CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA:UR9; ADR Nasdaq International Designation: CLVLY) is well positioned to progress its strategic initiatives to grow and expand, despite the challenging operating environment.

CLINUVEL's strategic approach has been deliberate to focus on the development and commercialisation of a lead drug embodying a novel technology for an unmet medical need. CLINUVEL has delivered on its main objective to commercialise SCENESSE® (afamelanotide 16mg) which is approved and launched for adult patients with the rare genetic disorder erythropoietic protoporphyria (EPP), in Europe and the USA.

We have established a growing business that has to date generated cash and profit to self-finance our expansion. In FY2020, the Group recorded its fourth consecutive year of positive cash flow and profit, and third consecutive final dividend. We are focussed on diversifying the business during the current global pandemic and economic contraction through the ongoing commercialisation and development of SCENESSE® and the development of novel melanocortin derivatives to treat a range of indications. CLINUVEL is well placed to deliver on its potential, targeting new medical indications, delivering new products, and seeking opportunities to expand and diversify the activities of the Group worldwide.

CLINUVEL

LEGAL NOTICE

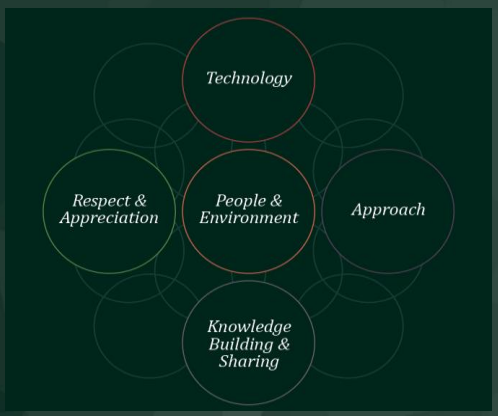
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied 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, the COVID-19 pandemic affecting the supply chain for a protracted period of time, 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, China 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 2020 Annual 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.

Your attention is drawn to our legal notice which we provide at the start of every public presentation.

PATIENT FOCUSSED ORGANISATION

Strong values, mission, vision

- Australian life sciences group, worldwide operations
- Patient focussed
- Values-led organisation, conservative approach to risk
- Developing, commercialising treatments for severe disorders with unmet medical need
- SCENESSE® (afamelanotide 16mg) commercialised
- Foundation built for targeted expansion
  - New product development
  - R&D – pre-clinical and clinical
  - Evaluate inorganic opportunities



CLINUVEL is an Australian based life-sciences group with worldwide operations. It is highly patient focussed, striving to develop and commercialise treatments for severe disorders with unmet medical need.

