

# CLINUVEL Investor Webinar

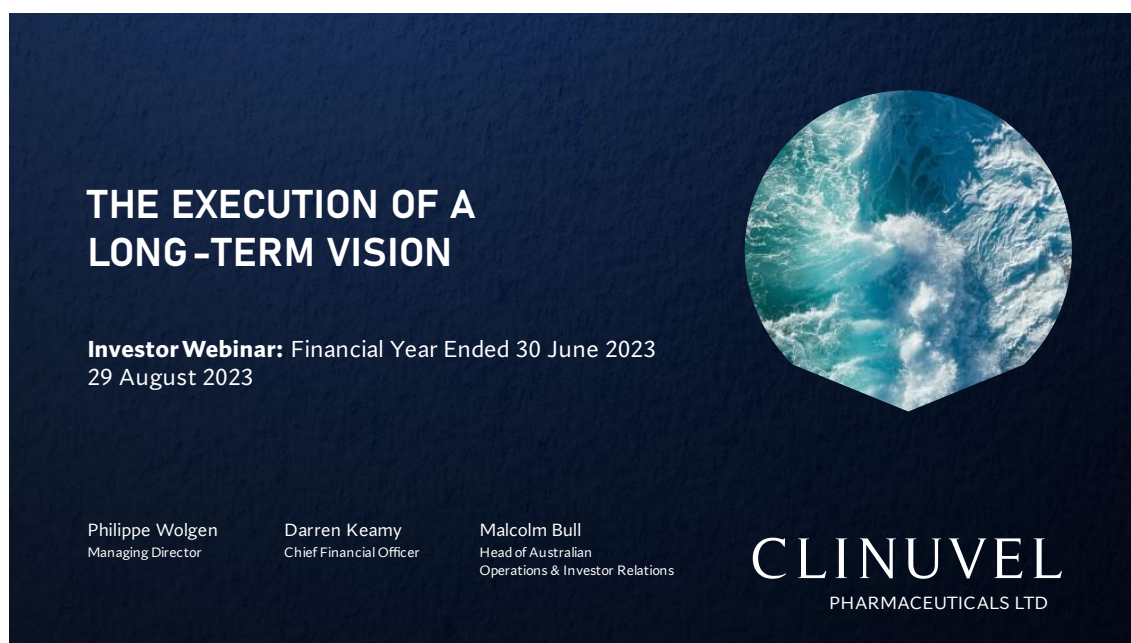
## Financial Results Year Ended 30 June 2023

Melbourne, Australia, 30 August 2023

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

CLINUVEL PHARMACEUTICALS LTD hosted an investor and analyst webinar on the financial results for the year ended 30 June 2023 at 18:00 AEST on 29 August 2023. The webinar discussion is set out below:

### Introduction and Welcome



**THE EXECUTION OF A LONG-TERM VISION**

**Investor Webinar:** Financial Year Ended 30 June 2023  
29 August 2023

Philippe Wolgen  
Managing Director

Darren Keamy  
Chief Financial Officer

Malcolm Bull  
Head of Australian  
Operations & Investor Relations

**CLINUVEL**  
PHARMACEUTICALS LTD

**Mr Bull:** Welcome to everyone joining us today for CLINUVEL’s Investor Webinar on the results for the 2023 financial year.

I’m Malcolm Bull, Head of Australian Operations and Investor Relations and I am joined by our Managing Director, Philippe Wolgen, and Chief Financial Officer, Darren Keamy. Welcome gentlemen.

Today’s focus is very much on the great results achieved in the financial year ended 30 June 2023, while addressing some of the questions asked by investors. I want us to cover some headlines first, and then recap the strategy and activities that have delivered the results, before delving into the results themselves.

Since we will be looking forward, I draw everyone’s attention to the slide on screen now - our forward-looking statement - which highlights that investors need to remain aware of various business risks that can arise affecting the realisation of planned outcomes. A copy of this statement is also available on the Company’s website.

## FORWARD-LOOKING STATEMENT

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), CYACÉLLE®, 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®, CYACÉLLE®, 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 2023 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.

