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

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 erythropoietic protoporphyria (EPP) in Europe and the USA.

To date, we have established a viable business that generates cash and profit to self-finance expansion and growth. The Group recorded its fourth consecutive year of positive cash flow and profit in FY2020 and is focussed on expanding and diversifying the business during the current global corona pandemic and economic contraction. A third consecutive final dividend has been declared today.

Our focus is on the ongoing commercialisation and the development of SCENESSE® and melanocortin derivatives to treat a range of indications. New targets have been set to expand and diversify the business and CLINUVEL is well placed to deliver on its potential by targeting new medical indications, delivering new products and seeking opportunities to expand and diversify the activities of the Group worldwide.

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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 2019 Annual Report and 2020 Preliminary Final 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.

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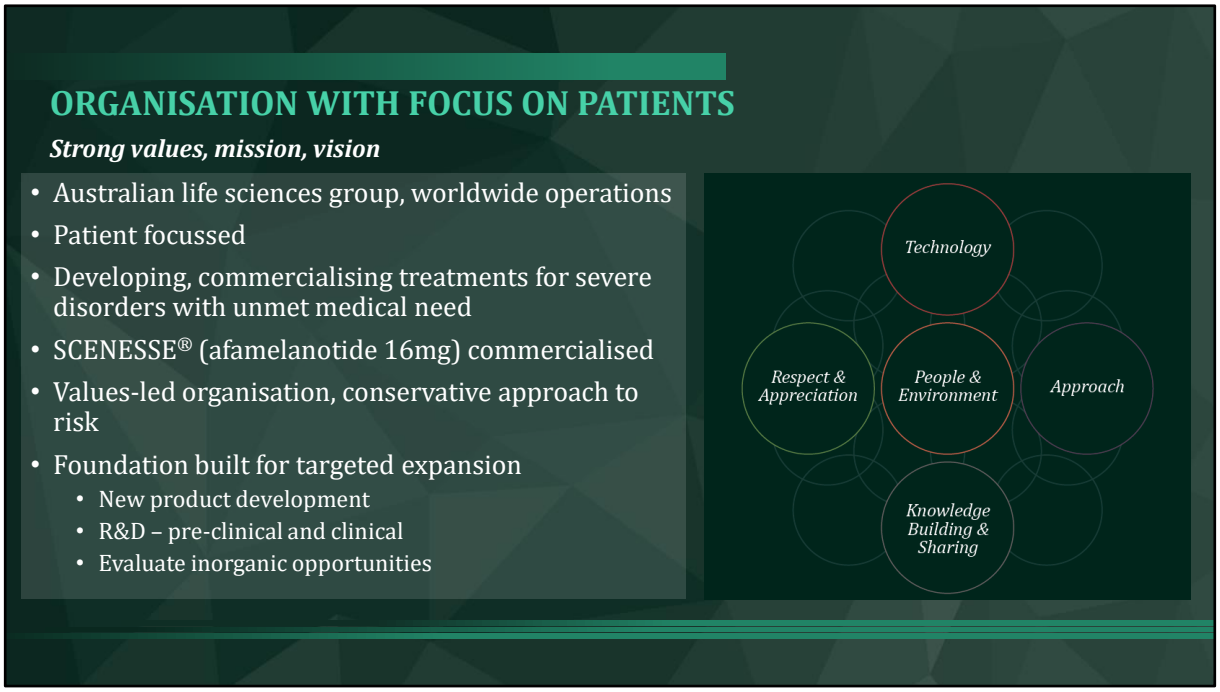

CLINUVEL is an Australian based life-sciences group with operations worldwide. It is highly patient focussed, striving to develop and commercialise treatments for severe disorders with unmet medical need.