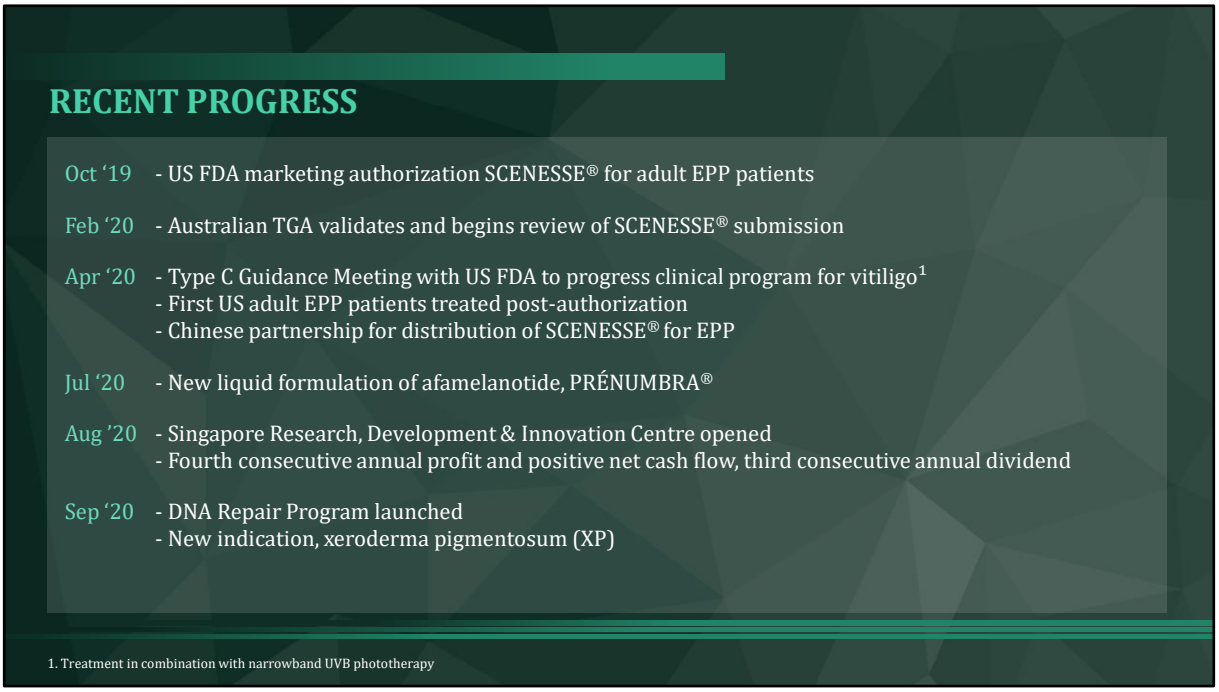
The Group's values – outlined in detail on www.clinuvel.com – guide how we operate, with our people central to execution and success. Our approach to business is prudent, reflected in our consistent long-term strategy and how we manage risk. We identify risks to the business, actively manage them and seek to be in a position to manage unanticipated risks that materialise.

CLINUVEL delivered on a longstanding strategic objective to develop and commercialise a novel pharmaceutical product, SCENESSE®, which has been approved and launched for adult patients with 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 S&P/ASX 200 Index.

The Group has deliberately built a strong balance sheet by accumulating net cash from operations since commercial launch; cash reserves on 30 June 2020 were 82% of assets and no debt. This foundation enables the Group to progress the distribution of SCENESSE® in Europe and the USA and other jurisdictions and to build incremental value in the current environment through targeted expansion opportunities, including:

- The development of new products, through the Singaporean VALLAURIX Research, Development & Innovation Centre (opened August 2020), 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) to address patient groups with recognised unmet therapeutic need.
- Evaluating potential inorganic opportunities in relevant fields to strengthen its position long-term.

CLINUVEL



Over the last year, business operations have grown, and in spite of the pandemic the research and development program has expanded.

CLINUVEL expanded access to SCENESSE® during FY2020. The product was approved by the US Food and Drug Administration (FDA) in October 2019 and was formally launched in the USA to treat the first US patients in April 2020. US EPP patients are treated at trained and accredited Specialty Centers, similar to CLINUVEL's program in Europe. New countries are treating patients in Europe, where SCENESSE® is standard of care, whilst engagement with payors in other European countries continues. 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.

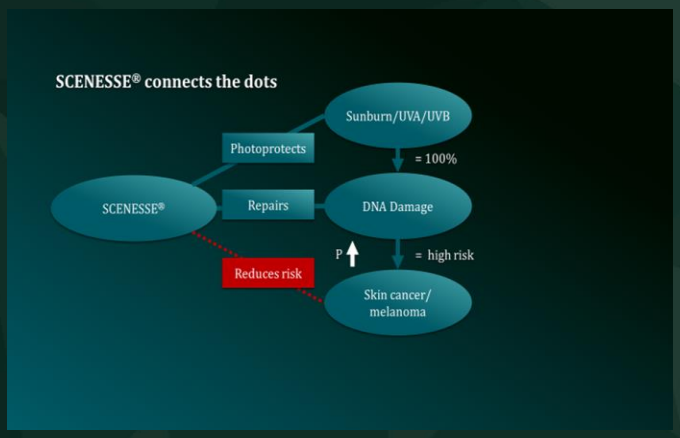
A registration dossier is pending with the Australian Therapeutic Goods Administration (TGA), with an outcome anticipated late 2020. CLINUVEL received confirmation of validation of the dossier in February with the evaluation being made under their priority review pathway. A collaboration agreement was reached in April 2020 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 has been developing new formulations for use in relevant patient populations. The first of these is PRÉNUMBRA® – a liquid (non-solid) controlled-release injectable – developed for use in acute disorders to be disclosed once ethics and regulatory approvals have been granted. Work on novel products continues at the VALLAURIX Research, Development & Innovation Centre in Singapore.

