November 2018
CLINUVEL *Communiqué*

CLINUVEL

LATEST RESULTS

The most recent quarterly financial results (1 July-30 September 2018) confirm the steady growth in clinical demand for SCENESSE® (afamelanotide 16mg) in erythropoietic protoporphyria (EPP), a rare genetic metabolic disorder.[1] EPP is classified as a condition of high unmet medical need, and for it not to have found any alternative therapy makes the treatment with our hormonal product SCENESSE® worthwhile for patients.

As to the financial management of the Company, CFO Mr Darren Keamy and his team are responsible for a steady course, providing the basis for CLINUVEL as a sustainable and successful entity thus far. Yet, the path to grow this Company to a diversified entity will remain challenging. We will explain some of these objectives and rationale at the AGM on 21 November.

Consequent to the Board of Directors' approval on 29 August of the 2017/18 financial statements – in which the Company reported a second consecutive net operating profit – the Board resolved to recommend the payment of a first-time unfranked dividend of A$0.02 per ordinary share. The total dividend pay-out amounted to A$957,159, and was paid on 8 October 2018 to those shareholders who were on the share register at the 24 September 2018 record date. The Board of Directors wished to return value back to our shareholders now that the Company was in a viable position to do so.

UNITED STATES

Some US physicians and patients have asked about timelines and availability of SCENESSE® in North America. In answering, we are obligated to observe the regulatory rules. It is not widely known by the public that the US Food and Drug Administration (FDA) insists that the formal discussions and exchange between sponsor and agency are confidential in nature and that a breach of this can have significant consequences for the validity of the review process. Therefore, within the boundaries of permissible news flow and information, the Company will give some impressions on the US regulatory route thus far.

This year we reported on the frequent interaction with the FDA, and in August (two months after CLINUVEL's submission of the final module) the agency had five potential ways of responding to it:

(i) full validation of all modules (comprising the scientific dossier on SCENESSE®); or
(ii) request for additional information on each module; or
(iii) further regulatory recommendations on the data package; or
(iv) advise withdrawal of the submission on the basis that more scientific data are required to make the data package fit for review; or
(v) refusal to file (RTF) on the basis of critical issues found in the scientific dossier.

In the communication between both parties it was apparent that - from the agency's requests and from the nature of the questions - no major outstanding issues had been identified which would lead or need to lead to a refusal to file, which was confirmed by the agency. Instead, the agency communicated that it had further and specific questions on product and manufacturing, and our teams set out to collect further information and answer these. As a process, our teams, together with associated third parties, analysed the retrieved data and provided answers to each individual question to satisfy these latest regulatory requests.

In many ways the regulatory clock was then stopped by the agency, which decided to allow more time for answers and itself making available more manpower to review the answers. Each division of the FDA has its modus of operating and discretionary power to go through a validation and

review period. No two submissions are the same and each may receive a different regulatory approach.

To appreciate the methodical approach taken by the FDA we go back putting in context the activities the FDA initiated to gain knowledge on - a poorly characterized disorder (EPP) and for the regulator a novel and thus far unknown - pharmaceutical product.

In March 2016, our teams were asked by the FDA to submit all clinical trial results individually and in pooled format for a first global review to take place. As expected and lege artis, the FDA's reviewers had received the individual study results in EPP after the completion of each clinical trial conducted in the period 2006 to 2013, hence the March 2016 request served the agency to refresh its memory and look collectively at individual and pooled data analyses. For this initiative and additional effort one ought to commend the FDA, since it is substantially understaffed and needs to give appropriate attention and time to all applicants of novel agents, biologics, generic drugs, and medical devices month by month. The FDA is logistically coordinating the abundance of scientific dossiers to perform a fair review.

In CLINUVEL's case, in July 2016 the FDA granted the company Fast Track Designation providing our teams the ability to submit the scientific dossier on a rolling basis. Preluding CLINUVEL's submission, the FDA conducted a Scientific Workshop on EPP in October 2016 having invited 150 US EPP patients and families as well as international expert academics in porphyria. An end-of-phase III meeting ("pre-NDA") was held in November 2016, and subsequently CLINUVEL was invited to submit its dossier on SCENESSE®.

