
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA:UR9; Nasdaq international designation: CLVLY) has delivered on its objective of commercialising a novel pharmaceutical product, with SCENESSE® (afamelanotide 16mg) approved and launched for patients with erythropoietic protoporphyria (EPP) in Europe and the USA.

The Group has now set new targets to expand and diversify following regulatory and payor acceptance of a novel concept in medicine.

CLINUVEL is well placed to deliver on its potential by targeting new medical indications, delivering new products and seeking opportunities to grow the Group worldwide.

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The CLINUVEL Group has delivered on a longstanding strategic objective to develop and commercialise a novel pharmaceutical product, SCENESSE® (afamelanotide 16mg), which has been approved and launched for adult patients with the rare genetic disorder erythropoietic protoporphyria (EPP) in Europe and the USA. Over the last 15 years of the development of the first-in-class novel drug, CLINUVEL has been led by a consistent management team, building the business to a position of recognised leadership within the life sciences sector in the Asia-Pacific region and to inclusion within the ASX / S&P 200 Index.

The Group's values – outlined in detail on www.clinuvel.com – clarify how we operate and intend to grow, with our people central to our execution and success.

The Company has set targets to expand and diversify following regulatory and payor acceptance of a novel concept in medicine. CLINUVEL is well placed to deliver on its potential by targeting new medical indications, delivering new products and seeking opportunities to grow the Group worldwide.

With the approval of SCENESSE® in Europe and the USA, CLINUVEL is working to diversify the Group and build value through targeted expansion opportunities, including:

- The development of new products, both through the Singaporean VALLAURIX laboratories currently under expansion, and by utilising in-house expertise in novel fields.
- Pre-clinical and clinical programs aimed at evaluating the potential of SCENESSE® and other molecules from the same family of drugs (melanocortins) for addressing patient groups with recognised unmet therapeutic need.
- Evaluating potential inorganic opportunities in relevant fields to strengthen its position long-term.

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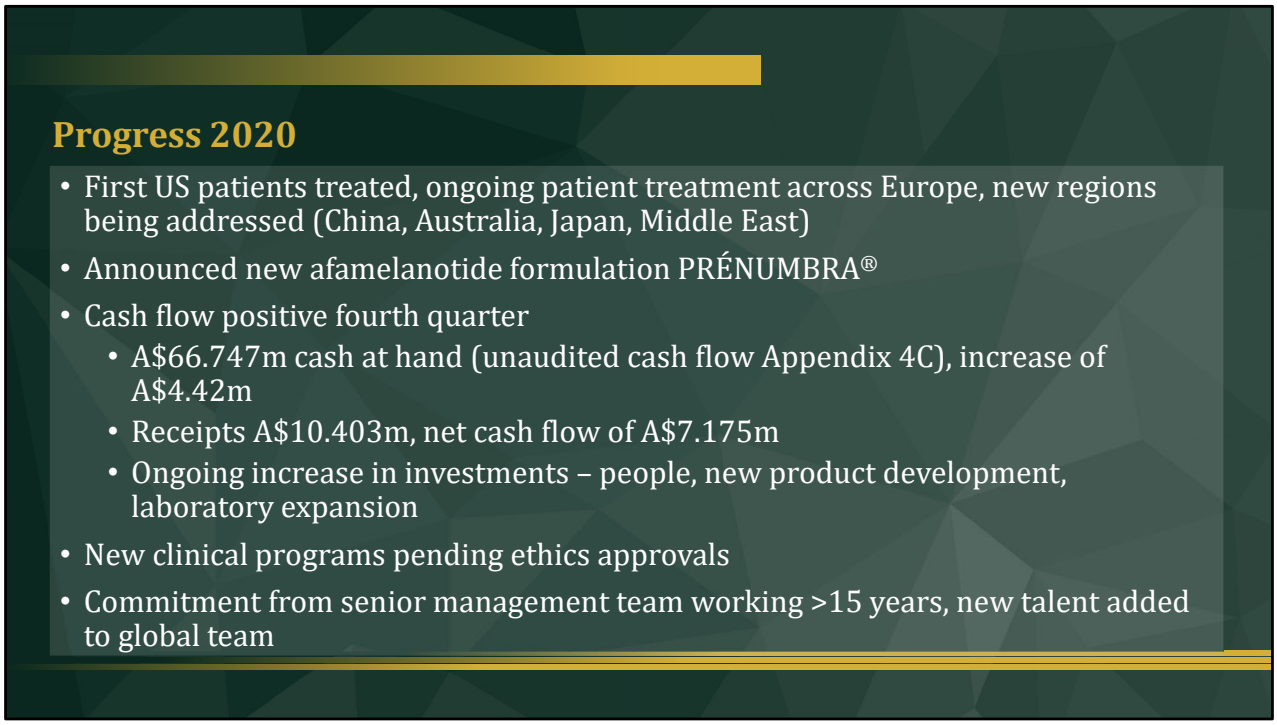


