



CLINUVEL

Company Announcement

INVESTOR PRESENTATION - BIOCENTURY NEWSMAKERS CONFERENCE

Melbourne, Australia, and New York, USA, 10 September 2018

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY) presented to the BioCentury NewsMakers conference in New York on Friday 07 September. A copy of the presentation and speaking notes is appended.

- End -

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>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Media enquiries

USA: Terri Clevenger, Continuum Health Communications,
T +1 (203) 227-0209, tclevenger@continuumhealthcom.com
Europe: Lachlan Hay, CLINUVEL (UK) LTD.
T +44 1372 860 765
Lachlan.Hay@clinuvel.com

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; 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.

Level 6, 15 Queen Street
Melbourne, Victoria 3000
Australia

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

www.clinuvel.com

For personal use only

CLINUVEL PHARMACEUTICALS LTD

New York, 07 September 2018

Lachlan Hay
General Manager
CLINUVEL (UK) LTD

ASX:
NASDAQ INTERNATIONAL DESIGNATION ADR:
XETRA:

CUV
CLVLY
UR9



CLINUVEL

CLINUVEL has taken the timely opportunity to present its story internationally.

As of Friday 07 September 2018, the ASX listed stock CUV been included in the S&P/ASX 300 Index.

Forward-looking statements, “safe harbor”

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; 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; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2017 Annual Report and 2018 Preliminary Financial Report. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.



This presenter may make forward looking statements. The audience is forewarned through the safe harbor statement to read and understand the risks of CLINUVEL's business.

Overview

- Specialty pharmaceutical company
 - Longevity (14 years) – Management and Board
 - No competition, no alternative treatment to SCENESSE® (afamelanotide 16mg)
- EU approved product, awaiting PDUFA date for orphan indication porphyria (EPP)
- Social responsibility to treat EPP children and depigmented patients
- Growth through organic/inorganic expansion
 - Two additional indications
 - 2nd generation products – Rx
 - OTC products for larger audience
- Profitable since 2017, first dividend declared 2018



For 14 years CLINUVEL has focused its development on one product, SCENESSE® (afamelanotide 16mg) in one orphan indication, EPP.

SCENESSE® is approved in the European Union for the prevention of phototoxicity in adult patients diagnosed with EPP. More information on this can be found on our website.

In June 2018 CLINUVEL filed SCENESSE® under “rolling review” with the US Food and Drug Administration (FDA).

The FDA recently issued additional questions as part of the dialogue between applicant and agency.

Beyond adult EPP patients, CLINUVEL intends to develop innovative solutions for children with EPP, as well as working to address the depigmentation disorder vitiligo.

SCENESSE® also provides a foundation for the Company to grow, both through organic and inorganic opportunities.

CLINUVEL's business - systemic photoprotection

- Genetic metabolic disorder(s)
- Intolerant to light emission (blue-green/UVB/UVA)
- High unmet medical need(s)
- No alternative therapy, no benchmark
- Afamelanotide 16mg, family of melanocortins (POMC)
- Rx) SCENESSE® approved by EMA '14
- World's first systemic photoprotective drug



Hu|wksr:hwf#burwsrusk|ui#HSS,#
devroxh#j|kw#qwrduqfh



At the core of CLINUVEL's business is the concept of medicinal photoprotection, providing protection to skin from light. This is a novel concept not having been explored by any other pharmaceutical company thus far. Due to the accumulation and storage of a phototoxic chemical reactant (protoporphyrin IX, PPIX) in EPP patients, absolute light intolerance will occur since PPIX will react with photons emitted along the visible spectrum of light. The light emitted along the blue and green wavelengths is the source which makes these patients very ill. Therefore – aside from SCENESSE® – no other therapy to date is effective, as it does not protect beyond 400 nanometers in wavelength. CLINUVEL has chosen to address this disorder as there are no alternative therapies available for patients and a high unmet medical need.

Afamelanotide, the active chemical entity in the final product SCENESSE® - the injectable controlled release subcutaneous resolvable implant - is a new molecular entity belonging to the class of proopiomelanocortins (POMCs). The drug mimics the body's own response to UV light by releasing the hormone harbouring specific properties as well as activating melanin (pigmentation) of the skin. The European Medicines Agency (EMA) approved SCENESSE® in 2014 as the world's first systemic photoprotective drug.

