CLINUVEL

# News Communiqué I

10 January 2023

## *Dear Shareholders, Friends,*

On behalf of the CLINUVEL team and Board, I wish all readers a healthy and harmonious 2023! Twenty-twenty-three needs to be a year which we will remember in terms of performance, output, and advancements.

We glance one more time to 2022 to see which lessons can be drawn and where we must improve.

The year started with the prolongation of German reimbursement for SCENESSE® (afamelanotide 16mg) after a 19-month battle with the Federal Joint Committee and the National Association of Statutory Health Insurance Funds. The arguments to continue the supply to German patients had proven reasonable while the data we had supplied was accurate. Importantly, our teams had shown to be a reliable partner to the German insurance groups, since we had not exceeded the agreed quota in terms of number of patients and treatments provided in the three previous years. The positive outcome was great.

As the year unfolded, the DNA Repair Program – focused on patients with xeroderma pigmentosum, XP – expanded with CUV156, CUV151 and CUV152 in multiple centres. In 2022, we also received the first positive results of CUV801, a study in which the use of afamelanotide in arterial ischaemic stroke patients was evaluated. We were carefully selecting acute stroke patients presenting at emergency units following a cerebral arterial clot lodged in brain arteries. Although, it was an open-label (uncontrolled) study, the data and brain scans (MRI[1]) gave the neurology unit, its specialists, and our clinical teams much hope for the further use of the drug substance in these patients.

In May, we obtained clearance to start afamelanotide as a monotherapy in patients of darker skin complexion (Fitzpatrick IV-VI) with vitiligo. Each quarter saw growth in our commercial performance, while assets had grown providing more leeway to expand the firm, but also enabling to issue a fourth consecutive dividend (60% increase). The year was further marked by addressing new (and existing) audiences during larger gatherings ('CUV Soirées') in Basel, Monaco, and Sydney, while we had seen the number of shareholders increasing by 7%, and in the last quarter a new Australian institution buying in. In April, we had the privilege to welcome Sir Andrew Likierman to the Board.

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## Overall performance 2022

To put 2022 in context, surpassing the conditions during the GFC, we have seen a drop of the S&P by 19.9% on 30 December 2021 compared to previous year (from 4,796 to 3,839), the Nasdaq Biotech Index fell by 11.5% (from 4,761 to

4,213), and the ASX-300 dropped by 7.5%, while CUV lost 21.7% on a year-to-year basis. This percentage decline in value is quite in contrast to the gain in the Company's assets booked over 12 months of 33%, with revenues increasing by 37%, and net cash by 47%. My sole soothing words to some of our investors is not to look at daily share price of CUV (or CLVLY/UR9), but rather stick to long-termism. In the end, market participants factor in long-term performance, pipeline value, and ability to execute; and until one reaches full scale, the share prices of stocks in innovative biopharmaceuticals behave cyclically and often do not correlate with commercial value realised. Whether during buoyant and bearish times, my views remain unchanged: we need to rely on financial ratios to benchmark against peers. Steady execution then provides a mere indication where we are on the curve.

As investors are used to from us, we keep close to market developments, which ultimately affect decision by Board and management. As economic headwinds are foreseen, prices of most asset classes are to fall across the Eurozone and US, we brace ourselves for uncertain conditions. In anticipation of a longer downturn, we wanted to avoid – at all costs – a combination of inflation and equity dilution the past years, since its compound impacts shareholder value. Unfortunately, we did anticipate a surge in prices in our sector, thereby arming ourselves with ample financial reserves to withstand new environments. Hence, we maintained a zero rate of dilution – that is since March 2016.

As we have seen in 2022, higher interest rates caused destabilisation of equity and bond markets, which would also send ripples across the pharmaceutical sector. CLINUVEL was not immune to the new economic realities, and our remedy has been to carefully balance financial performance with advancement in R&D. In the latter, I believe we can do even better, be more selective and gain faster pace. However, at the start of 2023, CLINUVEL is in a far better position than most shareholders or management would have anticipated – say a decade ago. Now, the art is to discerningly build from this basis.

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## Drug development 2023-2025

Developing novel therapies is a benevolent and privileged undertaking, whereby the fruits are only reaped when patients and specialised populations eventually receive end products. This process of arriving at the finished article

### We are working in 2023 towards

- **ACTH manufacturing** progress leading to a DMF[2] submission;
- **Vitiligo** – clinical progress through Phase II CUV104 and Phase III CUV105 (large study);
- **Stroke** – Phase II clinical study evaluating afamelanotide at higher and more frequent dosing;
- **XP-DNA-repair clinical program** – preliminary and final results Phase II studies CUV156, CUV152, CUV151;
- Specialised **consumer products** launched, two;
- **New indication** to be launched for afamelanotide, by securing global IP rights, identifying patients able to participate; and
- A host of **regulatory submissions.**

often must go through decades of research, two steps forward and one step back, a steady and metronomic procession.

Stemming from this thought, our main task is to expand commercialisation while advancing new developments, projects, and products. Fewer risks, and importantly less perceived risk, eventually lead to stabilisation of enterprise value.

I believe 2023 will need to be one when we outdo peers, ensure explicit output advancing multiple R&D programs, and further growing our EPP foothold. As such, we have drawn out a detailed plan for CUV's staff – at each level – to assume responsibilities for timely progress and delivery; this year, as opposed to previous, differs in that we have drawn in junior and newly joined staff to becoming accountable for their roles or parts in just-in-time projects. The extent of interdependency cross-border has grown, and there is a need for collective ambitions to coalesce. The 2023 modus will make it easier for analysts and market participants to put a value on the future of the organisation.

A new characteristic onwards is the way we will communicate technological and scientific progress. One is typically used to reading an Australian Securities Exchange (ASX) announcement outlining progress, data, and significance in concise manner. We have heard on occasion that the relevance of particular announcements within the context of the Company's direction and progress is not fully understood. Therefore, for 2023 we have changed the way we communicate through the ASX, by adding a technological narrative and simplified executive versions for all in-depth readers and generalists to fully understand the news flow and its overall relevance.

The clear vision is for the Company to lead in melanocortin technology, diversifying to medical and specialised consumer markets. In the glut of our ambitions lies the desire to become fully independent. A finishing line is drawn on 30 June 2025, period, 30 months from now.

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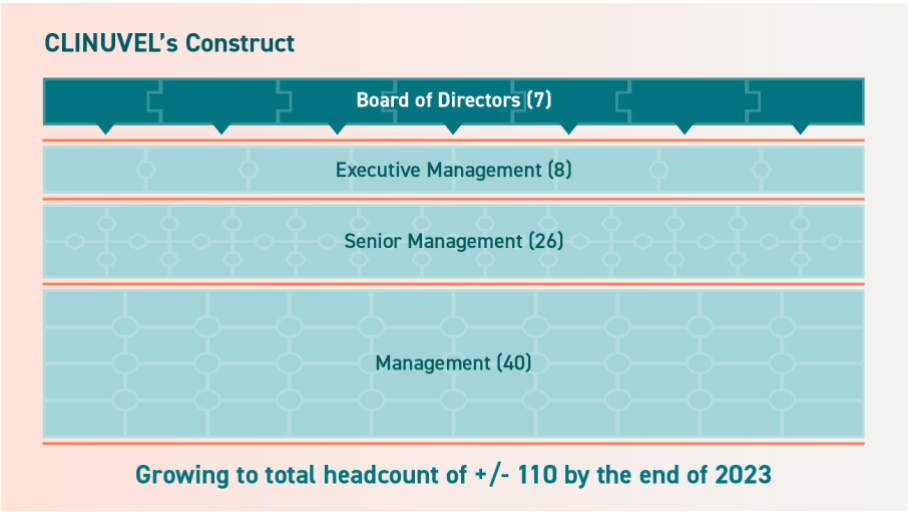
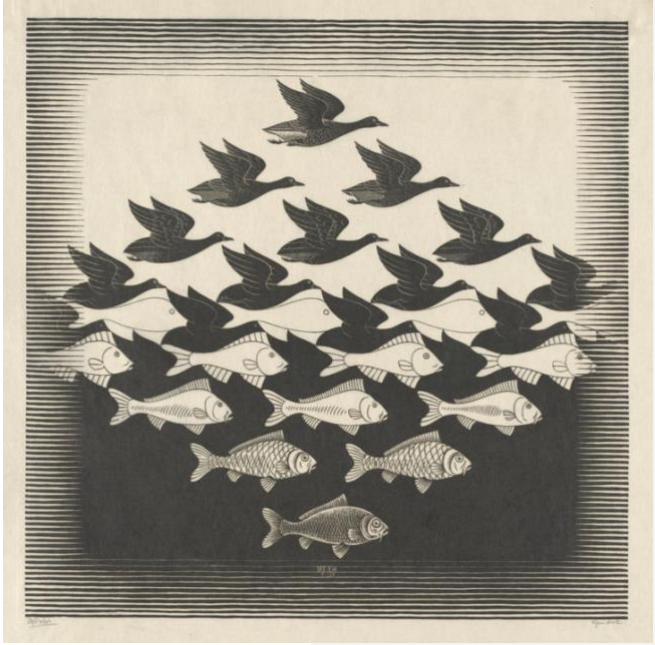
## Construct CLINUVEL

