

Dear friends, shareholders

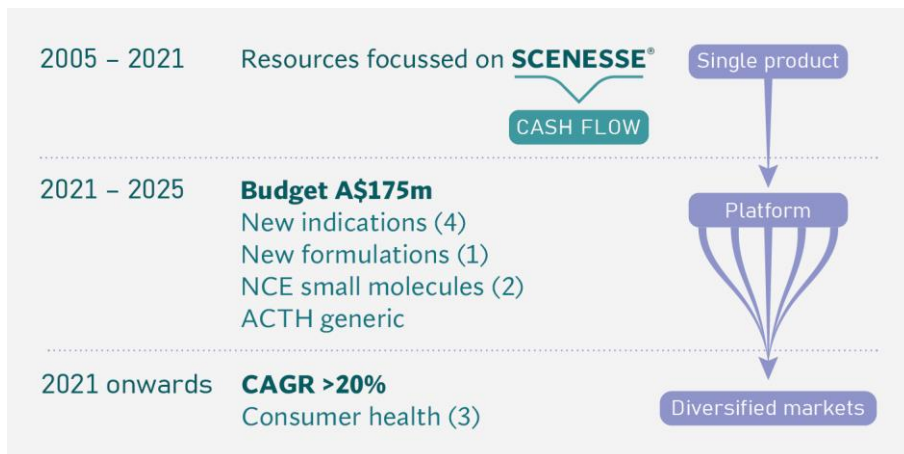
It is the *fifth year* since we started issuing bimonthly News Communiqués, and given the great encouragement recently received, we continue the updates indefinitely.

Today, we review the Company’s trajectory, and underlying reasons to diversify (refer to [Strategic Update VI](#)). The Company’s strategy is not a simple choice of combining a medical focus with consumer health, but rather a decision to use experience gained, knowhow, and technologies in pharmaceuticals concurrently, launching complementary lines of photocosmetics.

Communiqué III will illustrate the distinct opportunity the Company offers.

End Goal

Our goal has long been to establish a diversified life sciences group, with the strength to stand its own. Having attained leadership in photomedicine through SCENESSE® (afamelanotide 16mg), it was clear that further use of melanocortins would follow. The ultimate objective has been to establish a group, rich in pipeline (melanocortins), with new formulations, further molecules, and a division specialised in health care products for clearly identified audiences.



The work towards that defined and dual goal, pharmaceuticals combined with consumer health, is progressing. The very juncture where we find ourselves is reminiscent of 2005, when we initiated novel programs with very few examples from which to draw. We followed a defined path, and today we are one of the very few profitable bio-pharmaceutical companies growing year on year.

Once again, we find ourselves in uncharted territory, and after years of analyses and preparation, there can only be one similar outcome. We are



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turning CLINUVEL into a scalable business, reaching more beneficiaries, while ensuring that it will be widely known for its information, services, and products.

Strategy

How does one get there? What are the costs expected, where does the funding come from, and when to expect the completion of all these activities?

The starting point is the realisation that CLINUVEL is differentiated, operating a core pharmaceutical business, and translating its knowhow and technologies to solutions in consumer health. This model is not often followed but can be executed with diligence and using market intelligence. The ability to operate efficiently and at low cost has been a hallmark of our team, and is being replicated as we speak. The liquidity reserves built over a decade enable us to advance a diverse pharmaceutical program, as well as a demarcated global strategy reaching a targeted audience in need of specialised skin care.

In 2021, we shared five-year projected expenses totalling A\$175 million. Almost 36 months into this journey, we are right on track. Beyond our expectations, we have built cash reserves allowing for advancement of the pharmaceutical pipeline, and acceleration of a global branding & marketing program. For this, we formed a communication, branding and marketing (CBM) team, attracting professionals with a strong IT background, digital marketing, creative & design, and senior directors from the cosmetics and luxury goods sector. Two weeks ago, we issued the first [CBM Bulletin](#) outlining detailed steps and channels of communication to reach new populations. The deadline for delivering against the principal CBM goals is 30 June 2025. By then, a program spread over nine activities will be in full flight, taking the Company across three continents, and giving its cause global visibility. The prospect of a bifocussed company launching photocosmetics, while deriving its technologies from clinical applications, is unique and – quite frankly – thrilling. The final part of the overall corporate plan is to expand through acquisition, and integrated manufacturing.

Defining CLINUVEL

I have long held that CLINUVEL would reposition and simplify its story at the right moment in time, appealing to diverse populations and stakeholders. To succeed in that very goal, a team of professionals, acting as part of the CBM, is nearing its completion. The emphasis of the CBM's current activities is on content generation, preparation of digital channels and the launching of activities for a novel product line (CYACËLLE).

