



Coming full circle

Investor Briefing
Frankfurt 31 May 2023

Strategic Update VI

Good evening, it is a somewhat historical place here, since the restructuring of CLINUVEL actually started in Frankfurt in December 2005, 17 and a half years ago.

At the time, and at this venue, we held a meeting with some of the most prominent German families and wealth managers.

A series of meetings led, in April 2006, to a capital raise to secure the clinical programs designed, and with a clear vision of what was needed to build a viable business.

Today, we are back without having the need to raise money, but instead to discuss CLINUVEL's journey ahead over a dinner.

Our expectation is for you to follow the Company the next 24 months. I think that is a fair exchange here tonight.

After hearing from Mrs Arrom Bibiloni, CLINUVEL's Global Brand and Creative Director, we trust you will have understood the magnitude of our undertaking, the WHY, the HOW, and then it is my turn to tell you HOW MUCH and BY WHEN?



Forward-looking statement

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.

You see here the mandatory Safe Harbour statement to forewarn you against any speculative comments you may hear, since prospective events may differ from the actual and prospective Company's plans.



Photomedicine & photocosmetics

- 1980 "afamelanotide for sunless tanning"
- 1993 afamelanotide 1st in man
- 2005 restructuring to CLINUVEL
- 2014/19 EMA, FDA approval SCENESSE®
- 2022 6th consecutive year of profitability
- 2023/25 expansion use SCENESSE®, PRÉNUMBRA®, NEURACTHEL®

PHOTOMEDICINE

1. safety/stability/efficacy
2. anti-oxidative
3. DNA repair
4. melanogenic (tanning)

Risk-free-tanning products - mass demand

- ❖ ± \$50m counterfeit
- ❖ no off-label permitted
- ❖ expect CUV to lead

PHOTOCOSMETICS 2023/25

Transdermal, leave-on product lines

1. CYACÊLLE polychromatic range
2. DNA repair
3. melanogenic (risk-free tanning products)

3

In setting out to consider investing in any of our development projects, ventures and businesses, we ask ourselves two sets of questions:

1. is the plan economically viable long-term? And the sub question, are evidence or indications leading to accept that the investments justify progression to market?
2. is there substantial demand, and if so, what is the size of the total addressable market?

As iterated for many years, management of foreseeable risks and anticipating potential risks are part of CLINUVEL's periodic considerations.

On the left hand of the slide, the context of the Company, since its history matters in its daily decision making.

In the middle the expertise which CLINUVEL built over decades: a main domain of photomedicine, whereby melanocortins have proven to exhibit four distinct properties.

On the right hand side, the mass demand which has emerged from the first day of 1979, when the invention of melanocortins for human use was made.

The demand for risk-free tanning products or, in particular, untested chemicals has been shown by the willingness of masses purchasing online rogue and untested self-injectable, illegal chemicals to activate tanning.

Demand has been further shown over the years from frequent requests by dermatologists, nurses, and other medical practitioners, while the Company's has maintained a consistent position not to allow off-label use of SCENESSE®.

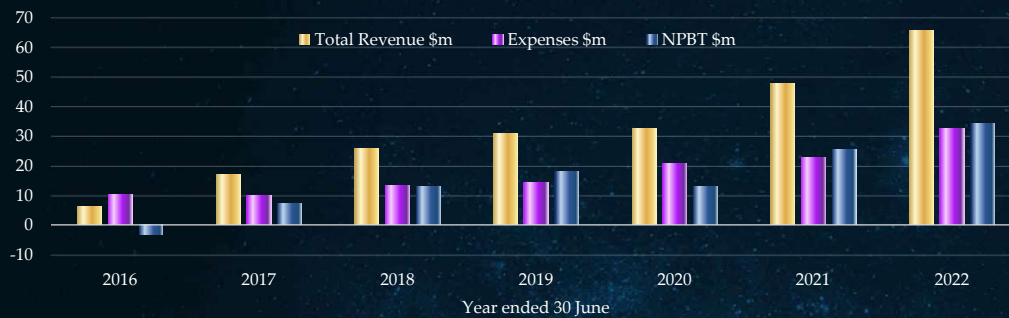
All factors, analyses and knowhow has led to the notion of Targeted Technology Translation, making melanocortins available for large parts of the population through photocosmetic products. In particular, those populations who are prone to incur solar damage and photoageing are addressed by CLINUVEL's products.

We made research attempts to develop and commercialise leave-on skin care products containing melanocortin peptides, and this approach is novel to the dermatocosmetic market.

