



## Communiqué IV, 2020 – 22 July 2020

Dear shareholders, friends,

As a new world presents itself indicating that the virus will not easily be eliminated as we are accepting to find a modus co-existentiae, albeit we need to pause for the more than 600,000 people who have lost their lives and countless more impacted by this pandemic.

For CLINUVEL, as iterated in the May [News Communiqué III](#), we have looked at changing operations as an adaptive response. In this Communiqué IV, we think about the emerging world and some of the key learnings related to our business. A paradox emerges: we find ourselves in an era of restricted activities, widespread anxiety about future outlook, and general slowdown in pharmacological activities, but at CLINUVEL we are, - perhaps more than at previous times - confident in the value we see coming from our R&D projects and commercial activities in Europe and US.

Over the past quarter, central banks and governments have stepped up fiscal intervention to avoid a lack of liquidity in the markets. Like we saw in 2007, interest rates have fallen further with a central effort to reignite economies by disincentivising savings on deposits. As the first stimulus appeared to wane, quantitative easing became the next instrument used by the FED, ECB and Bank of Japan as principal buyers turned to long-term treasuries and corporate bonds. Equally, other paper and the provision of bank loans are making up the total stimulus packages globally. From a wider perspective, in [News Communiqué III](#) we referred to the parachute rescues to households and those losing their jobs. In Australia, the Jobseeker and Jobkeeper schemes are aiming at both employers and employees when financial support is needed. In addition, the Australian Tax Office has put in place a Cash Flow Boost for companies eligible to receive a tax-free payment. Singapore has a Jobs Support

Scheme in place contributing towards the gross monthly wages paid to local employees.

Within the European Union, a deep divide is seen between political leaders as the richer, frugal countries refuse to assist the shortfall of the southern Mediterranean countries. As this document goes to publication, heated debates are being reignited in Europe as some of the leading nations argue for a €750 billion economic recovery package to help European countries offset the damage wrought by COVID-19. The Netherlands contends vehemently that such a plan would provide countries with unprecedented grants lacking the necessary surveillance. In the US, the debate between Democrats and Republicans about further stimulus has not reached a similar climax since the House of Representatives has already conceded to more than US\$2 trillion in stimulus.

In the UK, Chancellor Sunak's award of £1,000 "furlough bonus" for businesses which retain their employees beyond January 2021 is only one of the many measures to aid companies and employees during the summer. The total spending related to COVID by the Johnson government has been north of £350 billion and with an additional £100 billion expected for the current financial year. No doubt this will eventually lead to an increase in taxes, be it income or corporate taxes, in spite of the manifesto issued by the Tories at the time of the last elections. However, VAT rates in the UK have been temporarily reduced from 20% to 5% on tourism and hospitality-related activities.

Despite the collective support, there have been massive layoffs across the world. US unemployment was cited by the Bureau of Labor Statistics to have improved over June totalling 11.1% or 17.8 million unemployed. In total 141.2 million people are currently employed in the US, be it full or part-time, translating to a ratio of 12.6% in real unemployment.

On 07 August, we will receive the July figures from the US to assess the ongoing effects of COVID on unemployment. In comparison, in Germany we see 44.6 million people employed and 1.93 million unemployed: a total unemployment rate of 4.4%. The low numbers in Germany can be attributed to an efficient establishment of the “Kurzarbeit Programme” establishing short-term employment protection facilities. At the end of Q1 this year the UK recorded 3.9% unemployment, but then again, the Bank of England has caused wide-spread uncertainty by predicting a 10% unemployment rate by end of 2020. In the Euro zone an overall 7.3% unemployment has been estimated, while claimants on social benefits are rising sharply. In Australia, the adjusted unemployment rate increased to 7.4% in June. All these numbers should cause us to stand still and reflect as they are a catalyst for structural changes to our societies for years to follow.