CLINUVEL has expanded access to SCENESSE® throughout 2020, despite the COVID-19 pandemic.

The product has been formally launched in the USA, with US patients treated since April. US EPP patients are treated at trained and accredited Specialty Centers, similar to the program in Europe. The accreditation of up to 30 US Centers is planned, with eight trained to date.

New countries are treating patients within Europe while engagement with payor organisations continues. SCENESSE® is established as standard of care in a number of European countries. The first treatment results from the European EPP Disease Registry study have been independently published, showing ongoing longer-term maintenance of the safety profile of SCENESSE® and clinical benefit for patients receiving treatment.

A registration dossier is pending with the Australian Therapeutic Goods Administration, with an outcome anticipated late 2020. CLINUVEL received confirmation of validation of the dossier in February with the evaluation continuing under priority review. A collaboration agreement has been reached with a partner in China to make SCENESSE® available to EPP patients under a pilot program and collect data for marketing authorisation, while work is underway for approvals in other regions.

As part of the life-cycle management of afamelanotide, CLINUVEL is developing new formulations for use in relevant patient populations. The first of these formulations – a liquid (non-solid) controlled-release injectable – has been announced as PRÉNUMBRA® and will be developed for use in acute disorders. These will be disclosed once ethics approvals have been granted for clinical trials. Development work on novel products continues at the VALLAURIX laboratory in Singapore.

The Company has increased its investment but importantly has maintained discipline in cost management to deliver its fourth year of positive cash flow. Maintaining resource and discipline has allowed CLINUVEL to continue its operations throughout periods of economic and global instability as seen during the 2008-09 financial crisis. The Company has shown it is capable of delivering despite adversity in global markets.

The team which oversaw the growth of the business to date has made a commitment to continue their work and deliver for the Company's many stakeholders, while the global business has added new talent in the last 12 months to strengthen its approach. Collectively the Board and Management own 13.5% of the Company.

