COMPANY ANNOUNCEMENT

CLINUVEL Investor Webinar Financial Results Year Ended 30 June 2022

Melbourne, Australia, 31 August 2022	ASX: XETRA-DAX: NASDAQ INTERNATIONAL DESIGNATION:	CUV UR9 CLVLY

CLINUVEL PHARMACEUTICALS LTD hosted an investor webinar on the financial results for the year ended 30 June 2022 at 18:00 AEST on 30 August 2022. The webinar discussion is set out below:

Welcome and Introduction

Mr Bull: Welcome to everyone joining us online for this Investor Briefing on CLINUVEL's financial results for the year ended 30 June 2022. I'm Malcolm Bull, Head of Australian Operations and Investor Relations. Today, I am joined by our Managing Director, Dr Philippe Wolgen and Chief Financial Officer, Darren Keamy.

Today's briefing revolves around the results for the financial year ended 30 June 2022, the key activities of the year, as well as ongoing initiatives to bring the Company's objectives to positive outcomes. Throughout the briefing, we will answer questions relating to our financial results and at the end, some recurring questions on other topics.

Before we begin, please observe our forward-looking statement, which highlights that we may possibly talk about future plans, and investors need to be aware of various risks that can arise affecting the realisation of planned outcomes. A copy of this statement is available on the Company's website.

Financial Highlights

Mr Bull: To start, I'll hand over to our CFO, Darren Keamy, for the financial highlights.

Mr Keamy: Thanks Malcolm, it is a true pleasure to summarise excellent financial outcomes of the Group's operations for the financial year ended 30 June 2022. Investors should note that the figures we refer to are in Australian dollars, and these are rounded for ease of reference, and changes in comparison to FY2021 are provided.

So, to summarise:

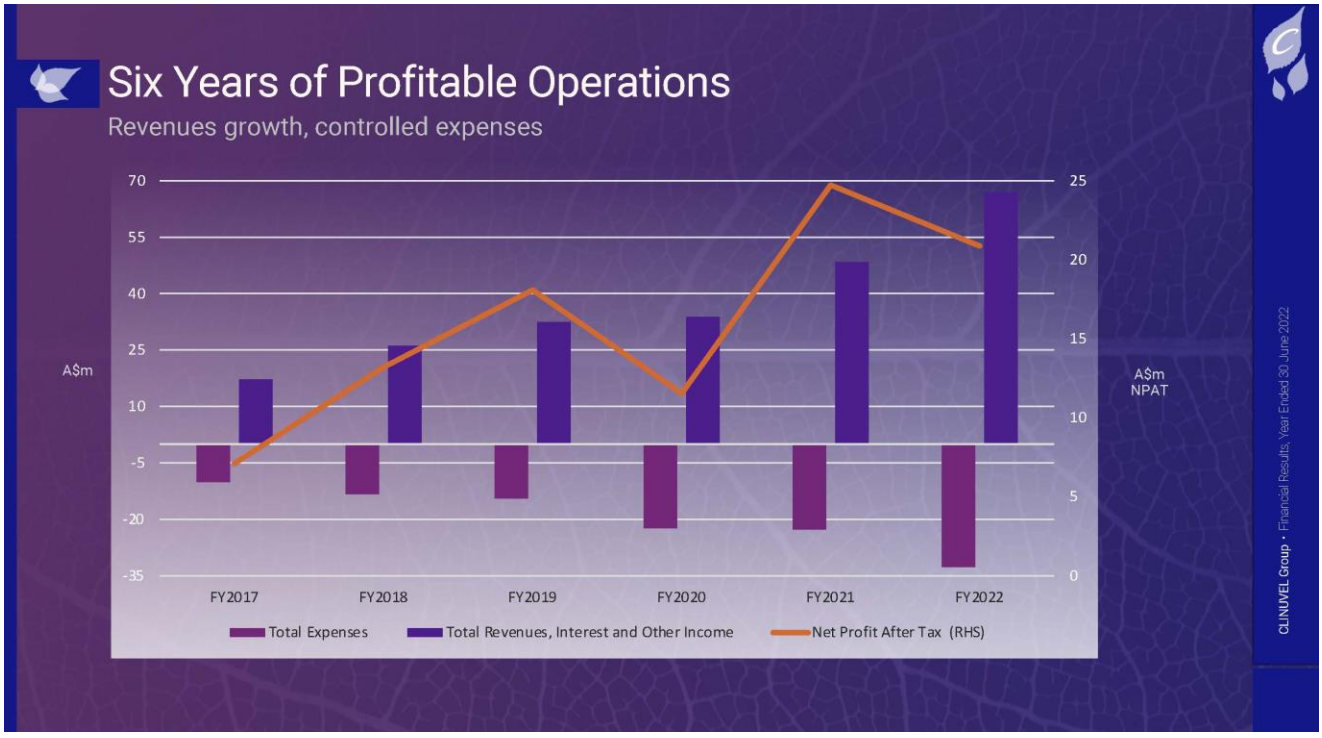
- Total revenues rose 37% to $65.7 million, and including interest and other income, was $67.0 million.
- Total expenses rose 44% to $32.7 million.
- NPBT rose 33% to $34.3 million.
- NPAT fell 16% to $20.9 million.
- This is the six consecutive annual profit since the commencement of commercial operations in June 2016.
- There has been positive overall growth of the Group's activities, an increase in investments and a year-on-year increase in headcount of 16%.
- Net assets increased by 27.2% to $125.6 million with the key change of the balance sheet being a substantial rise in cash balances of $38.8 million to $121.5 million.
- Two other key measures of performance to mention are Return on Equity was 17%, and Earnings Per Share of 42.3 Australian cents.
- To cap these results, we are now in the position to think about our shareholders even more and declared the fifth consecutive annual dividend which is a 60% increase from 2.5 cents last year to 4.0 cents on FY2022 earnings.

