CLINUVEL

5 December 2024

Fellow shareholders,

As my first year as Chairman comes to an end I would like to reflect on some important issues. Events this year have driven the recently expanded Board to research the Company's opportunities and to seek continuation of our successes. I am delighted that Dr Pearl Grimes, a global expert in dermatology and vitiligo, Mr Matthew Pringle with accountancy, governance and finance expertise, and Mr Guy van Dievoet with finance, banking and M&A expertise, are all making significant contributions to the Board.

Share price

When CLINUVEL engaged in clinical research, charts show that it took nine years to see the share price respond to a point when SCENESSE® (afamelanotide 16mg) was nearing market. During the decade the Company had to raise money to secure clinical trial funding. We find ourselves in a renewed phase of clinical development, but now we are profitable and carry sufficient reserves. Your Directors cannot be more pleased that this company has substantially eliminated financial risks.

There is no consistent or cogent explanation for the share price decline in CLINUVEL, with the Group financially outperforming bio-pharmaceutical peers each year. High share prices seen on the day of US FDA approval in October 2019 and in September 2021 were based on weak financials and not linked to our operations or pipeline.

My fellow Directors support the belief that a share price can never define a development team. For anyone scanning the market, it is clear that there can be large variations in prices between companies developing and marketing healthcare products; prices fluctuate without an obvious link with the advancement of their pharmaceutical science.

We are realistic that the results of clinical research trials are not a certainty. We also know that reimbursement of new medicines is highly uncertain. Yet, we have a team who know how to get us to that ultimate goal whilst minimising regulatory rejections. We have the best people in place to maximise the chances of success.

The analysts following CLINUVEL understand the story and are supportive of our approach in their communications with professional investors. There is confidence that greater value is being generated than that reflected in the market. While shorting of CUV shares rose above 2% in mid-2019, reaching a peak of 9.7% in April 2020 and currently stands at 6.5% (28 November 2024), it is pleasing that the shareholding of institutions has increased from 20% five years ago to 33% in September 2024, with Australian funds over the past few years leading this trend. The work of our IR team is being reflected in the number of institutional contacts and recent funds invested.

Financial performance, assets

This Board intentionally chooses to strengthen the Company's cash for investment in research, innovation, and people, but also to acquire new products, to assist our supply chain, and initiate legal defence when needed in drug development.

It is in the shareholders' interest that the Company's financial strategy carries the Company through periods when there are lows in share price and before material clinical progress is expected. My fellow Directors stand united in that we wish to see the strongest company and not one that lives on hope like the many dependent on research projects. I want to see us reporting strong financials during the periods of clinical trials and regulatory assessment which will take several years to complete.

As can be found in our financial reports, it is clear that we have grown from a low base of A$4.8 million cash reserves in 2005 to close to A$195 million at present. Very few life science companies attract management teams with the foresight to execute a plan over 10-15 years, as we have done, fewer still can point to such a track record.

Dr Philippe Wolgen, our CEO, has been very clear on the need for strength in CLINUVEL's cash flows, and the Directors support this wholeheartedly. The Board has decided that our cash should be used for R&D and strategic initiatives, not primarily for share buybacks and special dividends. As you know, the Company issues an annual franked dividend, one of the very few biotechnology companies to do so. Cash reserves defend the Company from the need for capital raisings in an uncertain environment and a depressed share price.

The latest Jefferies Healthcare Conference in London painted a bleak but realistic picture of the sector in that 25% of the listed biotechnology companies are trading on less than a year's cash. I cannot imagine CLINUVEL going back to the pool of companies dependent on short term financing. It is highly uncertain whether we would succeed raising money if it were needed.

Exciting outlook

CLINUVEL is an agile company, which is capable of changing direction or focus when new information becomes available or the operating environment changes. Recently, we announced that we would refocus our clinical programs on vitiligo, ACTH and porphyrias. In discussion with management, we understood the need to put resources into the programs which are closest to market and with the largest commercial opportunity. Additionally, the Board looks forward to the preparation of PhotoCosmetics which will provide us more attention from a consumer focussed market, and thereby brand awareness. The PhotoCosmetic business will provide a further source of revenue in the future.

In SCENESSE® we have a proven treatment for the disabling condition, erythropoietic protoporphyria (EPP), but also a marketable drug that can assist the reversion of a depigmentation ailment (vitiligo), which leaves patients of colour in despair. As Dr Grimes and Dr Wolgen both said during the AGM, using a systemic drug in a systemic disease makes a lot of sense, with the advantage being that it does not depress the immune system, unlike the JAK inhibitors. With a focussed team, led by Dr Wolgen, I believe we can once again achieve the impossible and get the drug to the American market for vitiligo. The prospect of this possibility gives thousands of people hope, and market interest will then increase as seen in the past.

Summary

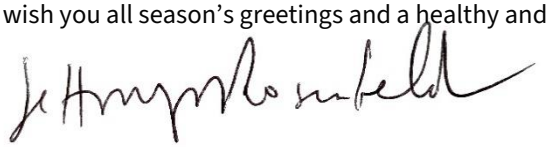
With CLINUVEL, I joined one of the greatest success stories in Australian life sciences. Many of our shareholders do not understand why the Company and its officers are being disparaged by a few shareholders who disseminate false and negative information thereby depressing their own share price. The Directors will fulfil their duty to protect all shareholders from the reprehensible comments of a few.

Clinical development calls for us all to be patient because it will take several years to bring SCENESSE® to market for vitiligo – a pathway we have mapped out in detail. The majority of shareholders want to see the Company achieving further success under the current leadership.

As I had presented during the AGM, we will further expand the Company as the clinical data reach us, with one or more acquisitions that strengthen our overall activities. The Board and management also support our financial outlay for scientific research in vitiligo, ACTH and porphyrias, and for other new opportunities. That is the best use of our resources. Between now and end of FY25 we are continuing to progress our stated strategies and working towards:

1) EMA decision on label extension (approval, rejection or deferral);
2) Expansion of the US Specialty Center network;
3) Presenting the Company at the American Academy of Dermatology (AAD) 2025 conference: the largest presence among US dermatology community;
4) Completion of recruitment of the CUV105 study and start of CUV107, pivotal studies in vitiligo;
5) Progress with the clinical programs for variegate porphyria and adolescent EPP patients; and
6) Further development of the PhotoCosmetic program.

I wish you all season's greetings and a healthy and successful year ahead.



Jeffrey Rosenfeld, Chairman

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, 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 2024 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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