known to CLINUVEL's stakeholders.

According to German legislation CLINUVEL is prohibited to discuss the exact nature and content of the procedure with GKV and the Healthcare Court of Arbitration. However, I believe that our patient shareholders deserve equivalent information, at least a broad note without CLINUVEL breaching the aforementioned confidentiality.

CLINUVEL entered the German market with SCENESSE® (afamelanotide 16mg) in July 2016[1] while the first obligatory contact with the German health authorities as early as 2014.

In evaluating the clinical benefit of SCENESSE®, the German Federal Joint Committee (G-BA) came to a ruling consistent with the European Medicines Agency (EMA): it deemed the benefit of SCENESSE® sui generis, of clinical value and '*non-quantifiable*'. CLINUVEL had reached that very same conclusion in 2010 following various clinical trial designs in erythropoietic protoporphyria (EPP) while the EMA had arrived at that point after two and half years of deliberations, in October 2014.

It is perhaps asking the impossible to expect an intermediary, regulator or national insurer (in this case GKV-Spitzenverband) to deepen its knowledge on a novel disorder and an innovative therapy in a specific first formulation within 12 months; congruency in scientific knowledge will likely not occur.

GKV-Spitzenverband ultimately has the power to reject a drug for the German market on the basis of disproportionate cost-benefit. The discussion ultimately led to arbitration, where the Court of Arbitration in Berlin took time to understand the constraints of EPP and ruled in favour of patient access to treatment.

CLINUVEL has succeeded where other pharmaceutical companies have fallen short and I cannot thank the entire CLINUVEL team enough for the hard work, persistence and integrity over the years.

EUROPEAN DISTRIBUTION

As shown in the Company's quarterly financial statements and flagged in the last update, treatment cycles determined fluctuation in cash receipts.

In each country we are witnessing, in the second year of distribution, an absolute increase in patients requesting treatment. More than 92% of EPP patients seek treatment for the second year under the post-marketing program. These percentages seem to mirror the pattern seen during the Special Access Schemes during 2010 to 2016 in Italy and Switzerland.

We are currently analysing variables such as latitude and altitude, as well as individual factors in order to better understand longitudinal treatment with SCENESSE®.

In a number of countries the market access and reimbursement of SCENESSE® is still in the hands of health economists, national health systems and specialised committees. News earlier this month from England is one such example.

US FDA UPDATE

In the process of ongoing document filing with the FDA, our regulatory teams have most recently been successful in obtaining a 'carcinogenicity waiver'. This implies that further carcinogenicity studies and data on SCENESSE® are not necessary, and any further doubts on the safety of this first in class drug having been allayed. This is a stark departure from the stance the FDA had taken since 2004. It was our plan that the longevity of the use of SCENESSE® in EPP and the data from the current European distribution would aid the FDA in its review.

We expect the modular filing for a New Drug Approval (NDA) to continue while further exchange are held on format and analyses.

When the NDA dossier is validated by the FDA CLINUVEL will seek a dialogue on further development of SCENESSE®.

EVOLUTION TO CLINUVEL-2020

CLINUVEL's knowledge on EPP has been accumulated over more than a decade. In this time our teams have truly become super-specialists in all aspects of optics, physics, the interaction of light and human biology (skin), and melanocortins. In many ways we have given the first shape to the concept of systemic photoprotection, a hormonal therapy to activate the natural protective response to light and ultraviolet. Objectively, there is no other company which has endeavoured to prove this concept: CLINUVEL's foray has been one of true innovation.

In the coming months CLINUVEL will unveil its adapted business model, expanding the Group beyond SCENESSE®. It has long been our wish to grow the Company beyond more than one commercial asset. The prerequisite was to identify, reinforce and test our core competences to appraise the directions in which we could grow. Analogous to the past years, we wish to minimise the risk of entering new fields and markets while making sure pilot schemes provide us the necessary confidence and feedback on the feasibility of further growth.