Mr Bull: Thanks Darren, these are welcome figures; you and Paul Lim and the finance team must feel pleased about the delivery this year.

Revenues, Expenses and NPAT

Mr Bull: To go beyond the highlights Darren, can you give more depth to the growth of revenues and expenses and the profit achieved this year, as well as in the context of the past six years of commercial operations? In other words, how would new investors need to look at these financials in the context of markets and our sector?

Mr Keamy: Well, on revenues, we have worked towards continuing positive annual growth over six years of commercial operations. To put context to our growth curve, since we entered the US – we achieved an increase in Total Revenues of 37% in FY2022 and 47% in FY2021. This path reflects increased patients treated; more physicians prescribing; more patients retained; and above all, efficiency gained through the work of the CLINUVEL team to proactively support distribution by collaborating with physicians, insurers, training and liaising with accredited centres and patients. So, the closer we are to our value chain, the better our results prove to be.



A few words to the expenses; they can fluctuate depending on the start of certain activities, but overall, they have increased over the last three financial years in a controlled manner –49% in 2020, 2% in 2021 and 44% in 2022 – to support the growth initiatives of the Group.

It goes without saying that the longer-term positive trend in revenues has allowed us to ramp up expenses to drive forward new R&D, new products, and new markets.

As to reporting the profitability of the Company, this year we make a distinction between three measures, NPBT, NPAT and non-IFRS adjusted net profit, since in the end, what matters is which expenses directly affect our cash position, since some material expense items are charged to meet accounting requirements and do not affect cash.

NPBT rose strongly in FY2022, and whilst the impact of non-cash expenses as well as income taxes payable reduced the net profit after tax, it is nonetheless a much-desired result for a life sciences company, not only in Australia, but also in the US and other markets.

I will speak later about the NPAT and non-IFRS adjusted results to see, how the expense items have affected our net position.

Review of the Year's Activities

Mr Bull: Yes, we'll return to the financials, but some participants have asked for a summary of the operational objectives fulfilled for financial year 2022. Perhaps I can invite our Managing Director, Philippe Wolgen to say a few words on the past year.

