

24 November 2023

Dear friends, shareholders,

Since News Communiqué IV was issued on 06 October, it has been a dense time for the Company with the following key events and announcements:

- 13 October the 2nd Monaco Soirée for entrepreneurs, institutions, and family offices.
- 18 October J P Morgan Biotech Round Table.
- 18 October the start of the CUV105 Phase III study in vitiligo.
- 31 October 2023 Annual General Meeting (AGM).
- 01 November briefing to journalists in Melbourne.
- 01-02 November non-deal roadshows (NDRs) with institutions in Melbourne and Sydney.
- 09 November Sydney Soirée for analysts, brokers, and institutions.
- 15 November presented at the Bell Potter Healthcare Conference.
- 20 November NDR with institutions in Hong Kong.

Looking at the past six weeks, the interest in CLINUVEL has been higher than at any other time, as witnessed by the number of institutions (Australia, Hong Kong) taking an interest in the Company. We believe it is owing to the lower valuation, the progress in vitiligo and growth of the Company as one of the very few profitable companies in the sector.

It is further seen in the number of independent analysts covering CLINUVEL, with a further two initiating research coverage in the past few weeks:

- Morgans Financial; and
- Morningstar, which is also being distributed by Ord Minnett.

We now have a total of seven independent analysts covering CLINUVEL, which is the highest number in the existence of the Company and of course, we welcome their bullish outlook on our activities. The search for new medications, new therapies for patients in larger markets seems to be attracting more attention to CLINUVEL.

This communiqué reports further on these events below.

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Recent company announcements

The Company's recent announcements are listed below:

Date	Announcement
18 October	CLINUVEL Starts Global Phase III Vitiligo Study
31 October	Chair's Address to the Annual General Meeting
	Managing Director's Strategic Update to Annual General Meeting
	Results of the Annual General Meeting
	CLINUVEL Appoints New Chair
02 November	Final Director's Interest Notice
10 November	Sydney Vitiligo Presentation
24 November	News Communiqué V

All of CLINUVEL's announcements are available on the [CLINUVEL website](#) and [CLINUVELNews](#). More specifically, announcements to the Australian Securities Exchange are available on the investor pages of the [CLINUVEL website](#).

Monaco Soirée

The focus of the meeting on **13 October** was to bring together institutional investors, family offices and press to brief on the progress of CLINUVEL. In particular, the vitiligo and DNA Repair (xeroderma pigmentosum) programs were discussed, as well as the translation of our science into PhotoCosmetic products.

The format of CLINUVEL's soirée events varies per country and city, and the feedback from the Monaco Soirée has been overwhelmingly positive.

Some shareholders ask whether the soirée series of events are a good use of funds, and whilst we believe so, the answer needs to be evaluated over time as more investors build interest and the media starts reporting on CLINUVEL as we progress towards the entry to larger markets.

Sydney Soirée

The dinner evening was organised on **09 November**, when analysts, fund managers and brokers attended the meeting. The meeting was held in a less formal format, whereby questions were raised by participants and answered.

The focus of the briefing at the soirée was on vitiligo, growth, and succession planning. The attendees included analysts, existing and potential institutional investors, retail shareholders, bankers and brokers, and journalists. [Use this link to the presentation](#) delivered by Director of Global Operations, Mr Lachlan Hay which explained:

- the role of NB-UVB in follicular repigmentation.
- the role of afamelanotide as a non-immune suppressant for relatively quicker systemic repigmentation compared to JAK inhibitor immune-

suppressant therapies that take longer to first response to repigment the skin.

- the promise of systemic repigmentation of CLINUVEL's CUV102 Phase II study and the full parameters of the CUV105 study with focus on repigmentation of the body (T-VASI50) as the primary endpoint.
- the path to market through CUV105 and a second Phase III combination study, CUV107 when CUV105 is half recruited.
- the size of the North American vitiligo population of which 22% (or an estimated 823,750) have Fitzpatrick Skin Types IV-VI and the conservative assumptions that see the addressable market estimated at US\$490-570 million in the first few years of vitiligo treatment.

