CLINUVEL

09 SEPTEMBER 2024

Fellow shareholders,

FINANCIAL PERFORMANCE

I take much pleasure in writing to you just days following the most memorable set of financial results CLINUVEL has published since market entry. In following a plan to set CLINUVEL apart from most small- and mid-size pharmaceutical companies, our executive team has built systems and shown financial prowess to withstand external 'headwinds'. During the 2023 AGM, Managing Director Dr Philippe Wolgen addressed whether CLINUVEL had reached a ceiling in the erythropoietic protoporphyria (EPP) market. Philippe shared the Board's view that we had no data or indication that growth would stall in the coming years; it is therefore with satisfaction that the FY24 results underscore the accuracy of intelligence gathered on our main porphyria and future markets. From a market perspective, the FY24 results have beaten consensus with all percentages up, such as total revenue and income (15%), NPBT (11%), NPAT (16%), and EPS (15%). We thank our shareholders for their support during what is seen as an excellent year.

The Board of Directors observes its fiduciary duty with great care, as it is cognisant that drug development of new molecules remains high – and perhaps even the highest – risk in medical research and for a commercial enterprise. The magnitude of the challenges is daunting if one only takes time to look at a number of ASXlisted companies the past year which have received clinical or regulatory setbacks. As an Emeritus Professor of Surgery at Monash University, and past Director of the Monash Institute of Medical Engineering, I have analysed how very few ideas, ventures, drugs and devices reach commercial stage, let alone become commercially successful. The goal in CLINUVEL has been to build a pharmaceutical group which overcomes unanticipated events and manages risks so that it is able to self-finance further developments to arrive at multiple revenue streams. Preferably a venture that does not end up in a desperate state of capital need. With this in mind, we should think carefully about our current balance sheet strength and understand its long-term benefits for all of us.

The Board assesses the specialised management team executing against objectives set at the beginning of the year, taking into account all factors, adapting to market conditions and the most up-to-date information received. We have seen clinical progress in stroke, variegate porphyria, xeroderma pigmentosum/DNA assisted repair, and vitiligo. Parkinson's disease is another potential target for treatment with afamelanotide and will shortly undergo clinical trial. There is a path to a North American vitiligo market, going through different stages to what would commonly be expected, but a pathway that has been carefully thought through.

During the 29 August investor webinar, Philippe remarked that "drug development is like a step procession – two steps forward and one back". From my experience, I agree that arriving at a scientific outcome is not a

linear pathway but is more complex. The ability to commercialise technology – no matter how good it seems – remains rare. Starting from the core of our pharmaceuticals, the goal to add PhotoCosmetics is ambitious but logical, given the data collected on melanocortins and their application in photoprotection and skin tanning.

REFRESHMENT OF BOARD OF DIRECTORS

When I assumed the position of Chair on 1 January this year, I set an objective to evolve the Board. I am therefore pleased that in the past months, the Nomination Committee has followed an external led review process and identified three candidates who would add to the skills needed for the future of the Company. The Nomination Committee has sought to engage with seasoned professionals who can see through a strategy in biotechnology, but also who understand the importance of risk management, financial probity, and those with evidence of pragmatism and commercial success. We also anticipate a growing US market and a North American foothold in vitiligo.

VALUE

In answering some shareholders who have been writing to me directly about the lack of share price movement, I reemphasise that a share price does not necessarily reflect the Group's actual health. There may be many factors which influence a daily closing price, but perhaps a manager's temporary decision to invest elsewhere while keeping CUV 'on the radar' is one factor. With new Australian institutional investors who came on our register recently, the belief among some shareholders that CLINUVEL may not be attracting new institutions through its presentations and sell-side analysts has shown to be unfounded.

CLINUVEL is not alone in going through a lull in markets; other profitable companies have followed a similar pattern. We know, however, from past experience that speculation on CLINUVEL's future porphyria markets drove the price to much higher valuations. That pattern is typical of biotechs, and it is likely that as clinical results in vitiligo and other indications advance, value may start to increase. Perhaps the value of the Company is at present below that assigned by analysts and desired by you, however it is much on par with that of peers in biotechnology.

More important than a temporary share price surge, majority owners express the desire to see a sustainable company with new technologies that can be made commercially available and are prepared to see it through patiently. I have noted that investing in medical technology attracts investors who willingly take a punt on multiple returns. The odds of success increase when investors identify a team which has a track record of bringing one or multiple drugs to market; in the Pacific region there are not too many of these teams.

The share buy-back program commenced on 28 March is one instrument to increase earnings per share, however it also provides an exit opportunity for those who have a shorter horizon. However, the net effect on share price may be small. We will draw the balance next year in March. The incumbent and incoming Board members wish to see a precise strategy focused on a long future continue, confident that it will lead to higher values as has been recorded previously.

The past few months since the Capital Markets Day in Sydney on 1 May, I have received useful commentary on our performance and strategy, while the majority of analysts recognise that many of their institutional clients track the story closely, being one of few growth stories in the sector.

To top off the season, on 28 August, the Board of Directors declared a fully franked divided of \$0.05 per share, which is the seventh consecutive year of distribution. The record day was 6 September and the payment date is 20 September.

ANNUAL GENERAL MEETING 2024

In chairing a group belonging to less than 9% of global biotech ventures posting profits year on year, I believe it is in the interest of all shareholders and patients to see the path of development completed under this team. It is no surprise that the Board seeks unconditional support of you, shareholders, at the AGM 2024 to secure continuity of the chosen strategy to develop SCENESSE[®], PRÊNUMBRA[®] and NEURACTHEL[®], while we are preparing a venture in related cosmetics.

The driver of the present business is based on the decision to meet clinical challenges and establish markets for melanocortins not yet explored by peers. If latitude and flexibility continue to be observed by our executive managers and staff, CLINUVEL may succeed in vitiligo and other diseases in the same way it has in EPP. However, I am aware that if disruption to our common path would occur, the Company will be set back years and uncertainty will creep in the minds of investors to lose interest in the success story.

I conclude on a high note: we fulfilled important goals by seeing new professionals added to the executive management team, appointing three Board members with a diverse background, and the services of the CSO and CEO extended. I am grateful that Philippe has agreed to lead the current programs and growth with one additional year until 30 June 2026, but we also regret to have initiated the search for his successor. The executive management team is strong and new talent has been added, therefore I have no doubt that in its current form CLINUVEL will continue to excel.

I hope to see you in large numbers at the AGM.

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Professor Jeffrey Rosenfeld, Chairman

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 <u>https://www.clinuvel.com</u>.

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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