The Company increased investment in the business and importantly, maintained discipline in cost management to deliver its fourth year of positive cash flow and profit and third consecutive annual dividend. This particular focus has allowed CLINUVEL to continue operations throughout periods of economic and global instability, such as the 2008-09 financial crisis. The Company has shown it is capable of navigating adversity in global markets.

We launched an exciting program in September to confirm the ability of SCENESSE® to repair UV-induced DNA damage, with initial focus on a new indication, xeroderma pigmentosum (XP).

DNA REPAIR PROGRAM



- CLINUVEL's DNA Repair Program aims to confirm that intervention with SCENESSE® causes elimination of DNA damage (photoproducts) and regeneration of DNA.
- SCENESSE® has been proven to protect skin from light (photoprotection) and shown to repair DNA damage.
- Since photoprotection and regeneration are necessary to reduce the risk of skin cancer, the role of SCENESSE® is obvious.

"P" stands for probability.

The DNA Repair Program announced in September 2020 aims to confirm the role of SCENESSE® to reduce DNA damage and regenerate DNA. Scientific evidence supports the use of afamelanotide, the active ingredient in SCENESSE®, to protect skin from UV and light (systemic photoprotection), and repair UV-induced DNA damage. The drug is now being evaluated in the rare genetic disorder XP.

Ultraviolet (UVB of wavelengths 290-320 nm and UVA of 320-400 nm) and high energy visible (HEV, 400-600 nm) light penetrates human skin causing oxidative stress and damage to the DNA helix within the nucleus of skin cells. Photodamage consists of loss of connective tissues and changes to the DNA strands (generation of photoproducts). XP patients exhibit extreme deficiency in repair of UV-provoked DNA damage and is characterised as a model for the most severe form of photodamage. XP has eight variants (XP-A to G, and V), reflecting eight different genes involved in nucleotide excision repair (NER), a process of identifying, "snipping", removing and replacing damaged sequences in DNA. If left unrepaired, damaged DNA can replicate and increase the risk of skin cancers, including melanoma. Due to the inability to initiate or complete the NER process, XP patients are at 10,000- and 2,000-fold risk of non-melanoma and melanoma skin cancers, respectively. Most XP patients experience skin cancer before adolescence, while the leading cause of death remains progressive non-melanoma skin cancers and melanoma in the third decade.

The first patient with xeroderma pigmentosum-C (XP-C) has received SCENESSE® as part of a Special Access Program which serves to confirm the safety of the product. Given the high mortality rate in XP-C, the safety of afamelanotide will be evaluated during 42 days of treatment. After confirmation of the safety of the drug, the DNA Repair Program will proceed with an open-label Phase II study involving six XP-C patients (CUV150) and a control study enrolling 10 healthy volunteers (CUV151), whereby clinical and histological (skin biopsies) evaluation of afamelanotide treatment will be undertaken in both groups. Details of the sponsored studies CUV150 and CUV151 will be released as they are finalised.