CUV102 Phase II study results



We also clarified that the cost of the CUV105 study is included in the five-year expenses plan of A\$175.0 million to 30 June 2025, whilst the cost of the planned CUV107 study is not.

Non-deal roadshows and conference presentations

The **J P Morgan Biotech Round Table on 18 October** involved several existing and potential institutions in person in Melbourne and virtually from Sydney. The Company provided an overview covering the past, present and the future, and answered questions posed by J P Morgan's Healthcare Analyst. Subsequent discussions have been held with interested institutional investors.

Following the AGM, the Managing Director and Head of Investor Relations conducted a **NDR on 01 and 02 November in Melbourne and Sydney**. Meetings were hosted by four independent analysts - Moelis, Jefferies, Wilsons Advisory and Bell Potter. These and separate one-one-one meetings involved 17 fund managers. We also met an investment bank and briefed three journalists. All expressed a positive and very bullish outlook on CLINUVEL for 2024, given the programs and prospects. Clarity was provided in discussions on the expanded clinical program and the rationale for translating our technology to PhotoCosmetic products.

The Company's presentation to the **Bell Potter Healthcare Conference on 15 November** highlighted the focus on the melanocortin family of hormones and how the ambition to treat conditions of the skin and brain is being

implemented through the expanded clinical program and the development of PhotoCosmetic products as we build an integrated melanocortin house.

The Managing Director conducted a **NDR on 20 November in Hong Kong** with the support of Bell Potter, meeting several potential institutional investors. The interest in CLINUVEL was positive with follow-up meetings to be arranged.

Having outlined the investor relations agenda through to the end of 2024 in [News Communiqué IV](#) and reported on the most recent interactions in this communiqué, the focus of investor relations on building relationships with institutional investors is clearly demonstrated. This occurs through introductions by independent analysts, supportive banks and brokers, and our self-initiated business development activities.

The number of independent analysts distributing research on CLINUVEL increased to seven during November with initiation by **Morgans Financial** and **Morningstar**. This followed the initiation of research coverage by **Bell Potter** on **04 October**. This means CLINUVEL's story now reaches more investors than ever before, and we are seeing this spur new institutional interest.

Private stakeholders (including family offices) remain a significant shareholder type at 36.5% of issued capital, whilst institutional shareholders hold 34.6%. Of this, 14.2% of institutional shareholders are based in Australia and New Zealand which has increased by more than two and a half times over the past five years. This is positive progress to rebalance the shareholding composition and we are striving to achieve more.

Global vitiligo program

The Company was excited to inform stakeholders on **18 October** that the first patient of dark skin had been treated in the Phase III study, CUV105 evaluating the effects of afamelanotide in combination with narrowband UVB (NB-UVB - light therapy) to repigment skin of vitiligo patients. The progress of this study has been well received by all stakeholders. Up to 200 adolescent and adult vitiligo patients with darker skin types (Fitzpatrick Skin Types IV-VI) will be enrolled in the study, comparing the use of SCENESSE® in combination with NB-UVB light therapy to NB-UVB as a monotherapy. The study evaluates whether afamelanotide in combination with NB-UVB provides faster, deeper, and longer-lasting repigmentation of total body surface compared to NB-UVB alone (T-VASI50). Several patient reported outcomes, including quality of life surveys, will provide data for secondary objectives. [Use this link to read the full announcement.](#)

Annual General Meeting 2023

The AGM was held on **31 October 2023**. The business of the meeting was covered in four resolutions:

- Resolution 1: Accept the 2023 Remuneration Report.
- Resolution 2: Re-elect Mr Willem Blijdorp as a non-executive director.
- Resolution 3: Re-elect Professor Jeffrey Rosenfeld as a non-executive director.
- Resolution 4: Refresh the Performance Rights Plan.

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A total of 24.1 million shares were voted in the 2023 AGM which is 48.8% of CLINUVEL's issued capital. This compares with 22.6 million issued shares voted in 2022 and a peak of 25.7 million voted in 2021.