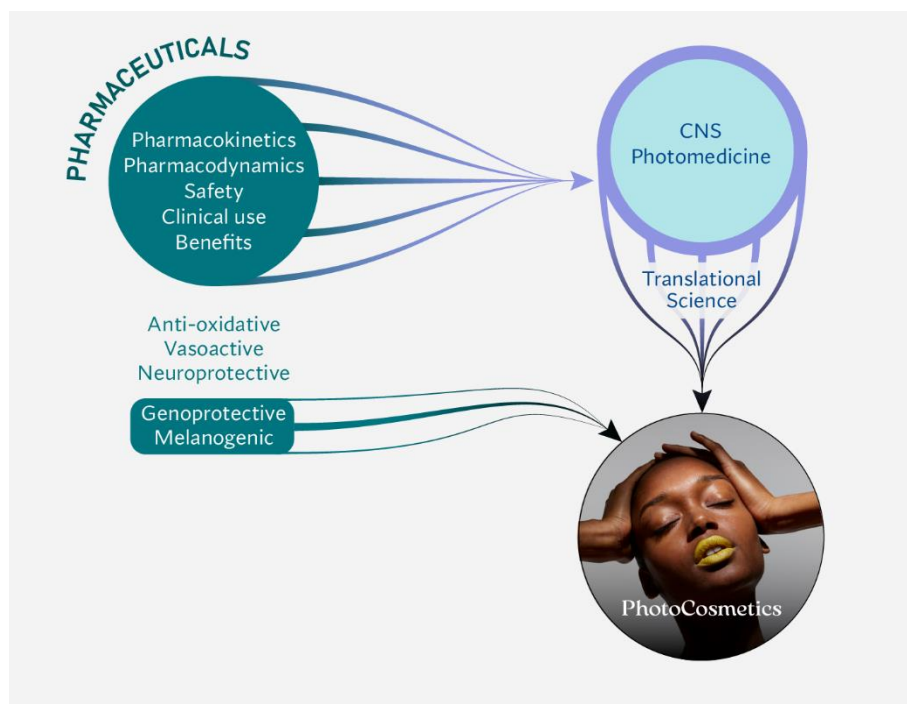
We view the notion of branding, marketing, PR, and IR as the sum of various forms of communication, an ability to tell complex stories through several formats, to multiple populations, and in a most compelling manner.

Among our teams there is a high level of excitement to see the Company maximising its efforts to obtain a position in photocosmetics and specialised skin care. The Company's origins, core activities, results and emphasis on safety are some of the characteristics distinguishing CLINUVEL from any other competitor in consumer health. One ought to keep in mind that the translation of melanocortins to transdermal formulations has long been demanded by physicians, analysts, and investors, and we work towards answering that single expectation.

From Photomedicine to Photocosmetics

CLINUVEL is building a twin business, whereby continuous pharmaceutical data generated, directly support communication on the benefits of photocosmetic products, and part of our consumer health business.

I believe that an uncharted road is not a reason not to explore and shy away from, rather perhaps a large opportunity. In introducing photocosmetics for populations who need skin protection from solar and high energy visible (HEV) light exposure, we take up the challenge to enter new markets. Those who need prevention of photodamage and skin cancer will benefit from our product lines. In accentuating this mission, we will be unique among our peers.



Value of Clinical Programs

Progress continues on the use of melanocortins as treatments for patients who lack alternatives.

In the xeroderma pigmentosum (XP) study CUV156, three patients have completed the trial, while other centers are evaluating the suitability of three further patients. CUV152 is ongoing and recruiting. The programs together will provide data and knowledge on afamelanotide's ability to assist DNA repair, with the planned CUV154 study to consist of both XPC and XPV patients. Results from CUV151 in nine healthy volunteers are being analysed to serve as control data on DNA repair processes. CLINUVEL is the first company worldwide to have accessed XP patients, subjecting them to systemic photoprotective therapy. The patients and their associations are excited about progress and clinical response.

The clinical trial protocol for CUV105, our largest study in vitiligo patients where afamelanotide will be used as a combination therapy, was filed with a central institutional review board, while sites are being recruited to participate. For CUV105, we estimate to recruit 150 adult patients, who will be randomised to either receive narrowband ultraviolet B (NB-UVB) phototherapy or the combination of afamelanotide and NB-UVB. Since the study will allow for higher dose frequency, the entire study duration is shortened to nine months,



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followed by three months of follow up. The endpoint is defined as 50% improvement of the total body score measured by the Vitiligo Area Scoring Index (VASI); this will be the first vitiligo study globally in which TVASI50 is used as primary and clinically meaningful endpoint, evaluating the potency of the combination treatment to repigment skin.

