CLINUVEL

17 October 2025

MANAGING DIRECTOR'S ADDRESS TO THE 2025 ANNUAL GENERAL MEETING

Friends, shareholders,

This is my 20th AGM. During these years, you've experienced a routine: glossy, intricate slides, the testimonial videos, financial projections and the next year ahead.

Not today.

We are breaking away from the convention. I will be speaking to one notion only: the **Value of Time and its impact on CLINUVEL's future**.

As MD, my job is to figure out the durability of a business concept, building moats around science, and ensuring each dollar earned by us has the highest probability of generating future revenues.

All while playing a game where the house wins over 87% of the time. That is not investment, it is gambling on an off-chance.

Today, after two decades, I share with you how we do the maximum to maintain the status of belonging to the minute group of biotechs worldwide which are cash positive, and how this business model provides – in our view – the best chance of excelling and building a lasting company.

In four distinct parts I wish to part with our thought processes, for you to switch off your biases for 15 minutes and think objectively what you want to do with your shares and votes the next year.

I Let's start with some numbers: A$4.90.

That is the fully diluted, pure cash sitting in this company for every non-diluted share on issue. No pipeline premium. Just cash.

At every single board meeting we perform a ritual that one probably would not find in many public companies. We provoke each other and ask: *"Should we give it all back? Every single cent of cash?"* Or do we double down and replough it into the programs you know about, and the ones you are not privy to, the ones unknown to you?

It's a ruthless interrogation of our own right to exist, and having the backbone to repeat that very question.

Our answer, unequivocally, has been and is to double down on the cogent technology we now have.

Then the question arises, why? Because after scrutinising every "opportunity" investment banks, life science specialists, and brokers throw at us, every asset on the block, every license opportunity offered, we analysed that the technology we're advancing in-house holds more commercial value than anything we've ever done diligence on, and we say this without cognitive biases.

Here comes an essential issue: is the Company comparable to others on the ASX or Nasdaq? Can we draw parallels somewhere?

No, in sporting terms, we are running the track with a double handicap: we are unable to unveil what we have, and thereby we consciously need to forgo the opportunity to attract speculative money and wider analyst support while preserving a competitive advantage, keeping it away from peers. Yet this approach is the very reason we're still in the room.

Now, some might believe that A$4.90 reflects a lazy balance sheet item. We see it as part of our strategic arsenal. Cash, in our view, has bought us five non-negotiable advantages:

1. **A Four-Year Runway**: In this business, time is the option price on a potential breakthrough.
2. **Credibility Armor**: It lets us look suppliers, creditors, and new partners in the eye.
3. **Executional Sovereignty**: It funds the programs you see, and the ones you don't. It's our R&D black budget.
4. **Shock Absorption**: Public offices shut down, manpower is short, regulators prioritise, decision makers are averse to newness and so forth. Cash is our independent suspension system. It means a clinical trial or regulatory hold-up doesn't become an existential crisis.
5. **The Privilege to Fail**: This is the big one. In an industry that punishes first-time failure with extinction, our cash reserves give us the privilege to be wrong, learn, and live to fight another day.

In my professional world, the nexus of value is risk, and the nexus of risk is liquidity, and to make the argument circular: cash influences our ability to take risks: our cash doesn't just sit there; it actively de-risks our entire endeavour.

II Which brings me to the second number you need to memorise: 13.8%.

According to a sobering MIT (2019, *Journal of Biostatistics*) analysis of over 406,000 trials and 21,000 compounds, 13.8% is the probability of a drug going from Phase I to regulatory approval. If you take out the carnage of oncology, it "improves" to a still-appalling 20.9%.

This percentage needs to sink in; I say that as an MD and an investor. These are odds which are worse than any of the multiple combinations on the roulette table.

The question we pose ourselves in-house is where will CLINUVEL sit in the future, knowing we beat the odds the past two decades? What are the chances of replicating the success at a larger scale once again?

So, when I hear resentment about our share price or our pace, I understand and even share the emotion as largest shareholder. But I reject the premise. Velocity and resources are parameters that have precisely zero influence on that brutal statistical constant.

For twenty years this company has been acrobatically navigating a labyrinth, our singular achievement is that we are still standing, with the resources deliberately planned to place intelligent bets against impossible odds.

The A$4.90 per share isn't a sign of inactivity. It is our war chest for the long game.

The 13.8% isn't an excuse; it is the battlefield.