## Key Headlines

**Q1 Mr Bull:** With that said, Darren, could you please tell us **the headline results?**

**A1 Mr Keamy:** Thanks Malcolm. In terms of headlines, total revenues and other income grew by 24% in the 2023 financial year to \$83.0 million. The profit before tax rose by 33% to \$45.6 million and the profit after tax rose by 47% to \$30.6 million, marking the seventh consecutive annual profit since the commencement of commercial distribution of our lead pharmaceutical in June 2016. These results reflect a group performing well in the prevailing operating environment.

## Strategy and Activities

**Q2 Mr Bull:** Thanks Darren. These are impressive results. Before we discuss the results further, I'd like turn to Philippe **to summarise the Company's strategy and overview the activities** of the year because this provides context to the results achieved.

## STRATEGY AND ACTIVITIES

Integration and diversification for long-term sustainability



Distribution  
SCENESSE®

- Increased patients, doctors and treatment centres



Melanocortin product  
development and clinical studies

- PRÉNUMBRA® and NEURACTHEL®
- Advance of studies in DNA Repair, VP and Stroke



Translation of technology  
to PhotoCosmetic products

- Launch of polychromatic screen, CYACÉLLE
- Development of DNA Repair and Melanogenesis product lines underway



**A2 Mr Wolgen:** Sure, let's cover the Company's *strategy and activities*, but first I need to acknowledge the outstanding results of the past year and the hard work of the CLINUVEL team who have made this possible. These results are not a constant we take for granted: each patient, each physician, each shipment is the subject of intense labour, and the year-on-year growth is entirely attributable to the work of our growing teams, no exception.

Now, on **CLINUVEL's strategy**, its evolution would be well understood by now. We developed the business over the years from 2005 to 2016 through focus on the development of a family of melanocortins, hormones, which would be used with care in certain diseases. From 2016 to 2023 we focussed on increasing the commercial foothold of the Company in Europe and the US, setting up our own distribution systems, against convention.

In summarising our strategy, we started off by developing the lead drug product in a relatively new field of medicine – photomedicine - and gradually expanded from skin to brain disorders.

In essence, our chosen path is to concentrically expand our activities around a family of hormones, making us specialists in this field, thereby adding a specialised consumer business to our quiver: PhotoCosmetics. So from photomedicine plus PhotoCosmetics, these two domains complement each other.

Our long-term objectives are, to expand:

1. **the use of melanocortins**, with SCENESSE®, PRÉNUMBRA® Instant, NEURACTHEL® Instant, and more melanocortins to come from the Pharmaceuticals Division.
2. **the use of new formulations**, ways of delivering drugs in our body.
3. **into specialised PhotoCosmetics**, giving us an advantage of using the peptides in consumer products for people:
  - A) at highest need for photoprotection,
  - B) DNA-assisted repair, and
  - C) seeking an MSH response.

So, in contrast to many other bio-pharmaceutical companies, we did not open our R&D register from the word go, but gradually turned CLINUVEL profitable and thereby diversify our business from our core competencies. It is almost a reverse strategy of what one is used to in our industry; focus in the beginning, widen this midway when earnings allow, and full throttle on R&D towards the endgame.

Another way to summarise our activities for FY2023 are that we focused on:

- the ongoing distribution of SCENESSE® in the EU-Switzerland-Israel-the US-Canada;
- advancing the use of afamelanotide in clinical trials for DNA repair, repigmentation and CNS disorders;
- the development of the melanocortin drug portfolio; and
- the ongoing development of the of PhotoCosmetic product range.

The discipline to advance the portfolio, grow the Group while increasing its profitability annually is like navigating many cliffs in shallow water.

To put all this in context, we spent around \$10 million in 2017, and revenues were \$16.9 million seven years ago, now we have increased expenses by a factor 3.7, while revenues grew by a factor five.