The Group's values – outlined in detail on www.clinuvel.com – guide how we operate, with our people central to our 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 and actively manage them and seek to be in a position to manage the 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 the rare genetic disorder erythropoietic protoporphyria (EPP) in Europe in June 2016 and more recently, in the USA in April 2020. 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, reflected in high cash reserves (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 in the current environment, to expand and diversify the Group, and to build incremental 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) to address patient groups with recognised unmet therapeutic need.
- Evaluating potential inorganic opportunities in relevant fields to strengthen its position long-term.

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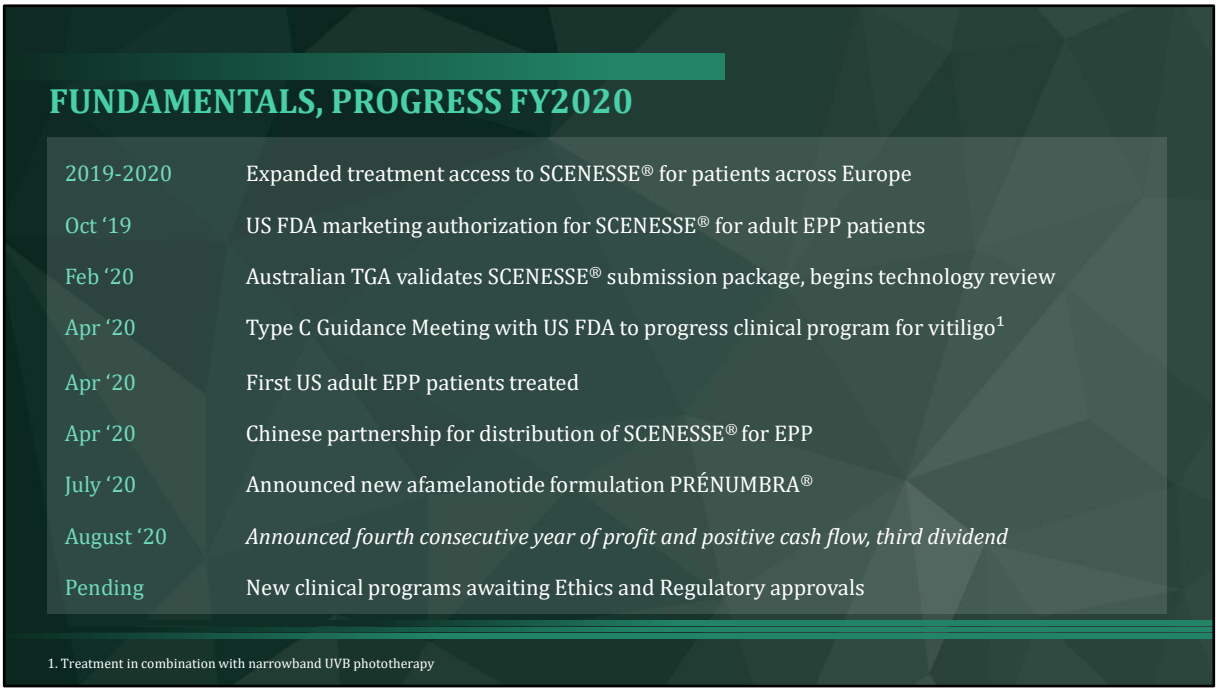


