Company Announcement

CLINUVEL

ASX: CUV
Nasdaq International Designation: CLVLY
XETRA-DAX: UR9

MANAGING DIRECTOR'S PRESENTATION TO CLINUVEL ANNUAL GENERAL MEETING

Melbourne, Australia, 11 November 2020

The following is a transcript of the Managing Director's presentation to the Company's Annual General Meeting, held virtually at 18.00 on Wednesday, 11 November 2020. Slides accompanying this transcript are appended.

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1. ANNUAL GENERAL MEETING – FIRST VIRTUAL MEETING
Good evening to all of you in Australia, good morning to all European and US shareholders, and I welcome quite a number of new members on the line.

Today we will discuss the growth trajectory of CLINUVEL, we certainly look back at a strong fiscal year, a team performing under the most demanding global conditions, and we will spend some time reviewing the Strategic Update announced to the Australian Securities Exchange (ASX) on 29 October. After my presentation, Board members and I will respond to some thematic questions received.

It is a privilege to salute the representatives of the patient organisations present online, and also greet members of the press, from the Australian Shareholder Association - Mr Claudio Esposito, to sector analysts such as Ms Sarah Mann of Moelis Asset Management.

Our illustrations and the transcript of our discussions are posted simultaneously to the ASX - such that absent shareholders are able to gain equal information.

During the limited time we have together, we will speak about the *why and how* we intend to execute the next stage of CLINUVEL's strategy, which is captured as Targeted Technology Translation, the expansion of our technologies horizontally in the medical domain and vertically into the mass dermocosmetic market.

We have simplified the strategic direction in the simplest form and with the least amount of scientific data, such that all will gain insight to the strategic direction the Company is following.

2. LEGAL NOTICE
The statements being made today during this discussion are not aimed to speculate in, do not constitute an offer to sell, or solicitation of an offer to buy, any securities of CLINUVEL.

3. CLINUVEL GROUP
The CLINUVEL Group has grown to eight subsidiaries organised within three Divisions. The CUV teams operate cross-functionally over five time zones. The cohesion of our team is remarkable high as we monitor the interactions, whereby output is quantified weekly.

The Pharmaceutical Division is centred around CLINUVEL's core business pharmaceutical development, focussed on taking drugs to market for patient populations with unmet medical need. The business model is geared towards seeking medical solutions for disorders for which there is currently no satisfactory therapy.

The Healthcare Solutions Division concentrates on non-prescription products derived from knowhow and active ingredients used in the Pharmaceutical Division.

The newly organised Division of Communications, Branding & Marketing is established to prepare communication to wider differentiated audiences, to relay the unique product attributes and benefits.

Last, underneath the divisional structure, the Research, Development & Innovation Centre in Singapore performs fundamental research on molecular science, biology, and follow-on formulations, while it actively engages with all three divisions.

The illustration is really meant to show the immutable connection between all three Divisions, and through that organisation we give our professionals the broadest possible exposure to other disciplines, a distinctive feature of working for the CLINUVEL Group.

4. PHARMACEUTICALS CORE BUSINESS

CLINUVEL is working towards a portfolio of five prescription products for a minimum of four patient populations.

We have opted first to focus on expanding the Company from within and utilise our nucleus knowledge of pharmacology of melanocortins. The Company decided that future earnings and value would come from our own R&D suite. And when it comes to CLINUVEL searching outside assets, the criterium is that a purchase needs to be short-to-mid-term accretive to value per share.

Therefore, the right way to think about our business is that the value of the Company will always start at the centre of our pharmaceutical franchise.

I can share with you that the market will learn from quite a number of new activities and operations the next 12 months, since we are deploying capital at hand.

5. PIPELINE PHARMACEUTICAL PROGRAM 2021

The chart demonstrates five targeted indications, although we interpret variegate porphyria (VP) and EPP as belonging to the same category of diseases.

The DNA Repair Program will get under way in Q1 2021, and the readouts from the XP study (CUV150, a Phase II study), and in healthy subjects (CUV151 study) are expected in 2021. In parallel we look forward to a fast outcome from the stroke study, these are all conditional to COVID restrictions being lifted.

Vitiligo progression depends first on the agreement on a final protocol with the US Food and Drug Administration (FDA), since there is consensus among our scientific team and global vitiligo experts to make the drug available to patients with darker skin complexions with 40% or greater loss of pigmentation. It is those darker skin types which exhibit most prominently the contrast between pigmented and depigmented skin.

The last and sixth indication has been prepared for considerable time and depending on the regulatory meeting in December with European Medicines Agency (EMA), we will know whether we are granted the green light to proceed in a chronic severe condition and for which there is absolutely no effective treatment.

That for now concludes our pipeline of clinical activities for 2021.

6. HEALTHCARE SOLUTIONS

We now switch to the second Division of the Group, the Healthcare Solutions. The obvious first questions to be raised:

- is there a rationale to establish this Division and how does this affect CLINUVEL's core business?