## Key Achievements

**Q3 Mr Bull:** With reference to these areas of activity, what **achievements stood out** this year for you Philippe?

**A3 Mr Wolgen:**

There are many, and also many which are not public since these are commercially sensitive, but some highlights were:

- Firstly, with SCENESSE® we have established a standard of care for EPP, with continued and increased demand year on year. More centres, more physicians, more patients, and the average number of prescription has gone up.
- It was also very encouraging to receive the first case reports on the use of the drug in adolescent EPP patients, and we're working to enable broader access to drug for these patients.
- We progressed studies in DNA repair or XP, stroke, and vitiligo, with all three of these programs set to report data. In vitiligo, we saw strides made to get a large Phase II/III study up and running in the US and EU, CUV105.
- The PRÉNUMBRA® Instant formulation was used first in the second stroke study (CUV803) and we progressed key manufacturing steps of the program for ACTH, NEURACTHEL® Instant.
- We launched the pilot of the first PhotoCosmetic product, the polychromatic solar screen CYACÊLLE. This is the Company's second commercial product and an important precursor to PhotoCosmetic product lines that assist DNA repair and melanogenesis.
- On the communications front, the Company maintained a peer leading frequency and diversity of communications. more interactions with existing and potential investors and key stakeholders, like our analysts, than ever before. The series of investor soirées worldwide are part of a global diversified communication strategy reaching new audiences, and which are being expanded.

## Financial Results

**Q4 Mr Bull:** Thanks Philippe. Let's turn back to the financial results; Darren, can you provide some **more details**?

### STRONG FINANCIAL RESULTS

Consolidated Entity	30 June 2023	Change
Total Revenues, Interest and Other Income, \$m	82.990	up 24%
Total Expenses, \$m	37.412	up 15%
Net Profit Before Income Tax, \$m	45.579	up 33%
Profit After Income Tax Expense, \$m	30.605	up 47%
Cash and Cash Equivalents, \$m	156.814	up 29%
Basic Earnings per Share, \$	0.62	up 46%
Net Tangible Assets Backing per Share, \$	3.29	up 31%
Dividend per Share Declared, \$	0.05	up 25%

All figures are reported in Australian dollars for the financial year ended 30 June. Refer to the Appendix 4E and Annual Report released to the Australian Securities Exchange for details.



Growth in revenues, profit and cash, inflows and balances

Strong balance sheet

Positive performance indicators

**A4 Mr Keamy:** Thanks Malcolm. I'll take some time to **highlight the key elements**. Before I do, a quick note that the figures we refer to are in Australian dollars and are rounded for ease of reference.

In summary:

- Total revenues, including interest and other income, rose 24% to \$83.0 million.
- Total expenses rose 15% to \$37.4 million.
- As mentioned, NPBT rose 33% to \$45.6 million and NPAT rose 47% to \$30.6 million.
- Net assets increased by 31% to \$164.6 million with the key change of the balance sheet being a substantial rise in cash balances of 29% to \$156.8 million.
- Two other key measures of performance to mention are Return on Equity of 19%, and Earnings Per Share of 62 Australian cents.
- To cap-off these results, and in recognition of the support of our shareholders, the Board has declared a sixth consecutive annual dividend – this year it is \$0.05 cents, up 25% on last year's dividend of \$0.04, which was a 60% increase from 2.5 cents on financial year 2021 earnings.

**Q5 Mr Bull:** Thanks Darren. These are results to be proud of. What are your thoughts on the results?

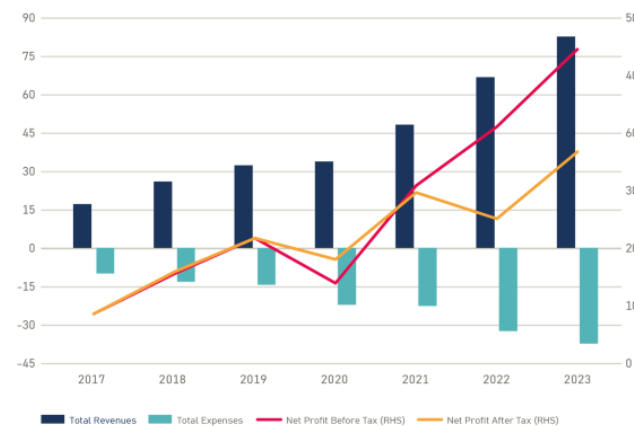
**A5 Mr Keamy:** I am highly satisfied with the outcome which is beyond our own projections and would like to acknowledge the hard work of my finance team and the support of the wider CLINUVEL team.

