CLINUVEL

In recent months the CLINUVEL Group has welcomed a number of Australian and international shareholders joining our register for the first time. I would like to add my personal welcome and thank our existing shareholders for their support through many difficult phases of development.

Our team has compiled this update for shareholders, long-term and new, to provide a snapshot of the Company's progress.

I look forward to sharing the next steps with you.

Sincerely,

Stan McLiesh

Chair

Photoprotection and Photomedicine

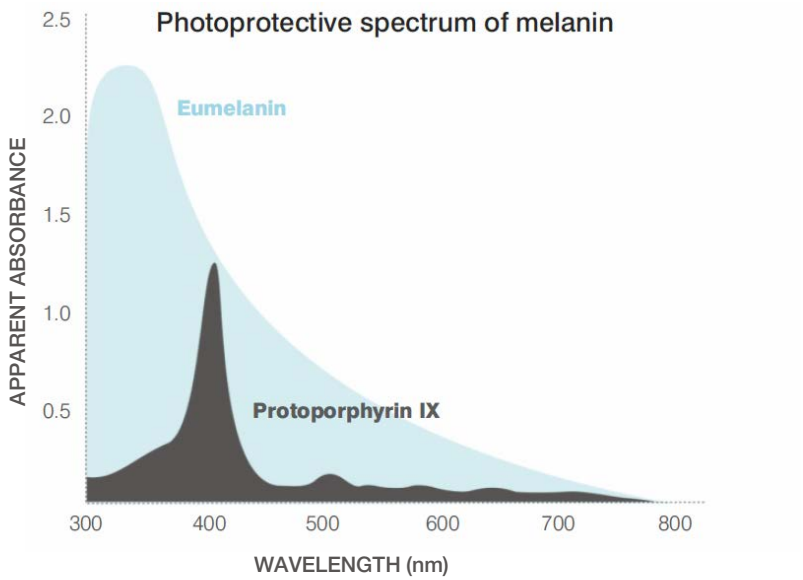
Increasing interest has been seen in the interaction between the human body and non-ionising radiation, part of the emerging field of photomedicine.

During the latter decades of the last century the scientific community first began to grasp the short- and long-term impacts of acute and chronic *exposure* to invisible ultraviolet (UV) radiation, particularly in fair-skinned populations in regions of high UV exposure. Nowhere was this more evident than Australia, where more than three percent of the population is treated for some form of skin cancer annually, but overall awareness of the problem has helped reduce skin cancer deaths. Conversely, research attention also turned to concerns around chronic *underexposure* to UV, with the role of vitamin D – the "sunshine vitamin" – being explored and implicated in a wide range of disorders. Underexposure to various wavelengths of light was also linked to a range of mental health conditions, with seasonal affective disorder (SAD) being the most prominent. In the early 21st century questions were being answered about how to find balance in our relationship with UV and light such that too much or too little exposure isn't detrimental to our health.

CLINUVEL has taken a keen interest and active role in research and development in photomedicine, investigating the interaction of light and human biology and pioneering the concept of medicinal photoprotection – protecting skin from light. By doing so, the concentration of resources and efforts on photomedicine has made CLINUVEL a leader worldwide. By working with patients who are most severely affected by light – those with the ultra-rare disorder erythropoietic protoporphyria, EPP – we have developed a first-line, first-in-class novel drug SCENESSE® (afamelanotide 16mg). This breakthrough has provided us with the foundation on which to build and grow the Group, and continue to deliver innovative medical solutions for complex problems.

As the first ever photoprotective drug, SCENESSE® activates eumelanin, the dark pigment in skin. Eumelanin is capable of selective light absorption, including at the wavelengths of light which excite protoporphyrin IX, the compound which causes phototoxic reactions in patients diagnosed with EPP, a genetic metabolic disorder which causes absolute intolerance to light (blue and green spectrum).

SCENESSE® works pharmacologically in several ways. One of the effects of the administration of afamelanotide 16mg is the generation of eumelanin in the skin of patients who are usually incapable of producing epidermal darkening under normal UV conditions. Afamelanotide is the lead agent developed by CLINUVEL and belongs to the class of proopiomelanocortins (POMCs). The molecule itself has anti-oxidative, anti-inflammatory and paracrine effects. Eumelanin's peak absorption, however, is at 340nm and continues well into the visible spectrum.



SCENESSE® (afamelanotide 16mg)

Active ingredient, dose	Afamelanotide 16mg
Formulation	Controlled-release subcutaneous injectable implant approximately the size of a grain of rice.
Approved indication (EU)	The prevention of phototoxicity in adult patients with EPP.
Afamelanotide doses administered to date	>7,900
EPP patients who have received at least 16 implants	50
Treatment continuation rate reported in the EU and Switzerland (patients returning after at least their first year of treatment)	>98%
Longest distance travelled to receive treatment	Approx. 4,000 miles (USA to Switzerland)
Peer-review articles featuring afamelanotide	>140
Academic conference presentations featuring afamelanotide	>50
Representation at 2018 European EPP Expert Meeting	Experts from 21 centres across 12 countries

** For full product information, see the SCENESSE® summary of product characteristics on CLINUVEL's website.*

SCENESSE® in Europe

SCENESSE® was approved by the European Medicines Agency (EMA) for the prevention of phototoxicity in adult patients with EPP in December 2014, with the first patients receiving the drug under the marketing authorisation in June 2016. Since then CLINUVEL has facilitated the treatment of EPP patients in six EU countries, as well as the ongoing use of the product under a special access scheme in Switzerland. A small number of Swiss EPP patients have received continuous treatment with the product for more than a decade.