Our scientific teams had anticipated that, during the commercial distribution of SCENESSE® in Europe, more safety and effectiveness data would become available and naturally had requested that the FDA allow its incorporation into the dossier to increase the information on the product under real-world conditions. Hence after such data had become available and submitted to the European Medicines Agency (EMA) the FDA also received these data to supplement the rolling review.

Accordingly, it remains throughout possible that the FDA may still have further questions and decide at its discretion which information it requires to arrive at an integrated view on the dossier, and ultimately to a balanced risk-benefit assessment of the product.

Our Chairman stated rightly in his recent letter to shareholders (October 2018) that the course taken by the FDA was anticipated and not of surprise to our teams, since SCENESSE® is defined as a novel chemical entity, in an innovative pharmaceutical formulation, with a new mode of action and manufactured with a set of processes and methods not comparable to any other pharmaceutical product available. The FDA is known to scrutinise innovative technologies to ensure that all aspects of manufacturing are controlled, and no surprises manifest once the product is commercially available in the US. It is in this context that the FDA shoulders joint responsibility with the pharmaceutical sponsor for the new commercial product when American citizens are exposed.

The Company awaits the FDA's decision on its own formal review process, either a Standard Review or an accelerated process under a Priority Review. Without contravening our agreement with the FDA on disclosure, the Company will share whatever commentary possible as regards progress with the FDA.

Another factor which will perhaps have an impact on the FDA's decision process is our suggestion of the US post-marketing program in EPP. The ongoing European Risk Management Plan encompasses strict pharmacovigilance with predetermined periodic reviews and analyses of safety data, and detection of possible safety signals. The US regulator is not used to reflecting on an integral surveillance program, and typically a qualified person for pharmacovigilance does not have the same remit in the US as it has in the European Union. CLINUVEL's proposal to the FDA is to harmonise the European commitments with a US program encapsulating all aspects of EPP patients' follow-up into one global program. In replicating quality management systems, pharmacovigilance, validated databases and further elements of the European surveillance program in EPP, more efficiencies and economies of scale can be achieved. Once a final agreement is reached, we will report how our US team will monitor American EPP patients in the longer-term.

EUROPE

In the United Kingdom, we reported on 10 October the interchange with the advisory body National Institute for Health and Care Excellence (NICE). NICE has a decisive role in recommending therapies for reimbursement by the English National Health Service England (NHS England), and, as reported, CLINUVEL has long been fighting to see SCENESSE® become available to English EPP patients on a fully reimbursable basis. The Appeal Panel outcome from the oral appeal hearing held on 31 July illustrated that our approach had been justified and correct, and we will pursue this avenue accordingly and until the English patients are treated. For reasons of confidentiality that has been agreed with NICE, the Company is unable to publish the present state of play between the parties.

To those patients who reside in England who are readers of this newsletter, the Company is acutely aware of your frustration of not having access to an existing treatment; even more so when there is no other effective alternative therapy. The Company is doing its utmost to change the situation. Whilst it is understandable that a state or health system needs to be vigilant about allocation of resources, agreements can be made with pharmaceutical companies as part of a covenant to provide a managed access into a country. CLINUVEL has shown to be able to respect these agreements in several countries, and it is hoped that NICE will embrace this idea in a way that ensures long-term sustainability of supply of SCENESSE® to English patients.

EXTERNAL EVENTS

Due to unforeseen circumstances incurred by our suppliers, a knock-on effect was seen to CLIUVEL's timelines for the new OTC product line and impacting the launch. We are confident that these issues will be resolved to ensure the registered product line can be launched in the New Year. At present the CUV103 Singaporean Phase IIa study in generalised vitiligo is being finalised by our clinical and regulatory team. Since the regulatory time committed to FDA activities is decreasing, the completion of the analyses of the pilot CUV103 study is ending. Finally, and as part of our self-imposed targets, we are awaiting the final protocol agreement with an academic centre which will conduct the pilot study in the third elected indication. CLINUVEL will announce this indication when all legal and administrative agreements have been completed.

