

6 October 2023

Dear friends, shareholders,

The recent decline in CLINUVEL's share price against the overall slump in the markets requires our perspective on matters. In this News Communiqué IV, we go 'in depth' to shed some light on the Company and how it will bring back share value to you all.

Let us start with the Investor Relations program which will bring further visibility to the Company.

Building a long-term market profile

CLINUVEL continuously reviews its active investor relations (IR) program, reflected in 2023-2024 activities to reach participants across markets. This includes:

1. engaging analysts and market makers (one-on-one meetings and larger meetings), focused on Australia, the USA, the United Kingdom, Germany, and Switzerland;
2. introducing and refreshing our story to institutional investors globally;
3. active investor meetings by invitation, both in small meeting settings and through larger events (including global luncheons/soirées);
4. company announcements, social media and digital channels; and
5. webinars following financial reporting (twice per annum).

The varied program includes traditional IR activities – such as hosted meetings, presentations at conferences, and one-on-one meetings. We have developed long-standing relationships across global markets, and these will need to result in longer-term investments in CUV.

The executive team works with investment banks and brokers to host meetings and arrange non-deal roadshows (NDRs) with their institutional clients. This includes work with MA Moelis, Jefferies, Wilsons Advisory, H. C. Wainwright, Bell Potter, Deutsche Bank, J. P. Morgan, Goldman Sachs, and other houses. In parallel, long-term engagement with independent sell-side analysts has resulted in increased coverage of the Company, with a new analyst team in Australia initiating research this week (for more information, please see our [website](#)).

The Strategic Update series and the regular News Communiqués are designed to complement this program, providing key updates on the Company to all stakeholders. This traditional program combines with CLINUVEL's Soirée briefing series, typically aimed at a business audience of family offices, entrepreneurs, and bio-tech investors who understand the complexities and potential of investing in our space. The feedback we receive is that many of you



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wish us to continue the format and frequency of news flow, and only a few wish to see less frequent news from the Company.

The Company is engaging a broader IR team globally as we look to the next stages of CLINUVEL's evolution and pursue an intensive calendar, as mapped out below. We have two professionals in IR, one in Australia and one in Europe. Shortly, we are adding our third person to the team to cover North America.

This calendar stands up to any of our peers in terms of quality of institutions engaged, frequency, and follow-ups provided. A profitable company at a low valuation, it can be expected that interest in CLINUVEL will be evoked. The mix between events, individual meetings, and hosted roadshows is purposefully designed to engage and spend more time with US, AU, and EU institutions.

Month	Company Events & Announcements	Institutional Events, Media Briefings & Soirées
Completed: July 2023 – September 2023		
Jul 23		One-on-one meetings with Institutions, and analysts
Aug 23		Investor Roadshow, Chair and IR, one-on-one meetings with key shareholders
29 Aug 23	Financial Results: Appendix 4E and Annual Report 23 Dividend Distribution Appendix 4G & Corporate Governance Statement Annual Results Investor Webinar – Q&A with >150 participants	One-on-one meetings with all analysts
30 Aug 23	Investor Webinar transcript	Annual Results NDR, Wilsons Advisory
31 Aug 23		Annual Results NDR Melbourne Briefing to Bell Potter Trading Desk
04 Sep 23		Annual Results NDR Sydney, Moelis MA and Jefferies Australia hosted meetings with institutions and one-on-one meetings held
19 Sep 23	CEO Letter	
29 Sep 23	Chair Letter, Notice of Meeting	
6 Oct 23	News Communiqué IV	
Planned: October 2023 – June 2024		
13 Oct 23		Monaco Soirée: institutions, entrepreneurs, family offices.
18 Oct 23		J P Morgan Bio Tech Round Table, Melbourne & Virtual
31 Oct 23	Annual General Meeting – in-person & webcast, Town Hall Q&A session Results of Meeting	
Early Nov 23		NDR Melbourne & Sydney, hosted institutional & one-on-one meetings Briefing to Melbourne Journalists
09 Nov 23		Sydney Soirée
10 Nov 23	Strategic Update VII	
15 Nov 23	News Communiqué V	Presentation to Bell Potter Healthcare Conference
20-21 Nov 23		NDR HK/Sing – Bell Potter
Mid-Dec 2023	News Communiqué VI	
End Jan 24	News Communiqué I	Los Angeles Soirée
Mid-Feb 24	CEO Letter	

Late Feb 24	Appendix 4D, Half Year Results, to 31 December 23	One-on-one meetings with analysts
	Half Year Results Investor Webinar	Half Year Results NDR Melbourne
		Briefing to Melbourne Journalists
Early Mar 24		Half Year Results NDR Sydney
Mar 24	Strategic Update VIII	NDR USA, virtual meetings with institutions
		Melbourne Soirée
Late Mar 24	News Communiqué II	
Apr 24		Capital Markets Day Sydney, hosted by Wilsons Advisory*
		One-on-one meetings
		Abu Dhabi Investor Event
May 24	Chair Letter	One-on-one meetings with analysts
Jun 24		Jefferies Global Healthcare Conference, New York*
		NDR New York, meetings with institutions
Late Jun 24	News Communiqué III	Singapore Investor Event
Planned: July 2024 – December 2024		
Jul 24		One-on-one meetings with analysts Bioshares Summit*
Late Aug 24	Financial Results: Appendix 4E and Annual Report FY24	One-on-one meetings with analysts
	Dividend Distribution	Annual Results NDR Melbourne
	Appendix 4G & Corporate Governance Statement	Briefing to Melbourne Journalists
	Annual Results Investor Webinar	London Soirée
	Annual Results Investor Webinar Script	
Early Sep 24	CEO Letter	Annual Results NDR Sydney
Mid-Sep 24	News Communiqué IV – 24	H. C. Wainwright Annual Global Investment Conference, New York*
Late Sep 24	Chair Letter & Notice of Meeting	NDR Roadshow New York
Oct 24		Monaco Soirée
Late Oct 24	Annual General Meeting Results of Meeting	
Early Nov 24	News Communiqué V	NDR Melbourne & Sydney, hosted institutional & one-on-one meetings
		Briefing to Melbourne Journalists
Nov 24	Strategic Update IX	Sydney Soirée
Mid-Dec 24	News Communiqué VI	

