

# CLINUVEL

16 JANUARY 2024

Fellow shareholders,

This first News Communiqué of the year will follow a slightly different format than usual. It will attempt to answer three questions that we have received in recent weeks. Throughout the year, we aim to use these News Communiqués to address relevant questions received.

We would start this year in high spirits, were it not for the wars raging in Ukraine and the Middle East, with no end to either in sight. It is sobering to think that one is helpless and voiceless in these conflicts. Yet witnessing the scale of human suffering and the senseless acts of violence being waged against civilians prompts deeper reflection on the purpose of existence. Families will be traumatised for generations and the rifts between nations will deepen. At CLINUVEL, we are conscious that we live in an asymmetric world and compassionate towards the plight of those living under conditions of war.

Continuing our reality check in 2024, overall fewer business defaulted in 2023 than had been predicted. Still, the picture for the healthcare sector is less rosy. In the US, there was a five-fold increase in the number of healthcare companies that filed for Chapter 11 in 2023 compared with the previous year. In total 18 firms with total assets worth US\$7bn went under. Most of these distressed companies were much larger than CLINUVEL.

Smaller life-science companies took a hit in 2023, however. Among such firms in the US, the default rate was three times higher than the average. The situation is similar in Australasia. According to *Bioshares*, as of last December 60 of the 100 listed Australian-New Zealand life-science companies had less than one year of cash left. Only nine of the 100 were cash flow positive, with the majority of these being device companies. Just two are biopharmaceutical firms.

Against this background, we are continuing our approach towards future growth and diversification. This will strengthen our position, quelling ongoing market concerns about being able to operate independently. Happily, analysts have raised their expectations for pharmaceuticals and biotechnology in 2024 compared with six months ago. A suite of IPOs is expected in the US market in the second half of the year, with equity raisings to follow as markets are forecast to strengthen. And earlier this month, the JP Morgan conference—the annual beacon of healthcare investment—suggested optimism for the year ahead.

On a more positive note, rate cuts are expected by the second half of 2024, although the return of rock-bottom interest rates is unlikely. We are rapidly approaching the Federal Reserve's target of 2% inflation on average over time for its personal consumption expenditures measure. This cooling-off is not matched in the Eurozone, however, where inflation has risen to 2.9%. Leading economists speak about the pendulum having swung towards employees, with labour markets in the US and EU dictating terms. Yet it is my belief that as artificial intelligence becomes more widely adopted, many jobs will be replaced by this new technology. In consequence, the balance of power will shift once again away from the global workforce. In CLINUVEL's supply chain of goods and services we experience variable increases in rates, overall keeping pace with mid-year inflation rates.

And so to the questions posed by shareholders, analysts and interested portfolio managers.

## Question 1: What is the relevance of the 16 objectives presented at the AGM'23?

CLINUVEL has two principal goals for 2024, which we have broken down into **16 objectives (see table)**, as outlined at the last AGM on 31 October 2023. The first aim is to progress our commercial foothold in the US and Europe. The second is to advance our development of the melanocortin drug candidates.

### Individual objectives CY2024

<b>1</b>	SCENESSE® adolescent outcome EMA
<b>2</b>	SCENESSE® Canada Health submission
<b>3</b>	Vitiligo CUV105 completion recruitment
<b>4</b>	Vitiligo CUV107 start recruitment
<b>5</b>	XP-DNA Repair CUV151 read out complete (selected markers)
<b>6</b>	CUV156 read out complete (selected markers)
<b>7</b>	CUV154 start
<b>8</b>	Paediatric PK study CUV052 start
<b>9</b>	VP CUV040 complete results
<b>10</b>	CNS CUV803 completed with final results
<b>11</b>	CNS and or New Indication
<b>12</b>	NEURACTHEL® manufacturing progress
<b>13</b>	Website launch
<b>14</b>	PhotoCosmetics E-shop launched
<b>15</b>	CYACËLLE global launch
<b>16</b>	Financial growth earnings: half year, final year end

We are working to strict deadlines. Our team is all too conscious that we collectively have 234 days, or 1,872 hours, to progress a number of R&D projects to an advanced stage by the end of the year. Meeting these 16 objectives will be crucial to progressing our activity pipeline and shoring up our future value.

### Progress in new markets

This year we expect to progress **the CUV105 trial in vitiligo**, which will evaluate the effects of combining afamelanotide with narrowband UVB (standard of care). The total addressable market for vitiligo is estimated to be worth US\$490m, which includes care for patients who require systemic (total body) treatment owing to extensive loss of skin pigmentation.