The question posed during years of analyses and reflection was what one would expect **CLINUVEL-2020** to look like, or which framework would one want to leave behind for the next generation?

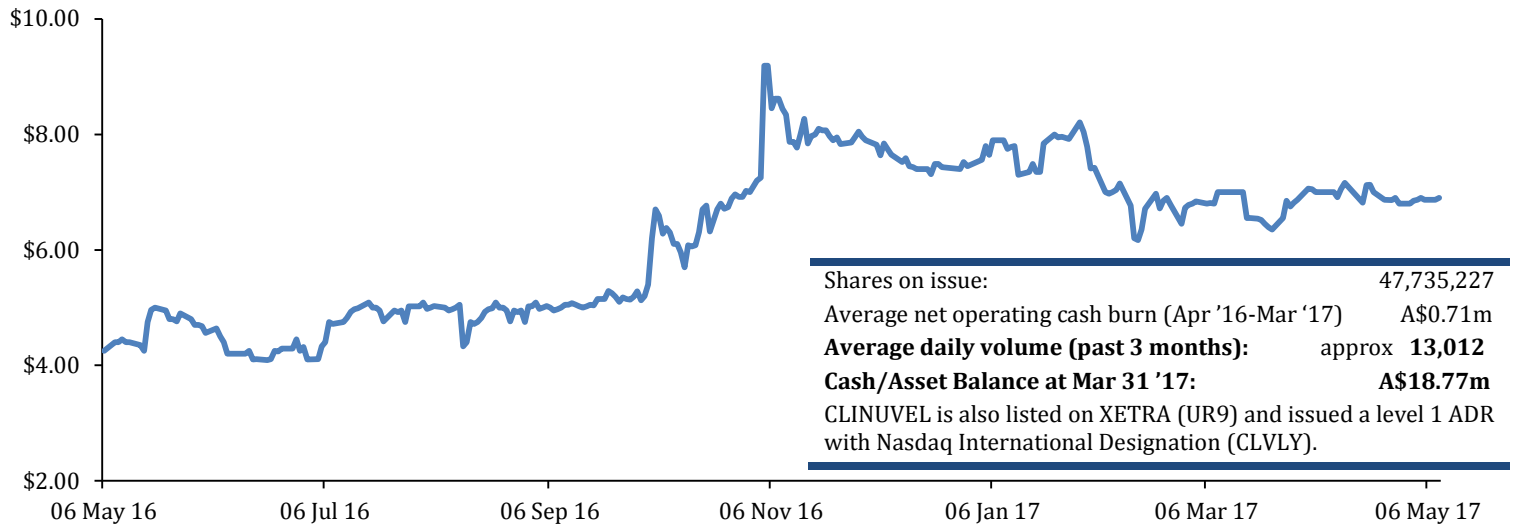
The Board's view is that SCENESSE® - once fully introduced in the EU and US market – would need to be expanded to the SCENESSE® ENFANCE (paediatric) version for EPP children to gain access to treatment. Second, the Company would need to become less dependent on SCENESSE® and incrementally grow into a diversified group.

In our future newsletters we will release sufficient information for our loyal investors to gain an understanding of our new directions without jeopardising CLINUVEL's assets and knowhow sought by emerging competitors. Seasoned stakeholders will appreciate the balance to be struck.

Philippe Wolgen

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at www.clinuvel.com. Information on EPP can be found at www.epp.care.

ASX: CUV



Shares on issue:	47,735,227
Average net operating cash burn (Apr '16-Mar '17)	A$0.71m
Average daily volume (past 3 months):	approx **13,012**
Cash/Asset Balance at Mar 31 '17:	**A$18.77m**

CLINUVEL is also listed on XETRA (UR9) and issued a level 1 ADR with Nasdaq International Designation (CLVLY).

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care.
Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Forward-Looking Statements

This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause CLINUVEL's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that CLINUVEL may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US.