The voting and outcomes per resolution are summarised below:

Issued Shares	Resolution 1 (R1)	Resolution 2 (R2)	Resolution 3 (R3)	Resolution 4 (R4)
Voted	24.089m	24.089m	24.089m	24.089m
Less Excluded and Abstain Votes	3.810m	0.390m	0.424m	0.310m
Eligible Votes	20.276m	23.696m	23.662m	20.097m
For	12.218m (60.3%)	17.768m (75.0%)	20.322m (85.9%)	11.773m (58.6%)
Against	8.058m (39.7%)	5.928m (25.0%)	3.340m (14.1%)	8.324m (41.4%)
Outcome	Carried – 1 st Strike	Carried	Carried	Carried

All resolutions of the meeting were carried with a first strike recorded against the 2023 Remuneration Report. If a second strike is recorded during the AGM in 2024, a resolution will be put to shareholders to decide whether to spill the Board and hold a re-election of directors.

We maintain our simplified structure and approach to executive remuneration and will continue to consult widely with stakeholders on the areas we can improve. The feedback of shareholders in discussions held prior to the AGM by Mr Blijdorp as Chair, with the Head of Investor Relations (refer Chair's address to the AGM), provided constructive suggestions which will be fully considered in future remuneration packages.

There was a higher vote against the resolutions of the meeting this year than in previous years, reflecting:

1. the disposition of shareholders on the decline in the share price during 2023.
2. dissatisfaction of some shareholders with the pace of growth and activity.
3. influence on some institutions of two proxy advisors who recommended voting against R1 and R4.

Shareholders had the opportunity at the AGM to learn that CLINUVEL's share price has mirrored many life-science companies which have experienced a worldwide sell-off as part of portfolio rebalances in the prevailing economic environment. Whilst CLINUVEL has achieved seven years of profitability, declared dividends in the last six years, and has built the strongest balance sheet in our history, it has been affected by the general market trend. In fact, the strategists of a prominent investment bank recently stated that they believe the sell-off of the healthcare sector is overdone and CUV is one of the most attractive opportunities for growth in the sector at current levels. (*Refer Goldman Sachs, Portfolio Strategy Research, Aussie Weekly Kickstart, Healthcare: Time for a checkup, 1 November 2023*).

... All resolutions of the meeting were carried with a first strike recorded against the 2023 Remuneration Report ...

On the pace of growth and activity, we are advancing our expansion strategy whilst achieving excellent financial results, but not at the pace desired by some outsiders. Perhaps our success has led to high expectations. However, the drug development path is long and takes time and shareholders who ignore this reality as they form heightened expectations are bound to be disappointed in biopharmaceuticals. As seen in many companies, some shareholders choose to express their frustration online with personal attacks on CLINUVEL staff and members of the Board, thereby distributing negative news on open forums, damaging the reputation of the Company and its workers. Thankfully, the majority of shareholders refrain from these practices.

Our investor relations team and communications team in general seek to provide regular updates on our progress to keep shareholders informed and we know our frequency and diversity of communication is peer leading. However, we cannot divulge commercially sensitive information that would provide an advantage to potential competitors or others at the Company's expense, even if this is considered by some to be obtuse.

On a positive note, we expect multiple catalysts to have positive influence on the share price over the next twelve months (refer below) and there is no doubt this will also be assisted by a return of positive market sentiment. This is subject to an improvement in macroeconomic conditions and geopolitical stability. As a growth company with strong performance and prospects, CLINUVEL is well placed to benefit from a change in market sentiment.

Over the last few years, the Company has simplified the remuneration structure and explained our approach, increased disclosure on the award of incentives, and benchmarked the CEO's remuneration package to an extended peer group of similar listed companies internationally. The peer group of 26 companies in 2023 have similarities in terms of complexity and innovative nature, scope and scale, technical and specialised skills, market value, progress achieving business outcomes, and risk profile. The two largest and internationally orientated proxy advisors have understood this and recommended their institutional clients to vote for the resolutions of the AGM. A few small Australian based proxy advisors ignore the increased disclosure and rigorous peer benchmarking and prefer to focus on a small, less relevant peer group to assess the CEO's remuneration package as relatively high and thus recommend their clients to vote against the remuneration report.