The **CUV105** study has the following objectives (“endpoints”): to achieve a total body repigmentation of 50% compared to an individual’s starting point (baseline), called T-VASI50; and to measure how long the repigmentation process takes. In addition, we are evaluating how repigmentation happens on the head and neck (F-VASI50), as well as the treatment’s impact on a patient’s quality of life. The study will last ten months in total.

In parallel, we are striving to become the first company to treat DNA skin damage incurred following exposure to UV radiation. We are supplying afamelanotide to patients living with xeroderma pigmentosum (XP) in the following trials: CUV152, CUV156 and CUV154, with CUV151 providing healthy controls. Not only are we providing relief for patients with a horrific disease, but these trials should prove for the first time that melanocortins can assist the repair of UV-induced DNA damage in skin cells. Our teams are hands-on and monitoring the trial sites in Europe, the Middle East, South America, and Africa.

The **CUV040 results** will indicate whether our photoprotective SCENESSE® treatment benefits patients with variegate porphyria. Results are expected in Q1.

The newest addition to the melanocortin family is the ACTH product **NEURACTHEL**®. The drug is currently undergoing GMP manufacturing processes, after which we will submit its regulatory dossier to the regulators, FDA and EMA. It will be the first branded generic product in our portfolio of melanocortin products.

In October, we announced our intention to establish the **Photomedicine Foundation**, an initiative designed to support individuals who cannot afford treatment or care for severe light-related disorders. We will donate a percentage of our net profits from the future sale of our PhotoCosmetic products to help patients in developing regions. This work promises to be deeply satisfying and we are heartened by the positive response that we have received so far. The Foundation will be independently overseen by five prominent individuals who are devoted to improving the health of patients affected by UV and skin cancers.

## Organisation

This year our challenge as an organisation remains to **integrate and coordinate new staff** across all disciplines, ensuring that we meet annual deadlines. CLINUVEL has undergone rapid growth in the past few years. Now we are consolidating personnel and recruiting senior management with new skills.

CLINUVEL has **three layers of management**: general management, senior management, and an executive team. In many ways, we operate according to a flat non-hierarchical model, whereby line managers are responsible for meeting targets defined at the beginning of each calendar year and for their team's career progression. In total the management team includes nine executives, more than 20 senior managers and over 60 managers. We owe our low turnover of staff to a number of factors. These include long-term employee programmes, high reported levels of job satisfaction, and the responsibility we entrust to professionals early on.

This model has driven the Group's commercial success; our next aim is to formalise our approach in an institutional structure, the CLINUVEL Academy. More information about this will follow in the coming months. Ample evidence suggests that giving professionals the chance to become specialists in drug development early on yields better long-term results, and a clear sense of career progression while supporting employee development. We believe that people are more important than any product we work on, it is those who find ways to solve problems who then drive the organisation. As part of our corporate communications, in April we will introduce our nine executive managers through public profiles.

We are devoting much time to **succession planning** at both the executive management and Board levels. We have clear profiles and processes in place to select the right people to lead the Company. The new leadership team will be inducted into CLINUVEL over a transition period, during which incumbents will be gradually phased out. This will ensure continuity and minimal disruption.

## Values and value

As the Company evolves, our lodestar remains the same. We look to develop novel therapies for patients with high, unmet medical needs. We will instil this philosophy in the next generation of CLINUVEL managers, as it is the thread that connects all our pharmaceutical and commercial endeavours and provides the purpose driving innovation. Patient satisfaction is at the heart of any new venture that we undertake. With SCENESSE® we are serving patients and their families, transforming their lives with recurrent, effective treatment.

## Question 2: Why has CUV's share price remained stagnant against increased financial performance?

Trying to find an explanation for the value of SME stocks has proven a futile exercise on main exchanges. CLINUVEL's stock rallied in the run up to EMA approval of SCENESSE® in October 2014, and once again ahead of FDA approval in October 2019. A last notable spike occurred in September 2021, when a single institutional shareholder bought up a large number of shares. With this in mind, we consider fluctuations in the share price to be purely event driven, rather than as a barometer for the financial strength of the Group. When CLINUVEL has reported lower earnings and a weak balance sheet in the past, the Company's share value was 40% to 60% higher, albeit under more favourable markets. It is important to note that back then, only one analyst group, *Bioshares*, was reporting on CLINUVEL's activities.

That is no longer the case. Today we count seven sell-side analysts who follow the Company's activities closely and issue periodic updates. There is also sufficient reason to believe that the wider distribution of these reports, coupled with our increased investor relation activities, will lead to more shareholders in future. At a PE of 23, we measure up against many of the midsize and large pharmaceutical companies, whereby R&D companies in Australia and US that are not profitable often command a higher multiple.