## Revenues, Expenses and NPAT

**Q6 Mr Bull:** Yes, very much a team result. Can you talk to the **details on revenues, expenses, and profit** for the year, but also for the trend over the past seven years since the commencement of commercial distribution of SCENESSE®?

### LONG-TERM PROFITABILITY

Year Ended 30 June, A\$m



Total Revenues include interest and other income.



7-Year CAGR

Total Revenues = 42%

Total Expenses = 20%

**A6 Mr Keamy:** OK, let's take revenues, expenses and profit each in turn.

On revenues, growth was achieved from further progress of the distribution of SCENESSE® in Europe and the US. Increased patients and treatment centres, and high patient retention, all combined to support the outcome. In addition, other revenues were boosted by higher returns on cash balances in the prevailing environment of higher interest rates.

Expenses increased by 15% in total, with increases seen across most expense categories to support the Group’s growth and expansion.

Consequently, profits increased, with both net profit before and after tax at the highest levels achieved.

Over the past several years from the time our commercial distribution programs commenced, the Group has achieved relatively consistent growth in revenues and profit – as well as cash balances due to positive net cash inflows. Our compound annual growth rate (or CAGR) over this period is 42% for total revenues and 20% for expenses. The growth reflects increased patients treated, more physicians prescribing, high patient retention, more demand, more penetration.

It also reflects the efficiency gained through the work of the CLINUVEL team to proactively support distribution through active collaboration with physicians, insurers, accredited centres and patients. This control of the value chain is the consequence of our integrated business model – to undertake more functions in-house – which translates to better results than otherwise would be achieved if we outsourced more.

**Q7 Mr Bull:** On **expenses** Darren, what drove the 15% increase?

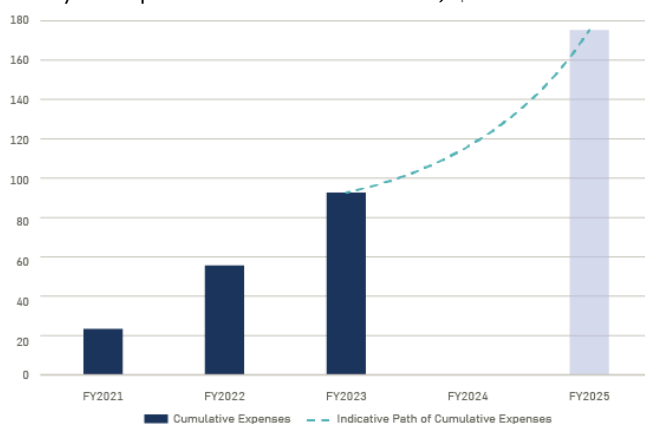
**A7 Mr Keamy:** There were increases across all expense categories, mainly to support the Group’s activities, with some inflationary impacts. The increase of personnel to attract new skills, and the related expenses is our largest category and rose by 17%, whilst a large increase in materials and related expenses was more than offset by changes in inventories. To give a little more detail, expenses associated with commercial distribution and finance, corporate and general expenses category rose 26% and 40%, respectively.

## Five-Year Expense Plan

**Q8 Mr Bull:** We have projected a positive trend in expenses over the five years to 30 June 2025 to support growth and expansion. We have now completed three of the five years; where do we stand Darren in relation to the plan to incur expenses up to A\$175 million by June 2025?

### CUMULATIVE EXPENSES

Five-year Expenses Plan to 30 June 2025 A\$m



Actual expenses FY2021, FY2022 and FY2023. Indicative path of expenses FY2024 and FY2025 to planned cumulative expenses of A\$175.0m.