A CHALLENGING GLOBAL OPERATING ENVIRONMENT

Adverse environment since early 2020 due to COVID-19

- IMF: "the worst recession since the Great Depression"
- Public spending 5% of world annual GDP; generational burden of indebtedness
- Monetary authorities stimulate to provide liquidity and confidence
- Dilutive capital raisings to replenish cash for operations

Forecast measure		USA	Euro	World
GDP change %	2020	(8.0)	(10.2)	(4.9)
	2021	4.5	6.0	5.4
Expected return to [pre-COVID] growth		Q1 '21-25	Q4 '21	Q1 '21- Q3 '23

Sources: IMF Global Outlook, April 2020; McKinsey & Company, COVID-19: Briefing materials, Global Health and Crisis Response, July 6, 2020

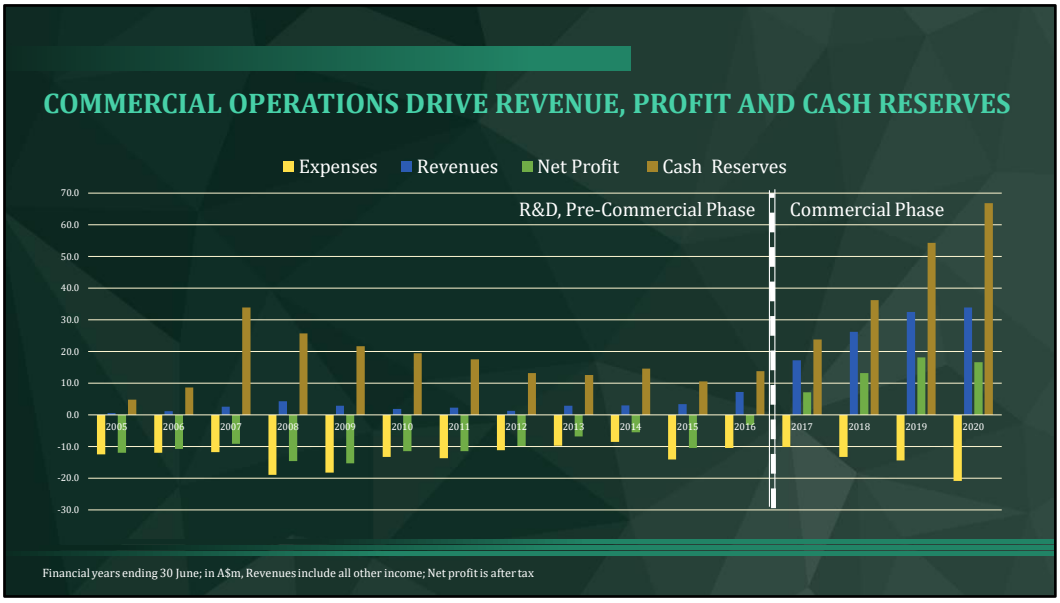
Let's turn to the unexpected and difficult operating environment for the context of CLINUVEL's recent and future performance.

The world has fundamentally changed in a short period due to the pandemic. In human dimensions, COVID-19 has infected over 36 million people and tragically caused over 1,000,000 deaths. The essential role of healthcare in all our lives has been reinforced by the pandemic.

In economic terms, 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. McKinsey summarises the economic impact in terms of a range of differing scenarios of severity. In their worst scenario, the world economy could contract by nearly 10% and take until Q3 2023 before growth returns to pre-pandemic levels. The Monetary Policy Committee of the Bank of England forecasts the return to pre-pandemic levels will take until the end of 2023. The US Federal Reserve FOMC's predictions range from -1% to 7% gain in US GDP in 2021, indicating much uncertainty in the eyes of policy makers. The European Central Bank forecasts one year from now, negative GDP growth of 0.9%; two years onwards, growth of 3.3%; and five years ahead, 1.4% growth annualised. This indicates difficult operating conditions may persist for some time and challenge the viability of many businesses.