My longer-term concern centres on our collective efforts to keep people away from both each other and work, as it will compound the economic slowdown. In this scenario, I fear that we will enter a faster conversion from a deflationary environment to a rapidly rising inflation rate post-COVID. As most economists would have agreed earlier this year that inflation was not a conceivable idea, there are more voices daring to contemplate a surge in prices. Although many central banks within the Eurozone strive to aim for a target of 2% inflation, I am no longer sure this target is realistic. The realities of daily transactions are that prices are on the rise in specific sectors, contrary to the wide-held belief that inflation is absent. We are compelled to think about the implications for CLINUVEL and all the measures we can take to prepare to manage various scenarios ahead of time.

As stated, from past years, I view fiscal deficits, spending spikes and public debt as the main risks to the stability of our ‘modern’ economy. The current climate is once again one where widespread lending by banks is promoted to keep businesses afloat, on one hand applaudable and on the other hand unsustainable, since lack of cashflows impacts the ability to service these debts let alone paying off the principal; I foresee that many companies will be at peril. From our perspective, we have consciously

kept CLINUVEL debt-free and away from additional financial risks, despite the low interest rates on offer, particularly in times when economic uncertainty rules.

Geopolitical issues have been my focus of attention, noting the deterioration of Sino-American trade and the decline of the Sino-Australian (trade) relations. It was only a few years ago, in March 2015, that China and Australia signed a free trade agreement. The geopolitical dynamics are of high relevance to us as we try to calculate the short and mid-range permutations and to discern new opportunities.

For the softer and not unimportant aspects of this all, I see the loss of morale and widespread disillusion among young aspiring professionals and changing demand for skills as a significant challenge to both the labour market and real issues in our economies. Our interconnectedness means that effects are not only felt across continents and sectors, but also across the various subsidiaries we operate. That said, within the Group, I see it as our task to increase productivity and preserve employment throughout adverse conditions, and ask from our staff that they commit to a stricter discipline while working from home to keep their eye on meeting both annual and longer-term (three year) corporate objectives. At the same time, I regard it as our duty to accompany the next generation of management leaders and guide young professionals through unprecedented times by offering work security. In return, I do wish to see superior performance and maximum use of skills and time. Eventually, this showing of corporate loyalty will be reciprocal (if it is not already).

In terms of implant supply, prescriptive treatment provided, productivity, and technological progress, the teams have done better than we could have hoped for and we are reasonably content with the overall output as the second lockdown in Australia and other parts of the world is underway.

Our management and Board have frequently published an aligned view on business metrics, such as cost control, cash positivity and overall profitability to navigate through turbulence and economic uncertainty in markets. Although short term gain is important to us, I see it as my first duty

to focus on a longer horizon and planning how CLINUVEL will emerge from the economic crisis.

At operational level, we are united by a set list of short and midterm performance objectives which have been highlighted at the November 2019 Annual General Meeting, and – inch by inch – we are moving towards these goals as best seen from the progress the past two calendar years (refer to the Public and Investor Relations section below). The success we have achieved in our sector has come in the form of a ‘dancing procession’, two steps forward and one back, and an inventory of the calibre of professionals within the Company gives me confidence that the diverse mix of talent will deliver on new challenging objectives we set ourselves.

There is a clear direction towards where CLINUVEL will be in two years’ time and, so to speak, we are working on a construct wrapped in a temporary scaffold. As we are building the permanent layers, new technical data are coming through, CLINUVEL’s

## USA DISTRIBUTION UPDATE

The number of US centres trained and competent to administer the SCENESSE® (afamelanotide 16mg)<sup>1</sup> treatment is increasing at a satisfactory rate, while all of the prescribing physicians have proven apt at administering the drug subcutaneously (underneath the skin). Generally speaking, for dermatologists the implant administration underneath the skin above the hipbone (supra-iliac crest) is a new procedure requiring some dexterity. For those who are used to taking frequent biopsies and performing Mohs surgery (a type of skin cancer surgery), the SCENESSE® procedure proves simple and without concerns. For others with less experience, CLINUVEL’s training and videos prove to be great help.