Last week we reported on the expansion of our research and development facilities in Singapore. Following CLINUVEL's acquisition of the 18% minority stake earlier this year, full integration of the VALLAURIX team has taken place. As we further our melanocortin research, the retention of knowhow and intellectual property was strengthened by entrenchment of several personnel's analytical capabilities into new R&D processes. We foresee that further product lines will come out of VALLAURIX, Singapore, although the Company is not without market competition in trying to secure top talent in what is considered by many businesses as a thriving and respected innovation hub in Asia.

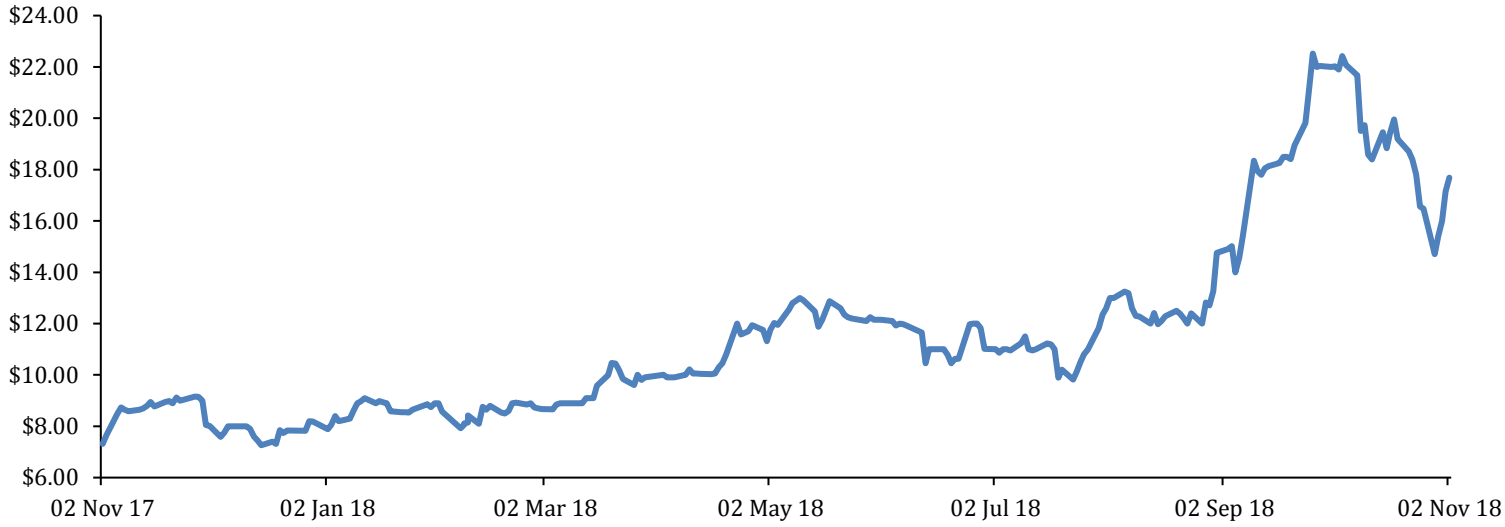
As the 'Brexit' date of 29 March 2019 is approaching, our teams are in final preparation for a European transfer of the marketing authorisation of SCENESSE®. Several functions will accompany the obligatory changes imposed by the geopolitical shift owing to the UK's departure from Europe. The outcome, whether a "softer" or "no-deal" Brexit, will have some implications for CLINUVEL. We will report in the next News Communiqués about our operational decisions.

I look forward seeing the new and existing shareholders in Melbourne at CLINUVEL's AGM on 21 November.

Philippe Wolgen

[1] SCENESSE® (afamelanotide16mg) 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.

ASX: CUV



Shares on issue:	**47,857,986**
Average operating monthly cash spend (01 Jul '18 – 30 Sept '18)	**A$0.95m**
Average daily volume (past 3 months):	87,041

CLINUVEL is also listed on XETRA (UR9) and issued a level 1 ADR program 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 photomedicine and 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, with the UK acting as the EU distribution centre. For more information go to http://www.clinuvel.com.

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 or other 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; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs.