Executive Summary

Financial results FY2023
6th annual dividend,
Revenue ↑ 24% Expenses ↑ 15%
NPAT ↑ 47% Cash ↑ 29%

Clinical progress
DNA Repair, stroke, vitiligo programs prioritised
CUV105 (n=200)
Vitiligo Expert Panel engaged
Variegate porphyria program ongoing

Leadership in melanocortins
3 pharmaceutical products
3 PhotoCosmetic ranges

Communications
CBM Division
Global IR Team

Conclusions

- Disconnect between price and fundamentals in weak markets
- Members encouraged to allocate proxy votes before 31 October AGM

19 September 2023

Dear Friends, fellow shareholders,

Financial results FY2023

I write to you at the time the Company has announced its sixth annual dividend, an increase of 25% to 2022. The annual issuance reflects the Board's strong desire to redistribute a percentage of profits to shareholders.

As global equity markets suffer a new retreat, the Eurozone is recording stagnation of growth, high fossil fuel prices, and anticipated further fiscal tightening causing greater uncertainty in the markets. In the midst of these mounting economic waves, there are better data coming from the US, and we believe that the end of steep rate hikes may come in 2024. As stated in the past, we see it as our task to manoeuvre CLINUVEL through volatile conditions while continuing to meet our objectives.

The recently released Financial Year 2023 results exceeded expectations, with increase of revenues by 23%, a surge of net profit after taxes by 34%, and expansion of accumulated cash reserves by 29%. The set of figures prompted sell side analysts to adjust target prices well above the current share price. While a further two new Australian institutions have since joined the register, some shareholders have looked for an opportunity to take profits, as trading volumes remained relatively low. We are well familiar with the pattern of smaller selloffs post annual results pushing the share price down, while a rebound is usually seen in the months after.

However, in contrast to many of our peers, the firm is financially stronger than at any point in history, having decreased its operational risks and advanced new technologies. Of note is that longitudinal analyses have not shown a correlation between the strength of the Company and its market value. Therefore, just from fundamental analysis, I have much confidence that CLINUVEL's market value will recoil.

Clinical progress

Both the preliminary DNA Repair[1] and stroke trials showed positive preliminary study results. Since afamelanotide has ubiquitous medical benefits, the ability to positively influence DNA skin damage, and establish an additional marketing authorisation with the molecule could not be more exciting. Equally, we are breaking new frontiers in attempting to evaluate our first molecule in moderate to severe stroke patients. The short-term aim is to advance both smaller studies to larger, pivotal clinical trials.

The most comprehensive clinical trial in preparation is in vitiligo (study CUV105). We intend to subject up to 100 patients of darker skin complexion to the combination of afamelanotide with narrowband UVB (NB-UVB) phototherapy, with a parallel cohort exposed to NB-UVB monotherapy, very much hoping to see similar results as found from the earlier study CUV102 in 55 patients.[2] Pending approvals from review boards, we intend to start this trial in 2023. The dosing schedule in CUV105 covers five months, with a further six month follow-up period. The recently announced Vitiligo Expert Panel – comprising four global leaders in pigmentation and photomedicine – has been engaged to advise on the development program and use of afamelanotide in the clinic, supporting the drug's path to market.

The three programs – DNA Repair, stroke and vitiligo – are prioritised to see afamelanotide coming to market as two distinct pharmaceutical products, a controlled-release and acute (instant-release) dosage form. Further indications are now being finalised following the recent success in the Muenster patent case, where the University admitted to having breached CLINUVEL's intellectual property rights.

Under guidance of Dr Quadbeck-Diel, a submission to treat adolescent porphyria patients is under review by the European Medicines Agency (EMA) and, in anticipation of further discussion on long term effects in younger patients, we are preparing the CUV052 study in three centres. The dosing frequency will cover a single SCENESSE® implant, during which time biochemical and skin analyses will be conducted.