The construct to arrive at that point has been talent in charge as divisional heads, specialised managers overseeing projects, flanked by those who have shown the ambition to build a career within the Group. In addition, stability and financial buffers enable the execution of all plans, rendering the Group autonomous along most components of the pharmaceutical chain. Last, a company progressing on its sails of meritocracy, where people are assessed on



their intellectual capacity, energy, ability to generate new concepts and initiatives aiming to add value.

## Epilogue



*M.C. Escher – Sky and Water ii*

CLINUVEL is morphing into a broader pharmaceutical, devoid of long-term liabilities and shown to be an attractive business proposition. In the past we have seen very few opportunities to deleverage by divesting non-strategic assets, hence one could explain our reliance on retained earnings to build the firm to its present state.

As central banks pledge to continue tightening monetary policies, the expectations on inflation are improving while further interest rate hikes are expected in 2023 from both the ECB and Fed. Consumer and business confidence are expected to suffer further. Nevertheless, we have reason to remain bullish on a faster recovery of equity markets than predicted at present. For one in our sector, we believe that portfolio managers will carefully balance their equity allocations in life sciences distinguishing between pure speculative R&D companies, and those posting longer-term earnings. Fund managers are already asked to separate the chaff from the wheat by rationalising their pickings of assets, and this approach may well distinguish CUV in the coming year.

In 2023 we aim to further vary our offerings, entering a specialised consumer market and advancing our melanocortin portfolio, including NEURACTHEL® (an ACTH product). We will continue our efforts to provide more visibility on the Company among specialised investors by organising global Soirées d'Investissements (investor gatherings) across a number of capitals. Throughout the year, we will participate in several investor conferences organized by Wilsons Advisory, Jefferies, Morgans Financial, Goldman Sachs and H. C. Wainwright. Communication will proceed in parallel with our online dissemination through CUV-ambassadors (CUVAs). All these activities will need to result by the end of 2023 in higher awareness among investors and specialised consumer audiences.

We often are asked by both professional recruiters and investors what CLINUVEL's earmark has been the past decade and half, its points of recognition and uniqueness. In analysing, in October 2022 our executive management reached consensus on how best to capture CLINUVEL's business, ethos and modus operandi to date:

### *"Resourceful – Pre-emptive – Longitudinal"*

What is the narrative to the trilogy? Our people have proven skilful in finding solutions when water was at its highest level and abandoning would have been the logical option. We generally act on ample information, interpretation, and assimilation of data while experience adds to paint future scenarios and prepare in time. Last, we adopt a longer-term approach to business, patients, staff, suppliers, investors, and most undertakings, it engenders a systematic and consistent follow-up, going long to creating value. I trust this cue helps to disseminate the word on CLINUVEL.

As one of very few innovative bio-pharmaceuticals, we strive to reward longer-term investors (39% holding more than 13 years, 32% holding more than 15 years) by issuing an annual dividend. We will review our earnings on 15 August 2023 to determine our position on next issuance.

You may have gleaned that I have difficulty in containing my enthusiasm for 2023, my expectations are high, the only prerequisite for all the deliverables *to see light* is for staff and Board to remain in full spiritual and physical health. If so, barring unforeseen calamities, the rest of the puzzle will need to come together throughout the year.

I leave you with the notion that we appreciate what we all have in these darker economic and belligerent times, please embrace the privilege to create or assist the Company for the benefit of many.

*Philippe Wolgen*

1. Magnetic Resonance Imaging. For more details on the results of CUV801, please see this announcement.
2. Drug Master File.

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

**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 2022 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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