Under the terms of the EMA approval, CLINUVEL is required to monitor the long-term use of SCENESSE® in EPP patients, and has established compliant pharmacovigilance systems to enable the close analysis of reports from European EPP Expert Centres (EEECs).

CLINUVEL only distributes SCENESSE® to EEECs where patients are able to receive multidisciplinary expert care. Forty-four of these centres have been identified across Europe, with the team working to improve treatment access for patients for whom there is no alternative therapy.

US FDA

CLINUVEL filed a new drug application (NDA) with the US Food and Drug Administration (FDA) in June 2018. An approved NDA will allow the Company to make SCENESSE® available to adult EPP patients in the US. Pending validation of the NDA dossier, and allocation of priority or standard review, CLINUVEL expects the FDA's active review time to take 6-12 months, although up to 24 months may be required for the additional analysis and questions from the agency.

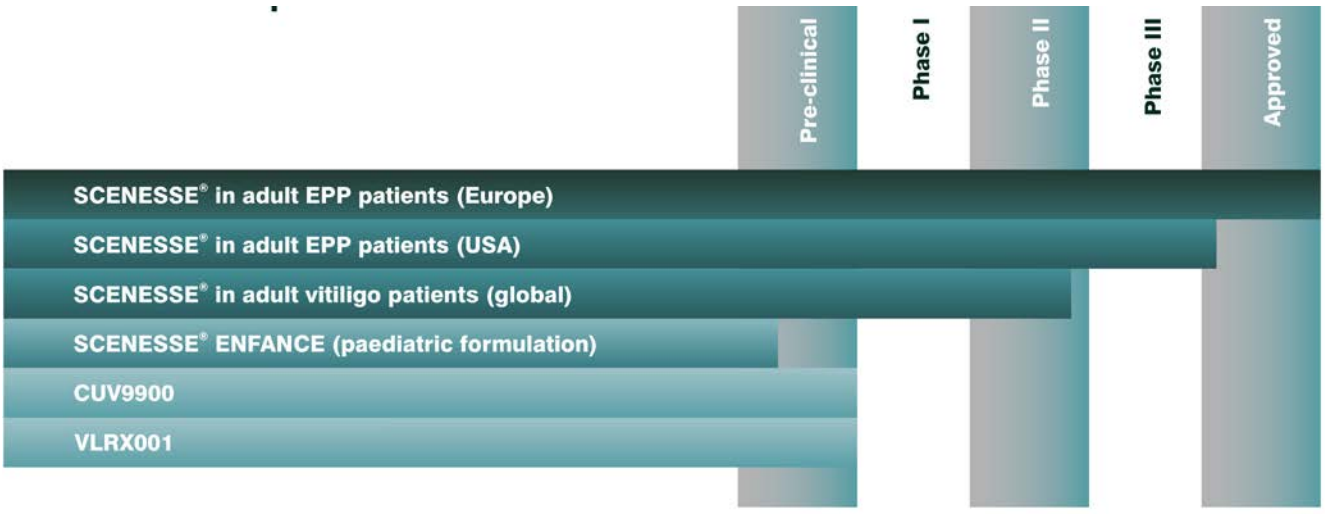
FDA New Drug Application Review Process

Research and Development

In addition to ongoing regulatory activities for CLINUVEL's first-in-class drug SCENESSE® for adult EPP patients, the Company is progressing both clinical and non-clinical research and development programmes. During 2018 results will be announced from a Phase IIa pilot study of SCENESSE® in the pigmentation disorder vitiligo, where the drug is used in combination with narrowband ultraviolet-B therapy to halt pigment loss and repigment the skin. Further clinical research into vitiligo will be determined in line with the US review of SCENESSE® for EPP.

The Company's scientific research team – based in Singapore – is progressing three key pharmaceutical projects, with a paediatric formulation of afamelanotide and two follow-on molecules. Work is also underway to deliver complementary non-pharmaceutical products in future.

CLINUVEL R&D Pipeline



Financials

CLINUVEL reports cash flow statements quarterly, with full financial year (1 July to 30 June) results released by 31 August. Since 2006 the Company has raised over A$95 million to finance the development of afamelanotide, with the total funds committed in the program to date of A$172 million. These expenditures need to be seen against research costs incurred by peer companies, and these demonstrate the efficiency of CLINUVEL's R&D over the past decade and a half. CLINUVEL observes financial discipline across all companies in the Group.

Cash and cash equivalents (30 Jun 2018)	A$36.198m
Average approximate operating monthly cash spend (01 Jan 2018 - 30 Jun 2018)	A$1.030m

ASX: CUV

Shares on issue	47,824,427
Fully diluted	49,574,987
Market cap (20 Aug 2018)	A$597.81m

Share price and volume
(ASX: CUV 21 Aug 2017 - 20 Aug 2018)

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 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; 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.

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