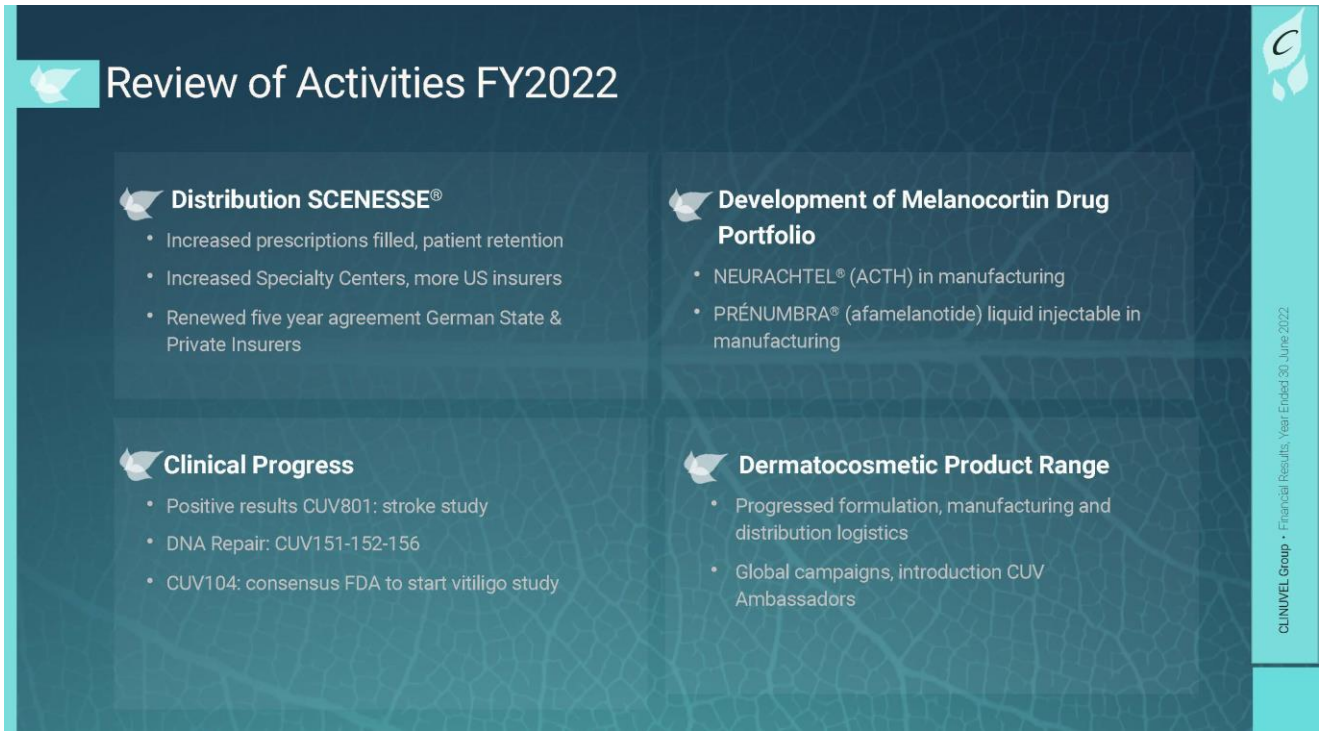
Dr Wolgen: Sure, thanks Darren and Malcolm. The results Darren has summarised for the Group are the outcome of a longer-term strategy, based on the integration of business functions, a model we had started years ago. As a business you wish to build in operating procedures at each level of the divisions, while being sufficiently flexible to change course if required. In FY2022, we were able to expend on more R&D initiatives, enhance our melanocortin portfolio with NEURACTHEL®, an ACTH analogue, start the DNA-repair program evaluating afamelanotide in XP with three studies ongoing; start and complete the first stroke study CUV801; manufactured the first pilot batch part of our OTC product lines; bring in more specialised talent; and form a CBM team, mandated to build larger audiences for the Group.

We have been fortunate in managing supply in the midst of global economic and geopolitical disruptions, while overcoming pricing pressures from insurers, as witnessed by the agreement reached with one of the EU reference countries, Germany.

If I had to summarise the key activities for FY2022 they have been focussed on:

- the ongoing distribution of SCENESSE®;
- development of the melanocortin drug portfolio;
- progress of the expanded clinical program; and
- ongoing development of the of non-pharmaceutical product range for first product launch.

For the longer-term shareholders, you have gradually seen a mono-focused team inching to diversify its activities; my main concern in spreading our wings is still to drive projects forward in a timely manner without losing too much focus required to record meaningful progress. For this to occur, we substantially increased our headcount in FY2022.



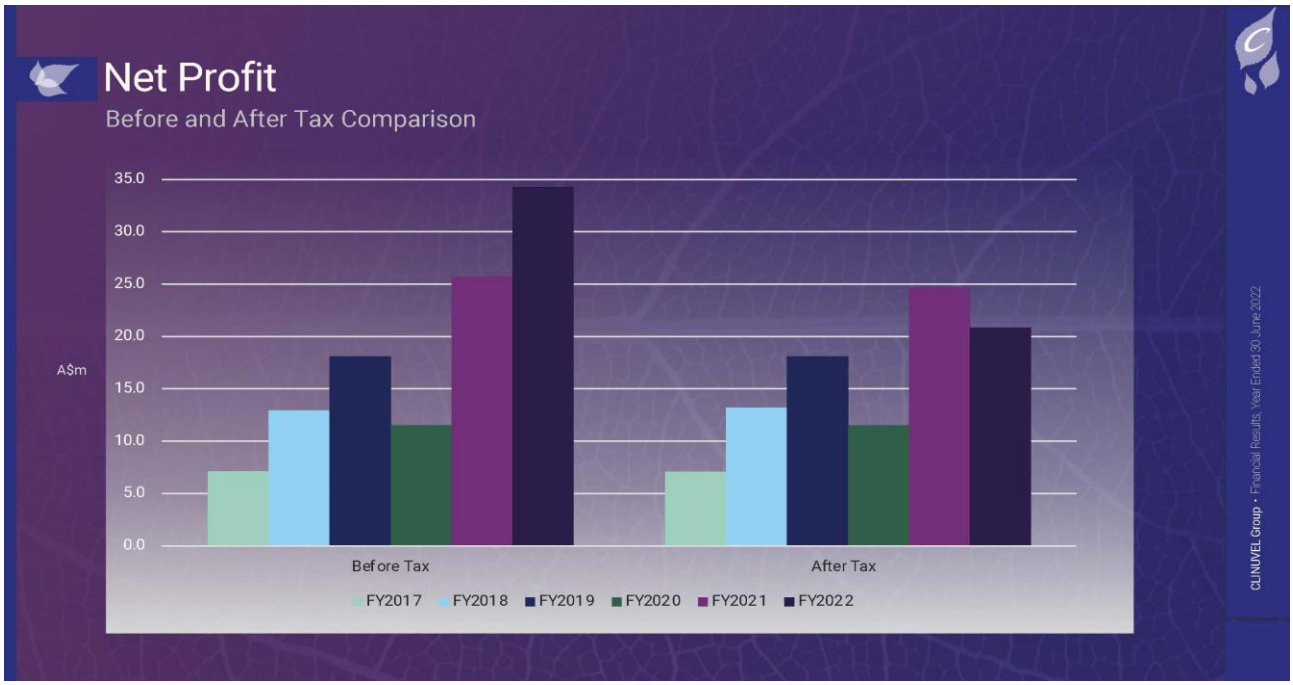
Most relevant to today's discussion are our commercial efforts translating into financial results:

- We saw increased patient access in the EEA and USA and Israel.
- We reached a milestone five-year agreement with the Joint Federal Committee and State and Private Insurers in Germany to continue reimbursement of SCENESSE®, a hard-fought battle;
- We expanded the melanocortin drug portfolio by adding an ACTH analogue and introducing an ACTH formulation, NEURACTHEL®.
- We continued the development of PRÉNUMBRA® Instant, which we recently announced would be used first in the clinic in the next stroke study - for this to take place we secured exclusive manufacturing of the analogue.
- We started three studies in DNA Repair, central remained xeroderma pigmentosum (XP), while CUV151 serves as a control study of disease-free subjects.
- We started, completed and released the positive results of the first study in arterial ischaemic stroke (AIS), CUV801.
- We reached an accord with the FDA with a way forward for the next study of SCENESSE® as a monotherapy in vitiligo, CUV104.
- We also progressed the work on the OTC product range and are getting closer to the launch of the first polychromatic product line.

Mr Bull: Thank you Philippe. In my role as Head of Australian Operations, I interact daily with the teams worldwide, and it is clear that the Group the past year has ramped up its activities on many fronts, and these broader and simultaneous activities are very different from the Company I joined three and half years ago.

Reconciliation of NPBT to NPAT

Mr Bull: Darren, if we return now to the financial results. We have received a number of questions on the difference between the NPBT, NPAT and non-IFRS outcomes. Can you shed light on these and walk us through the differences?



Mr Keamy: Yes, I can. First you can see differences between NPBT and NPAT over the six years of commercial operations, and the divergence widening between the two profit measures in recent years.

Broadly speaking, the Company was able to benefit from setting off the tax losses it had accumulated in those years prior to commercialising SCENESSE® against the first five years of profits it had recorded. This resulted in negligible past tax obligations and afforded us to recognise income tax 'benefits' in the income statement upon recognising a tax asset on the balance sheet. In past years, we saw NPBT and NPAT to be quite similar in result, and even a higher NPAT relative to NPBT from recognising an income tax 'benefit'.

However, during FY2022, those usable tax losses were consumed, and the Company's deferred tax assets were reduced as a result. This contributed to a deferred tax expense for the year of $6.2 million.

In addition to this adjustment, current tax for the year and payable in the next financial year was reported as $7.4 million.