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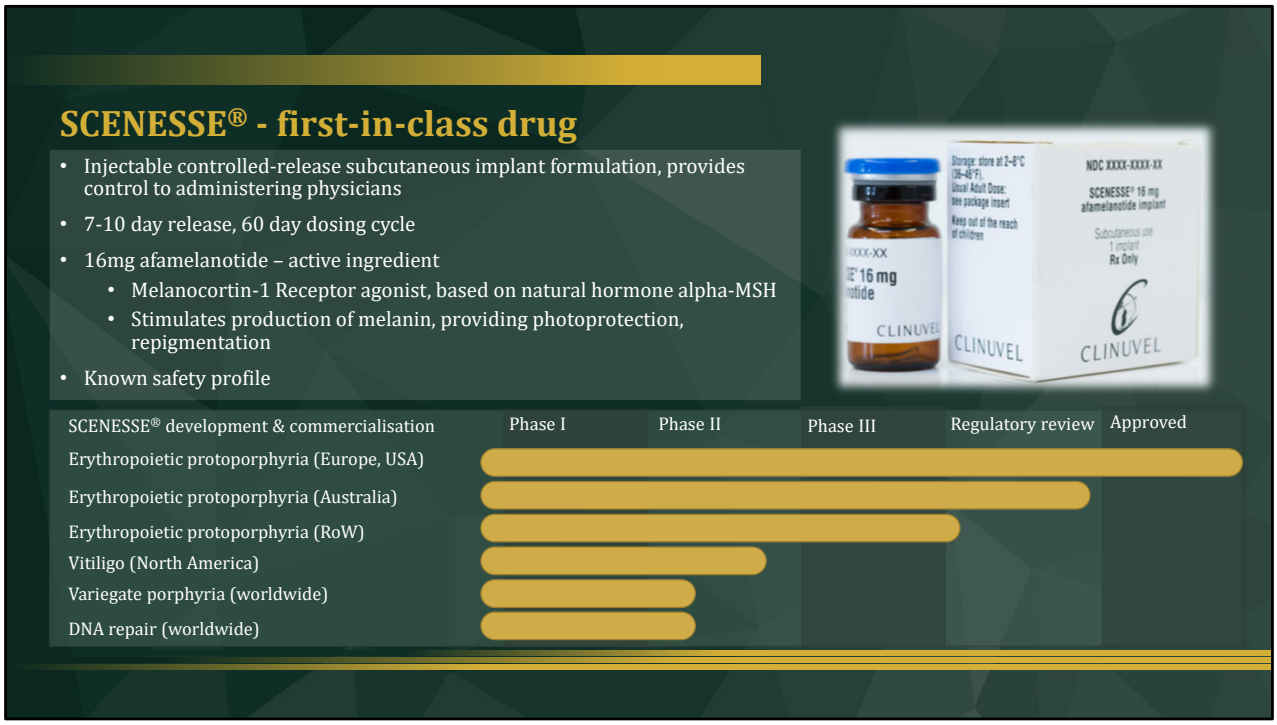



SCENESSE® is CLINUVEL's first approved pharmaceutical product. The novel drug is a controlled-release injectable implant formulation containing 16mg of the active ingredient afamelanotide and is administered by trained and accredited physicians in an outpatient setting. The implant gradually delivers afamelanotide in a controlled manner over 7-10 days. In EPP, patients are administered one implant every 60 days. For further information on dosing, see the approved European Summary of Product Characteristics and/or US Prescribing Information available on CLINUVEL's website.