Gradual and controlled to support growth

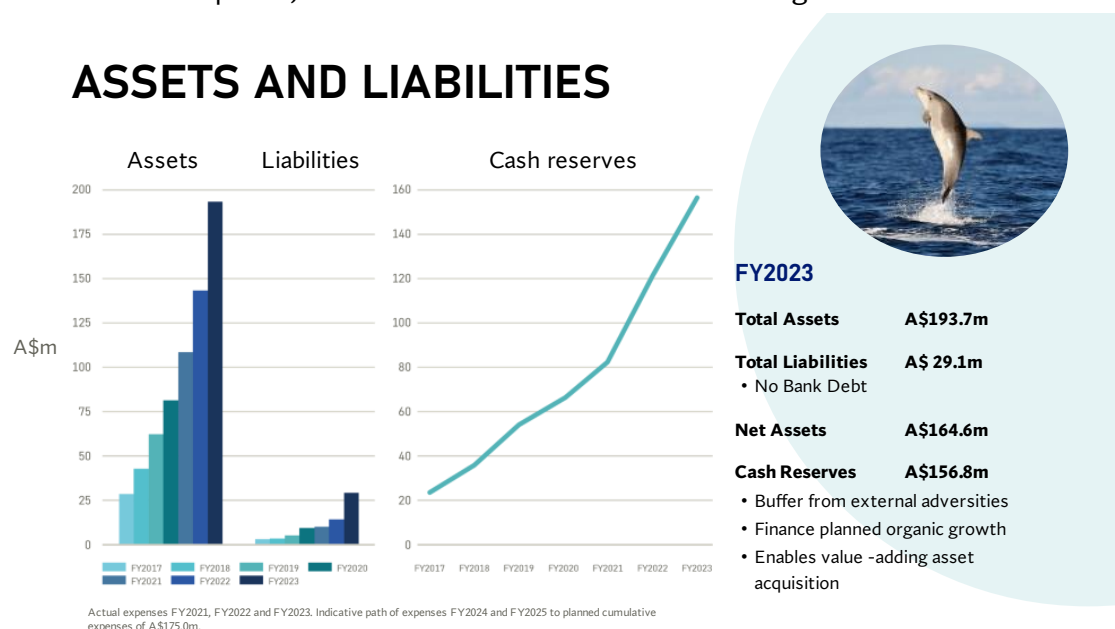
Three years cumulative expenses = 53% of five year plan

**A8 Mr Keamy:** We have incurred \$93 million, or 53%, of the projected amount in the first three years of the five-year plan and are well on track to achieve the \$175 million projection. Keep in mind this excludes capital expenditures and expenses associated with the branding and marketing of the PhotoCosmetic product range. Also, when the plan was formed, inflation was modest and as we know, this has increased higher than was predicted.

## Assets and Liabilities

**Q9 Mr Bull:** Darren, turning to **the balance sheet**, how would you summarise our position?

**A9 Mr Keamy:** Last year a comment was made that assets towered over liabilities, and that observation has not changed. We increased net assets by 31% in the past year, driven mainly by the increase in cash reserves from net cash inflow. The balance sheet is extremely strong with no debt or leverage, and high liquidity due to the accumulated cash reserves. Our liabilities are largely trade payables and short-term tax obligations, which can be covered. The Finance team actively manages the balance sheet, particularly trade receivables and payables, as well as the accumulated cash reserves to ensure good value is earned from deposits, ahead of its future use to aid business growth.



## FY2024 and Beyond

**Q10+A10 Mr Bull:** OK, looking forward, we have been asked about **the key catalysts for FY2024** and beyond, and there are a few that I want to highlight:

- Philippe mentioned the use of SCENESSE® in adolescent patients and we do expect updates on the proposed European label expansion;
- Clinically, there should be further results from the DNA repair and stroke programs, and the commencement and progress of CUV105, a late stage study in vitiligo;
- In PhotoCosmetics, there will be global launch events of CYACËLLE and ongoing development of the DNA Repair and Melanogenesis product lines; and

- CLINUVEL will become a widely disseminated name.