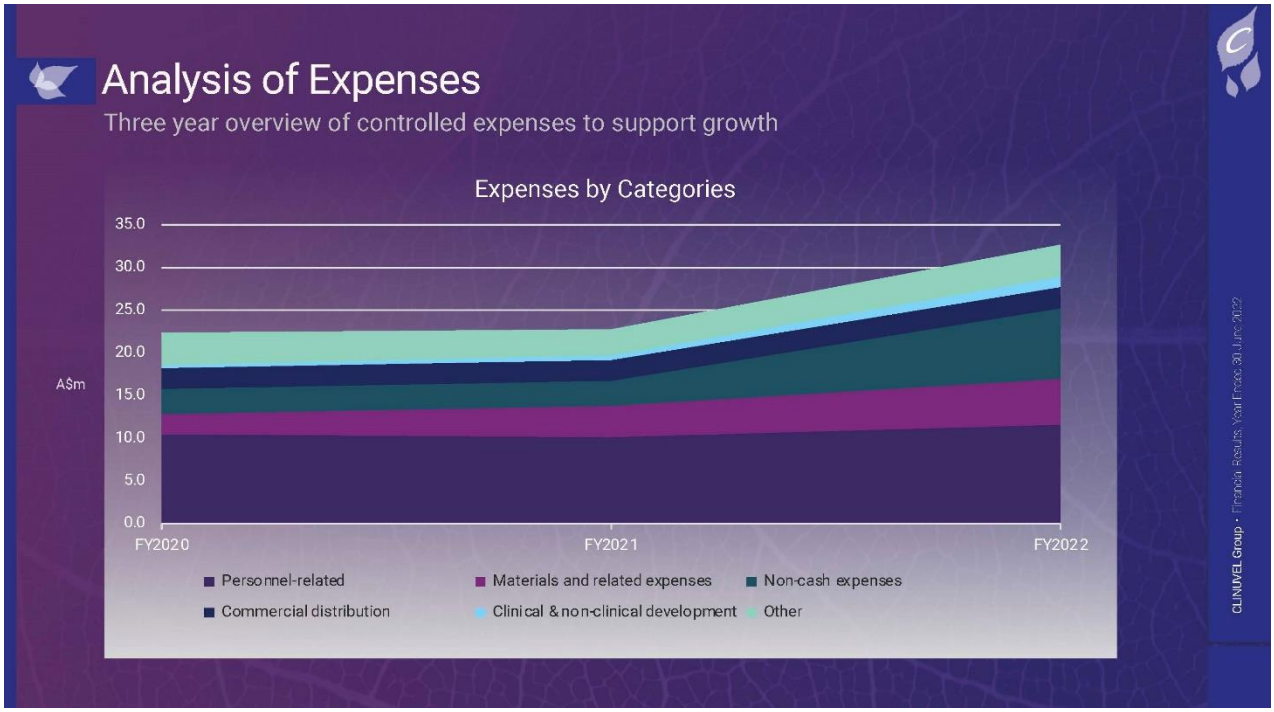
Also relevant for the Group and myself as CFO, is to understand the impact of certain expenses particularly those of a material nature and whether they impact the Group's cash position. One of these charges is the expensing of performance rights, being prospective equity instruments for staff to earn over a vesting period of up to four years. These instruments are valued in accordance with accounting standards, but they do not impact cash. Hence, by removing certain material non-cash items from the statutory reported NPAT result, we arrive at a non-IFRS adjusted profitability measure of approximately $27 million, nearly equal to FY2021.

Going forward, the Group intends to continue to highlight the expenses charged and the effect certain material non-cash items has on profit, because this impact can be confusing for shareholders.

Mr Bull: Thanks Darren, that makes sense and answers some important questions.

Analysis of Expenses

Mr Bull: As you have mentioned Darren, expenses have increased significant over the past three years. Can you comment on where the expenses are being incurred?



Mr Keamy: Yes, the increase in expenses is deliberate, controlled to support the growth of the Company, and Philippe has already provided an overview of the diversity of the Group's activities. To give you an overview of increases in key categories:

- Our largest expense category is Personnel which increased by 14.1% in FY2022. As advised in the Annual Report, the year-on-year increase in the number of employees of the Group was 16%.
- We also experienced a hike of 48% in Materials and related expenses, and some of these reflect marked-up activities within an inflationary environment.
- Thirdly, non-cash items disclosed in the income statement such as depreciation and amortisation, share-based payments and unrealised movements on foreign currency balances aggregated together rose 42% in FY2022, and these non-cash items comprised our second largest expense category in FY2022.
- Finally, other expenses relating to our administration, legal and marketing functions increased by 23%.

Five Year Expenses Plan

Mr Bull: Perhaps, I can go back to you Philippe; we had projected a positive trend in expenses over the five years to 30 June 2025 to support growth and expansion. Can you comment on this please?

Dr Wolgen: You are alluding here to the projected expenses and the expenses recorded during FY2022 and whether they fit the overall targeted results. As we stated in 2021, to achieve a number of value-added objectives over five years, the Board and management laid out a plan costing out cumulative expenditures of $175 million over the five years to 30 June 2025.

At the end of this trajectory, a number of key objectives would need to be fulfilled, in essence the regulatory approval of SCENESSE® in an additional indication, the launch of NEURACTHEL®, several consumer health products, and other R&D projects engendering further value.