Reflecting the difficult operating environment, companies globally have been very active raising capital, mainly for operational support. The number and value of capital raisings far exceed pre-pandemic levels:
- Global equity raisings from existing shareholders totaled US$129.5bn May 2020, compared to US$59.45bn 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.
- The healthcare and pharmaceutical sector in Australia raised A$2.48bn between late March and June 2020 alone.

CLINUVEL's deliberate strategy and prudent management approach over the long-term, has positioned it well to manage the challenging operating environment and progress its strategic initiatives. CUV shareholders have not been asked to contribute new capital to finance the business since March 2016, prior to the commercialisation of operations. There have been no new capital raisings, no dilution of shareholders and no discount to market associated with capital raisings. Instead, CLINUVEL has the confidence and security afforded by sufficient cash reserves from operations to continue its research and development program. This is critical for a biopharmaceutical company, avoiding unnecessary dilution and the perceived overhang of potential capital raisings to finance operations.



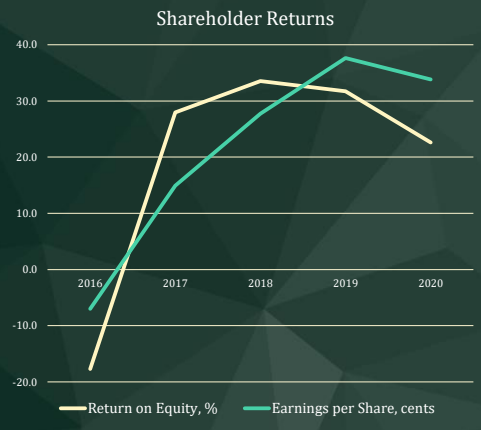
CLINUVEL is a 'story' of growth and Australian success to date. The time series of expenses, revenues, net profit and cash reserves show CLINUVEL's progression from the Research & Development (R&D) Phase (FY2005-FY2016) into the Commercial Phase (FY2017-) of operations. In the R&D Phase, expenses exceeded revenues as SCENESSE® was developed; clinical studies undertaken and completed; regulatory approvals sought and obtained. External funding of operations was essential, through several self-managed capital raisings totaling A$94m. The cost of developing SCENESSE® of A$154m, based on FY2005-2016 expenses, is lower than the >US$1bn typical cost of novel drug development. The growth in revenues and control of expenses since launch (2016) is reflected in CLINUVEL's first profit in FY2017, the first full year of commercial operations; a higher profit in FY2018; a third consecutive and record profit in FY2019; and in a difficult operating environment, a fourth consecutive profit in FY2020.

Positive net cashflow has enabled the accumulation of cash reserves. Since the Company last raised capital in March 2016, cash reserves increased from A$14.170m to A$66.747m as at 30 June 2020 – a 44% compound annual growth rate and 23% increase in FY2020. The strategy of the Group has been to establish a track record of positive operations with cash reserves that enable the Group to withstand global downturns and self-finance planned growth and expansion, without the need to raise capital in adverse markets. Cash reserves funded the increased expenditure on operations and strategic initiatives of the Group. Cash to support ongoing operations in the current environment is critical and CLINUVEL has sufficient reserves to cover more than three years of its FY2020 expenses. Reflecting balance sheet strength, the ratio of cash to assets is a high 82% and debt is zero.

In the context of a difficult operating environment, CLINUVEL posted an annual net profit before tax of A$13.136m in FY2020. The Board also declared a third consecutive unfranked dividend of A$0.025. This is the same level as FY2019 which was an increase of 25% on the first dividend of A$0.02 declared in FY2018. The third dividend equates to 7.4% of NPAT. Given the resilient profit result and management of cash reserves, the Board declared the distribution of earnings to augment the overall return to investors on their investment in the Company. The dividend strikes a responsible balance between returning funds to our shareholders and retaining sufficient cash reserves to enable the Company to operate within its means, in the event of an increasingly adverse operating environment. CLINUVEL is one of few biopharmaceuticals that consistently pays a dividend. The consistency of a third dividend is a demonstration of appreciation of supportive investors, particularly the long-term investors who actively funded the business through participation in past capital raisings over more than a decade of the R&D Phase of SCENESSE® and remained committed in their support since the commencement of commercial operations in June 2016.