* To be confirmed

During 2023 there have been further downward movements in markets. The S&P/ASX Small Ordinaries Index (the 300 largest ASX-listed companies, less the top 100) has retracted over 5%. The NASDAQ Biotechnology Index (NBI) in the US, a key indicator of the life-sciences sector, is currently trading at a five-year low. The global revaluation has led to a sell-off of many life-science companies, whether they be R&D orientated or profitable. In Australia, good companies like ResMed, Starpharma, Mesoblast and others have experienced significant share price decline like CLINUVEL.

As many brokers tell us, we are not alone on the bus, and we need to ride it out since no magic pill exists, even for revenue generating companies, or profitable ones.

We are seeing three-year CAGR growth of revenues of over 30% and, as Philippe Wolgen recently said, we see no reason why this growth path should

not continue. Whilst we experience a temporary retreat in the share price, the development pipeline continues and financial strength increases, day-by-day.

Without giving guidance, we firmly believe the share price will bounce back, like it has many times in the past, and this time we will be on the best financial footing ever.

DNA Repair Program results presentation

With much anticipation, data from CLINUVEL's DNA Repair Program will be presented later this month at the European Society for Photodermatology (ESPD) meeting, part of the 2023 European Academy of Dermatology and Venereology (EADV) Congress in Berlin, Germany.

The CUV151 study evaluated the DNA repair capacity of afamelanotide on skin exposed to ultraviolet (UV) radiation, with results in healthy volunteers demonstrating a reduction in DNA skin damage shortly after UV irradiation (15 minutes) and over a subsequently longer time point (48 hours). Reference will be made to the CUV156 study in XP, and the clinical impact. The EADV Congress is the first international presentation of results, with the ESPD being one of the leading global expert groups focused on photomedicine, UV radiation, and solar damage.

Clinical program

A focus for 2023 has been ensuring more patients than ever have access to treatment for erythropoietic protoporphyria (EPP), as well as seeking to understand whether our drug SCENESSE® (afamelanotide 16mg) may provide clinical benefit for patients with variegate porphyria (VP – study CUV040), who experience similar phototoxic reactions following light exposure.

Both the European and US teams have expanded in the past year, while focusing on improving our commercial infrastructure to better support patients and the specialist physicians who provide care. New treatment centres are being established on both continents, reflecting continued and new demand from patients, as well as confidence from the medical community in our post-authorisation programs.

The real life experiences of EPP patients keep coming in, and it is reasonable to state that the treatment is life changing for many. More literature appears on the use of SCENESSE®, and new clinical insights are gained.

We previously noted a Swiss study which reported a hepatoprotective effect from the treatment, with further results now suggesting this effect is dose dependent.¹ This is an interesting observation on the long-term use of the drug, showing there is more value from further study and the longitudinal approach we take to patient follow-up.

Work is well advanced to start enrolment in the CUV052 study, evaluating a single dose of SCENESSE® in adolescent EPP patients. In parallel, a small but growing group of these patients is seeking out treatment worldwide, which we are closely monitoring in line with our pharmacovigilance responsibilities.

Our pilot VP study (CUV040) is fully enrolled and set to report next year, with anecdotal reports suggesting the drug has, thus far, been well tolerated in this patient group.



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CEO interview series

CLINUVEL is increasing visibility of our story across a range of platforms and channels. As flagged in the recent [CEO Letter](#), this includes the executive team discussing our melanocortin development pipeline and targeted translation of our technology from photomedicine to PhotoCosmetics.

In an extensive interview, our managing director recently sat down with senior business reporter and analyst Susannah Streeter to discuss both macro impacts on CLINUVEL as well as the foundations and trajectory of the Group. Three segments of this discussion are being released, with the first two now available on the [CLINUVELNews website](#).

Annual General Meeting

Finally, a reminder to all shareholders that CLINUVEL's 2023 Annual General Meeting (AGM) will take place on Tuesday 31 October at 10am (AEDT), with the [Notice of Meeting](#) released last month.

Consistent with recent years, the AGM will be webcast live for shareholders who are unable to attend in person to be able to observe the meeting. Shareholders are encouraged to submit proxy votes and questions prior to the meeting at <http://www.investorvote.com.au/>. Shareholders who wish to attend the AGM via the live webcast can do so by [accessing this link](#). For more details on the AGM, please [contact investor relations](#).

I look forward to seeing shareholders at the AGM and at many of our upcoming events.

Malcolm Bull

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¹ Minder, A.-E., et al. (2023). Afamelanotide Is Associated with Dose-Dependent Protective Effect from Liver Damage Related to Erythropoietic Protoporphyrin. *Life*, 13(4), 1066.

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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