We're not just playing to be occupied, but to win.

A third set of numbers on our compass.

III A$410 million spent and A$227 million in reserves.

Over 20 years. And what did that possibly give you as shareholders?

1. we have spent – on average – A$20 million per year on developing an NME for two markets, and generated sufficient funds to reinvest in a pipeline;
2. a net profit margin of 35% is a stellar number in pharmaceuticals in comparison to mid and large pharma;
3. a A$1 million revenue or US$688,000 per employee is far above the median in pharma between US$200,000 and $400,000;
4. A$36 million in net profit over A$55 million in expenses, indicates that for every dollar spent we generate A$0.65 in profit, that is a rate of return we never had planned for and 50% more than pharma is used to;
5. a contribution margin of over 60% to cover our fixed costs; we are a company which manages its operating leverage such that we can switch on and off our variable costs;
6. we have invested and will continue to invest between 20% and 25% of revenues in research and new product development, including clinical trials;
7. the ratio of total annual spent to total net usable cash reserves (minus creditors' obligations = current liabilities) = 25%.

These are benchmark percentages on par or above pharmaceutical development in larger companies.

This is not a coincidental financial dashboard, but one deliberately crafted, living within one's means and assuring a going concern for our auditors and you, shareholders.

IV The Inflection point opening a Future (and how far away is that horizon?)

A Which catalysts did we announce, how many did we meet, how many missed?

We have fulfilled six out of 13 catalysts shared with you in 2024, it means the Board has set these at maximum stretch.

Five are still ongoing, one carried over to FY26, one still to come before year end. Of those we received one negative outcome, Health Canada postponing review.

That means we will have a success rate in progressing the Company to our own internal metrics of 53% to 62% for the year, and there where we fell short carried over to next year.

We critically look at ourselves periodically, while the Board sets objectives at a maximum threshold.

B So, what comes next? Are we navigating on hope or reality?

I share some of the inflection points the Company is working on and finalising, while observing commercial privilege:

I The next generation of pharmaceutical products

SCENESSE® in vitiligo is in an advanced trial, and to be followed by regulatory interaction to get confirmation on the regulatory pathway. To date, we have seen that patients gain pigmentation of skin, substantially turn darker, responding to systemic melanocortin therapy.

NEURACTHEL in CNS, this work is progressing on manufacturing, and dossiers are in preparation to be submitted in the first country in 2026. An update on ACTH is to be expected in 2026, pending feedback from our partners.

These are two large markets for the Company, and two where we can make a meaningful clinical difference and/or be competitive.

A few words to vitiligo:

- Recruitment succeeded, and off this came the knowledge that high recruiters wish to prolong recruitment in the study CUV107.
- We are turning a part of the Company into a CRO, services to organise trials and all systems in place: we have some way to go, but the contour is there. My prediction is that within 9-12 months we will have fully automated management systems in place not many would have (innovation).
- The initial results are promising as you see from the eight cases published by treating physicians. For our teams there have been several key take-aways:
  - one needs to turn patients' skin a few shades darker to achieve the repigmentation of the vitiligo affected skin;
  - the pigmentation seems to linger/persist for months in these cases;

- patients are enthused and grateful (due to the visible nature of the disorder); and
- we are innovating on all fronts, and regulatory interaction is to follow soon.

II The next generation of formulation, drug delivery

- In 2014, we began a bet on a next-generation formulation in Singapore. For a decade we faced setbacks, one after the other. There were moments we lost faith in our ability to crack the code.
- Then, this January, a breakthrough. Not a fluke, but repetitive, reproducible data. A decade of persistence has now culminated in a decision to advance new drug delivery technology to preclinical studies. This isn't just another project; it is the validation of a twenty-year philosophy and relentless efforts while preserving cost-consciousness and surviving crises.
- The ultimate prize is yet to come. We are adding one part of drug development to our quiver, from a specialty pharmaceutical in peptides and hormones, we are adding drug delivery technology, lending itself to new peptides in a drug delivery platform.

Our cost discipline means our capital is now directed not just at growth, but at a transformation – potential spin-offs that could dwarf the current entity.

The Board and I see the potential of these new assets not as an increment, but as a multiple of the Company's current worth, without exaggeration they are transformational. Not because we say so, but because there is an expressed large demand for the formulation we are progressing.

We are no longer a biotech company hoping for a lucky break. We are a holding company for scientific sovereignty, built for the long game, and we are just getting started.