Given CLINUVEL's work and focus, the authority to speak about long-term use, safety, and benefits of these photocosmetic products, clearly resides with a team who have dedicated their work to applicability, use and unaddressed need among people of highest solar risk.

The combination of photomedicine and photocosmetics in one company is logical and unique.

Financial performance 2005 – 2023



FYE 23 results:
4th week August

Discipline 2005 – 2023

| | |
|-----------------|--------------------------------------|
| Financing | debt-free |
| Equity | min dilution < 300% |
| Liquidity ratio | retaining min. cash: 2 years of OPEX |
| Profitability | CAGR > 30% (7 yrs) |
| Redistribution | 5 years of dividends |
| ROCE | 27% (6 yrs) |

| Institutions | Jun 2022 | Dec 2022 | Mar 2023 |
|--------------|----------|----------|----------|
| Moelis | \$23.14 | \$17.56 | \$23.21 |
| Wilsons | \$30.50 | \$23.53 | \$30.07 |
| Jefferies | \$32.00 | \$36.90 | \$37.30 |

In answering some recurring questions, we discuss why CLINUVEL has remained profitable among the majority of biopharmaceutical companies; we review its approach and current business model. The past performance is of relevance to discuss CLINUVEL's future operations, and expenses foreseen.

CLINUVEL had chosen a particular and differentiated business model, with the aim of turning the Company profitable at its earliest opportunity. Simultaneously, a number of metrics were kept in sight, in respecting its share capital by ensuring minimal dilution for its shareholders. With less than 300% dilution over 17 years, CLINUVEL outperformed most of its peers.

After the Company reached first profitability, it targeted retaining a cash equivalent of a minimum of two years of operating expenditures.

At a growth rate of 30% over five years, the Company has been able to increase its R&D spending, diversify its activities and remain debt free, while - since 2016 - it stayed away from additional equity funding.

As a differentiating factor, for the past five years the Company has been able to issue dividends to its shareholders.

At a return on capital employed, CLINUVEL has performed well. Its valuation has remained reasonably stable the past two years.

A number of independent sell-side analysts have recommended a target price well above its current share price (May 2023); unfortunately, the Company is prohibited from sharing the analyst reports with its shareholders, since the three banks reserve their rights to distribute these reports to their clients only.

Out of fairness to all of CLINUVEL's shareholders and ensuring information reaches all, we take the initiative to show the target prices of the analysts in the table.

The graph shows the point of first profitability within one year of go-to-market strategy for SCENESSE®. The Company's decision to build in-house distribution, work directly with hospitals, care providers and insurers, has been a defining moment and a calculated risk taken. This decision led to the Company posting its maiden profit FYE 2017.

CLINUVEL's case is illustrated as expenses were monitored, contained, and managed by bringing and retaining in-house talent, allowing for many of the functions to be fulfilled.

The FYE results 2023 are expected during the fourth week of August.



Financing

2021-2025 A\$175M
 31 Dec 2022 \$72M expensed (41%)
 31 Dec 2022 cash reserves A\$140.7M



I Pharmaceuticals

| | | |
|-------------|--------------------------------------|------------------|
| SCENESSE® | - expanded use in | XP, vitiligo, VP |
| PRÉNUMBRA® | - 2 nd gen. afamelanotide | AIS |
| NEURACTHEL® | - ACTH | CNS disorders |

II Photocosmetics

| | | |
|------------------------------|-------------------------|---|
| CYACÊLLE | - polychromatic screens | highest risk populations |
| 2 nd product line | - DNA skin repair | |
| 3 rd product line | - risk-free tanning | fair, freckled, blond/red hair, blue eyes |

III Manufacturing

- next generation controlled-release
- In-house facilities - parenteral formulations
- transdermal formulations

In 2021, CLINUVEL disclosed its five-year projection of A\$175M to be expensed until 30 June 2025 (FYE).

As a yardstick of how the Company is tracking against its projections, at the mid-way point of the timeline, 41% or A\$72M of expenses were incurred. As of 31 December 2022, the Company had built a cash position of A\$140.7M, well ahead of its own projections against R&D and running costs.

The Company's principal focus is on building out its pharmaceutical activities, while technology and knowhow are further used for the establishment of specialised consumer health products, photocosmetics: This initiative will lead to three product lines (eight products) to be marketed, distributed through specialised channels. The first pilot launch of CYACÊLLE took place on 1 March. The commercial launch of the CYACÊLLE line will follow on a global scale.

A third initiative is the establishment of a manufacturing division, aiming for CLINUVEL to commercially produce its next generation formulations.