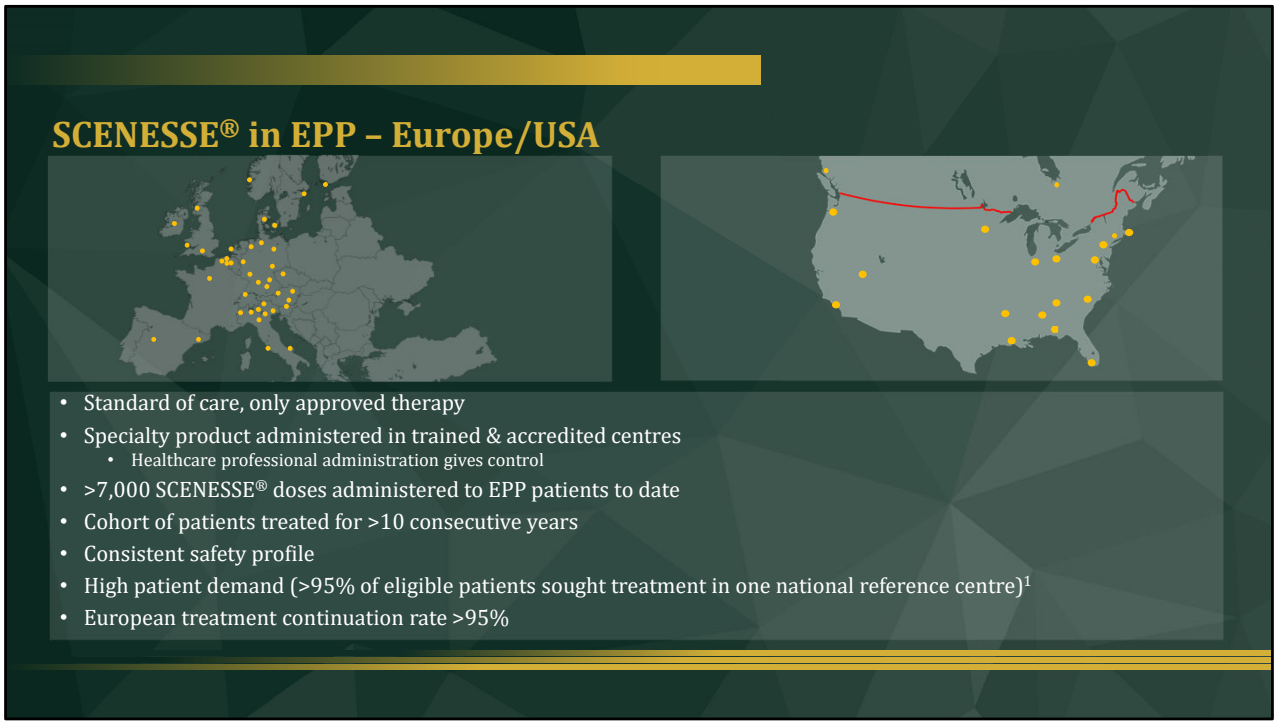
Afamelanotide is an analogue of the naturally occurring alpha-melanocyte stimulating hormone, which acts on melanocortin receptors in the body. When afamelanotide binds to the melanocortin 1 receptor (MC1R) on melanocytes, it stimulates the production of a dark pigment called eumelanin, in the skin, mimicking the body's natural processes. Melanin acts as a barrier between skin cells and light, protecting the cell from radiation damage from specific wavelengths (in EPP this is primarily visible blue light and the upper end of the ultraviolet spectrum, UVA).

Following approval in Europe and the USA, CLINUVEL is pursuing approvals of SCENESSE® for EPP in other regions worldwide. A decision is expected from the Australian TGA in late 2020. On a prevalence basis, there are an estimated 5,000-10,000 EPP patients worldwide, with work underway in multiple regions to facilitate patient access.

CLINUVEL has identified other indications where afamelanotide may provide clinical benefit to patients.

- Proof of concept studies of the drug in the pigment loss disorder vitiligo have shown that the drug can repigment skin when administered in combination with narrowband ultraviolet B therapy. Vitiligo affects up to 45 million individuals worldwide, with the greatest impact on patients with darker skin types who report a loss of identity and social isolation. Following a meeting with the US Food and Drug Administration (FDA) in April, the Company is working closely with experts in North America to finalise a new study protocol (study CUV104).
- Variegate porphyria (VP) is from the same "family" of hereditary disorders as EPP and causes phototoxic reactions to visible light and UV. A proof-of-concept study in two European centres is pending approvals.
- Research from CLINUVEL's programs and other expert labs has shown that afamelanotide can repair damage to DNA caused by exposure to ultraviolet radiation. CLINUVEL is working to evaluate this effect in humans, with protocols prepared in target patient populations currently pending approvals.

Throughout the development program CLINUVEL has focused on ensuring the safe use of afamelanotide, with over 10,000 doses of the drug administered to date. The drug has maintained a positive safety profile, with the controlled-release SCENESSE® implant minimising drug exposure while enabling physician control over administration and dosing.