In conclusion, CLINUVEL's performance and share price are not correlated, a phenomenon which affects other stocks – to the dismay of all shareholders. There remains little doubt in my mind that CLINUVEL's share price may rise from its current low base, owing to our consistent growth rate and solid pipeline. As the Company progresses, particularly in regard to our vitiligo programme, we will attract more investors.

## Question 3: Does CUV focus on family offices and not on institutional investors?

This question suggests an ongoing lack of appreciation of the investor relations activities we have reported over the past year. Most recently, News Communiqué IV (6 October 2023) detailed the IR calendar of activities covering 1 July 2023 to 31 December 2024 which is peer leading in terms of disclosure and activity and also highlighted the focus on attracting new institutions to the register. My presentation at the 2023 AGM (31 October) conveyed the increase in investor relations activity in recent financial years and planned in FY2024 (refer table below). News Communiqué V (24 November 2023) reported the institutional focused activities conducted in October and November. These reports are available on [our website](#) and say it all to answer the question on the focus on institutions and the pace of our investor relations activities.

### Summary of investor relations activities

Financial year	2022	2023	2024 (planned)
Roadshows & conferences	13	9	13
Institutional & analyst contacts	131	183	+300
CLINUVEL events	6	10	10
Newsletters, Strategic updates, CEO & Chair letters	13	12	13

The activities of the IR team were supported in key meetings and institutional roadshows in the US, Australia, and Asia, by the CFO, and myself. Reflecting these activities, and the distribution of research reports to institutions around the world by the expanded panel of analysts, we received more requests for information from institutional investors over the last year. The interest generated was notably reflected in a rise in the share of Australian institutions of CUV's issued capital. Over the year, their ownership increased from around 13.0% to 15.0% and over five years, increased from 5.5% at the end of 2018.

Naturally, our aim for 2024 is to attract new investment, from institutions, supportive family offices and prominent individuals in the life-sciences industry who believe in CLINUVEL's long-term vision. Given the amount of attention that the Company is receiving from analysts, we have never been in a better position to access institutional investment. All analyst reports are attributing a higher price to CUV, based on our continued growth.

Institutional feedback from recent roadshows in Australia and Hong Kong has been overwhelmingly positive and, from my experience, enthusiasm among portfolio managers eventually leads to investments. In 2024 our investor relations team will be represented on three continents, supported by four banks and three brokerage firms to arrange meetings with institutions. At the same time, we are paying close attention to German-speaking markets (AT-DE-CH) where we have a large number of shareholders. In response to this high demand, we are hosting our first investor day in Düsseldorf this March.

## Summary

As our team returns from the summer break in Australia, we begin to tackle the challenges that lie ahead in 2024. The words of the entrepreneur Nic Haralambous in 2019 resonated with our mission: to innovate in photomedicine and to radically improve patients' lives for the long-term. With this in mind, we have adapted his words to suit our needs and made it our mantra:

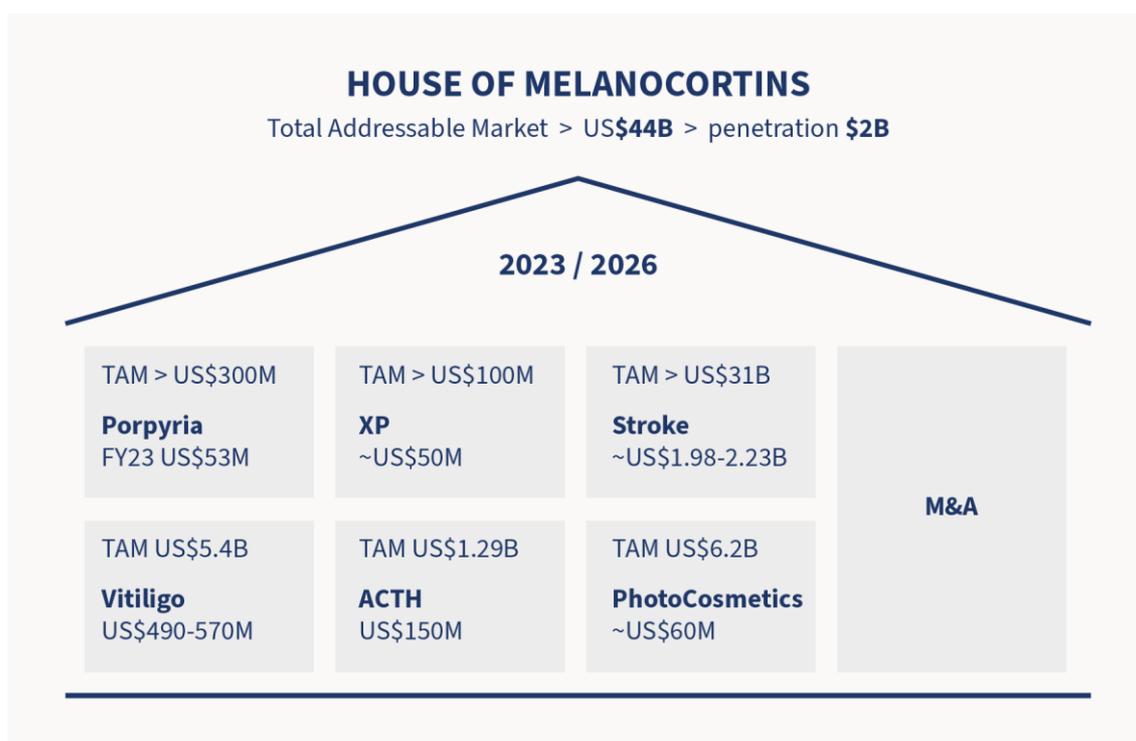
“Finance and plan in decades. Think in years. Work in months. Live each day as the last.”

