

# CLINUVEL

## AGM 2024 – CHAIR'S ADDRESS

Melbourne, Australia, 16 October 2024

ASX: CUV | Börse Frankfurt: UR9 | ADR Level 1: CLVLY

### INTRODUCTION

It is my great pleasure to welcome shareholders to our 2024 AGM. This is a valuable opportunity to review our past performance and future plans. I will begin by highlighting the indisputable success of our last financial year: it is the strongest since CLINUVEL listed almost 25 years ago.

We developed and commercialised SCENESSE®, a breakthrough drug for the rare, unmet condition EPP. Now we are evolving from a successful, profitable company with a single therapy into a diversified, global biopharmaceutical company at the frontier of photomedicine. To do this, we are building a sustainable, long-term future with multiple revenue streams.

We are investigating how our pioneering melanocortin technology can treat a wider range of medical indications. This includes vitiligo, a condition with few effective treatments which affects up to 2% of the global population. As we are devoted to transforming skin health in the broadest sense, we are also developing PhotoCosmetics. This ambitious new venture will mark the first time that melanocortins enter the world of luxury skincare. We will transform skin health and disrupt the premium cosmetics industry in the process

### CRITICAL DECISION MAKING

I see decision making as central to the success of the business. It is a topic with personal resonance too. During my 40-year career as a world-leading neurosurgeon, I have tended to patients with life-threatening brain and spine diseases. As a Major General and Military Surgeon, I operated on gravely injured soldiers in the field. And as the inaugural Director of the Monash Institute of Medical Engineering, it was my job to make a call on whether newly invented medical technology could thrive beyond the lab, in the marketplace. All that is to say, I have made innumerable critical decisions in my professional life. Since January, I have used these carefully-honed skills to lead this Board. I would like to emphasise that CLINUVEL's rise is solely down to the decisions taken by the Board and Management. You can have the most innovative technology in the world, but it will go nowhere without the right people and vision to ensure it succeeds.

As a Board, we have information at our fingertips that no one else does. This unique intelligence informs the decisions made daily by a handpicked senior team whose job it is to solve complex issues and ensure the company's continued growth. It is their bold, at times even counterintuitive, solutions that have helped CLINUVEL weather difficult periods over the past 20 or so years. The result has been two decades of success. This transition has been driven in large part by the commitment and expertise of our CEO, Dr Philippe Wolgen. He has shaped CLINUVEL's path forward and has tirelessly worked with the Board, senior management and the entire company.

When you invest in CLINUVEL, you are not only investing in our business. You are also investing in our people, in the knowledge and skills that they bring to the Company. The majority of our shareholders understand this and trust management to keep the Company on track, investing in a team that resurrected the Company and led it to profitability. I would like to also point out that the Board has no obligation to disclose the deliberations behind every decision. This is true for any leadership team striving to better a public company in a competitive environment.

There are some investors who are vocal about their disappointment with the share price. However, no Board has direct control over share prices. Nor should its sole focus be on moving these prices. Our share buyback program is helping support the share price, though as other companies' experiences show, the boosting effect may be short lived.

Unfortunately, CLINUVEL has about 25 anonymous posters who incessantly criticise all aspects of our operations and our financial results. Despite this campaign of digital disruption, most of these investors have reaped returns from CLINUVEL's stock for over 15 years. They are neither experts in our business, nor in the field. The battle they are waging against CLINUVEL from their keyboard is bad for themselves, the business and all shareholders. Which begs the question, if they are so unhappy, why do they not sell their shares? I urge you not to be swayed by their vitriolic, misinformed posts and vote for continuity, stability and future potential. That will provide the surest path to CLINUVEL's continued success. All the resolutions today are about placing your trust in us, in the knowledge, that we will make decisions in the best interests of our shareholders.

## **FINANCIAL PERFORMANCE**

CLINUVEL is going from strength to strength. The glowing financial results of FY24 are a testament to this fact. We have a robust commercial operation treating EPP patients in Europe and North America. These are growth areas. In both markets, the number of patients we are treating have increased year on year.

For eight consecutive years, we have steered the Company through annual growth in revenues, profit and cash reserves. This upwards trajectory continued in 2024. I would also draw your attention to our peer-leading metrics. Our earnings per share and return on equity are metrics many of our peers would envy.

CLINUVEL is self-sufficient. By that, I mean that we have enough money to self-fund our own R&D. This gives us the freedom to decide when, where and how to reinvest our sizeable profits after tax—now worth \$35.6m. A cash reserve worth A\$183.9m, the largest sum in CLINUVEL's history, is financing our expansion into new markets. We are actively considering mergers and acquisitions. On behalf of the Board, I wish to acknowledge the CLINUVEL team for their dedicated efforts. Our robust financial position is the engine of our future growth, enabling us to deliver on our key objectives.

## **BOARD EXPANSION AND RENEWAL**

When I became Chair earlier this year, I prioritised expanding the Board and diversifying the skillset of its members. They must be equipped with the knowledge and capabilities to lead us into the future. As part of this process, the Board undertook an extensive, external-led review. It is my pleasure to welcome three experienced professionals with diverse backgrounds who complement the existing directors. As Mr Matthew Pringle, Mr Guy van Dievoet and Dr Pearl Grimes step into their roles as non-executive directors, we will harness new skills across finance, accounting, governance, M&A and dermatology, and Dr Grimes is a world-leading specialist in vitiligo. They will bolster CLINUVEL's talent, knowledge and connectivity, and help secure long-term stability.