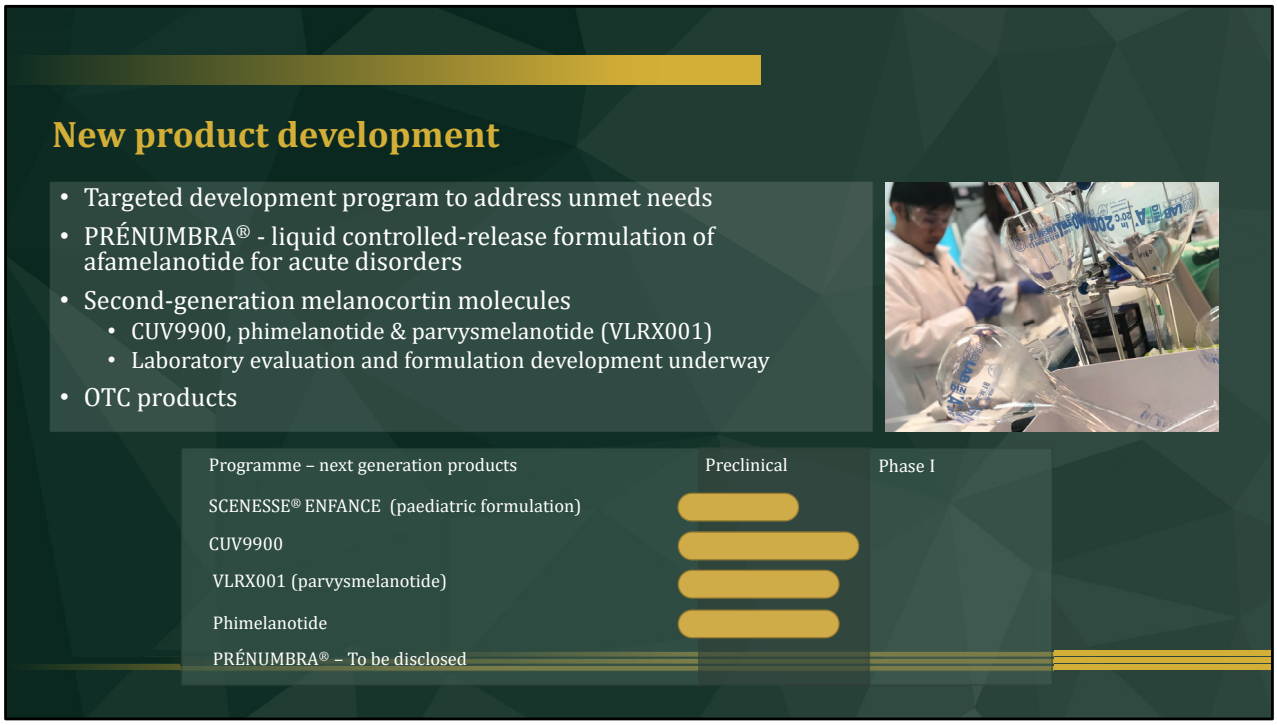

SCENESSE® is the only treatment to have been fully evaluated in randomised placebo-controlled clinical trials for EPP and is the only approved therapy. Results from studies and longer-term use of the drug have been published in peer-reviewed journals, with the first paper from the European post-authorisation safety study published this year.

SCENESSE® has been accepted as standard of care in Europe with coverage from government and private payors and insurance firms. Over 40 insurers – national and national – have agreed to reimbursement of SCENESSE® in the USA through Prior Authorization, acceptance as special drug or formulary listings.

Over 7,000 SCENESSE® doses have been administered to EPP patients worldwide. Patients involved in the first clinical trials of the drug have continued to receive treatment year on year, with the longest-term treatment spanning more than a decade (>60 doses).

The impact of EPP upon patients, and the lack of an alternative therapy, has resulted in high patient demand. CLINUVEL is clear in its view that the discussion between a patient and their treating physician should determine the decision to commence any therapy. This has resulted in high levels of known patient uptake, with one reference centre reporting >95% of eligible patients electing to receive SCENESSE® treatment. Year on year treatment continuation is reported at >95% in Europe.

[1] Wensink et al (2020).