We are also aware of many shareholders who wanted to vote for the resolutions, but their voting was not facilitated by their custodian banks who in some instances did not distribute the Notice of Meeting. We respect the decision of beneficial shareholders to hold their shares through custodians but at the same time, urge those who want to vote to find custodians who participate in the voting process.

We received mainly positive feedback on the format of the AGM which in addition to the business of the meeting, encompassed:

- the Chair and Chair (elect) addresses;
- the Managing Director's presentation which addressed many shareholder questions;
- a Q&A session hosted by analysts from Wilsons Advisory which asked questions received from shareholders prior to the meeting; and

- general shareholder questions from the floor.

Both Mr Blijdorp and Professor Rosenfeld were re-elected as non-executive Directors. Mr Blijdorp advised that he will step-down as Chair and Professor Jeffrey Rosenfeld advised he had been appointed Chair, both effective 1 January 2024. Their respective addresses are available on the [CLINUVEL website](#).

In his address to the meeting, Chair (elect), Professor Jeffrey Rosenfeld said, *“I have developed a deep understanding of the business since joining the Board in late 2019 and I believe I am well-positioned to oversee the Company execute on its current plan on behalf of its shareholders. I wish to thank Mr Blijdorp for his sage advice to the Board and the Company. We have benefited greatly from his extensive business experience, and we will continue to do so through his continuing directorship”*.

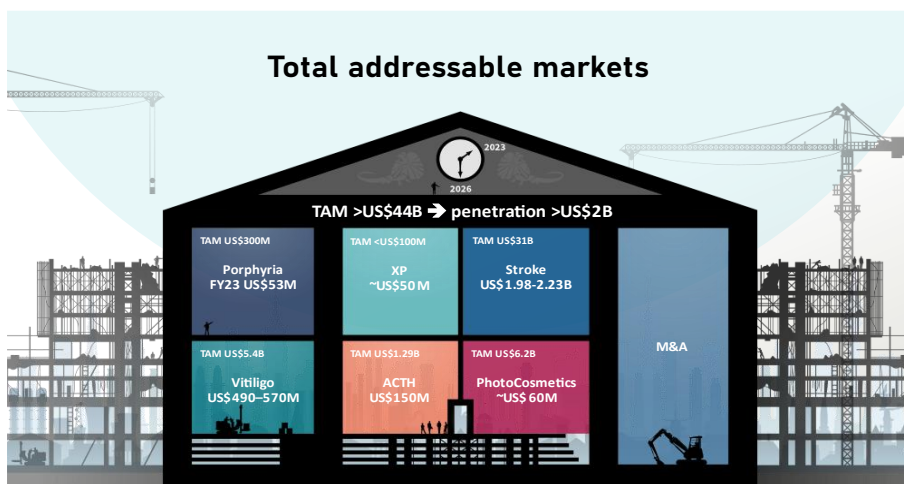
The Managing Director’s presentation answered many shareholder questions about the expanded clinical program, healthcare solutions objectives, and the investor relations program. He also highlighted the creditable progress in recent years gaining new institutional investors, particularly in Australia and New Zealand, and increasing the number of independent analysts. The depressed market and impact on many companies was also highlighted to provide context to CLINUVEL’s share price to stakeholders. Analysts from Wilsons Advisory, one of the independent analysts of CLINUVEL, asked the questions of shareholders tabled with Investor Relations before the meeting and they were answered with new insights to those in attendance and online. Those critical of the Q&A format with analysts asking shareholder questions submitted prior to the meeting, followed by questions from shareholders attending the meeting, acknowledged that many questions had been answered and that the meeting did not conclude until all questions from the floor were exhausted.

The webcast of the AGM, encompassing the Managing Director’s presentation, is accessible [using this link](#).

Strategic Update VII

The Managing Director’s Strategic Update VII to the 2023 AGM provided a comprehensive overview of the clinical programs being advanced and their addressable markets, as well as the planned launch of the PhotoCosmetic product range.