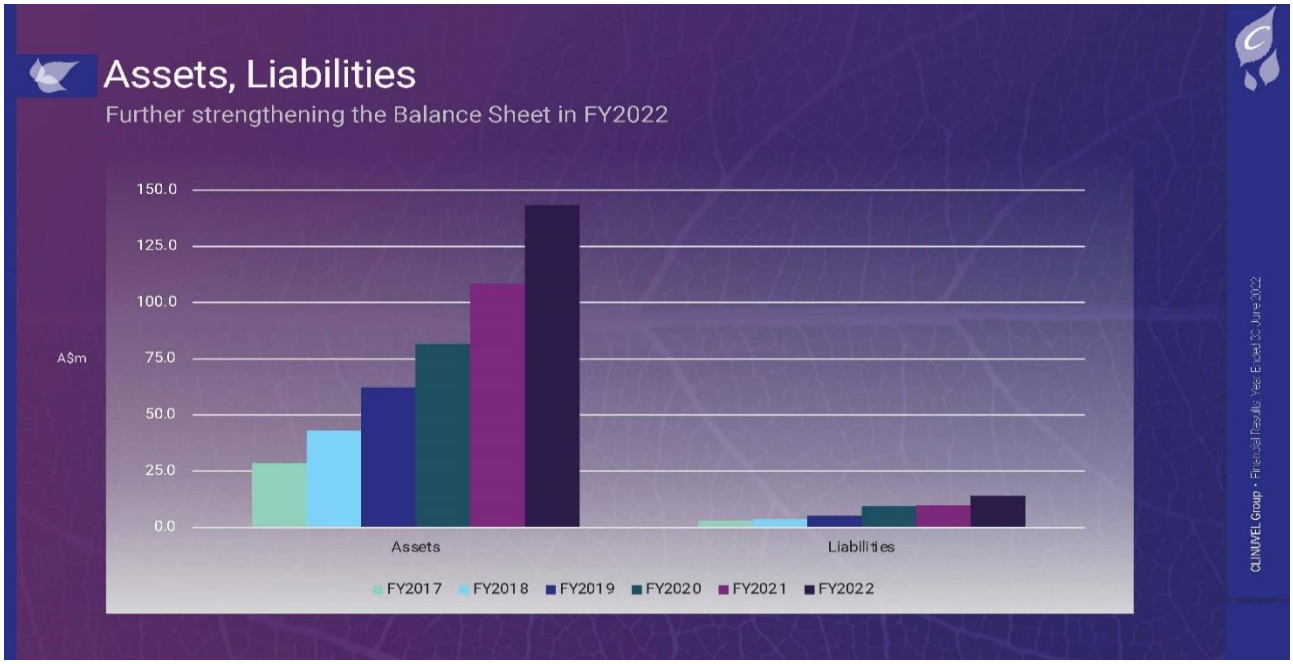
If one adds the total expenses, one arrives at a total of $55.5 million, and this leaves us $119 million over the next three financial years, so we are nigh on course adhering to our five-year plan.

Mr Bull: Can you clarify for an investor that these expenditures are operational in nature and do not include capital expenditures.

Dr Wolgen: That is correct.

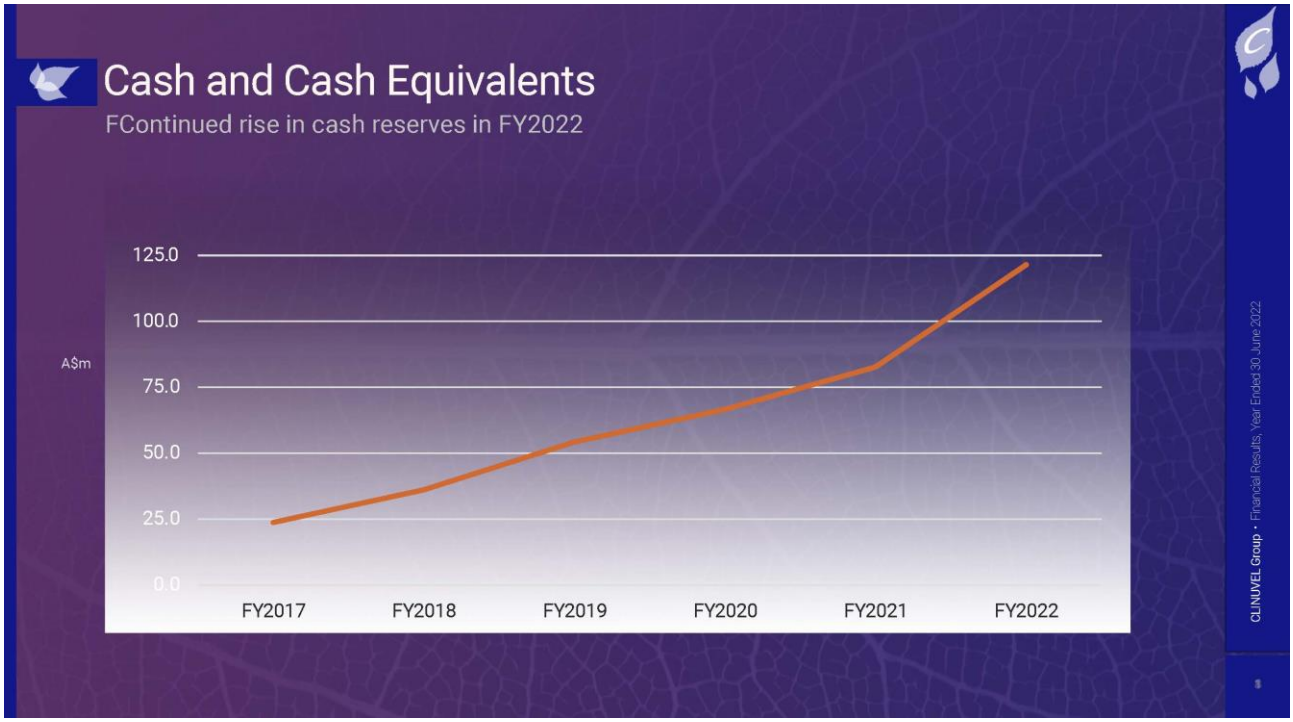
Assets and Liabilities

Mr Bull: Darren, turning to the balance sheet, our assets have increased over the last six years and in absolute terms, tower over our liabilities. For your comment please.