Our teams often receive queries as to whether the implant administration requires a scalpel, incision, and sutures. The answer is negative, SCENESSE® is administered through a trocar injection under continuous manual pressure and no incision or closure of the puncture site is required. Patients receive a small band aid or dressing and typically

portfolio of melanocortin products is emerging and our aim is on record to be a diversified house to lead on melanocortins and specialty drugs. Clinical value is being established while enterprise value will follow.

In the case of melanocortins coming to the fore globally, it appears that the time is right for this technology to mature. From our early analyses, “the directional gamble” CLINUVEL took in 2005 has had considerable merit and this provides the confidence to continue developing proopiomelanocortin (POMC) molecules for future use. In November, I communicated that it is rare that ‘novel’ technology survives three decades, most frequently technology becomes obsolete within 15 years for superior science to emerge. In the case of melanocortins, the reverse is true: as time passes there is more relevance found from adjacent fields of science to justify the use of POMC technology in a broader range.

leave the clinic after 30 minutes of observation. In the US, the frequency of dosing is six implants per annum, and it appears that the majority of US patients will be requesting treatment all year around.

As part of the start of US distribution, our cross-functional team is systematically engaging with the US insurance providers allowing Prior Authorization (PA) for US erythropoietic protoporphyria (EPP) patients. We refer to the mechanism of PA in the [announcement](#) made on 23 March. The US pricing of SCENESSE® under “medical benefit” is uniformly being adopted while the system of institutional processing of the reimbursement is variable across different states whereby generally payment terms range from 60 to 120 days. Each state bound insurer typically has a contract or arrangement with the local Specialty Center (“within network”), and after agreeing PA and treatment codes, the insurer reimburses the treatment center for the SCENESSE® implant and administration procedure. After the Specialty Center has received the insurance funds, it in turn reimburses CLINUVEL for the cost of the

drug. This cycle of receiving funds is proving to take longer than is the case in the European Economic Zone.

Thus far, only one physician has been requested to resubmit for PA, while all other prescribers have received approval to administer SCENESSE® within two weeks after submission.

The number of insurers agreeing to PA has strongly increased keeping pace with the number of patients

signed up to our program seeking treatment reimbursement since April and the number of Specialty Centers spread across the US is surpassing our projections. The speed of ordering and drug administration relies on the turnaround of approvals by each insurer per state. In some of the larger Centers, the final paperwork is awaited for the inclusion of SCENESSE® in the local institutional formulary. All in all, we are executing ahead of our planning.

## **EXPANSION OF CLINUVEL**

In these times when supply chains and hospitals are slowing down or freezing the conduct of clinical trials, naturally we have been discussing how to maintain the center and progress of CLINUVEL. In these times of adversity, compact teams like CLINUVEL can demonstrate resourcefulness and creativity in solving unexpected problems. Our growth is set against the range of effects of the pandemic providing for different scenarios.

We view the expansion of the Group as essential and, as stated in past years, this will stem from both organic forms of projects, products and clinical applications, while the inorganic part will aim to vertically integrate services and functions. The past years we have seen the costs of manufacturing,

labelling, printing, packaging, medical and OTC product branding gradually increase as dictated by third parties. This comes with the large chains in pharmaceuticals, and our focus is to bring most functions under one roof to control speed of process as well as costs.

I expect more of these activities to materialise in the coming months, despite the global slowdown. I view diversification as welcome, or in street wise terminology, whatever it takes to build a solid business on several pillars. Although, CLINUVEL is at present in an optimum economic state, I do not regard it as a comfortable position and more activities are needed to grow the Group.