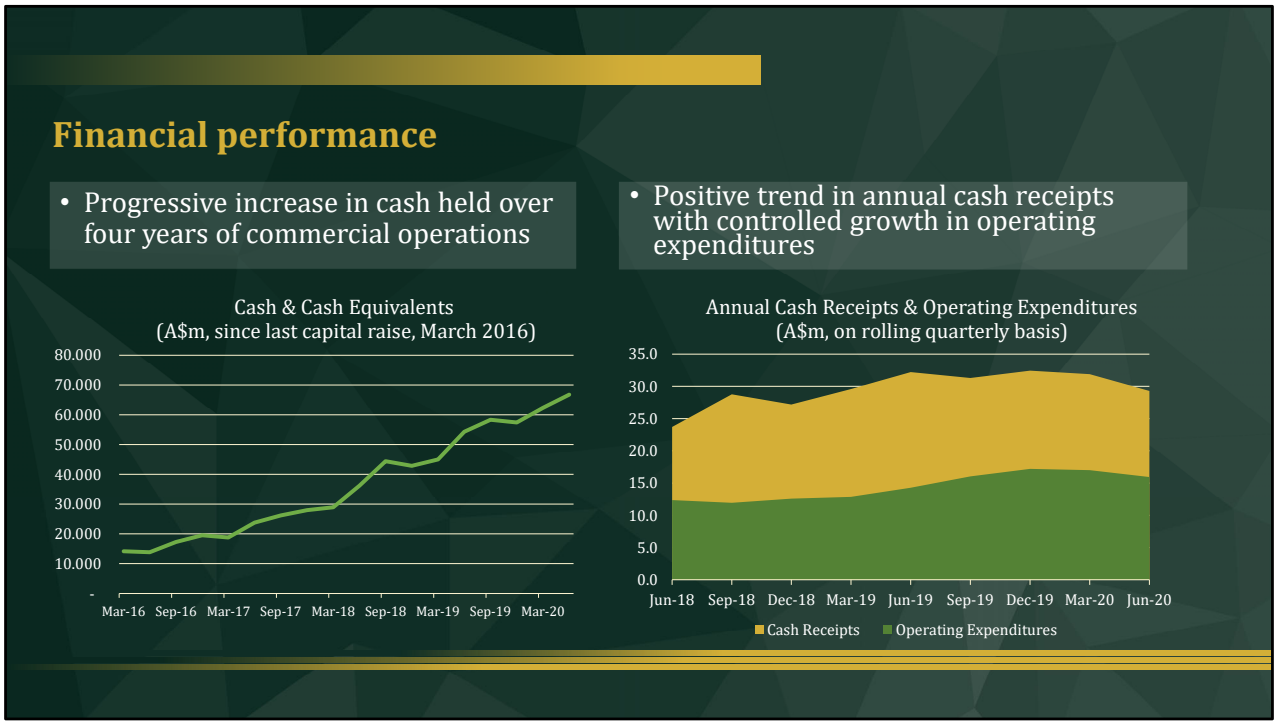

CLINUVEL is scaling up its R&D work and increasing its investment in new product development. Key to our development approach are:

- Selectivity – in indications, investigators/clinics, partners and staff.
- Focus – working in specific areas of genuine unmet need to help patients who have no alternatives, no first-line therapies.
- Knowledge – building upon our expertise and experience gained during 15 years of research and product development.

The Company has announced the development of the PRÉNUMBRA® liquid controlled-release formulation as part of the life cycle management of afamelanotide to address acute disorders.

In parallel, development work continues with new melanocortin molecules and over-the-counter products through the Company's VALLAURIX laboratories in Singapore. While the expansion of the laboratory was affected by government's circuit-breaker to contain the pandemic, development work was largely unaffected. It is expected the new facilities will be completed by the end of the third quarter of calendar year 2020 to further progress R&D on novel melanocortins, and prescription and over-the-counter (OTC) products.

The first OTC products are being subject to user acceptance and relevant non-clinical and clinical evaluations.




CLINUVEL has achieved positive annual net cash flow from operations over the last four years of commercial operations.

CLINUVEL held A$66.747m in cash at 30 June 2020. The Company last raised capital in March 2016. Since then the Company has taken its cash reserves from A$14,170,000 to its 30 June level of A$66,747,000 – a 44% compound annual growth rate.

The Company has maintained a disciplined approach to resource management throughout its development cycle and over the last four years of commercial operations, ensuring that it is capable of withstanding global downturns without the need to raise capital in adverse markets and to self-finance its planned expansion and growth.