Leadership in melanocortins

A long-term English shareholder and one of our analysts posed a similar question: *"how does management see the melanocortin journey and the completed house over a 5-year window, whether the Company could provide further details?"* A well-defined future outlook is pertinent, and through today's address and several video channels, our executive team will discuss our path forward along expected timelines.

"CLINUVEL's overall objectives are crystal clear. We are looking to increase profitability and diversify our activities through multiple divisions."

CLINUVEL's overall objectives are crystal clear. We are looking to increase profitability and diversify our activities through multiple divisions. For this to occur, we established four divisions, pharmaceuticals, healthcare solutions (differentiation of PhotoCosmetics), manufacturing and CBM.[3] The ultimate aim is to turn all divisions profitable within five years.

I will systematically go through the four divisions and their growth prospects.

Pharmaceuticals is developing SCENESSE® in XP, VP[4] and vitiligo, whereas PRÉNUMBRA® Instant is being developed for the treatment of acute stroke. In addition, we are progressing the manufacturing of NEURACTHEL® Instant to be used in infantile spasm and relapsing episodes of multiple sclerosis. We intend to add further complementary technologies by acquisition and in-licensing arrangements.

Healthcare solutions is responsible for the development of the three PhotoCosmetic product lines to be marketed to specialised consumer groups. The product focus is on providing polychromatic solar care, DNA-assisted repair and risk-free bronzing emulsions. These product lines will be marketed globally, increasing visibility and presence through campaigns at scale. Additionally, the intention is to add more proprietary molecules and excipients through acquisitions, expected to be completed the next 24 months.

CLINUVEL will operate its own manufacturing facility enabling production of liquid and transdermal formulations under Good Manufacturing Practices. The plans to establish these facilities will be disclosed in the coming financial year.

Complementing the quartet, the CBM team will operate independently, containing key functions in creative & artistic, branding, marketing, social media, digital services and offerings, and communication. More qualified staff and services are shortlisted to ensure we successfully access new and wider audiences; these activities will be shared in Q1 2024.

Summarising, all four divisions are poised to expand with further expertise, services, and products.

It is anticipated that current cash reserves (A$157m at 30 June), added by future free cash flows, will cover most of the expansion plans. Our long serving financial team has shown how they responsibly manage the financial

household of the Group, and therefore there is no doubt that the same professionals will continue its course to the benefit of the owners of this business.

Communications

We view investor relations as part of the broader communications remit of the CBM function, coordinating all content and news flow generated by the Company. Listed on the ASX, we accordingly maintain the Head of Investor Relations, Mr Bull, operating out of Australia. Recently, Ms Hardy was added to service the EU market. With a longstanding background of working with family offices and in wealth management she will focus on a growing pool of investors expressing interest in the Company. Shortly, we are adding a new IR manager covering North America. This ensemble will be able to execute a global program, attracting further institutional, family office, and ultra-high-net-worth investors.

"Live product launches are planned in major cities around the globe, whereby artistic design will provide the Company with a recognisable identity and prominence."

The plan is underway to run various investor relations and communications programs in parallel, by presenting at industry conferences, participating in bespoke roadshows organised by a brokerage house, and conducting our upcoming soirées in Monaco, Sydney, Los Angeles, Singapore, Abu Dhabi, and London. I am certain that the multipronged strategy will attract long-term shareholders to CUV's register. Based on analyses of the investor meetings held in FY23, it is apparent that the Group has firmed up interest and attracted new shareholders.

Mrs Arrom Bibiloni and the digital team are finalising a new website, one which follows recently completed brand guidelines, and radically departs from traditional pharmaceutical online platforms; more on this from the Director of Brand Strategy & Creative in her next Bulletin.

On a different front, the pilot digital campaigns resulted in targeted audiences receiving the first polychromatic product CYACÊLLE, with 600,000 recurrent views over three campaigns. The CBM team learned from first analyses that there is a desire for elaborate information from those at highest risk of solar damage and skin cancer, principally our first audiences who will get to see the PhotoCosmetics campaigns. In a second stage, broader online audiences will gain access to the product range. We partnered up with several third-party service providers, some of those specialised in digital engineering for the generation of tailored databases with common characteristics, and which fit our target audience profiles.