Medicinal photoprotection – medical innovation/breakthrough

EPP



2nd indication Q4'18



Vitiligo



General population



Proof of concept in porphyrias (EPP)

- Systemic protection to visible light (>408nm)
- Rare disorder 1:140,000
- Global disease registry

Photoprotection, DNA repair

Systemic repigmentation (total body)

- First pharma company to address loss of pigmentation
- Positive early safety/efficacy data

Systemic & topical photoprotection

- 2nd generation melanocortins
- Additional indications
- Complementary product lines – OTC



CLINUVEL

Having developed its first innovative product with SCENESSE®, management has designed a clear plan to grow the business to help serve other patients with unmet need and a broader consumer base.

Later this year the Company expects to announce a new clinical program focused on photoprotection and evaluating the drug's ability to repair DNA damage following light and UV exposure.

In addition, CLINUVEL will be one of the first pharmaceutical companies to address the needs of patients with the pigmentation loss disorder vitiligo. Early clinical trials (Phase IIa) have indicated that SCENESSE® is well tolerated by these patients when used in a combination therapy with narrowband UVB phototherapy. Further results are being analysed from a study in vitiligo patients in Singapore. Decisions to further this program rest on the Company's ongoing discussions with the FDA, reviewing the use of the drug, dose regimen and product characteristics.

CLINUVEL undertakes its fundamental research in Singapore, within the wholly owned subsidiary VALLAURIX PTE LTD, where work on second generation products is ongoing. The Company is also actively evaluating further opportunities in order to establish a sustainable business hinging on multiple products, various indications and use of products, and specific knowhow to serve larger groups of patients and the general public in the future, as part of CLINUVEL's 2020 strategy disclosed in 2017.

This slide shows the development from apex to base, very much keep in mind the burden of proof for any pioneer embarking on changing medical conventions.

Clinical experience – afamelanotide extensively tested

- 1991-2018 34 clinical trials >975 patients
 >7,900 afamelanotide doses to date
 >5,700 SCENESSE® implants

• SAFETY

Most common “side effects”:
nausea, headache, bruising at injection site, fatigue, flushing
No new safety signals to date
Positive safety profile

- Dose regimen 1 resorbable implant formulation
 Subcutaneous injection every 60 days



CLINUVEL

There is extensive clinical data and experience from the use of afamelanotide since 1991, and data continues to be captured under the European post-authorisation programme.

Most importantly, as can be expected from regulators and from applicants developing novel products previously not used in humans nor patients, the Company emphasises its commitment to monitor patients and safety of the product from long-term use (pharmacovigilance).

In pioneering in pharmaceutical development, there is a clear understanding from CLINUVEL’s teams to focus on safety long-term. For this the Company controls its development, distribution and quality management systems in Europe (and shortly in the US following CLINUVEL’s intentions to make the drug available in the US).

Many of the results from afamelanotide have been published, including the Company’s phase III clinical results in EPP which were published in the *New England Journal of Medicine*.

Effectiveness and patient impact - SCENESSE®

Lead indication EPP

- Inability to expose to light sources (visible/invisible λ)
- Conditioned since birth to avoid light (ingrained anxiety)
- Phototoxicity, anaphylactoid reactions



Phototoxic reaction in an EPP patient. Image courtesy of the Koerner family.

Afamelanotide has radically changed the way I approach my daily life... This medicine has freed me from the debilitating consequences of EPP and from fear of suffering them.

Swiss erythropoietic protoporphyria (EPP) patient
representative of 98% treatment continuation



The image – kindly provided to us by this young patient's family – shows a patient approximately 24 hours after a phototoxic reaction, with severe swelling, exudation (water formation) and general disease following sun/light exposed skin.

Tragically in this disease patients are forced to learn from an early age, even if they remain undiagnosed, the impact of phototoxicity and anaphylactoid reactions from short light exposure, and patients over the years withdraw from society.

There is no equivalent disorder to describe the ordeal of EPP, there are no adequate tools to measure the impact of disease, and there is no precedent to compare the complexity of EPP. CLINUVEL's motivation to further assist these patients stems from the overwhelmingly positive response from patients and experts physicians over the years since SCENESSE® was made available during clinical trials. Without bias and simulation, both physicians and patients started to report dramatic effectiveness and change to their lives, assuming a life which had not been possible prior to SCENESSE® treatment.

In many ways, launching a novel mode of action and drug therapy forces an applicant to explain in detail to stakeholders, regulators, and advisory bodies that conventional approaches to medical problems cannot be applied in the case of EPP. In Europe this led the EMA to approve the drug with overwhelming majority of votes, and led the European insurers in many countries to reimburse the drug.