As explained in the Strategic Update on 29 October, we had known since 2006 that in afamelanotide and melanocortins we could hold a suite of potent molecules which positively affected damage of the skin caused by UV radiation. These molecules had shown to be capable of decreasing so-called *photoproducts* – chemical bonds formed within single strands of DNA following UV exposure, known as cyclobutane pyrimidine dimers.

However, the pathway to the DNA-repair Program was far from linear, and we could not start without proving to the regulatory authorities that afamelanotide, or SCENESSE® (afamelanotide 16mg)[1] in its current dosage form, was shown safe in a larger set of patients who had been exposed to the drug for sufficient years under commercial conditions.

As scientific data accumulated, and analyses became repetitive and predictable, authorities gained confidence in the consistent pharmacology, and the SAFETY of afamelanotide was affirmed.

As time lapsed, our pathway to a human DNA program opened up and allowed for several melanocortin formulations to be developed for both prescription products for medical use as well as non-prescription dermocosmetic products for wider markets.

Along this line, for us to address a global market of users at high risk of photo-induced DNA skin damage, CLINUVEL required a new infrastructure of a specialised scientific team, regulatory professionals and personnel focussing on future distribution, hence the creation of the Division - Healthcare Solutions.

Essential is to realise that the core business, pharmaceuticals, provides CLINUVEL with a competitive advantage in expanding into dermocosmetics, since scientific validation of the technology originates from the pharmaceutical R&D expertise built over decades.

Both the output and synergy between Pharmaceutical and Healthcare Solutions naturally calls for greater efforts to provide global visibility to CLINUVEL's unique cause.

7. HEALTHCARE SOLUTIONS

The diagram shows the three product lines and line extensions in development, whereby due to a change in manufacturing we encountered last year, we will be releasing our first product line of non-prescription leave-on products in 2021.

From this Division we will see output of topical products where market dominance is throughout possible in a segment of dermocosmetics which is at present underdeveloped. Many products promise regeneration and rejuvenation of skin, however seldom based on a new class of molecules tested in human pathology during decades.

On the other hand, CLINUVEL has a different focus and will be introducing leave-on products, topical formulations, providing DNA-restoration for those at high risk of long-term solar radiation.

Naturally, one may then ask - would CLINUVEL be able to play a role of significance at all in such a competitive market dominated by the larger cosmetic players, such as COTY, Estee Lauder, L'Oreal, Procter & Gamble, Shisheido and Unilever making up 80% of the global cosmetic market? At face value, one could question whether venturing into a retail segment would generate additional enterprise value, however one is not eyeing disruption to an existing market, rather one is introducing technology which originates from a long executed pharmaceutical program. This specific origin, scientific focus and pharmacology itself sets CLINUVEL apart from any of these six cosmetic dominators.

That then begs the question, *how* is CLINUVEL going to compete, assuming the technology is *that* promising?

The answer takes us to the most important component – and perhaps a determinant of commercial success in this segment.

8. COMMUNICATIONS, BRANDING, MARKETING

CLINUVEL's Board had been seeking the relationship between shareholder value and visibility of a pharmaceutical program. By and large one can state that orphan drug markets excite but do not provide wider visibility due to the relative size of the disease entity. However, each patient, each state of pathology matters to us as we will all discover individually as we age, therefore from a medical viewpoint CLINUVEL reached maximum visibility among targeted patient populations.

However, at this next stage of growth, we seek not only to serve larger markets, but also to communicate high relevance of our causes and objectives to wider audiences.

The DNA Repair Program answers all quests for relevance, visibility, and market size, since photodamage and the relationship between solar radiation, DNA damage and risk of skin cancer affects almost all fair-skinned individuals on the planet.

This program compelled us to establish a Communications, Branding and Marketing (CBM) team.

9. CONNECTING TO AUDIENCES

In changing demographics, we see a partition between those who stay behind and those who seek new platforms, new content and relevance of offerings.

As media consumption habits evolve constantly, CLINUVEL needed to embrace the opportunity to emerge as a patient and consumer focussed company.

With that focus, connecting to diffused audiences worldwide requires CLINUVEL to tailor messages and content across platforms. A professional team – agency style – is asked to grow audiences before it introduces its current and relevant products. A next step further in arriving at a continuous dialogue with viewers and users is by concentrating on data driven engagement.

Stepping away from the traditional pharmaceutical approach, CLINUVEL chose to be progressive, addressing and connecting to the current and next generation of users.

10. STRATEGY

The strategy CLINUVEL followed has come together based on mandatory SAFETY of the technology. The approach to deploy our first molecule afamelanotide has led to market access in three continents, and longevity to value generation for patients and shareholders.

Our technology of melanocortins lends itself uniquely for a dual strategy: prescription and non-prescription markets.

The most exquisite yet unexpected part of the pharmaceutical legacy is that the very assurance the Company had to give to regulators on safety of afamelanotide - spanning decades of reviews of data - has now become one of CLINUVEL's unique propositions and the prime asset allowing us only now to commoditise derivative products downstream for wider retail markets.

Therefore taking a distant view and looking at CLINUVEL, I would argue that it is in a unique position which very few companies would be able to emulate, since its technology originates from a highly regulated environment translating its products to non-prescription retail markets with an emphasis on SAFETY and genuine care for human biology.

