

# HALF YEAR RESULTS

Ending 31 December 2021

28 February 2022

Dear Shareholders, friends

On 24 February, the world plunged into instability, initiated by delusional warfare causing widespread economic disruptions, cyber threats, and fear in the markets. Eighty-three years after the last global military aggression in Europe, we are overcome by the invasion of the Ukraine. As the West chooses to watch rather than intervene, the Russian leadership implies to strike NATO with unprecedented vigor should the alliance decide to deploy its troops on the ground. As the tragedy is unfolding, few dare to discuss our memory and pledge not to allowing history to repeat itself, as an autocratic regime has started an inexcusable annexation.

Since 2018, through our bimonthly News Communiqués, we have written on management's deliberations on geopolitical shifts, macro-economic data, but always bringing these back to the long-term strategy and sustainability of CLINUVEL. We formulate scenarios on systemic risk and sequelae to preempt and avert a possible impact on our cherished company. Sensitivity to negative externalities, and emphasis on fiscal aptitude and moderation, enabled the company to navigate the GFC, various flash crashes, COVID-19 and the current crisis, that is without the need to scale down operations or resort to reactive measures.

In further differentiating CLINUVEL, we disclose 'Olympic objectives', encompassing a four-years breakdown of corporate targets aligning those of staff, management and you. Above all, these targets serve as a realistic roadmap, while assiduously stretching our abilities to meet these; we surmise that value is accruing as individual goals are attained.

As to our status, the Half Year Results ending 31 December 2021 (published on 23 February) outstripped internal expectations but also the consensus of side analysts. We posted A\$24.6 million in total revenues, A\$16.2 million in expenses and A\$8.7 million profit before tax, further strengthening our balance sheet. Our teams are delivering on cue, and under the circumstances I could not expect more from our managers.

In realising a vision, in November 2021 we published total planned expenditures estimated A\$175 million spanning five financial years (2021-2025). These projected investments allow for the establishment of a diversified group harboring a portfolio of pharmaceutical products and non-prescriptive OTC products. The executed plan will put the Company in a unique position, centered around a group of melanocortins - potent hormones - serving high medical need in a vast number of life threatening and severe disorders. In sync, the communications-branding-marketing team is preparing new markets for our first OTC product line serving populations at highest risk of skin

cancer. A supporting wall, perhaps even a *conditio sine qua non* for future success, is the continued safety monitoring of SCENESSE® (afamelanotide 16mg).

Regretfully, we have all witnessed an unpredictable oscillation in CLINUVEL's share price from A\$21.62 on 25 February 2021 to a 12 month high of A\$43.58 on 23 September, to a low of A\$18.27 on 24 February. The most recent decline in share price is in stark disagreement with the Company's commercial progress, while its financial strength has increased significantly over 12 months.

While we continue to eliminate known business risks, it is certain that we will encounter new uncalculated challenges. However, operating from an even stronger footing, and notwithstanding turbulence in the markets, I have no ambiguity about the investments and output from our teams. The global executive team of eight managers holding a median 14.5 years of service, and the senior management team of nine professionals with a tenure of median 6.8 years are surrounded by more than 50 managers who have joined us in the past years. This ensemble has focused, innovated, and commercialised afamelanotide technology, and collectively we are working towards realising it a multiple of times, new products, new markets, new audiences. With confidence, vigilance and cadence, value will continue to be created.


Turning to the actuality of our lives, on behalf of the Board, I express deep concern and empathy to our staff and shareholders with family and friends in the Ukraine.

On Wednesday 2 March, via a webcast to our shareholders, I will address three recent questions:

1. CLINUVEL's market position.
2. Financial management.
3. Growth.

Given some of the commentary and queries our IR team have received, we advise for you to rely on direct information released by the Company, by reason that our staff is in the best position to examine and comment on business issues in the context of the entire Company's strategy.

I look forward to speaking to you on Wednesday.



Philippe Wolgen  
Managing Director  
CLINUVEL Group

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 2021 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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