CLINUVEL
Communiqué VI

23 December 2022

Dear Shareholders, Friends,

I take the opportunity to wish you a welcome break during the holidays, a time to reflect, to recharge, to evaluate and plan. This best captures how we spend the end of the calendar year, clearing our minds for a full cycle of new challenges.

Technical progress and integration of newly joined personnel were the central themes in 2022, and it is my wish to see 2023 turn into a plentiful year of activities, results and further growth. By staying the course of solving medical and healthcare problems, value is being added.

My personal objective is to see a house no longer on scaffolds by June 2025, so to speak a vertically integrated group able to execute all its functions, including scaled-up manufacturing. Simply put, we are in a race against the clock to fulfil these ambitions and ensure executive managers can navigate the Company to its next level. At the close of the year, executive management counts 9 professionals who have resided a median 15 years in the Company, an unusual longevity in pharmaceuticals; it is fair to say that ample talent is coming through, the same goes for the next layer of senior management.

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In January 2023, the first results on XP patients treated with afamelanotide will reach us as validation of the data is being completed by a global expert centre and a publication is being prepared. In synchronicity, we expect first readouts of the DNA-repair program to be available early in the new year. The significance of Clinuvel's XP-DNA-repair program is potentially ground-breaking, as generally commented by photobiologists and dermatologists. The use of melanocortins (smaller hormones) in reducing photodamage and assisting the repair of DNA-damaged skin, is not only novel, but positive results would indicate an innovative pathway to reduce risk of photo- or solar damage. Since mutations caused by solar radiation are the prerequisite to progress UV-exposed tissue to skin cancers, reducing photodamage is addressing a global problem at its roots. From a top-down view, Clinuvel's XP-program then serves as a proof of concept for wider populations in search of a preventative option. We believe that the medical option reducing risk of solar damage will open new opportunities, which need to be well communicated at scale to both medical and specialized consumer communities. Innovative technology needs widespread communication, otherwise potential beneficiaries will not be reached, and the research efforts made will be in vain.

Broader communication aimed to reach millions of people at risk of skin cancer requires an approach not akin to that usually found in pharmaceuticals, however in our mind it is absolutely indelible for any kind of success. What would success look like then?

Predominantly, the objective is to gain more visibility for both CLINUVEL's cause and to its products. Therefore, in anticipation of progress in the pharmaceutical DNA-Repair program we allocated resources to establish a Communications, Branding and Marketing team, as originally laid out in our 2021 plans. The clear objective is to establish online aggregated audiences affected by a risk of photodamage and skin cancer, raising awareness and establishing a long-term dialogue while paying attention to a medical problem, which has taken on epidemic proportions.

In 2022, we intensified a communications strategy along 3 pillars, the conventional investor relation programs engaging banks, brokers and funds on an individual basis, following publication of financial reports and results, while participating in 6 life science conferences. The second consisted of three targeted 'soirées' in major cities bringing together analysts, banks and their clients, brokers and family offices, and shareholders. The third one encapsulates the use of social media channels to reach targeted audiences, mediated by people with significant online profile and integral personalities having an aggregate of millions of followers. By the end of 2023, we aim to engage 60 'ambassadors' representing 3 'Highest Risk' groups, and 10 known personalities in the public eye. These three parts of the program will need to ensure that more visibility is given to the Company's causes. We see a worldwide communication program in pharmaceuticals and dermato-cosmetics as obligatory. We remain conscious that this approach is not characteristic in our sector.

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In 2023, I expect to see the completion of ACTH manufacturing. This will then need to be translated to a drug master file for registration in major markets. The commercial use of ACTH will cement our standing as a melanocortin house.

The year will also see first results of parvys-, and phimelanotide as novel molecules to be used for topical applications, small molecules related to afamelanotide.

To stay with clinical research, we expect the start of the CUV803 clinical trial, a follow up trial in twelve stroke patients. The CUV801 clinical trial gave sufficient information to justify continuation of this challenging program, since the new clinical trial protocol dictates the use of afamelanotide within hours of suffering an ischemic stroke (dislodged arterial clot). Hence, here we are managing patients at risk of worsening, a high-risk population requiring fast intervention.

Finally, the coming year will be marked by vitiligo, first results of the CUV104 clinical trial, and then preparatory work to start a larger CUV105 clinical trial in vitiligo. As the vitiligo market is being defined and rewritten, it becomes clear that a drug which is not affecting the immune system remains in much need. The alleged use of JAK-inhibitors in vitiligo attracts much controversy, since immune suppression long term does not bode well for any patient who has lost skin's pigmentation.

In 2023, we will see our first steps in distributing the first OTC product line, CYACÊLLE®, a polychromatic screen protecting against the broad spectrum of light. The OTC lines are complementary to the pharmaceutical development program, and a pharmaceutical entity diversifying into specialized consumer markets remains rare. However, there is a good rationale why we embark on this venture.

One of the greatest challenges to the year ahead remains the full integration of new personnel among our companies. Co-ordination is required across time zones to safeguard our performance and growth. This is far from a new observation, yet the changing expectations of working predominantly from home - as provoked by the pandemic - is a reason for heightened attention, and a phenomenon to reflect on the coming weeks.

We are buoyant about the coming year, of growing operational complexities, of more responsibilities assigned to the divisions and senior members of staff, and all this requires careful planning and clear targets.

To memorize the notion of 'situational awareness' often spoken about when discussing CLINUVEL, we keep a close eye on the development in Australian and US equity markets. Is the sector as a whole convalescing? And if so, which sub-segments are leading? Is the IPO market opening up? How is investor appetite shoring up to back these ventures? Indices we monitor to understand where we are in the cycle and which markets to address?

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Pleasingly, we saw some Australian institutions join the register during November and December, very much following the recent Sydney Soirée, the Wilsons Advisory Rapid Insights Conference and focused one-on-one meetings. The additions to CLINUVEL's register is often a result of years of diligence, frequent lengthy discussions between management and the prospective investors on the back of continuous growth of earnings and progress of the pipeline. We positively view investors who allocate during downturns, since they seem to focus on macro-economic indices and grasp the cyclical nature of life sciences. On the other hand, full acknowledgment is at place for CLINUVEL's 39% longer-term shareholders, those who consciously decided to be there for the long ride. As started last year, in 2023 we will continue our efforts to reach all smaller shareholders directly, although often communication is made harder by their nominees managing wider portfolios.

In looking back, I must thank our staff for the work put in to advance the Group, the sage Board of Directors who oversaw all the challenges management faced, and all the patient shareholders who have gone through the vagaries of the markets as the life science sector saw its value decline.

With appreciation

Philippe Wolgen

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 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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