The key strategic message is that we are on our way to build a comprehensive melanocortin house which will provide treatments to a wide range of conditions of the skin and brain. In doing so, we try to manage many of the R&D and commercial risks and control our spending, such that we maintain a healthy balance sheet. As we diversify into a sustainable pharmaceutical group, we continue to integrate the key functions of a pharmaceutical business within our house.



The catalysts expected over the course of the next 12 months are shared below. There are clinical studies to be commenced and/or completed, with read-outs in some of the clinical programs. Product developments are expected in both the pharmaceutical and healthcare solutions divisions and the half-year and full year financial results will complete the catalysts expected.

Multiple catalysts

	Next 12 months
SCENESSE®	use in adolescents- EMA guidance regulatory filing Canada
Vitiligo	CUV105, n=200 – complete recruitment CUV107, n=200
XP – DNA Repair	CUV151-156 readouts CUV154-158 study start
VP	CUV040 – study complete
CNS disorders	CUV803 – readouts (PRÉNUMBRA®) new indication– study start
NEURACTHEL®	manufacturing progress
PhotoCosmetics	website launch; ecommerce CYACELLE global launch events
Finances	earnings growth

Communication with shareholders

Following the interactions held with shareholders prior to, during and after the AGM, it is timely to reiterate that CLINUVEL will respond to the queries of shareholders if presented in an acceptable manner, without inappropriate language. CLINUVEL does not respond to shareholders who are rude and vulgar or have a track record of distorting information on the Company in online forums.

We received many messages of congratulations to the Chair (elect) from shareholders. The Chair (elect) and executives have responded to various communications. The Chair (elect) will address all stakeholders in a forthcoming letter and video to shareholders.

Queries of registered shareholders on payment of dividends

Following the payment of the 2023 dividend in September, we have received feedback from a handful of shareholders who have either not received the payment or not been able to easily bank their dividend cheque. Some of these shareholders are based in New Zealand where the monetary authorities are phasing out cheques or in the USA.

For the sake of clarity, the Company declares dividends in its reporting currency, Australian dollars (AUD). In the absence of arrangements with Computershare, the administrator of CLINUVEL's share registry, dividend cheques can only be sent in AUD to the shareholder address on their record.

If you change your address, you need to amend your details with Computershare. If you are in Australia and prefer not to receive AUD cheques, you can provide your bank account details to Computershare for electronic transfer via direct credit. If you are located overseas, you can arrange with Computershare to elect to use their global wire service for payment of dividends. This involves conversion of the AUD amount to your local currency and direct credit to your nominated bank account. Information on this payment option is accessible through this link to [Computershare's international payments service](#).

Computershare can arrange to have the 2023 dividend cheque cancelled if not yet presented and paid electronically.

Registered shareholders can log into Computershare [using this link](#), or through your Computershare investor log in, if you have set this up. The contact number for Computershare in Australia is 1300 555 159 and for shareholders located outside Australia is 613 9415 49 062.

Summary and conclusions

We are working through multiple catalysts to enhance the demand of CUV and are actively engaging with analysts and institutions per the investor relations program outlined in [News Communiqué IV](#).

The Company counts seven independent analysts at present, a high number not seen in its history. The expectations and mood around the Company are high and provides us much energy, despite the downturn in markets.

The prospects of CLINUVEL are bright and it would be a mistake to cloud this with the negativity of a handful of shareholders when it is not warranted. Based on feedback from shareholders at the AGM and discussions which followed with a range of stakeholders, we are buoyed to advance the initiatives of the Company in the year ahead and look forward to sharing our progress with you.

Before the calendar year concludes, Chair (elect) Professor Jeffrey Rosenfeld will issue a letter and video to shareholders on his vision for CLINUVEL, the Company's expansion path, and communications. The Managing Director will subsequently issue News Communiqué VI of the year, prior to the break for the festive season.

... We are working through multiple catalysts to enhance the demand of CUV and are actively engaged with analysts and institutions ...

As always, we wish all stakeholders ongoing safety and success in your objectives and thank you for your support.

Malcolm Bull

- END -

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.

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 specialized 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>.

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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