Under protocol CUV803, six patients with mild to moderate stroke have been recruited, and a further six diagnosed with severe stroke will be enrolled. In this study, the second afamelanotide formulation, PRÉNUMBRA® Instant is being evaluated for its safety and effect on oxygen-deprived brain tissue.

People and Environment

As part of the methodical expansion, we are bringing in additional senior talent with different skillsets. Among many, we are incorporated a new physician, an in-house counsel, head of creative and branding, head of engineering, and senior managers in formulation science. While quite some staff members are being added in rapid succession, much attention is given to ensure full integration.

The past years, managers have been enrolled in rotational programs exposing them to various disciplines within the Company, and at this stage we are setting up a CLINUVEL Academy providing advanced training, and bespoke programs to evolve talented staff to senior and executive positions, part of our mission to secure long-term knowledge and expertise. The value of longevity has been communicated previously, and this is exemplified by the current executive management team, who have a median tenure of 15 years; new managers will be added to the most senior team as part of their career development, while retention of staff remains a key objective across the Group.

Conclusion

In summarising our thoughts, as part of CLINUVEL diversifying its portfolio, we intend to complete the development of one first-in-class commercial drug, four indications, a next generation afamelanotide formulation in development, one generic drug, two small melanocortin molecules for transdermal use, and three consumer health product lines.

Above, all professional talent has been attracted and experienced managers retained, realising a longstanding ambition to establish a pharmaceutical group centered around melanocortins.

Our owners are seeing quite a radical extension of activities compared to how the Company had started, while economic growth is being maintained year on year. As one of the few profitable bio-pharmaceutical companies, we issue dividends to demonstrate appreciation for loyal shareholders, while we continue to strengthen the Group's financial position. There always remains a debate of value versus time, chosen strategies and end goals, however for CLINUVEL the current strategy is most suitable, and the one that will generate most value for all.

Over time, feedback from attendees and shareholders received after investor meetings and Soirées is excellent. The format and direct interaction are valued well, whereby the meetings offer the opportunity for new attendees to interact with managers. As part of our global program, we intend to continue these events throughout 2023 and 2024 (see table below).

Month	Soirées & IR Events
May '22	Basel
September	Monaco
October	Sydney Melbourne Twilight Briefing
March '23	New York
May	Frankfurt
June	Melbourne Twilight Briefing
July	Mallorca
October	Monaco Soirée
November	Sydney Soirée Singapore Soirée
December	London Soirée
January '24	Los Angeles Soirée

Note that the timing of all events listed is indicative and may change.

During a recent event in Frankfurt, a question was posed on management's intentions to see the ambitions through, and the Company's direction. The management team and directors are unanimous in that we all intend to complete this journey to build CLINUVEL to a unique group through clinical advancement, organic growth, acquisition, addition of manufacturing, and photocosmetics. After the German meeting a hypothetical question was posed whether CLINUVEL would be at risk of not completing its mission and plan, if a group of shareholders or external party would present plans for change of strategy, given the large retail investors base.

My answer to that question was that such a scenario would be unlikely, and even less likely to succeed.

We have always seen innovation in bio-pharmaceuticals as equivalent to managing various degrees of risk across the business. A complex and unconventional program was executed against all odds, rendering the Company profitable year on year. The management team counts a total of 120 years together in the Company, while directors carry a few hundred years of accumulated experience. Sure, there are many ways leading to the same destination, but our analyses and knowledge of intricacies of CLINUVEL gives us the conviction that the current pathway is the optimal one.

In many ways, we are all invested in this project, many dedicated to melanocortin technologies, some committed to project finance, and the majority through equity (11.3% held by management and Board), including a Chair who personally invested A\$13 million in 2018, at a critical time to rescue the Company from a cataclysmic market event, since a shareholder needed to liquidate; our Chair stepped up, where others could not, and therefore shielded the Company and all shareholders from a longer term decline in value. It shows there is critical approach to complex issues, creed and will to succeed.

I believe that CLINUVEL will grow to a group of highly diversified companies, where cost and operational synergies will make it a distinct group. The CLINUVEL story has always stood out as differentiated from most bio-pharmaceuticals, but achieved profitability precisely because it has found



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solutions where others could not. The creativity of finding new profitable avenues is poised to continue under the guidance of current managers.

The end of year financial report is expected by the end of August 2023, and these will be presented to institutional investors and via a webinar with our shareholders.

I wish you good health, and much patience in current markets, these will recover as the past has shown.

Philippe Wolgen
Managing Director


- END -

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), CYACËLLE®, 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®, CYACËLLE®, 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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