Mr Keamy: Yes Malcolm, that reflects the approach we have to business in general and the strength of CLINUVEL in particular. The balance sheet is extremely strong with no debt, and high liquidity due to the accumulated cash reserves. Our liabilities are largely trade payables and short term tax obligations.

The net cash generated during the year bolstered cash reserves significantly and the rate of increase is particularly noticeable.



Use of Cash Reserves

Mr Bull: Philippe, we covered the deployment of accumulated cash reserves in the last News Communiquè, number IV, but we continue to receive questions on CLINUVEL's approach here. Do you have any more to say to the cash reserves being built and their use?

Dr Wolgen: Sure, we cannot state our approach often enough. In the interest of all shareholders, R&D bio-pharmaceutical companies would be well off in carrying sufficient cash to operate two-to-three years without leaving shareholders and markets second guessing as to when the Company needs to raise more funding, debt or equity. The overhang depresses notional value and introduces uncertainty among investors. Yet, as a reasonably successful commercial company, CLINUVEL has returned in 2021 to increasing its R&D expenses to drive a pipeline for future value, and this R&D was projected to be financed by the Company's cash at hand and future proceeds from its operations.

Second, a margin of cash reserves is needed to withstand economic downturns and six-sigma events, those 'force majeure' events which one never sees coming, but actually take place more often than one projects. It is part of CLINUVEL's risk management, to control its finance and generate and maintain a liquidity ratio. With this approach, all shareholders benefited from a going concern, not being rerated by auditors, not being forced to raise further equity in uncertain markets at deep discount.

Third, cash allows for redistribution of a percentage to our shareholders. Of our net profits, we distribute this year 10% to our shareholders, that is without jeopardising or impacting our plans.

On a personal basis, 35% of our shareholders consist of family offices, retail investors who have chosen to stay more than 15 years in CUV. For those who supported us, I believe dividend communicates and sends a message of appreciation, since it is rare for a biopharmaceutical to do so.

As Darren mentioned, the Board declared an 60% increase of annual dividend of four Australian cents in relation to FY2022 earnings.

FY2023 and Beyond

Mr Bull: To summarise our discussions, we have seen a sixth consecutive annual profit reflecting strong demand for SCENESSE® and established a viable track record as a first-in-class drug therapy. This is the outcome of long-term, disciplined strategy, and the deployment of an integrated business model. The returns to shareholders are sound. We currently have strong foundations to allow growth and are among very few biopharmaceuticals in Australia or the US to post profits year on year. We focused on particularly, the safety of SCENESSE® to allow translation of its use in wider applications.

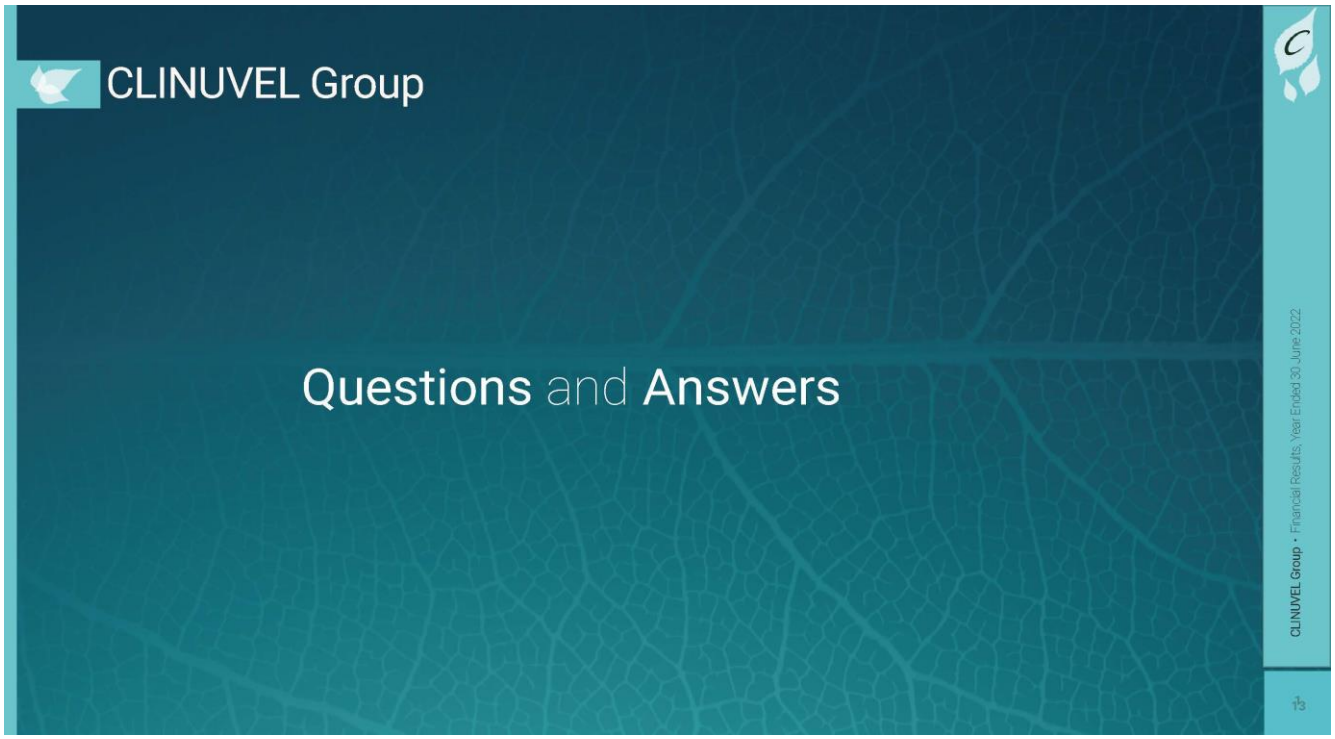
The Group's financial management allows for diversification, redistribution and security benefiting all shareholders, patients, and their families.