### Why are these simple phrases necessary?

In short, to ensure that we are all singing from the same hymn sheet. The ambition that drives a growing company needs to be shared and appreciated by all employees on a daily basis. We must be willing to break with the past and look to the future. As we realise our vision of becoming a profitable, diversified and independent entity, these maxims remind us of CLINUVEL's purpose, our long-term vision and why we operate.

The questions one may then ask,

- Is the wait for CLINUVEL worth it?
- Will CLINUVEL's journey eventually create further value for shareholders?



We strongly believe that our journey will reap further returns for shareholders. Once fully executed, our business plan will give the Company a monopolistic position in both the pharmaceutical and cosmetic sectors.

No other company in the world is uniting melanocortin research, drug development and manufacturing under one roof. We are providing effective, revolutionary healthcare solutions for patients with no medical alternatives. These include vitiligo patients of colour, XP patients, and people who are prone to sun-induced skin damage and skin cancers, to name a few. These therapeutic domains require novel treatments, and the total addressable markets are sizeable.

We are aiming to introduce melanocortins to luxury consumers through PhotoCosmetics, two groundbreaking skincare lines that are powered by our unique technology. The idea behind this endeavour harks back to scientific efforts that cosmetic companies abandoned two decades ago, owing to a paucity of data about melanocortins and safety. By contrast, CLINUVEL has accumulated more than 20 years of expertise and knowledge about this group of hormones, which we are drawing on to formulate our next-generation skincare. Establishing a melanocortin-based cosmetic line is a novel, ambitious challenge for a pharmaceutical group. As we put our business plan in motion this year, we are entering the next phase of CLINUVEL's exhilarating journey.

From my position, I see an unusually dedicated and consistent management team who over the last two decades have learned the specifics of this business. Recently we have hired engineers, mathematicians, corporate financiers, data managers, pharmacovigilance and quality managers, legal and finance experts, pharmacists, and a physician to execute this unique project. One of our challenges will be to keep these professionals in the firm long enough, shielding them from recruitment by competitors. In the meantime, we have built a financial vault that allows for progress and insures against any unexpected setbacks.

**CLINUVEL will be embarking on a new venture for a listed company with a novel proposition: to provide therapeutic care for patients alongside science-based skincare for high-risk populations.** If our current team remain in good health, succeed in integrating new talent in a timely manner, and continue to develop the business, then CLINUVEL's objectives for 2024 will be met. We remain flexible and adaptable. Should a vocal minority demand changes, we can be nimble—creating alternative business goals and adding new projects that reallocate our resources. As a publicly listed company, one needs to keep an open mind regarding the wishes of our owners.

CLINUVEL's shareholders have three choices: to support our journey, request structural changes to the business plan, or invest elsewhere.

Importantly, prospective investors express their support for our strategy and watch the roll-out of our plans with excitement. We are confident that our teams will meet all 16 objectives in 2024, guaranteeing company growth for the eight consecutive year. I stand by the following words: *"this team has defied all odds before, and will do it again"*.

There are great parallels between sport and business. The same qualities needed to succeed in an athletics stadium or on a football pitch—determination, resilience and self-belief—are useful in boardrooms too. This year I draw inspiration from the thrilling, era-defining performance by US athlete Dave Wottle in the 800-metres final of the 1972 Munich Olympic Games. With that, I wish you a year of full physical and mental health.

Philippe Wolgen

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#### 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.**

**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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