## **SCENESSE® VERSUS PRÉNUMBRA®**

In July, we revealed our second systemic pharmaceutical product in development. With PRÉNUMBRA® we are progressing a new formulation as part of the life-cycle management of afamelanotide. There is a clear sequence to follow, and now that the regulatory agencies accede to the safety profile of afamelanotide and accept the introduction of a novel hormone analogue, we broaden the technical dossier to additional pharmacological modes of action and applications of the molecule. In this technical endeavour it is essential to take the regulatory decision makers along. In regular dialogues and formal additions to the New Drug Application (NDA), one seeks expansion of the pharmacology modules (formally

written sections) to justify how a new molecule would affect different organs and receptors. In lay terms, translation of a medicinal product requires continuous discussion with regulatory authorities to minimise surprises and resistance.

The sequence of timing was essential, first European followed by US approval, Australian progress and – gradually – the expansion in systemic diseases which remain yet untreated. Following years of more than 20,000 data points of analyses, the time had come for progress into a non-solid dose formulation, PRÉNUMBRA®. The ultimate evidence to use new formulations comes from in vitro data generated in our laboratories, pre-clinical studies (limited to the

regulatory minimum required) and human exposure. Sometimes, one discovers new data from dosing strengths, frequency of administration, and (inevitably) from side effects of a drug, and together these data provide progressive insights summing years of work.

At CLINUVEL, we sought to expose as many different disease populations as possible to gather data on the pharmacological profile and side effects of SCENESSE®. These data are invaluable and part of CLINUVEL’s specific knowhow providing a competitive position over others who are trying to emulate our programs. Our scientific teams have gradually acquired knowledge on the optimum therapeutic windows for a liquid controlled-release injectable formulation to be used in a number of diseases which either lack an effective therapy or where existing therapies provide too many side effects.

The main clinical objective is to make afamelanotide available in three further disorders where considerable clinical gain is to be expected for patients and where, eventually, a commercial opportunity exists. For these programs we aimed to use a liquid pharmacological product while shortening the length of clinical trials, whereby two key considerations dominate:

- a. the toxicology and safety from the use of afamelanotide had been well proven after two decades of use; and
- b. existing clinical data from the SCENESSE® implant count towards the building of a regulatory dossier (marketing dossier) for PRÉNUMBRA®.

In these upcoming trials sponsored by the Company – as opposed to physicians’ initiated trials – we start with a set of realistic endpoints (clinical objectives) to demonstrate minimally important difference; that is a clinical benefit to patients which genuinely helps them in their prevention or management of the disorder. The value of a new medicinal therapy lies in its clinical relevance and acceptance by payors and insurers.

In PRÉNUMBRA®, we aim to establish a formulation which allows higher and flexible dosing in acute and

life-threatening conditions. Whereas, in PRÉNUMBRA® there is now an ability to use a liquid dose which is administered underneath the skin (subcutaneously), with the SCENESSE® implant there is no opportunity to adjust the dose when it is needed. The non-solid formulation will release the active drug afamelanotide in a specified manner tailored to treat particular diseases.

Differences in Afamelanotide Formulations		
	SCENESSE®	PRÉNUMBRA®
Key pharmaceutical ingredient	Afamelanotide	Afamelanotide
Polymers	Yes	Yes
Injectable	Yes	Yes
Route of administration	Subcutaneous	Subcutaneous
Dissolvable	Yes	Yes
Removable	Yes	No
Dosing	Fixed	Flexible
Patients	Adults	Adults
Administration	by a physician	by a physician
Self-injectable	No	No
Category	chronic, EPP	acute, life threatening
Toxicology known	Yes	Yes

We keep emphasising the maintenance of a flawless safety profile in the evolution of CLINUVEL. In other words, without the highest degree of confidence that the active substance would remain safe and tolerable over a long period of time, we could not proceed to a higher dose in treating acute disorders. Without this safety profile there is, in reality, no further investment warranted. Our latest detailed analyses in Q1 2020 was based on 15 years of continuous data on the use of afamelanotide which provides the final threshold for making the liquid formulation available. Although, one can never be totally certain about adverse reactions to a drug, as part of technological risk management we have arrived at a point where causality between drug and mild side effects is consistent and sufficiently known for regulatory authorities to acknowledge the 20 years of exposure, translated in technical terms to

more than 30,000 days of patient exposure coming from more than 10,000 dose administrations.