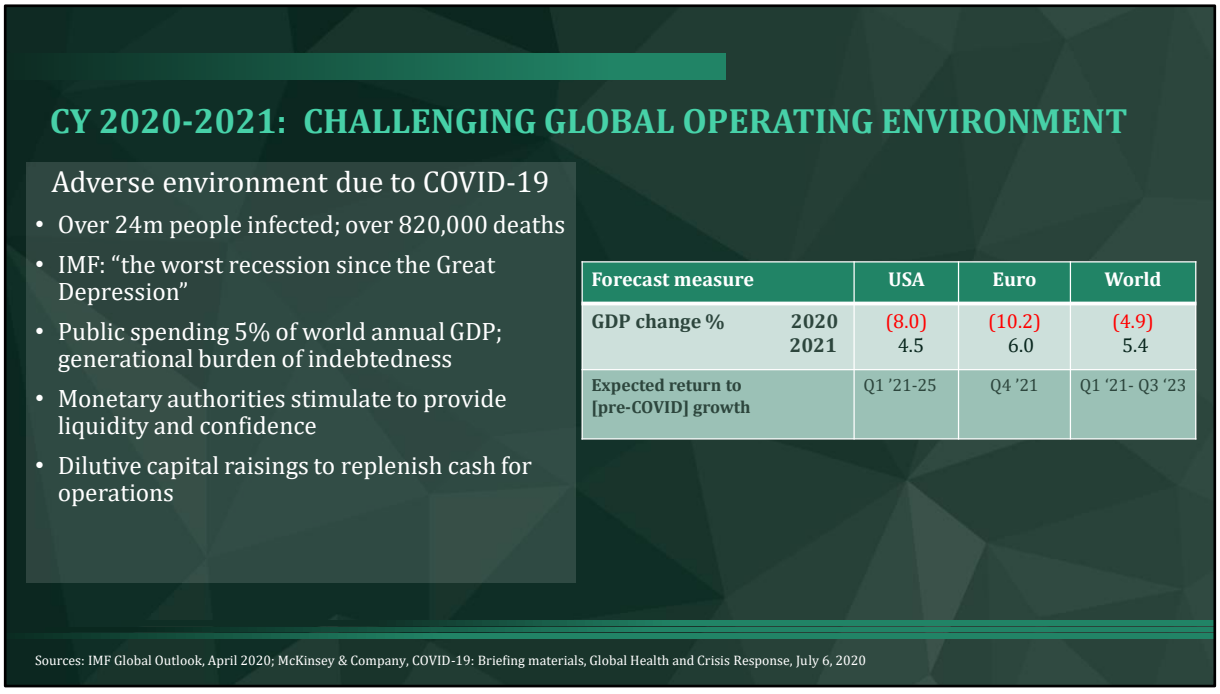
CLINUVEL expanded access to SCENESSE® during FY2020 and progressed its research and development program, despite the coronavirus pandemic. The product was approved by the US Food and Drug Administration (FDA) in October 2019 and was formally launched in the USA to treat the first US patients in April 2020. US EPP patients are treated at trained and accredited Specialty Centers, similar to the program in Europe.

New countries are treating patients in Europe while engagement with payors in other countries continues. SCENESSE® is established as a 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 (TGA), with an outcome anticipated in late 2020. CLINUVEL received confirmation of validation of the dossier in February with the evaluation continuing 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 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 and regulatory 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 in the business and importantly, maintained discipline in cost management to deliver its fourth year of positive cash flow and profit. 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.