III Funds available to spend on R&D&I in next three years

1. We will publish our forecast expenditures for three years in Q1 2026.
2. This team has made its first five-year forecast public in 2021 and was accurate in its predictions, we underspent 3.1% over five years demonstrating a remarkable fiscal probity.
3. Even if markets would be subject to a major correction, tariffs would be imposed on pharmaceuticals, regulatory objections to be received, our task is to present you a commercially viable company, as opposed to a biotech scrambling for cash.

I remind you here domestically that out of 101 ASX listed biotechs and medtechs, more than 55% have less than one year cash (as Mrs Susan Smith has stated, reflecting *Bioshares'* analyses).

V Summary

In the recent years stock markets have soared – mainly driven by AI – while biotechnology and, the last two years, the NBI stayed behind.

It is no secret that prospects and fantasy of what may come from life science technologies drive up prices. Earnings are only fuelling those who wish to update models, they are not providing much enthusiasm in capital markets.

Consuming one's cash reserves at a faster pace and reinvesting all of it does not provide any assurance of success, as a matter of fact there is plateau in how much resources pose an efficient ratio in peptide development.

In 2004 I performed a full year diligence on CLINUVEL and believed I could form a team to unleash the potential of the molecule. Today, after 20 years, I look back and believe that with afamelanotide used and commercialised in EPP and coming for vitiligo, we would have maximised its utility.

However, the decades of investment in technologies nobody was interested in is going to yield surprising results, not a false promise but based on experiments, data and analyses. We are adding a drug delivery platform that goes beyond our ambitions or expectations as management or Board. Each dollar we insistently invested is holding a multiple in future value.

Well, what about the Value of Time, would there have been better opportunities out there?

Sure, there must be. However, sustainability of a biotech that issues modest dividends, that is profitable and carries cash to fund the next generations of products are worldwide rare.

Or to speak with the words of Blackrock, Nasdaq desk:

> "a profitable biotech is a contradiction *in terminis*,
> a biotech that doesn't come to market [for funding] is a black swan,
> a biotech that does that on one product and funds its pipeline is an impossibility"

If you add the fear of competition, tariffs, and price cutting in pharmaceuticals, it is no wonder that stocks like CUV can trade low on multiples, certainly in markets which are not known for deeper life science investors.

Some investment banks are intelligent and comment CLINUVEL is doing the right thing, because there is no such thing as sufficient cash in biotech.

Other bankers wish us to speed up spending and redistribution as it would urge us to seek more capital on markets, but these very bankers are unsure whether they can underwrite an offering for CUV. Our Board is of the same opinion of not having any indication that capital would be available for CLINUVEL in the markets.

Stock buybacks may seem an opportunity to increase one's EPS, but can have exactly zero effect on the long-term fundamental value. They do provide shareholders a temporary satisfaction, while others will sell down on this opportunity to neutralise the desired effect of share price appreciation, in a stock that trades A$1.5 million per day on average.

However, a SBB negates the very mandate research companies have, namely, to invest wisely and efficiently in new technologies, because redistributing wealth presumes two facts:

A that revenues will perpetually continue

B that capital is available for one's technology

Our assertion is that neither are certain in CLINUVEL's case, hence cash provides us the kerosene for the research projects that are under wraps.

We have spoken about Value and Time, we have explained in detail a rationale; you usually do not get a Board's or management's rationale at an AGM or Strategic Review but the resultant of decisions, today if you read back the transcripts we have provided a clear reasoning of how we successfully managed the Company, benefiting all of you.

If this team continues in its configuration, I know what the developments will bring, on an objective analyses: a globally revolution in drug delivery platform. Do not forget these last words from a manager who is known to be cautious and conservative.

Thank you.

Dr Philippe Wolgen
Managing Director
CLINUVEL Pharmaceuticals Limited

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL I: 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.

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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. All statements other than statements of historical or current facts made in this document are forward-looking. We identify forward-looking statements in this document by using words or phrases such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "foresee," "intend," "likely," "may," "objective," "potential," "plan," "predict," "project," "seek," "should," "will" and similar words or phrases and their negatives. Forward-looking statements reflect our current expectations and are inherently uncertain. Actual

outcomes or results could differ materially for a variety of reasons. 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 and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; 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, the UK, Israel, China, Japan, and/or LATAM regions 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®, CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic 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, cosmetic industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2025 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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