20 September, 2016

Dear Shareholders,

This summer our team supplied the first SCENESSE® (afamelanotide 16mg) treatment for erythropoietic protoporphyria (EPP) patients in the Netherlands and Austria. It has been a long journey and our gratitude goes to the forbearance of patients, physicians, and shareholders alike in supporting the efforts of a dedicated Clinuvel staff, who must take pride and credit for an outstanding achievement. Four months after the very final signature of the post-authorisation commitments by the European Medicines Agency, EPP patients now have, for the first time, a standard of care in Europe.

While we had subsidised SCENESSE® in Switzerland and Italy for a number of years through special access schemes, the pharmaceutical product is now being supplied to the first two countries under uniform post-authorisation conditions.

Timing is everything in pharmaceuticals. Expansion of the Clinuvel Group has been planned for years and would only occur after gaining certainty of product release in Europe. The objective to make Clinuvel financially independent answers requests from active investors who have funded the focussed research in EPP. As a consequence of the European distribution, the company now finds itself in a remodelling state, establishing a new composition of teams.

As Chair I oversee the functioning and make up of our senior management team and Board. It is riveting to stand in the middle of the ensemble of established and new skillsets. I unequivocally see a relationship between the calibre of people employed by Clinuvel and our success to date. Many executives in the pharmaceutical industry will agree that very few companies, particularly those located in the Asia-Pacific region, have developed a product from pre-clinical to market authorisation by virtue of singe-minded focus on a rare disease. Our CEO is the conductor of the symphony, making our philharmonic play from the same music sheet. The next challenges expectedly require new members of the orchestra. The UK distribution team has seen new additions, and equally the R&D centre in Singapore is gradually increasing in numbers. As we speak we are restructuring our US operations and we are putting in place a team to assist our leading regulatory team in the finalisation of an FDA filing.

With a fully functional experimental and drug development laboratory, we have in *VALLAURIX PTE LTD* an emerging arm of the Clinuvel Group working on a suite of novel and complementary products. Competitors have been keeping a close eye on our new developments and therefore we will work silently until products are ready for human use.

In 2006 the Board demanded our existing management fulfil a number of internal objectives. In reciprocation in 2007 our CEO expressed his ambition to make Clinuvel independent of funding from capital markets. We have now agreed to explore ways to expand the Group with the aim of being able to pay for the mandatory development of a paediatric formulation in EPP and SCENESSE® for vitiligo.

The US FDA has acknowledged the SCENESSE® data package and the need to treat EPP patients at the earliest occasion. The recent news that the FDA had positively assessed Clinuvel's EPP data as ready for filing for an NDA, together with the Fast Track Designation, must be seen as a chronicled breakthrough for the company entering the US. I cannot start to express how much work our teams have done over the years to come this far, but perhaps a comparison reflects my thoughts. One never knows how the kitchen of a starred restaurant prepares its dishes, but some of us know the sous-chefs get up at four o'clock in the morning to get the freshest

Australian Office: Level 5, 160 Queen Street Melbourne Victoria 3000 Australia T +61 3 9660 4900
Swiss Office: 135 Baarerstr, 6301 Zug, Switzerland T +41 41 767 4545
UK Office: Wesley House, Bull Hill, Leatherhead, KT22 7AH, Surrey, UK T +44 1372 860 765
US Office: 40 Worth Street, Suite 1053, Floor 10 New York, NY 10013, USA T +1 646 527 7310
www.clinuvel.com

products from the markets. The past 12 years many of our teams have worked 24 hour shifts to get SCENESSE® to US patients.

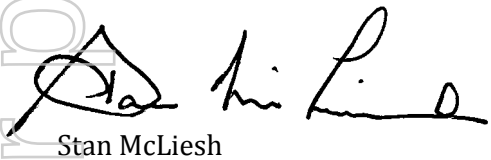
As part of the FDA review process the regulatory authority will host an EPP Workshop for patients and expert physicians on 24 October to learn first-hand about the disorder and prospective treatment. Shortly after, our team will have a meeting with the relevant Division to discuss the filing of our data package 'on a rolling basis'. Much groundwork is still expected from our scientific teams for SCENESSE® to become a registered and reimbursed product in the US. The task of filing an adequate drug dossier and coordinating suppliers, manufacturers and a team of specific experts is under way. More on this will come in future months. Additionally, we had long planned to combine the vitiligo safety data with the EPP program to provide the FDA with an additional level of confidence on allowing a first-in-class drug on the market for the orphan indication. Management's overall approach is on course with the recent completion of the final pre-clinical study in vitiligo.

Regrettably some Clinuvel shareholders have made attempts to approach patient organisations and physicians directly to gain more information ahead of company announcements. This is a perilous practice that can result in increased scrutiny of the company by government and regulatory agencies and may lead to possible delays as a consequence.

I have witnessed the past months that Clinuvel's key professional investors have not only remained strong supporters, but some have increased their stake in the company. Some of their direct feedback is that Clinuvel's robust approach and patience provides them much confidence in terms of consistency and delivering on promises of making the SCENESSE® treatment available in Europe and US. Alongside our clinical, regulatory and commercial achievements the value of Clinuvel is thought to increase, and the recent share performance seems to confirm this.

I share my final thoughts with you before I pick up my pen again for the Annual General Meeting in November. The Clinuvel Board has had a vision to see SCENESSE® come to market since we appointed a new team in 2005. Under guidance of our senior management and the entire staff we have realised a journey which had seemed many light years away. By staying calm at quite a number of times when resistance and obstacles were met, and with certain intelligence, we have arrived at today's status. Many more hurdles will undoubtedly be faced, but I have full confidence that the balance of professionals has the prowess to keep impressing us in years to come.

I would publicly like to thank the entire Clinuvel team for their focus and hours they have put in on behalf of the patients and shareholders: your willingness to focus on specific subjects is much appreciated, you are all passionate about making a difference to patients' lives and I expect you all will keep progressing us along our strategic pathway.



Stan McLiesh
Chair,
Clinuvel Group

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals (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), is approved by the European Medicines Agency for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). For more on EPP go to 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.

Investor enquiries
InvestorRelations@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; 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.

Level 5, 160 Queen Street
Melbourne, Victoria 3000
Australia

T +61 3 9660 4900
F +61 3 9660 4999

www.clinuvel.com