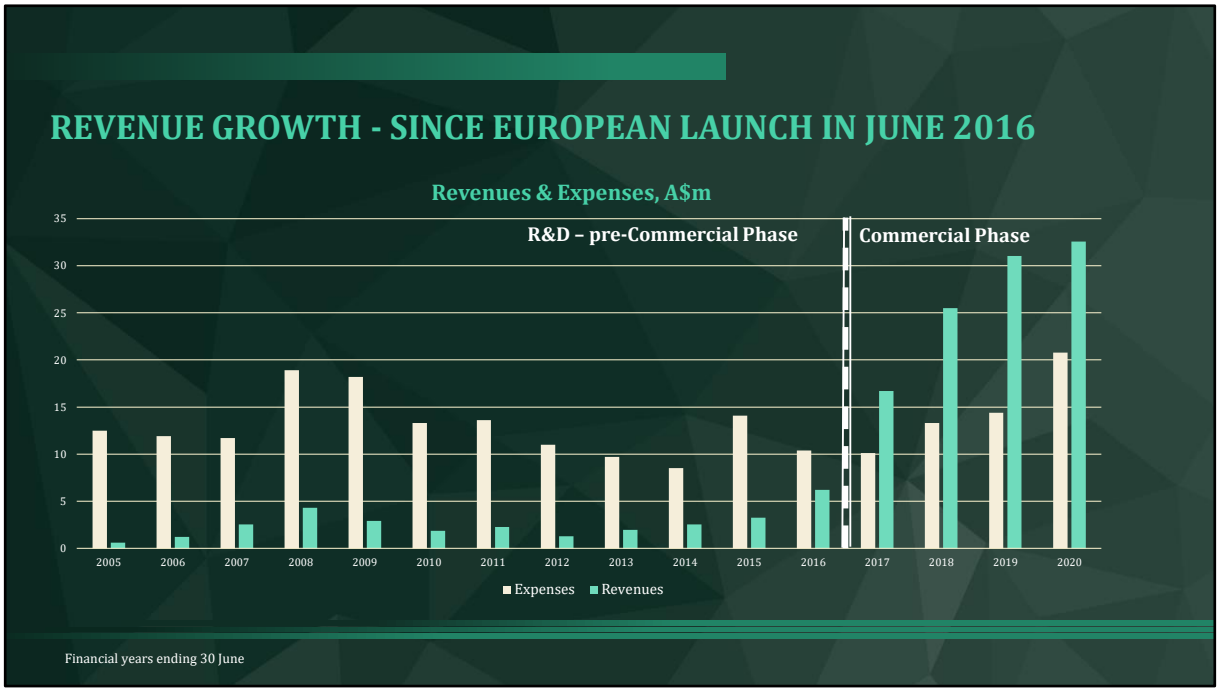
Let's turn to the unexpected and difficult operating environment for context to the profit result achieved in FY2020.

The world has fundamentally changed in a short period due to the pandemic. In human dimensions, COVID-19 has infected over 24 million people and caused over 820,000 deaths. The essential role of healthcare in all our lives has been reinforced by the pandemic. CLINUVEL, along with other biopharmaceutical companies providing treatment to patients in need, are part of this sector and provide investors with an opportunity to support the sector and benefit from the performance of effective operators.

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. On 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 GDP for the US for 2021, indicating how much uncertainty there is 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 5 years ahead, 1.4% growth annualised. This indicates difficult operating conditions may persist for some time and challenge the viability of many businesses.

In the context of this difficult operating environment, CLINUVEL posted an annual net profit before tax of A$13.136 million in FY2020. This is the fourth consecutive annual net profit of the Group. The CLINUVEL Board has declared a third consecutive annual final unfranked dividend of A$0.025 in appreciation of long-term investors who have funded the business over the research and development phase and into the commercial phase of the Company's life-cycle.

Overall, this presentation illustrates how CLINUVEL is positioned to manage the challenging operating environment and progress its strategic initiatives. CLINUVEL's strategic approach has been deliberate in focusing on the development and commercialisation of a lead drug embodying a novel technology for an unmet medical need. We have established a viable business that generates cash and profit to self-finance expansion and growth. Our focus is on the ongoing commercialisation and development of SCENESSE® and its derivatives to treat a range of indications. This will enable CLINUVEL to evolve into a diversified biopharmaceutical business.



CLINUVEL is a 'story' of growth. The time series of total revenues and expenses shows CLINUVEL's progress from the Research & Development (R&D) Phase into the Commercial Phase of operations. Data is in Australian dollars (A$) for the financial years, 1 July to 30 June.