Treatment with afamelanotide has sought not only to protect patients from light, but improve patients' existence, addressing a lifelong conditioned behavior to avoid light exposure. This conditioned behaviour to hide from light, and very well knowing the consequences of a photoreaction, is best compared to a reflex to fire: nobody can be forced to put her or his hand into burning flames.

The retention rate of patients and prescription rate of SCENESSE® in Europe and Switzerland is over 95% over the years, a measure of effectiveness.

CLINUVEL's operations

How do we do it?

Special access since 2010

SCENESSE® commercially distributed since 2016

Direct, controlled EU distribution to EPP expert centres

EMA risk management plan, global disease registry, "PASS"

Results to date

66.1% increase in patient treatments 2016 to 2017

98% treatment continuation rate reported in EU/CH

US patients flying to Switzerland to seek treatment

SCENESSE® Uniform Price



¹No alternative effective therapy exists for SCENESSE®

²Price in Lauer-Taxe is published by IFA GmbH



CLINUVEL's European distribution of SCENESSE® originates from our team's focused approach. The map shows available EPP expert centres in Europe.

Our first distribution experience had been developed during clinical trials and special access programmes which first commenced in 2010 in Italy, then 2012 in Switzerland. First commercial distribution under the EU marketing authorisation commenced in 2016.

The Company has an agreed comprehensive risk management plan with the EMA and controls direct distribution of the product to expert centres (no third party distributors). Data continues to be captured on the drug's safety and effectiveness through a global disease registry and through a post-authorisation safety study (PASS).

Treatment uptake and continuation rates are encouraging, and we are aware of a growing number of EPP patients crossing the Atlantic to seek treatment who are prepared to pay, and in some cases receive already reimbursement from US healthcare insurers.

A uniform European price has been established, with the example here provided as published in the German Lauer-Taxe, a list available to hospital pharmacists seeking to order SCENESSE®.

US FDA timeline



Our US approach will be similar to that taken in Europe. A number of US expert centres have been identified. Work to make SCENESSE® available in the US started a long time ago. The FDA's interest in SCENESSE® was first received in 2006, while proactively the US FDA hosted the first ever scientific workshop in Silver Spring in 2016 to better understand the EPP patient experience. Transcripts from this workshop can be found online. The rolling review of the SCENESSE® new drug application (NDA) is ongoing, with the Company asked recently to provide additional information to the FDA as part of the process. The Company has filed for Priority Review in the US, and once the FDA has filed all its final questions to which our teams provide all satisfactory answers, an outcome as to Priority Review and PDUFA date can be expected from the Division of Dermatology and Dental Products.

Financials I CLINUVEL's DNA

- Disciplined financial management 2005-2018
- Debt-free
- Expertise in house



CLINUVEL has approached its financial management differently from most of its peers. Its focused attitude towards melanocortins and one drug to be developed for one disease entity initially, meant that cost control and responsibilities were highly prioritised during the years of financing the programme.

Over the years CLINUVEL used straight equity issuance, often at a premium to market, while selecting its investors with a common long-term view to generate value.

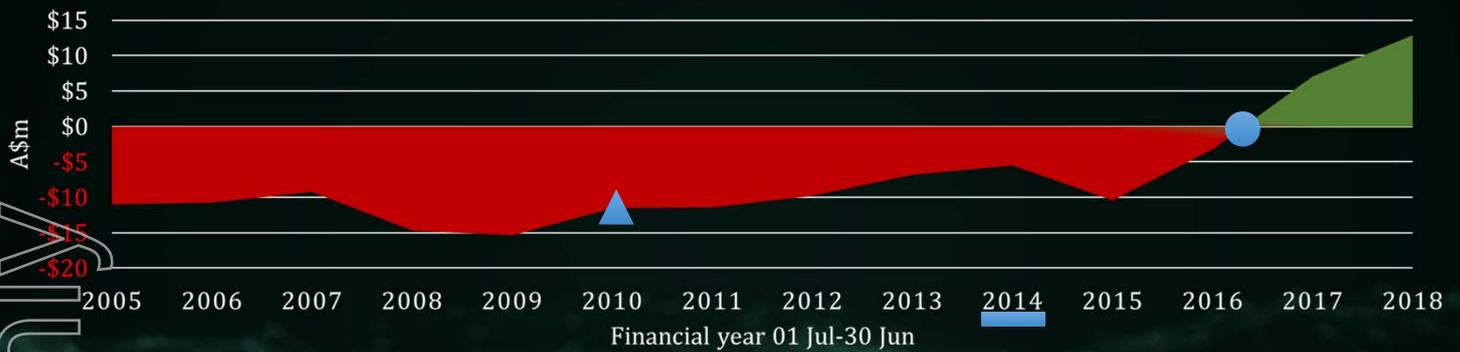
The Company has not taken on debt finance nor engaged in schemes to factor its revenues or royalties.