The audited financial report for the year ending 30 June 2020 is due to released by the end of August 2020. Although not obligated to do so, CLINUVEL elects to publish quarterly cash flow reports to keep investors updated.

## Global economic impact COVID-19

- IMF: "the worst recession since the Great Depression"
- Public spending 5% of world annual GDP; generational burden of indebtedness
- Dilutive capital raisings at discounts to replenish cash for operations
- Healthcare and pharmaceutical sector not immune

| Forecast measure | USA | Eurozone | World |
|---|---|---|---|
| GDP 2020 change % | (3.5) – (11.3) | (5.4) – (13.5) | (3.5) – (9.7) |
| Expected return to pre-pandemic levels | Q1 2021-2025+ | Q1 2021-2025+ | Q1 2021- Q3 2023 |

Source: McKinsey & Company, COVID-19: Briefing materials, Global health and crisis response, 6 July 2020 and other media sources

The world has fundamentally changed in a short period due to the coronavirus pandemic. It is prudent for CLINUVEL to assess risks and opportunities in this environment, adjusting its business accordingly.

The IMF's Global Financial Stability Report of April 2020 makes for sobering reading with the economic climate expected to be the worst since the 1929 Great Depression.

Companies globally have been very active raising capital, mainly for operational support. Australia has been no exception. The number and value of capital raisings far exceed pre-coronavirus levels.

- In May 2020, global equity raisings from existing shareholders totaled US$129.5bn, compared to US$59.45bn in May 2019
- In Australia A$30bn has been raised in the half year to June, compared to A$29.8bn and A$29.3bn for the full years 2019 and 2018, respectively.
- A$2.48bn has been raised by the healthcare and pharmaceutical sector in Australia between late March and June 2020 alone.

McKinsey summarises the economic impact in terms of a range of differing scenarios of severity. On the worst scenario, the world economy could contract by nearly 10% and take until Q3 2023 before growth returns to pre-pandemic levels.

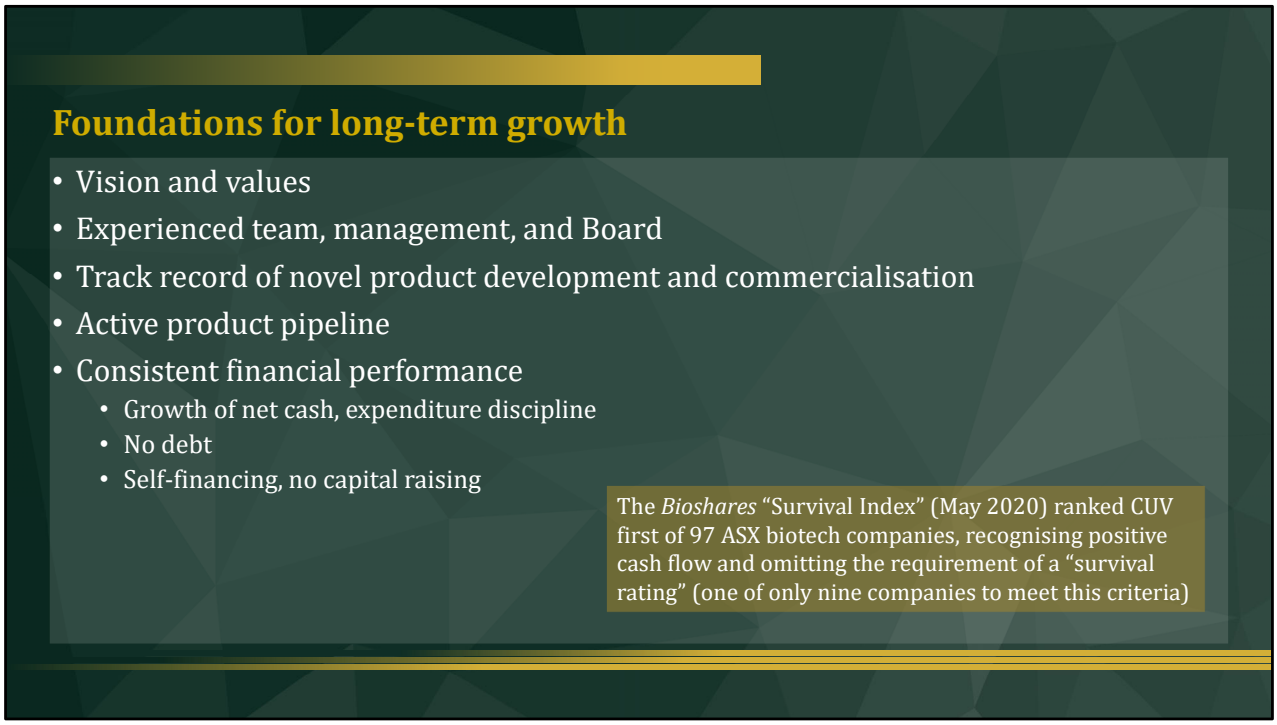
This indicates difficult operating conditions may persist for some time and challenge the viability of many businesses. CLINUVEL is well positioned to manage this challenge and progress its strategic initiatives.