We also say farewell to one of our valued directors. Mrs Brenda Shanahan steps down today after 17 years. I wish to express my sincere gratitude to Brenda, on behalf of both myself and the Board. 17 years of service to any endeavour is commendable, but Brenda's commitment to the Company and our vision has been truly remarkable. Her in-depth knowledge of both CLINUVEL's journey and Australian capital markets has guided many of the decisions taken at Board level over the years. Brenda leaves having made her mark on CLINUVEL.

## **VALUE**

In my recent Chair's letter, I wrote that CLINUVEL's market capitalisation does not reflect the value that we are building, nor our future prospects. The company is not alone in this regard. With recent fluctuations in global markets, the valuations of many biotech and life-science companies are fluctuating. To allay any doubts, I would remind you that CLINUVEL is in a better position than most of its peers. We are one of very few biopharmaceutical companies to have developed a new therapy, achieved regulatory approval in the US and Europe, and have successfully marketed a product. Those strong foundations are just the start. The Board takes the view that the preferred way to grow the business is through the expansion of melanocortin products for both therapeutic and PhotoCosmetic applications. Seven independent analysts also agree that our efforts to unearth new sources of income look promising.

To keep up easily with our new developments, I would direct you towards our rejuvenated social media accounts. Both our Investor Relations and Communications, Branding & Marketing teams are regularly sharing content about CLINUVEL's progress which is reaching diverse audiences. We have more coverage by analysts, investor briefings and webinars, non-deal roadshows, conference attendances and presentations. This year we

have gradually ramped up social media campaigns and intend to step up these plans in 2024. Together, these will increase CLINUVEL's prominence and visibility. This is important not only for PhotoCosmetics but also for our pharmaceutical presence. These efforts are key to CLINUVEL becoming a household name.

## **OWNERSHIP**

Several existing shareholders have increased their holdings in the past year, while new institutional holders have also joined our register. This diversifies and strengthens CLINUVEL's ownership. We know that our business has global appeal and are heartened to see that the bulk of our shareholders are split between Europe, North America and Australia. We wish to maintain this geographical spread. I thank those who have already been in contact to express their support for our long-term plans. Your messages are welcome.

I would urge any shareholder who has been critical to look at CLINUVEL with fresh eyes – and I hope you see what I and many others see – a vibrant, innovative, nimble, profitable company, without debt and with the ability to take advantage of its substantial cash reserves. I believe our strategies for future growth and success warrant strong shareholder support.

## **ACKNOWLEDGEMENTS**

The winds of change are blowing across CLINUVEL. We have been on a recruiting spree in the last 12 months, adding a new Chief Financial Officer, Mr Peter Vaughan, a new Director of Global Clinical Affairs, Dr Emilie Rodenburger and a Company Secretary, Mrs Claire Newstead- Sinclair. I wish to again thank our Managing Director and CEO, Dr Philippe Wolgen, for his superb management of the Company. He has kindly agreed to a one-year extension of his employment contract. While we are saddened that he wishes to step down, we must accept his motivations. Between now and 30 June 2026, we will secure the services of a new CEO, ensuring a smooth hand-over before Philippe's tenure concludes. For his part, I know Philippe is energised and committed to advance the Company's key objectives to round out his leadership of CLINUVEL. I must say, the global team and the Board are right behind him.

As we welcome the three new non-executive directors, I also want to express my appreciation of the dedication of Mrs Shanahan, Mrs Smith and Dr Agersborg for their unwavering commitment to CLINUVEL over the past year.

## **CONCLUSION**

A bright future lies ahead for CLINUVEL. We are building a diversified portfolio of melanocortins and formulations which will stand the test of time in terms of sustainability and the provision of treatments for those in need. Looking after both patients and those who desire advanced skincare is the driving force for the Company. Providing long-term care and constructing close relationships with end users is an integral part of our culture. So is our commitment to add value for our shareholders.

Further major changes will be made under my watch. We are determined to manoeuvre the Company into a position where we can capitalise on SCENESSE<sup>®</sup>, PRÉNUMBRA<sup>®</sup> and the ACTH product NEURACTHEL<sup>®</sup>. By seizing these opportunities, we will multiply the Company's current value. Based on the information we have received and prevailing market benchmarks, I am confident that the share price will climb once again. That said, we will not let others' fascination with share price distract us from our course, nor from achieving the goals we have set ourselves.

I hope you see why I and many others in this room believe in CLINUVEL. I believe our strategies for future growth and success warrant strong shareholder support. I have no doubt whatsoever that in its current form, CLINUVEL will continue to excel, disrupt and be seen as a beacon of innovation.

Thank you for your attention and now let us celebrate the success of CLINUVEL and the achievements of the past year.

Professor Jeffrey Rosenfeld



Chairman of CLINUVEL Group

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#### About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; Börse Frankfurt: 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 specialised populations. 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, assisted 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 2024 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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