Importantly, CLINUVEL's current success hinges on retention of talent and providing continuity without outsourcing many of its functions.

For pivotal work the Company utilises the services of third parties, service providers and research organisations, but again with a long-term view to use the same key personnel in all these activities spanning more than a decade.

Financials II P&L – disruptive technology SCENESSE®

Net Profit (Loss) Before Tax (AUD)



| | |
|---|--------------|
| Total funds committed to SCENESSE® program to date: | A\$172m |
| Industry standard development costs | US\$600-800m |
| Profit after tax (FY18) | A\$13.224m |
| Unfranked dividend per ordinary share (FY18) | \$A0.02 |



The Company's P&L history saw an inflection point resulting in the first two years of profit in FY2017 and FY2018. Highlighted here are first revenues from the Italian special access programme in 2010, and increased expenditure to facilitate post-approval scale up from 2014. Compared to the industry standard, even for orphan drugs, CLINUVEL has delivered an innovative product for a fraction of the expected cost. This factor is increasingly important for insurers and payors worldwide, how did a Company manage its resources and at what cost did it develop new technology?

The Company's first ever dividend was declared this year.

Financials III ASX: CUV – 12 months



The 12-month share price graph reflects ongoing progress of the business as more foreign (non-Australian) shareholders find the Company on the ASX, Level 1 ADR OTC program (Nasdaq International Designation) or Xetra. Increased stock liquidity has been seen the past two years.

The Company's officers are regularly asked whether the ASX can recognise the full value of the pharmaceutical success stories, and this question is part of various considerations Board and management make in evaluating the various exchanges.

CLINUVEL Group ownership

ASX: CUV

XETRA-DAX: UR9

ADR: CLVLY (Nasdaq International Designation)

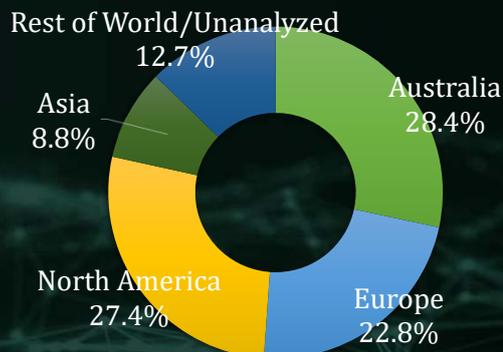
Market Cap (07 September)

A\$735.5m

52 week high-low

A\$6.36-\$15.40

| | |
|--|-------|
| Board, management and staff | 8.87% |
| Lagoda Investment Management | 7.12% |
| FIL Investment Management | 5.45% |
| Ender1 LLC | 5.43% |
| Family offices Switzerland/Germany | 11% |
| Private investors UK/Netherlands/Austria | ~5% |



CLINUVEL

CLINUVEL has been selective in building its register such that investors understand the Company's long-term goals. Somewhat different to many ASX-listed companies, a large percentage of CLINUVEL's shareholders are based outside of Australia.

Conclusions

- Specialty pharmaceutical company
 - Longevity (14 years) – Management and Board
 - No competition, no alternative treatment to SCENESSE®
- EU approved product, awaiting PDUFA date for orphan indication porphyria (EPP)
- Social responsibility to treat EPP children and depigmented patients
- Growth through organic/inorganic expansion
 - Two additional indications
 - 2nd generation products – Rx
 - OTC products for larger audience
- Profitable since 2017, first dividend declared 2018



CLINUVEL has a number of important events in coming months, with the near-term goal of enabling treatment access for US patients, and longer-term goals of treating other groups for whom there are no alternatives. The ongoing success originating from our management of SCENESSE® needs to lead to further development and hopefully to further regulatory approvals.

In conclusion, the status of CLINUVEL is being hailed in Australia as coming from a team which has taken a focused, selective approach and one which intends to continue to build the business in line with our core values. Often heard but seldom fully realised and followed through, we maintain at CLINUVEL that people make products. Products and technology alone are insufficient to build a company.

In our business model, profits are now being reinvested into R&D, with value being realised to our long-term investors.

Q&A

Lachlan Hay
General Manager
CLINUVEL (UK) LTD
Lachlan.Hay@clinuvel.com
+441372 860 765



I welcome questions from the room.