The patent life of new pharmaceutical products requires active management, therefore one wishes to see the start of the patent clock running as late as possible to ensure maximum patent life. Intellectual property in pharmaceuticals has been the subject of an intense debate in western parliaments since there are two camps arguing the positions of pharmaceutical enterprises monopolizing treatment options. Our views have not changed over the years on protection of our intellectual property. At the end of the day pharmaceutical companies which are

actively investing in technologies for untreated diseases deserve longer term protection as incumbents. This is even more pressing when the funding is entirely from financial markets with the aim of finding innovative solutions. Governments can assist if and when they share in the risk upfront and early on, but scrutinising expenditures post-factum is just a comfortable but unrealistic debate across reclining chairs.

In the US, we are seeking further patent extension for SCENESSE® under the Hatch-Waxman Act to compensate for the length of the FDA approval process.

## PUBLIC AND INVESTOR RELATIONS

The ongoing coronavirus pandemic also reinforces the importance of company announcements to keep stakeholders around the world informed on a timely basis on the progress of the Group.

We mentioned in News Communiqué III that CLINUVEL personnel in investor relations and public affairs were adopting available technology to communicate effectively with stakeholders, as face to face physical meetings have become too risky to personal health due to the coronavirus pandemic.

The increased activity of the Company over the last two years in the performance of its strategic initiatives is seen from the rise in the number of company announcements to the Australian Securities Exchange (ASX). From 44 announcements in the year ending June 2018, the number rose to 62 and 67 in the years ending 30 June 2019 and 2020, respectively. Since January 2020, the key announcements and updates have been:

Key Announcements to the Australian Securities Exchange – 2020, year to date		
Date	Announcement	Details
16 January	CLINUVEL Newsletter	Communique I – 2020
31 January	Appendix 4C – quarterly	Cash Receipts, December quarter 2019
03 February	Australian TGA Commences SCENESSE® Review	Dossier to be reviewed under priority registration pathway
10 February	Request for FDA Guidance Meeting SCENESSE® in Vitiligo	Request for Type C Guidance Meeting
24 February	CLINUVEL to Expand its Singapore Laboratories	Laboratory expansion with Singapore Government grant
26 February	Appendix 4D Half Year Results	Financial Report, half year to December 2019
27 February	Corporate Presentation Half Year Results	Focus on December 2019, half year results
02 March	Supply of SCENESSE® Unaffected by Coronavirus	SCENESSE® and its excipients unaffected by coronavirus
03 March	FDA Meeting Confirmed to Advance SCENESSE® in Vitiligo	Type C Guidance Meeting confirmed for 29 April
12 March	Chair Letter to Shareholders	Chair's Letter I - 2020
19 March	CLINUVEL Newsletter	Communique II – 2020
23 March	US Distribution Update	Corporate presentation on US distribution SCENESSE®
23 March	CLINUVEL to Launch SCENESSE® in USA in April	Phased US treatment rollout planned
16 April	First US Patients to be Treated with SCENESSE®	CLINUVEL's innovative drug launched in USA
23 April	CLINUVEL Starts SCENESSE® Supply into China	Agreement with Winhealth Pharma to launch pilot program
28 April	Appendix 4C – quarterly	Cash Receipts, March quarter 2020
01 May	FDA Type C Meeting for SCENESSE® in Vitiligo	Type C Guidance Meeting held with FDA
08 May	Chair Letter to Shareholders	Chair's Letter II – 2020
19 May	CLINUVEL Newsletter	Communique III – 2020
20 May	Presentation UBS Global Healthcare Conference	Corporate update presentation to virtual conference
05 June	Presentation Jefferies Global Healthcare Conference	Corporate update presentation to virtual conference
13 July	PRÉNUMBRA® - New Liquid afamelanotide Presentation	Second formulation of afamelanotide
22 July	CLINUVEL Newsletter	Communique IV – 2020

These announcements are available on the CLINUVEL website, [www.clinuvel.com](http://www.clinuvel.com). The frequency of News Communiqués and Chair's Letters (six in total, so far this year), is a distinguishing feature of CLINUVEL's communications approach, with the Managing Director and Chairman committed to regular and direct communication to stakeholders throughout the year.