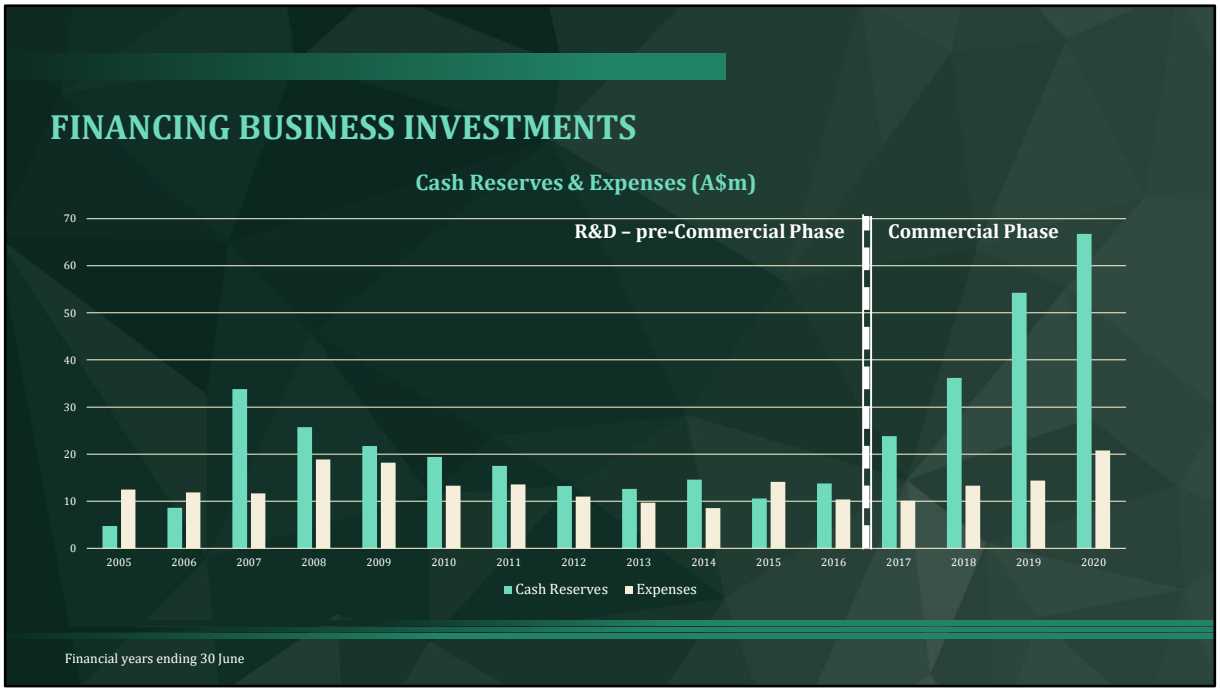
The R&D Phase from FY2005 to FY2016, shows expenses exceeded revenues as SCENESSE® was developed; clinical studies undertaken and completed; regulatory approvals sought and obtained. External funding of operations was essential, achieved through several self-managed capital raisings totaling A$94m. The cost of developing SCENESSE® of A$154m, based on 2005-2016 expenses, is lower than the +US$1bn typical cost of pharmaceutical drug development.

The Commercial Phase commenced upon distribution of SCENESSE® in June 2016. The growth in revenues and control of expenses since launch 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.

Total revenues grew by 4% in Europe during FY2020 and 5% overall to A$32.565m. On a constant currency basis, commercial sales of SCENESSE® in Europe decreased by 7.9%, whilst sales reimbursements from special access schemes increased by 29.9%. In the months of March, April and May, the resources of many hospitals in Europe were stretched, and priority was understandably given to treatment of patients with COVID-19. Patients with severe disorders such as EPP were turned away, to the mutual heartache of all concerned. This was the experience particularly in Italy, an early and adversely affected country. CLINUVEL personnel worked in creative ways to assist the provision of treatment to EPP patients by redirecting patients to hospitals with treatment capacity and arranging for after hours treatment. This puts in context the revenue outcome achieved.

Total expenditures doubled in the last four years to support growing commercial operations and the strategic initiatives of the Group. Total Expenses were A$20.773 million in FY2020, a deliberate and controlled increase of A$6.389m or 44% on expenses in FY2019. Total expenditures on R&D and commercialisation costs, comprising clinical study costs, drug formulation research, manufacture and distribution, regulatory fees and research, development and commercialisation-specific overheads such as personnel, were A$9.630 million in FY2020, increasing 40% from A$6.871 million in FY2019. The increase in overall expenditures reflects the Group's focus to further invest in its commercial rollout to treat patients in the EU and, for the first-time, the USA. Commercial sales commenced in the US in April 2020. Based on progress in accrediting Specialty Centers, arrangements with private insurers and the demand of adults with EPP for treatment, the fundamentals support a rising and ongoing contribution to sales from the US.