Live product launches are planned in major cities around the globe, whereby artistic design will provide the Company with a recognisable identity and prominence. In these launches, both CUV Ambassadors and CUV Intriguing Personalities will play a central role. These events are being meticulously planned by our team together with a group of marketing consultants. Key is the coordination of relevant content generated and digital marketing material. Under the editorship of Mrs Arrom Bibiloni, the CBM Bulletins will provide a step by step unfolding of all marketing activities over the next 24 months. The online pilot studies on pre-launched products provide a fertile ground to learn at individual level, while broader distribution will follow scaled campaigns resonating with larger audiences.

Importantly, we estimate that annual costs required for proper marketing of CLINUVEL's product ranges will amount to a fraction of the expenses traditionally seen in the cosmetic industry, without sacrificing the personal touch required to engage with identified audiences.

Conclusions

Over decades, we became steadfast in the belief that *the aptitude to execute at minimal costs is the foundation of successful bio-pharmaceutical ventures*, since competition for external funding is increasingly fierce, and debt most often leads to an unescapable downward spiral. We are privileged to have a team conscious of both the need to book progress and control costs. SCENESSE® reached market for under A$150 million in research and development; when we accomplish the objective of establishing a melanocortin house of three pharmaceutical products, plus three PhotoCosmetics, we would have spent an order of magnitude less than pharmaceutical peers.

Factually, there is no correlation between the Group's momentary valuation seen daily and its financial strength. More so, during two previous periods (Oct '19 and Sep '21) in buoyant equity markets, the Company reached a market valuation of A$2.2 billion, albeit accompanied by a much weaker financial balance sheet. In contrast, at present the Group's financials are stronger than at any time since its IPO in 2001, while CUV's price is a mere indication of weaker markets for biopharmaceuticals.

Therefore, it is well-timed to have access to cash reserves, enabling the firm to navigate uncertain economic environments, continue research activities, and increase our commercial footprint. Appropriate self-criticism is that our teams need to accelerate R&D and marketing activities to take a definitive lead in all markets.

"... we have no hesitation in our team's ability to replicate several times over what it has done with SCENESSE®: development, formulation, and commercialisation."

Overseeing all moving parts of the Company, we have no hesitation in our team's ability to replicate several times over what it has done with SCENESSE®: development, formulation, and commercialisation. Daily, we are privy to the single most important characteristic of this firm, our people's ability to solve problems for which at first sight there are no practical solutions on the horizon. Dr Wright, Dr Hamila and Mr Hay, but also the unified Board of Directors are professionals who possess the willingness and audacity to tackle technical and financial issues which, for many of us, would be a reason to look elsewhere for alternative opportunities.

Although not deterministic, the time to fulfil our objectives is an important factor. Technological progress needs to be at pace with the budgets set for five years. As can be seen from the Annual Report 2023, we are exactly tracking along the predicted allocation of funds up to A$175 million to 30 June 2025. Of this total, we anticipate expending A$82 million over just under two years. Since we are tracking ahead of our own projections in terms of profitability and cash resources, we will shortly share five-year objectives to 2028, taking into account all new activities to expand the Group.

As to the direction of the firm, we are most conscious that several roads may lead to the promised land, however indicative of the complexity of the undertaking and focus required, most industry actors who aimed at translating and developing melanocortins have ceased their attempts. This executive team has successfully developed a first-in-class molecule once, and will do it twice and thrice, save for unexpected failing of health.

In learning from other bio-pharmaceutical cases, we have come to the notion of entrepreneurship being a discipline centred around risk management. At the same time, one is all too aware of opportunity costs coming with a plan spanning two decades or more. However, the ultimate outcome of realising a grander vision, turning CLINUVEL into a global brand, surpasses those costs. The Group has the potential of being globally recognised for its values, attitude, and seeing through complex plans by overcoming adversity. These intangible traits are entrenched and will one way or the other lead to commercialisation of our products in an evolving digital era. We foresee a shift in how markets will be selecting firms on consciousness, consistency, and ability to execute with most efficient economics. As an unusual case of extracting technological value, we are converging photomedicine and PhotoCosmetics for two audiences – patients and specialised consumers – to understand the two associated disciplines.