## CATALYSTS FY2024

SCENESSE®	use in adolescents	EMA outcome	
Vitiligo	CUV105, n=150, TVASI50	start	
XP	CUV151-156	read outs	✓
VP	CUV040	1 <sup>st</sup> results	
AIS	CUV803	1 <sup>st</sup> results	
NEURACTHEL®		manufacturing	✓
PhotoCosmetics		global launch, ecommerce	
New Indications		to be announced	

### Further Investor Questions

**Q11 Mr Bull:** We can now turn to some specific questions. First, for you Philippe on **the pace of commercial growth** that can be expected. Given similar questions were posed last year, you can say growth is always on the mind of our investors, and analysts. Could you address this please?



**A11 Mr Wolgen:** I appreciate the focus on growth. Although we don't provide forward guidance, I can advise that we see a robust growth path ahead of us in the distribution of SCENESSE® for EPP in all markets. We continue to expect growth in patient numbers, prescribing doctors, and treatment centres. There is no reason why growth should stagnate or flatten out.

**Q12 Mr Bull:** We have received questions on **the pace of scientific growth and R&D**, what can we expect from CUV in the next few years?



**A12 Mr Wolgen:** Growth in pharmaceuticals comes with risk, certainly when it concerns innovating new technologies.

Failing in innovation comes at a high price, value destruction and often irreversible loss of confidence. Therefore, we try to minimise development risks by gradually increasing our knowledge and data and try to find solutions to technological problems which we believe can and need to be solved in time. We have recently seen in Australian life science markets and the US how failure to deliver novel technologies can decimate one's value in one day, recoil is different from that position.

Therefore, risks of innovation should better be taken when the balance sheet can afford it, in other words when one is not dependent on equity or debt, and when a stock price is not exuberantly priced.

So the pace of R&D can and should always be higher, but it is more a function of the complexity of working with melanocortins and their bio-availability than resources.

I am confident that our team will deliver on at least three pharmaceutical products, three PhotoCosmetic products, and new markets.

Vitiligo and XP will be new additions to our existing market.

**Q13 Mr Bull:** Some comments have been made in **questions on clinical progress** and timelines. Still with you Philippe, what can you say about this?

**A13 Mr Wolgen:** Those who make these comments do not, or are not in the position to, appreciate issues associated with undertaking clinical studies involving ill people and the external factors that can impact the pace of studies.

As a matter of fact, one should carefully select with whom a company wishes to work, because the physicians in clinical trials may well become the prescribers of one's drug in the future.

To give you a concrete example, strategy is an often used but important notion:

- In the US, we have chosen for a direct distribution business, unlike most pharmaceuticals: it has both advantages and disadvantages.
- In the EPP market, we selected, trained & accredited our own prescribing centres: each centre requires diligence, careful qualification and selection. We now have over 60 centres trained & accredited to prescribe SCENESSE®.
- In addition, we anticipated a vitiligo market: so, in expanding our foothold in EPP, we were already thinking about vitiligo and the distribution of SCENESSE® once it would come to market for indication number two, vitiligo.
- Whereas most market experts had said that we would not be able to set up, distribute and negotiate pricing in the US, our teams have delivered on both fronts.
- The same critique we have heard about the vitiligo market.
- We are training & accrediting up to 120 centres spread over the US to be able to directly distribute SCENESSE® to vitiligo centres nationwide.
- Thereby, we need to steer away from competitors.

So pace, yeah. There is strategy, there is execution along an adjustable plan until we reach our target, and then we proceed to the next set of objectives. Time is of essence, since we are all moving on in time, but is subservient to the objectives to build intrinsic value.

Having, for instance, 120 prescribers believing in the product and willing to prescribe is not reflected in a share price but surely provides much value to a Company.

I trust this explicit example shows today's attendees how we think and work.

**Q14 Mr Bull:** On **expenses** Darren, what proportion is R&D and why is this not shown as a separate line item?

**A14 Mr Keamy:** CLINUVEL's R&D expenses are not just the 'non-clinical and clinical research and development' expense category. The expenses incurred on R&D are spread across multiple expense categories. For example, the costs associated with our Research, Development and Innovation Centre in Singapore are research and development in nature but are expensed over a range of categories such as premises, utilities, materials, and personnel. This reflects our integrated business model in which key functions are undertaken in-house, all of these functions harbour R&D components. This gives us more control over costs and the quality of outcomes we have achieved. As a guide, R&D related expenses can range from 30 to 40% of total annual expenses, depending on the intensity of R&D activities and timing of expenses in a given year.