There are a range of strategic initiatives to support our future growth and evolution into a vertically integrated pharmaceutical company providing treatments for multiple patient groups.

We have a growth strategy in the regions for which SCENESSE® is an approved treatment. In **Europe** we are working on reimbursement agreements to distribute SCENESSE® for EPP in more European countries; expanding the number of Expert Centers; and increasing patient treatment access. In the **USA** we completed the key pre-distribution logistics and facilitated first treatment in April 2020, within six months of FDA approval and amidst the global disruption caused by the coronavirus pandemic. We continue to progress the accreditation of Specialty Centers to provide treatment to EPP patients.

The **product development pipeline** is focused on active research and development of treatments for a range of indications. We are developing a pediatric formulation of afamelanotide; evaluating SCENESSE® as a treatment for vitiligo and progressing medicinal photoprotection through DNA repair of the skin; researching the use of afamelanotide (as PRÉNUMBRA®) and other molecules to treat acute disorders; and developing topical formulations – both pharmaceutical and over-the-counter.

We also monitor and assess **inorganic growth opportunities** as they arise and as these would complement the CLINUVEL team.




In summary, CLINUVEL has laid solid foundations for its growth regardless of the operating environment:

- The Company's vision and strategy has been proven with the commercialisation of a novel drug (from concept to regulatory and payor acceptance).
- The management team has remained stable for 15 years and has the support of an experienced board. New talent is being added to complement.
- Following success in product development and commercialisation from 'laboratory to patient', new products and indications are being added to an active development pipeline.
- CLINUVEL has generated positive cash flow and a 44% compound annual growth rate of cash reserves.
- A viable business generating positive net cash flow, and the ability to self-finance its growth and expansion program.

## Appendix: references & further reading


**Afamelanotide in erythropoietic protoporphyria**

- Biolcati, G., et al., (2015). Long-term observational study of afamelanotide in 115 patients with erythropoietic protoporphyria. *The British Journal of Dermatology*, 172(6), 1601–1612.
- Langendonk, J. G., et al., (2015). Afamelanotide for Erythropoietic Protoporphyria. *The New England Journal of Medicine*, 373(1),
- Minder, E. I., et al., (2009). A systematic review of treatment options for dermal photosensitivity in erythropoietic protoporphyria. *Cellular and Molecular Biology* (Noisy-Le-Grand, France), 55(1), 84–97.
- Neumann, N. J. (2018). Afamelanotid. *Internistische Praxis*, 59(1), 155–159.
- Wensink, D., et al., (2020). Association of Afamelanotide With Improved Outcomes in Patients With Erythropoietic Protoporphyria in Clinical Practice. JAMA Dermatology.

**Melanocortins, pigmentation, photomedicine**

- CLINUVEL Scientific Communiqués I-V – www.clinuvel.com


Further reading is referenced to provide further insights into CLINUVEL's research and development program.


This presentation has been authorised for release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.



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