RECENT FINANCIAL PERFORMANCE

12 months ending	30 June 2020	30 June 2019
Key Financial Results	A$ '000	A$ '000
Total Revenues	32,565	31,048
Total Expenses	(20,773)	(14,384)
Net Profit Before Tax	13,136	18,115
Net Profit After Tax	16,647	18,134
Operating Cash Flows	14,188	18,456
Cash and Cash Equivalents	66,747	54,269
Net Tangible Assets	73,669	57,180
Key Performance Statistics		
Current Ratio	11:1	12:1
Equity to Assets Ratio	0.9:1	0.9:1
Basic Earnings Per Share	33.8 cents	37.6 cents
Return on Equity	23%	32%
Share Price (CUV) Change	(24%)	206%
Unfranked Dividend Per Share	$0.025	$0.025



In FY2020, total revenues grew by 5% to A$32.565m and total expenses increased by a deliberate and controlled 44% (A$6.389m) to A$20.773m, to support the growing commercial operations and strategic initiatives of the Group. The outcome for FY2020 was a NPBT of A$13.136m with a higher NPAT of A$16.647m due to the recognition of deferred tax assets in the balance sheet of A$3.150m. Operating cash flow of A$14.188m bolstered cash reserves to A$66.747m.

Expenditure growth in FY2020 was mainly for R&D and commercialisation, comprising clinical study costs, drug formulation research, manufacture and distribution, regulatory fees and research, development and commercialisation-specific overheads such as personnel. The increase in expenditures reflects the Group's focus to invest in its commercial rollout to treat patients in the EU and, for the first-time, the USA since April 2020.

CLINUVEL delivered positive returns on equity (23%) and earnings per share (33.8 cents) in FY2020. This contrasts with many other biopharmaceutical companies listed on the ASX who have negative earnings per share and return on equity because they are either in the R&D Phase, or revenues from licensing of products and milestone payments on product development from partners, do not exceed ongoing operating and R&D expenses. A strategy to pursue multiple treatments for multiple indications ahead of commercial profitability contrasts with CLINUVEL's approach to focus on the development and commercialisation of one drug for one indication, achieving positive net cash flow and profit to self-finance the expansion of treatment to more patient groups. CLINUVEL is committed to expand but can manage variable expenses by moderating the pace of product development, if required by environmental circumstances, to maintain a positive cashflow and profitable business. Such is the prudence and responsibility required to adjust to adverse changes.