The Group's ongoing activities are focussed on:

- growth in the distribution of SCENESSE®;
- building regulatory dossiers to expand use; and the
- launch of the first polychromatic dermatocosmetic product.

You may see some announcements on read-outs of study results when available and clinical programs in general, as they commence and progress.

Mr Bull: In the time we have left, I'd like to turn to some non-finance questions, noting there will be further opportunity for questions at the Annual General Meeting.



SCENESSE® for EPP

Mr Bull: Philippe, first, we have a few questions on SCENESSE® for EPP. First, what is our market penetration and is demand likely to level off?

Dr Wolgen: The growth we are experiencing, particularly in the USA, is well beyond our own expectations. The penetration of the EPP market is said by independent analysts to be relatively low (at circa 2/3%). In general, we have never commented on penetration of the EPP market, but we agree that there is ample room to grow, and we are not foreseeing a plateau.

Mr Bull: Another area of investor focus is possible competition. Can you address this?

Dr Wolgen: We have discussed this one several occasions. CLINUVEL is a pioneer in photomedicine, in having developed the first systemic photoprotective therapy. Of course, there will be competition, we always foresee that in the fields we explore; we will attract others.

This is not a winner takes all scenario, as one uninformed commentator stated recently. These statements should be contrasted with the assessment of one of the most respected independent analysts of CLINUVEL who has the lengthy experience as a physician to understand that there is room for more than one therapy in the EPP market should a competitive situation arise.

CLINUVEL will compete, but we are not about to telegraph to the world and our competitors our plans in answering a well-intentioned question. Let's not be naïve, competition is about strategy and tactics; we will guard our competitive firepower until it needs to be used.

Healthcare Solutions Program

Mr Bull: With regard to healthcare solutions, the rationale is to translate our expertise in pharmaceutical drug development and photomedicine and regeneration of the skin damaged by exposure to light to audiences in the general population, currently underserved by existing dermatocosmetic products. Philippe, who are the target audiences?

Dr Wolgen: I am most happy to speak to this topic in our upcoming Strategic Update V, on 17 and 18 September. We will spend much time on communicating the why, how, and when.

Conclusion

Mr Bull: Okay, at this time, we need to conclude the Investor Briefing with thanks to Darren and Philippe for their informative comments and answers to questions.

Mr Keamy: Thank you.

Dr Wolgen: Thank you, and good evening to all.

Mr Bull: I wish to thank all shareholders for attending the briefing and sending in questions. We appreciate your support throughout the year, and we trust you appreciate the dividend increase coming your way.

Our appreciation is also extended to the independent analysts on the phone today, and who have provided new reports on the Company during the past year.

A transcript of this Investor Briefing will be released to the Australian Securities Exchange, for all stakeholders to read at their convenience.

The next key shareholder events are Strategic Update V in September and the Annual General Meeting 2022 which will be held late October in Melbourne. This will be an in-person meeting and provide an opportunity for shareholders to also dial-into and view the meeting.

We wish you all good health and progress in your individual objectives. Thank you again for your support of CLINUVEL.

- End -

CLINUVEL's Appendix 4E and Annual Report is available on the Company's website, www.clinuvel.com.

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia as an orphan medicinal product for the prevention of prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). SCENESSE® is approved in the USA to increase "pain-free" light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; XETRA-DAX: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor Enquiries
https://www.clinuvel.com/investors/contact-us

Forward-Looking Statements

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 and/or other world, regional or national events 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), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner 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, Israel, 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®, PRÉNUMBRA® or NEURACTHEL® 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 and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability 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 2022 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 preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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