CLINUVEL

23 December 2024

A video address from Clinuvel's Chief Executive Officer has been released alongside this letter and can be viewed on CLINUVEL's website at https://news.clinuvel.com/2024/12/23/managing-directors-end-of-year-message-2024

Dear shareholders,

Just before the break for festivities, I do wish to leave you with some thoughts on our Company.

Our managers define investing in CLINUVEL as exploring controversial and innovative concepts in pharmaceutical development, thereby assisting many patients. We are acutely aware of high development risks in our sector, but seem to manage these through analyses and experience. Against eight years of sustained growth in earnings, this year we have witnessed a substantial share price decline. While it is quite common to find price swings in biotechnology, it is quite an unusual feat to find profitable ventures. Having lived through multiple market corrections and crashes, and having analysed markets, we intentionally designed a financial strategy that would protect all shareholders through periods of price weakness, and one that would steer the Company away from serial external funding. We succeeded in that plan, and we see the current strong financial position as the best insurance policy shareholders have during periods when clinical research is ongoing and catalysts are forthcoming. Inversely, if CLINUVEL would have resorted to capital raises under current circumstances, it is doubtful we would have remained in control of our assets, while substantial dilution would have been expected.

The strength of this Company is predominantly characterised by its people, those who have lived through eight existential crises when markets were betting against the chances of success. Our managers are used to – and trained to withstand – adversity. If they all remain in good health this team will prevail and the CUV price will surge, albeit this time from a position of financial strength. Investing in value is a long-term intention, whereby one needs to have the stomach to go through share price excursions.

Foreseeing that our next "large concept" would take time, we set out to build a fortress preserving funds and reploughing our earnings into vitiligo, a depigmentation disorder greatly affecting patients of darker skin complexion. This is a bold concept which took years for regulators and expert physicians to accept. The same team which fought to get SCENESSE® (afamelanotide) approved for EPP in 2014 and 2019[1] took it upon themselves to repeat the efforts for vitiligo, a sizeable and worthwhile opportunity.

It is not the first time that funds and nay-sayers in the markets openly seem to speak against CLINUVEL's chances and doubt the probability of our teams reaching the next set of commercial objectives. It may also not be the last time. CLINUVEL endeavours to succeed in developing melanocortin technology, where most pharmaceutical competitors have walked away.

I have deep respect and confidence in the group of managers and Directors we currently have in the Company, those who stayed together for two decades and those who more recently had joined. They share a hunger, ambition and persistence to grow the Company on vitiligo, ACTH[2] and through acquisitions. There is little doubt that the house of melanocortins will be a large commercial opportunity once realised by these managers.

It is simple, when one allocates funds to CLINUVEL, one takes a stake in its people. It is evident from history that it is down to our teams to realise clinically meaningful concepts which are complex but pose as attractive opportunities.

In that sense, CLINUVEL's public stock is to be regarded as a *Weglege-Aktie* or *Schubladen-Aktie*, *un action pour un tiroir*, a stock under the mattress, one where you turn to every five years and one which will spike in price once clinical catalysts come through. We have seen this pattern of price surges at three distinct times during CLINUVEL's operations but when we were not nearly as financially robust as today. Therefore, if our teams continue progressing the business as is currently the case, price will reach highs on news flow as markets typically opt in to invest in binary outcomes. The opportunities summarised as *vitiligo and ACTH* will transform the Company from one focussed on orphan diseases to one able to take on large pharmaceutical actors.

In Q1 2025, you may see public news and press covering how CLINUVEL will compete and attempt to disrupt a North American vitiligo market with a systemic solution for the most severe form, a systemic disease. The advantage that afamelanotide 16mg holds over any other drug candidate globally is that it offers a visible medicinal solution for vitiligo patients of dark complexion. Our technology is unique and well suited to make a difference to patients' lives.

Simply stated, the opportunity CLINUVEL offers is found in a combination of its novel drug candidates, formulations and derived PhotoCosmetic applications. The vision and attempt to expand the Company on these three elements is one not many peers choose, however on a journey to differentiate from the pack and become a sustainable pharmaceutical name our teams have shown the ability to minimise development risk. Kept together, this ensemble of managers will further deliver outcomes, and from then onwards the price of CUV stock will follow.

On this note, I thank all patients for their participation and belief in our teams, prescribers and clinical investigators for their care, and CLINUVEL's staff and Board members for their work around the clock.

My conviction on CLINUVEL succeeding in its mission to develop afamelanotide is not based on blind faith, but on information and data points generated, decisions take by our managers and Board, and a vision which is being realised month by month. Being privy to this gives me the strength to be patient for the day the scaffolds come off the house.

I wish you a peaceful holiday.

Philippe Wolgen

[1] SCENESSE® is approved for adult patients with erythropoietic protoporphyria (EPP) by the European Medicines Agency (EMA) and US Food and Drug Administration (FDA)

[2] Adrenocorticotropic hormone, currently under development by CLINUVEL as NEURACTHEL®

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, 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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