In terms of expenditure mix, total R&D and commercialisation expenditures accounted for 46% of the Group's total expenses in FY2020, compared to 48% FY2019, 45% FY2018 and 41% FY2017. General operations expenses, incl. personnel costs, were 42% of total expenses in FY2020, up from 40% FY2019, but lower than 43% FY2018 and 49% FY2017.



The profitable operations of the Company have enabled cash and cash equivalents (cash reserves) to be accumulated to A$66.747m as at 30 June 2020. The Company last raised capital in March 2016 and has since taken its cash reserves from A$14.170m to A$66.747m – a 44% compound annual growth rate and an increase of 23% in FY2020.

The strategy of the Group has been to gradually expand and establish a track record of positive operations to build cash reserves and enable the Group to withstand global downturns, without the need to raise capital in adverse markets and to self-finance its planned expansion and growth.

Cash reserves have funded the increase in expenditures on operations and the strategic initiatives of the Group. Cash to support ongoing operations in the current environment is critical and CLINUVEL has sufficient cash 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. This is commented as a flawless balance sheet.

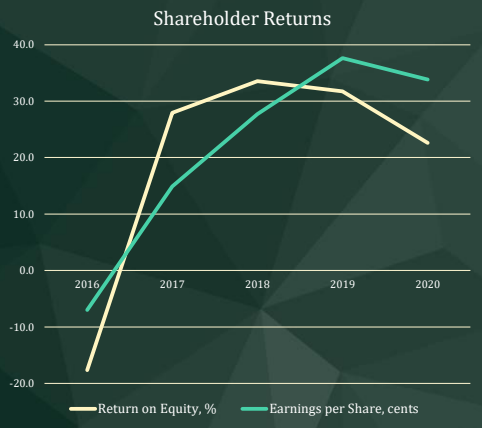
Whilst CLINUVEL is committed to expand the business and has cash to progress its plans, variable expenses can be managed by moderating the pace of product development, if required by environmental circumstances, and thereby meet its objective to maintain a positive cashflow and profitable business. Such is the prudence and responsibility required to adjust to adverse changes.

In summary, CLINUVEL's deliberate strategy to build its cash reserves provides confidence and security to continue its research and development program. This is critical for a bio-pharmaceutical company, avoiding unnecessary dilution and perceived overhang of potential capital raisings to finance operations.

CLINUVEL

KEY FINANCIAL SUMMARY AND PERFORMANCE MEASURES

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



The table summarises the financial results of FY2020. NPAT of A$16.647m was higher than NPBT by A$3.150m due to the recognition of deferred tax assets in the balance sheet. Operating cash flow was A$14.188m and bolstered cash reserves to A$66.747m.