**Q15 Mr Bull:** For Philippe, a few questions received focus on **how we are managing the diversification strategy** – can you comment on this?

**A15 Mr Wolgen:** Well, with great care is the answer: there is not one day that is easy in this Company, yet we are advancing on all fronts against our own scorecard.

The key to success lies in the people we are attracting, new skills, engineers, biochemists, chemists, financial managers, comptrollers, an inhouse lawyer, clinical specialists, market access specialists, regulatory talent and more.

**Q16 Mr Bull:** We have also received comments on **the expansion of our business**. Some comment that the market may be uncertain about the direction of the business. What would you like to say about this Philippe?

**A16 Mr Wolgen:** Let us speak briefly about **the direction, expansion and diversification of a pharmaceutical business**, what exactly are we doing?

First, we undertook to launch a first-in-class molecule, afamelanotide in a genetic disorder.

Second, we diversified by working the life cycle of the molecule and coming up with next generations of the molecule in new formulations.

Third, we expanded by bringing in a generic melanocortin, NEURACTHEL® - ACTH - which gives us exposure to larger markets.

Fourth, we introduced smaller molecules for transdermal use.

Fifth, we are entering consumer markets as a pharmaceutical company.

Sixth, we enhance our skill base by growing the Company organically.

Seventh, we are bringing in manufacturing.

Eighth, we set up a CBM team to reach many more audiences and turn CLINUVEL into a globally recognised name in consumer markets.

Ninth, we will diversify by M&A.

This is in our view the way to withstand market oscillations, and in doing so we are at the same time increasing our cash buffers for further reinvestments. The one word that jumps out is 'discipline'; across all functions. Our teams have shown this now for two decades, and it should continue.

This is our answer to manage risk, it is an answer to the previous perception of building a one-product company. We stepped away from this risk and are building the Group in a deliberate manner by having nine different avenues of expansion, and thereby lowering business risk which is notoriously high in bio-innovators.

Our people count has increased by 95% over the past four years, we have also expanded the executive team to nine, with a median 16 years of tenure. The next generation of talent has been hired, and responsibilities delegated across senior managers.

For this to occur, we need focus, discipline like we have shown the past two decades without background noise, a uniform management team and visionary Board.

**Q17 Mr Bull:** That is a comprehensive answer. Final question Philippe, your **tenure as CEO** expires 30 June 2025. Do you have any update on your position and / or replacement?

**A17 Mr Wolgen:** I intend to serve out my employment agreement until 30 June 2025, and thereafter the Board is discussing succession.

The Company is about the executive and senior management team and its continuity of knowledge and replenishment with new talent constantly.

My task is to retain these managers such that skills and years of knowledge are not leaking away; that is the kernel of the Company.

## Conclusion

**Mr Bull:** It is time now for us to conclude the Investor Webinar with thanks to Darren and Philippe for their informative comments and answers to questions.

**Mr Keamy:** Thank you.

**Mr Wolgen:** Thank you, and good evening to all.

**Mr Bull:** Thank you to all attendees of the webinar and to those who submitted questions. We appreciate your support throughout the year, and we trust shareholders welcome the dividend payment coming your way.

We extend our appreciation also to the independent analysts on the line today, who have provided ongoing reports on the progress of the Company during the past year.

A transcript of this Investor Webinar will be released to the Australian Securities Exchange, for all stakeholders to read at their convenience.

The next key shareholder event is the Annual General Meeting 2023 which will be held late October in Melbourne. This will be an in-person meeting and provide an opportunity for shareholders to also dial-in and view the meeting.

We wish you all good health and progress in your individual objectives. Thank you again for your support of CLINUVEL.

– END –

CLINUVEL's Appendix 4E and Annual Report is available on the Company's website, [www.clinuvel.com](http://www.clinuvel.com).

### 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.

**Authorised for ASX release by the Company Secretary 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 2023 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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