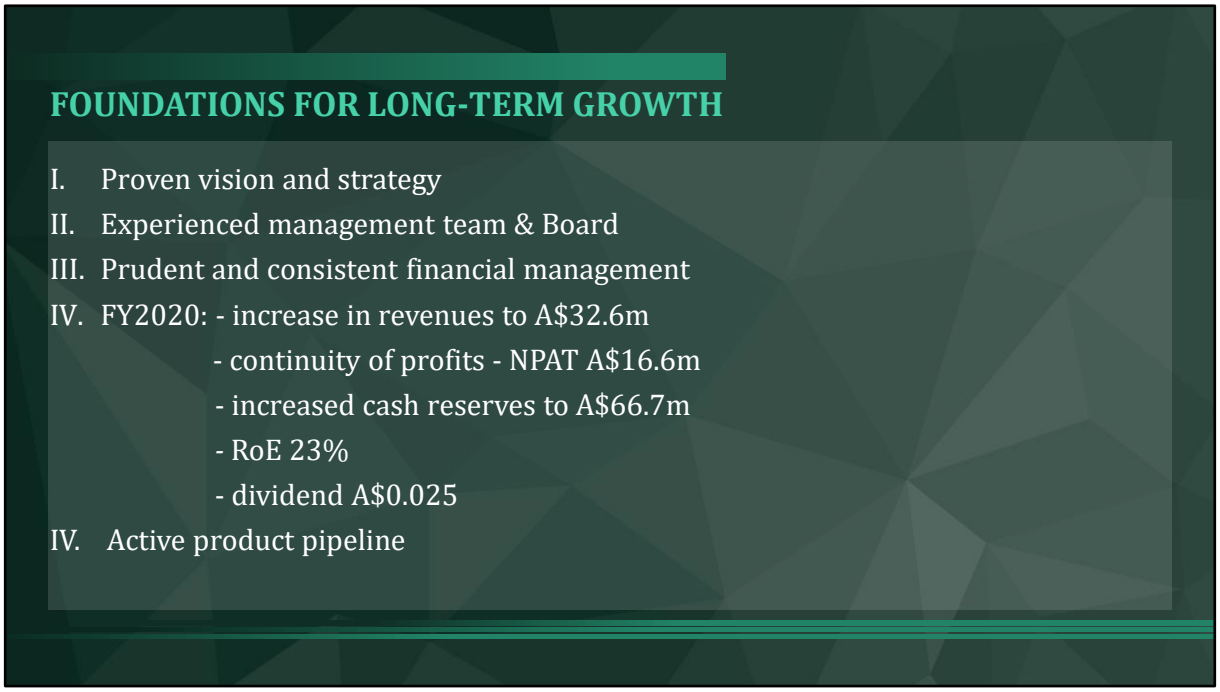
A range of strategic initiatives support our future growth and evolution into a vertically integrated pharmaceutical company providing treatments to multiple patient groups.

We have a growth strategy in the regions for which SCENESSE® is an approved treatment. In **Europe**, SCENESSE® has been accepted as standard of care with coverage from government and private payors and insurance firms. 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 within six months of FDA approval and facilitated first treatment in April 2020, amidst the global disruption caused by the pandemic. We continue to progress the accreditation of Specialty Centers to provide treatment to EPP patients. From three Specialty Centers upon launch, we now have 25 accredited out of the 30 planned across the US. Over 50 private insurers – local and national - have agreed to cover the cost of treatment of SCENESSE® under Prior Authorization arrangements, acceptance as a special drug or their formulary listing.

The **product development pipeline** is focused on active research and development of treatments for a range of indications and specifically:

- developing a pediatric formulation of afamelanotide;
- evaluating SCENESSE® as a treatment for vitiligo;
- confirming the ability of SCENESSE® to repair UV-induced DNA damage, focusing initially on xeroderma pigmentosum (XP);
- researching the use of afamelanotide (as PRÉNUMBRA®) and other molecules to treat acute disorders; and
- developing topical formulations – both pharmaceutical and over-the-counter (OTC) products.

We also monitor and assess **inorganic growth opportunities** that have the potential to complement CLINUVEL's team and capabilities as they arise.



In summary, CLINUVEL has laid solid foundations for future growth and expansion and is proving resilient in the difficult prevailing 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).
- A stable management team of 15 years, complemented by new talent and supported by an experienced Board.
- CLINUVEL has generated positive net cash flow and profit over four years of commercial operations, paying its third unfranked dividend in FY2020.
- The balance sheet is strong with cash to self-finance planned growth and expansion of the business.
- Following success in product development and commercialisation from 'laboratory to patient', new products and indications are being added to an active development pipeline.

Thank you for your attention.

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

Level 11, 535 Bourke Street, Melbourne, Victoria, Australia, 3000
www.clinuvel.com

CLINUVEL

Driving Growth and Expansion

CLINUVEL PHARMACEUTICALS LTD

Presentation to

Morgans Scone
Value in the Vines Investor Conference 2020

09 October 2020

Malcolm Bull
Head of Investor Relations

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