"The Group has the potential of being globally recognised for its values, attitude, and seeing through complex plans by overcoming adversity."

We leave you with lasting thoughts. The economic worth of a single life, of one day lived free of pain and without the anxiety of incurring second degree burns is hardly quantifiable by today's measures. Cost-effectiveness tools are inadequate in comparing medicinal treatments with 'photoprovoked' (caused by light emission) diseases. Is phototoxic pain more severe or less of a handicap than chronic herniatic disability, diabetic polyneuropathy, or hereditary angioedema? These are injudicious questions until the day we ourselves come to suffer from loss of health, of freedom. As CLINUVEL investors, we will remember this futile attempt to compare "quality of life" among thousands of diseases to arrive at a uniform cost effectiveness figure.

With admitted inability, unwillingness, and in breach of its own guidelines and the UK Equality Act (2010), NICE and NHS England are now unlawfully depriving EPP patients from accessing SCENESSE® treatment.[5] In having

reserved our rights, we are now preparing a legal dossier refuting NICE's position: this case deserves adjudication calling to attention the inaptitude of NICE-NHS.

While we are aware of the privilege, all of us, shareholders, may take a moment to relish the notion that we collectively change lives and contribute to the wellbeing of many patients and families. Realisation of hope engenders long lasting appreciation among the medical community, it is the main driver for our teams, and should provide you pride to be a contributor. We share with you an example, how a Dutch EPP patient in severe distress expressed his ultimate despair of enduring debilitating phototoxic episodes all year round, and on several occasions had reached out to insurers to increase the recommended number of annual SCENESSE® treatments. With humility and in recognition of his persistent ordeal, our teams granted him further treatment on a compassionate basis. The patient's sense of relief, delight and freedom is fully not describable, nor captured on a balance sheet. Thank you all for making this happen.

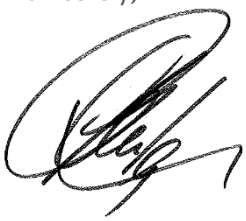
Each year we regard the Annual General Meeting as a democratic test of our strategies, a significant moment when members can decide the direction of the firm, whether you wish continuation of the business plan or for dramatic changes to personnel – and therefore strategy – including Board and subsequently management.

Having analysed many bio-pharmaceutical companies, in particular those using technology platforms to expand their business, we are clear of how we will complete the grand plan we had started nearly two decades ago. Thereby, we fulfil a life's ambition of all senior managers and Board, translating melanocortin hormones and diversifying the Group, while providing global visibility.

With full respect to shareholder rights assigned under the Australian Corporations Act (2001), if CLINUVEL's members wish to exercise their rights and ensure the current strategy be continued in the best interest of the shareholders, it is recommended that you cast your votes prior to the AGM (to be held on 31 October).

Thank you for your support and I hope to see you along this exciting journey.

Sincerely,



Philippe Wolgen

CEO, CLINUVEL Group

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Notes

[1] Results from the DNA Repair Program include studies in both xeroderma pigmentosum (XP) and healthy volunteers.

[2] The CUV105 study seeks to enrol up to 200 vitiligo patients with darker skin types, Fitzpatrick IV-VI, 100 of whom will be randomised to receive NB-UVB monotherapy. Results from the CUV102 study have been published as Grimes, P. E. et al., (2013). The Efficacy of Afamelanotide and Narrowband UV-B Phototherapy for Repigmentation of Vitiligo. *JAMA Dermatology*, 149(1), 68.

[3] Communications Branding and Marketing, based in the Company's UK office.

[4] Variegate porphyria. The CUV040 study is ongoing in six patients.

[5] National Institute of Health and Care Excellence (NICE) and National Health Service (NHS) England.

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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