CLINUVEL's shareholders are dispersed around the world. The most recent data of June on beneficial shareholdings indicate the largest geographic shareholder concentrations are in Europe, North America, and Australia, in that order. The composition of shareholders by type of shareholder is also changing due to increasing institutional interest which has driven a recent rise in North American based shareholders. The challenge to CLINUVEL is to ensure updates on its progress are provided to shareholders on a timely basis, both directly and through multiple communication channels across the globe, in line with the requirements of relevant regulators and the needs of the Group. Upon an announcement to the ASX our communications team ensures the news is distributed via the CLINUVEL email updates list, is

## SHORT SELLING

We have received questions on the continuous short positions against CUV (ASX) and CLVLY (Level I American Depositary Receipts traded over-the-counter and sponsored by the Bank of New York Mellon). As we speak, the shorts registered against CUV (ASX) make up 8.00% of total issued shares, after peaking at 9.65% in April 2020.

Management does not see it as its task to provide an explanation of share trading and short selling, however, a number of characteristics of this activity in respect of CLINUVEL have stood out. For the sake of providing factual information to supportive shareholders who have invested both in the Company and the management team, some words on this topic are warranted. We recognise how frustrating it is for some of the long-term shareholders to see the share price fluctuate and

posted to the Group website ([www.clinuvel.com](http://www.clinuvel.com)) and social media channels, and is disseminated to worldwide media outlets. In general, and perhaps less commonly seen, the Company also puts out media announcements in simpler terms for a wider audience to understand the less technical publication.

As with recent communiqués, this Communiqué IV will be translated in German and posted on the website as promptly as possible for the convenience of German, Swiss and Austrian shareholders. The feedback we receive on this as a further initiative to communicate more extensively is appreciated

The calendar of planned events is updated, noting the prevalence of our participation in virtual conferences since the onset of the coronavirus pandemic, when these events have not been cancelled.

In the coming weeks, we will be announcing the aforementioned June quarter 2020 Cash Receipts and the annual financial results for the year ending 30 June 2020 will be released by the end of August. We will subsequently complete the 2020 Annual Report and prepare for the Annual General Meeting to be held in November.

Month	Planned Events
January	JPM Healthcare Conference, San Francisco
March	Jefferies Healthcare Summit, Zurich Photodermatology Society Meeting, Denver Skin of Colour Society Symposium, Denver American Academy Dermatology Meeting, Denver – CANCELLED 23rd Asia Pacific Pharma Congress, Singapore – POSTPONED
May	UBS Global Healthcare Conference, virtual UV & Skin Cancer Prevention Conference, Mechelen, Belgium - CANCELLED Congress Italian Society of Dermatology and Venereology, Florence – CANCELLED
June	Jefferies Global Healthcare Conference, virtual American Society for Photobiology Meeting, Chicago
July	British Assoc. of Dermatologists, virtual
September	Wainwright Global Investment Conference, virtual ESPD Photodermatology Day (TBC)
November	Jefferies Healthcare Conference, London (TBC)

drop, as has occurred since October 2019. On the other hand, we note some shareholders see it as a welcome opportunity to invest in CLINUVEL based on its fundamental performance.

In the stock market, the practice of “shorting and distorting” is a well-known activity amongst brokers and market speculators, knowing that gains can be made by spreading false and negative news about a company. By persisting in this behaviour, the hope of market disruptors is that current shareholders will eventually become anxious and sell their stock, driving the price down even further. In a period whereby profit taking is expected, for instance when CLINUVEL achieved its epic success by obtaining FDA approval on 08 October 2019, it was quite easy to gamble against a company’s stock price by finding parties willing to lend out stock.