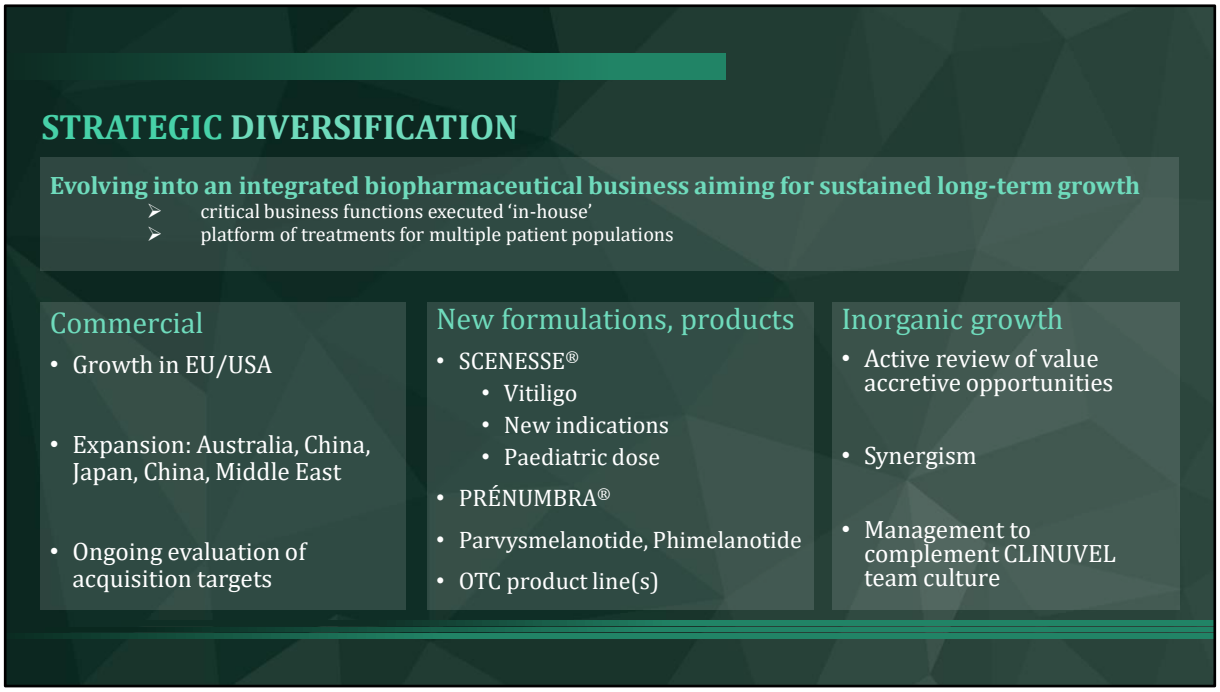
As a company with a track record of positive profitability, CLINUVEL delivers healthy returns on equity and earnings per share: 23% and 33.8 cents, respectively, in FY2020. This contrasts with many other biopharmaceutical companies listed on the ASX who have negative earnings per share and return on equity. Such groups are either in the R&D phase, or their 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. We have focussed 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.

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

- Global equity raisings from existing shareholders totaled US$129.5bn in May 2020, 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 was raised by the healthcare and pharmaceutical sector in Australia between late March and June 2020 alone.

In contrast, CLINUVEL's strategy and management approach means CUV shareholders have not been asked to contribute new capital to finance the business since commercialisation. There have been no new capital raisings, no dilution of shareholders and no discount to market associated with capital raisings.

Instead, at a time of a global recession larger than the 2008 financial crisis and unparalleled since the 1929 Great Depression, CLINUVEL has declared a third consecutive **unfranked dividend of A$0.25**. This is the same level as FY2019 which was an increase of 25% on the A$0.02 first dividend of the Company 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.



A range of strategic initiatives 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**, 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 17 accredited out of the 30 planned across the US. Over 40 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. We are developing a pediatric formulation of afamelanotide, evaluating SCENESSE® as a treatment for vitiligo, evaluating the effectiveness of melanocortins in DNA repair, 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.

A more detailed strategic update will be provided mid-October 2020.

In summary, CLINUVEL has laid solid foundations for its growth 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).
- The stable management team of 15 years is complemented by new talent and supported by an experienced Board.
- 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 net cash flow and profit over four years of commercial operations, paying its third unfranked dividend for FY2020.
- The balance sheet is strong with sufficient cash to self-finance planned growth and expansion of the business.

Thank you for your attention.

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

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www.clinuvel.com

CLINUVEL

Resilient Performance Underpins Growth

CLINUVEL PHARMACEUTICALS LTD

Preliminary Final Report

Financial Year Ending 30 June 2020

27 August 2020

Darren Keamy
CFO and Company Secretary

Malcolm Bull
Head of Investor Relations

CLINUVEL