

29 APRIL 2022

London, 29 April 2022

Dear shareholders, friends,

Both from a professional viewpoint and as largest private holder, I have felt the urge to share my uncensored mind on the disproportionate decline in CLINUVEL's value.

Naturally, I experience chagrin as a substantial shareholder, but in earnest I am more concerned and engaged with the many of you who had invested 12 to 17 years ago, speculating that the Company would sustain a \$2B plus valuation throughout 2022 given its financial strength to date.

For the benefit of the 2.5% recently joined shareholders, I distinguish CLINUVEL's genesis through a few sections, and address the all-important issue of timing.

## **Early years**

A new business plan was required for a company nearing insolvency in October 2005. Operating at a cost of capital of 14% to 16%, we financed the project mostly across two equity rounds at nearly \$62 million. Directors had not agreed on prospective earnings as too much R&D uncertainty loomed. At the time, pharmaceutical executives on the Board, surrounded by their advisors, ran internal analyses consigned to multiple commercial scenarios: all valuations came out considerably lower than today's.

## Middle years

From 2010 to 2016, limited equity placements totalled \$28 million at premium to market, a significant departure from common practice, but underpinning our position that CUV had been trading at discounted value. All shareholders have benefited from our decision to step away from the pattern of serial equity issuances at a discount to market. In parallel, we cut pharma expenditures to a minimum, while advancing SCENESSE<sup>®</sup> (afamelanotide 16mg) to market.

The regulatory pathway was equally novel and at times fraught with significant, yet calculated, risk. The gain of our managers overcoming the challenges was calculated as an indelible value to the Company in taking this experience forward to new medicinal therapies for future growth.

## **Recent years**

The final chapter of the trilogy enumerated a commercial expansion. Contrary to industry habits, we established teams focused on distribution, market access, and pricing. Fast forward some years, pricing negotiations played out well in the majority of countries, whereby the Company reached profitability during the first year of commercially distributing SCENESSE<sup>®</sup> (2016/17). As predicted some countries would resist any agreement on pharmaceutical pricing proposed, arguing allocation of resources towards other therapies.

Our strategy aims for organic and inorganic growth. The house is building a pipeline of melanocortin molecules and new formulations. As a logical nexus to our photoprotective injectable SCENESSE<sup>®</sup>, we set out to develop a series of topical (leave on) products serving to protect and assist DNA damaged skin inflicted by solar radiation.

We work with a number of investment banks and brokers through well-defined acquisition targets for the accretive match.

# Time

Naturally, time translates to value in our sector and there is a definitive answer as to how long it will take to see the final diversified construct.

In navigating the fuselage, I would be bitterly disappointed in not seeing all plans realised within the term of my final employment contract, ending July 2025.

Four years ago we made public our objectives to be achieved by end of 2023, and our staff is aligned in attaining the majority of these. Save for good health, if our global ensemble continues to work the odd hours in fulfilling a once-in-a-lifetime opportunity, then realisation should be within reach. For having entered a knowledge economy, specialised professionals matter most, hence much effort is put in retaining them.

Lest we forget, we have witnessed the eruption of the chrysalis maturing to a financial stronghold, giving us corporate choices. By staying the course, we eliminate the perennial investors' concern that innovators are unable to survive the consequences of unexpected market conditions.

As bitterly cold winds blow, CLINUVEL fortifies it financial fur, and as current sentiments ebb, the overall strategy may well be recognised.

# Conclusion

If the recent healthcare indexes - NBI and XHJ – are of any reference, one sees higher volatility across the underlying listed stocks. As the NBI reached a high of over 5,400 in September 2021, it has retreated to a level around 3,850 at present, a loss approximating 30%. Uncoincidentally, on 23 September CUV reached an all-time high of \$43.58 to come off to current levels, a stronger decline but very much following the biotech trend worldwide. In essence, we see a temporary flight from perceived high-risk sectors and theme stocks, as CLINUVEL is currently characterised, to blue chip safer havens.

Our challenge remains to identify and attract new institutional shareholders, willing to invest longerterm as opposed to those who enter and exit positions short-term. Gauging from our interaction with a number of US and EU specialised funds, I cannot help but be confident that we will succeed in this mission too.

As to you long-term holders, testing times force us to reflect on the original investment decision, and our hope for future markets and market value. It is certain that many more challenges will befall CLINUVEL during its odyssey, however I experienced that there is an intangible – but real – value embedded in the resilience of a focussed team.

I have long regarded the daily mark to market glance at 1600 hours as a distraction, and in so far daily operations and labour towards our construct matter, market sentiments or even euphoria neither rocks the boat nor alter our objectives.

As eight to nine year cycles wash over us, my teams will come through this nadir too, *for we had prepared CLINUVEL precisely for these events and corrections occurring*. I leave you with a parable, in reminding that the Company could equally have been in a development phase facing clinical or regulatory setbacks, holding little cash at hand under current market conditions. We incessantly worked to escape the what-ifs, and so we have.

During a recent visit to Disraeli's residence at Hughenden Manor, in absorbing his speech to the House of Parliament in 1834, I could not help to think about your vehicle: *"I have brought myself, by long meditation to the conviction that a human being with a settled purpose must accomplish it, and that nothing can resist a will which will stake even existence upon its fulfillment."* 

Keep your composure at times when it matters, thank you.

Yours sincerely,

Philippe Wolgen Managing Director CLINUVEL PHARMACEUTICALS LTD

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Authorised for ASX release by the Chair of CLINUVEL PHARMACEUTICALS LTD

## 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 <a href="https://www.CLINUVEL.com">https://www.CLINUVEL.com</a>.

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## 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 2021 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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