Clinical programs afamelanotide

Erythropoietic Protoporphyrin (EPP)

Genetic disorder
 Absolute light intolerance, phototoxicity
 Expansion SCENESSE® – adolescents 12–17 yrs



Variegate Porphyria (VP)

Blister, phototoxicity after UV-HEV exposure
 Ph II/III : n=12 patients (CUV040) - ongoing
 Pep¹ : reduction phototoxicity, blister formation



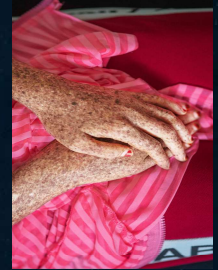
Vitiligo (GV)

Gradual loss of skin pigmentation
 Patient loss of identity (QoL)
 Changed regulatory views
 Ph II/III : n=150-200 patients (CUV105) - in final preparation
 Pep¹ : TVAS50
 Sec¹ : 1st time to repigmentation F-VASI25, QoL



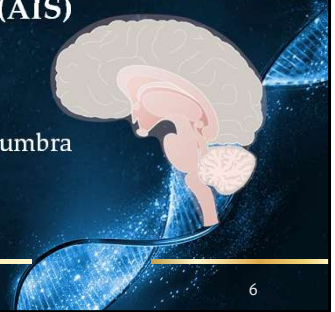
Xeroderma Pigmentosum (XP)

Genetic disorder
 Highest risk of photodamage, Sk/Can
 4 trials : 25 patients - ongoing
 Healthy vol. control
 Pep¹ : reduction photoproducts
 Sec¹ : assisted DNA repair



Arterial Ischaemic Stroke (AIS)

Unmet need, > branch A2-M2-PS
 Ph II : n=12 (CUV803) - ongoing
 Pep¹ : safety
 Sec¹ : increased CBF, decrease penumbra



*EPP image courtesy of the Koerner family; vitiligo image courtesy of the investigators in CUV102 study
¹Pep = primary endpoint, Sec = secondary endpoint/s

CLINUVEL's current clinical program is summarised in this illustration. For a more detailed explanation and further information, the reader is referred to the **Strategic Updates IV (13 May 2022), Strategic Updates V (19 September 2022), and Sydney Investors' meeting (14 October 2022).**

Current studies under way are in Variegate Porphyria (CUV040), Xeroderma Pigmentosum (CUV151, 152, 156), and Arterial Ischaemic Stroke (CUV803).
 First read outs are expected later this year.



Clinical pipeline

Melanocortins: 8 programs – 4 photomedicine + 4 central nervous system
 4 Rx products – TAM > \$2B

| Products | Indication | Age group | Phase I | Phase II | Phase III | Commercial |
|---------------------------------|------------------|-----------------------------|------------------|--------------------|---------------------------------------|------------|
| SCENESSE® | EPP ¹ | adults | | | | EEA-US |
| 1 SCENESSE® | EPP ¹ | adolescents | | | regulatory interaction, update '23 | |
| 2 SCENESSE® | VP ¹ | adults | | | read out '24 (CUV040) | |
| 3 SCENESSE® | XP ¹ | >15 yrs | | | read out '23/'24 (CUV156-151-152-154) | |
| 4 SCENESSE® | vitiligo | adults IV-V-VI ² | | | final preparation (CUV105, n=150) | |
| 5 PRÉNUMBRA® INST ³ | AIS ¹ | adults ⁴ | | read out ('23-'24) | | |
| 6 NEURACTHEL® INST ³ | MS ¹ | adults | in manufacturing | | bioequivalence | update '23 |
| 7 NEURACTHEL® MR ³ | CNS ¹ | adults | in manufacturing | update '24 | | |
| 8 NEURACTHEL® MR ³ | IS ¹ | >2 yrs | in manufacturing | update '24 | | |

The attention to medical safety over decades has been CLINUVEL's premise to expand.

¹ EPP = erythropoietic protoporphyria; VP = variegate porphyria; XP = xeroderma pigmentosum; AIS = arterial ischemic stroke; MS = multiple sclerosis; CNS = central nervous system disorders; IS = infantile spasms
² Fitzpatrick skin type IV-V-VI
³ instant release, modified-release
⁴ moderate to severe

The pipeline of CLINUVEL is explained as consisting of eight programs: four in photomedicine, four in CNS disorders. The total addressable market of all indications is estimated at more than A\$2B worldwide. The table shows the stages of CLINUVEL's programs, and expected news flow.

In identifying disorders for its programs, the Company is looking at unmet medical need, whether there are existing alternative therapies, its patient populations, and greater societal relevance.