Historically, the rise in short selling of CLINUVEL shares started in April 2019, and in retrospect the newsflow on CLINUVEL has been very positive; there is absolutely no reason to currently hold that the Company will cease to perform. Management and the Board are motivated, progress is being made both commercially and in further development of new products and indications, and the financial health of the Group is excellent. There is a wide held belief in our field that this is the most driven and ambitious team one could possibly find among many Asian-Pacific life science companies.

Of course, the shock movement of economic plates exerts its influence on all businesses including CLINUVEL. While the stock markets have performed surprisingly well and many companies are gaining access to capital as it is needed, at CLINUVEL we have seen some unusual trading patterns the past months.

The Company will continue in the same mode and is fully aware of the concerns of its benign shareholders who are investing and supportive of the Company and its direction. However, the

Company distances itself from those who disseminate negative and disparaging news on us. In this environment, some market participants see the opportunity fit to distort and short stocks within the gaze of regulatory oversight. The Australian Securities and Investment Commission has oversight of market trading in Australia and we at CLINUVEL play a role to point Australian, German, and US authorities in the jurisdictions where our shares are traded in the direction of these market participants and stock bashers and all those who distort the CLINUVEL narrative openly. Our duty is to protect shareholder value, and in these uncertain times we see it even more pertinent for financial regulators to step up and trace these individuals where it is needed.

Often, the short sellers infiltrate communities of retail shareholders online and influence news flow among brokers by distributing incorrect and often false rumours on the targeted company: the distorted news spread by short sellers mostly follow common themes varying from critique on strategic direction, spending and costs, overall share value, lack of expected returns, calibre of management and preference for other exchanges. During these periods, short sellers aim to discourage existing and new shareholders to remain in or enter a stock. The practices are widespread among many exchanges and eventually financial regulators step in, track and hold the culprits accountable and take the appropriate measures.

Our task is to provide all stakeholders with periodic information (such as this bi-monthly News Communiqué), market updates, material news flow, reassurance and comfort when due, but also negative news, if and when it emerges.

Finally, on a high note, the outlook for CLINUVEL is bright despite the global coronavirus pandemic. Our Board and management team are justifiably optimistic about the Company, its commercial future and growth.



## SUMMARY

For those who have followed CLINUVEL for longer, there may be recognition in our pattern and approach to the business. Despite yesterday's successes, we are seldom content and strive to maintain status quo or progress.

In the context of the global economic changes taking place, we project and plan all activities to further execute and build value. The challenges are enormous, both from the perspective of taking technology to a mature and commercial level but also in anticipating risks. CLINUVEL's outlook is good, but it all hinges on our initiation, discipline, and hunger to execute. The platform to work from is as strong as we had desired in 2005. But past performance means very little in my view, we had a great year but there is very little reason to celebrate in today's environment.

In the September News Communiqué V, we will speak more about the DNA program, vitiligo and the new indications awaiting Ethics and Regulatory approvals. Although we are frustrated by the current

lengthy review by the various authorities, we are in full preparation to start when the paperwork is signed off.

My team has reported encouraging support of long-term owners for CLINUVEL's performance, and on this occasion, I express my appreciation to you all.

Philippe Wolgen

<sup>1</sup>SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at [www.clinuvel.com](http://www.clinuvel.com).

## ASX: CUV

Share price

(ASX: CUV 21 July 2017 – 21 July 2020)

Shares on issue	49,410,338
Fully diluted *	49,548,671
Market cap (21 July 2020)	A\$1.213bn



\* excludes the shareholder approval of 1,513,750 performance rights to the CEO at the 2019 AGM, to be issued within 12 months of the date of approval.

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 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); our ability to achieve expected safety and efficacy results 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, 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® 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 based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure 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 2019 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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