Transformational program



1. Strategic marketing
2. Branding, partnership management
3. Events management
4. "Creative" management
5. A/V production

The decision to brand the Company and its consumer health products could only have been taken after deliberations on its impact on the pharmaceutical division, the core business. Unlike many bio-pharmaceutical companies, CLINUVEL will spend a percentage of its net profits on actively promoting the Company's values, causes, and photocosmetics.

The program aims to raise worldwide awareness in a staggered approach, by addressing specific channels, populations at risk and those at highest risk of solar damage. Distribution of the commercial products follows these channels, both directly and indirectly by appointed partners.

In total nine programs and channels have been identified, as illustrated. Novel is the engagement with ambassadors (CUVAs), intriguing personalities with specific following and exposure (CUVIPs), social media, and live events globally. Media exposure will remain part of the strategy, since authentic journalism will highlight the credibility and longevity of the Company.

Essential in the decision to globally market and brand the Company is the establishment of an in-house communications-branding-marketing team. The key functions and skills are illustrated.

It is fully recognised that this approach does not fit a conventional bio-pharmaceutical SME, however the prospect to build a global group cannot be achieved without global exposure. This stage a most exciting one in the history of CLINUVEL, one that has been well prepared and calculated.

Conclusion

“pre-emption – resourceful – longitudinal”

1. Financial strength

– discipline enables CAGR 30%, cash reserves to execute

2. Core pharmaceutical business

– transformation to 8 programs, 4 Rx products CNS, 4 photomedicine

3. Photocosmetics complementing pharma

– 3 product lines: 1. polychromatic,
2. DNA repair,
3. risk-free tanning

4. Global branding & marketing programs

– increasing awareness, visibility



An US analyst recently asked our IR team: “Why is CLINUVEL emphasizing profitability in a sector not known to reach that point, why is its vision so different than its peers?”

Vision is too often used in publications and daily language, and alludes to a large picture, a dream-like appearance of a goal. Rather, at CLINUVEL we define the long-term plan turning into realistic goals:

“identify demand, fulfil purpose, repetitively adjust a master plan & test its economic viability, differentiate, establish tenacity across the team, and execute longitudinally”

It may well be that CLINUVEL’s business plan is unlike many other bio-pharmaceuticals, however its consistent approach has greatly been appreciated by regulatory authorities, and payors, decision makers who ultimately matter.

The financial discipline observed, the costs carefully managed throughout the years, gives the Company an ability to execute several clinical programs without the periodic need for external funding.

The change from total focus on one drug for one particular disease (EPP) has gradually changed to a diversified approach building a wider portfolio. This change has been made possible through CLINUVEL’s financial management, and retention of many professionals. The core business is pharmaceuticals, and this longer-term approach enables CLINUVEL’s management to make its technology and knowhow available for photocosmetic products serving wider populations. A targeted translational strategy is quite unique in pharmaceuticals, where a hybrid of pharmaceuticals and consumer health products are not often established.

Demand for melanocortins in transdermal formulations and products has always dominated CLINUVEL’s discussions on the future of the Company, this is not surprising given its history.

The focus of decades on safety has allowed for development of melanocortin peptides to be used as daily products in the new skin care category, photocosmetics. The Company is developing and releasing a number of product lines, accompanied by a global marketing program. The efforts aim to provide more visibility to the cause and mission of the Company to reduce photodamage and thereby the incidence of solar risks leading to skin cancers.

The domains of photomedicine and photocosmetics are extensions of each other. Given the large demand for solar care, DNA repair, and self-tanning products, it is logical that CLINUVEL introduces a new skin care category, based on its family of melanocortins, expertise, and understanding of the need for photoprotection, photoprevention, and photorepair.

Both the progress of its pharmaceutical business and its new foray into cosmetics will provide the Company wider attention worldwide.

The CLINUVEL model forces us to understand the contradictions over time: focus allowed divergence.

CLINUVEL’s team directed its initial efforts and resources to one molecule, the afamelanotide melanocortin. From that point onwards, it started to learn about other melanocortins, delivery methods and diverged its attention two decades later to translate its accumulated knowledge and science to other molecules of the same family. Then it proceeded to treat new unaddressed disorders with new formulations, and eventually formulating the peptides in photocosmetics.



Thank you for your interest...

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>

www.clinuvel.com

Level 11, 535 Bourke Street

Melbourne - Victoria, Australia, 3000

T +61 3 9660 4900 F +61 3 9660 4909

Thank you for your continued interest and please follow us the next 24 months, we will be in Sydney, Melbourne, Singapore, London and Monaco.