As the tide is turning, and the demand for authentic dermocosmetics will follow in due time, all involved at and around CLINUVEL believe it will be well positioned in an underdeveloped market segment.

11. TECHNOLOGY TRANSLATION DNA REPAIR

In working from the attributes of melanocortins as chemical entities, it is easy to follow the product strategy.

Targeted Technology Translation becomes synonymous with the use of specific knowledge from *prescription* to *non-prescription products* (pharmaceumables).

The first product line to be released is a product line offering polychromatic protection for extreme conditions and targeting populations at risk of solar and high energy visible (HEV) light insult.

The second product line aims to provide DNA-protection and repair in individuals at risk of solar damage and specific high-risk populations. Awareness of the healthcare risk is relatively high among these users, and the communications strategy will need to result in engaging the broadest interested audience.

12. COMMERCIAL UPDATE

The most important parameter for gauging treatment efficacy - or in other words whether a new medicinal therapy truly works and is requested by patients themselves - has remained the treatment adherence rate of patients. In the case of SCENESSE®, the retention rate is unusually high and commented as very rare in pharmaceuticals treating non-life threatening conditions: the percentage varies now between 94% to 97% in the European Economic Area.

Without incentivising or inducing physicians to prescribe a drug, the best measure of whether a treatment is effective lies in the annual analysis of these data per latitude per country.

When we think about the fragile relationship between drug companies and European state and private insurers, we have frequently spoken in the past about the role of 'trust'. I will suffice by stating that CLINUVEL has not increased its price in Europe since March 2017, not even adjusted for consumer price index while our suppliers have raised their costs year on year.

13. SCENESSE® - SYSTEMIC PHOTOPROTECTION IN EPP

Undoubtedly, the news of the US launch has been overshadowed by the outbreak of COVID in February. Although, the Company did not receive notification of delays or cancellation of treatments in the US, it is safe to presume that patients have been reluctant to travel to treatment centres.

CLINUVEL's US team showed the highest level of flexibility, when it was decided to change our model by including all non-expert centres and distribute directly to Board-certified dermatologists. With the FDA's approval we quickly adapted and trained & accredited 28 medical centres. The Director of North American Operations, Dr Linda Teng, and her team, are credited publicly for showing operational prowess in these times.

Originally, it was planned for the drug to reach a maximum of 30 centres by July 2022, but our US team has performed precociously. More activities are planned to bring SCENESSE® to US patients.

Treatment under Prior Authorization implies that all patients require written confirmation from their insurer before receiving the drug from their physician in his office.

Additionally, these US prescribers require confirmation from the insurers of the appropriate treatment codes, which allows them to charge for both the medical consultation and drug administration.

As we have explained, a Savings Program is under way for US EPP patients working off individual Insurance Plans.

Relevant is the observation that some US patients are now requesting a second and third dose since they had started SCENESSE® treatment in April 2020.

14. FINANCIALS

During a Columbia seminar Bill Gates had cited the best business book he had ever read, John Brooks' Business Adventures written in 1969, remaining very current:

"…….it doesn't matter if one has the perfect product, or great marketing… what you need is the right people to lead and run your company……"

In the present form, we have created at CLINUVEL an animated team who knows to perform in the most dire economic climate, working all hours, answering calls weekends and holidays – a culture of give without reservation. No business activity seems off-limits to this eager and hungry team.

For those new shareholders on the line today, the enterprise value of CLINUVEL surged from A$45 million in 2005 to over A$1B today, a 20 fold increase while having reached a peak of A$2.2B intraday on the 8 October 2019 following FDA approval. CLINUVEL's value appreciation during that window is a direct result of a program planned and executed with forethought and precision.

15. REVENUE GROWTH

Having witnessed the work ethics and creativity of this team the past 10 months operating remotely under COVID, only few are privy to the efforts it took to arrive at today's financial success.

Behind each economic graph there is a story, and this one illustrates the aptitude of professionals collectively working to increase performance shown as a compounded annual growth rate of 31% in 2020 averaging more than 30% the past four years.

In 2018, a journalist quoted CLINUVEL the most frugal biotech in Australia, however a controlled increase of expenditures is testimony to the contrary and serves as a foundation for further value. In 2020, the Group increased expenditures towards diversification by 44%.

A measured financial strategy can hardly be rejected under the economic hardship the world has faced for many companies are calling for governmental assistance, bridging loans or equity raisings or simply go into receivership.

With this attitude towards risk alone, in 2020 our teams have performed above expectations, growing revenues by 4.9% and achieving profits after tax of A$16.6 million which led to an increase of cash reserves of 23%, and providing return on equity of 23% - and that is against the largest financial economic crisis in a post-war era. A high-level view would speak against disruption of this upward trend provided the viral load of COVID eases off in 2021.

CLINUVEL's financial metrics are crystal clear and our objectives are to have a minimum of two to three years of cash on hand to weather exactly these kind of economic shocks which – taken in a historical context – are far from alleged black swan events. At CLINUVEL, I want to see our senior management team prepare for adversity, remain cost-efficient and creative in finding solutions, and by adhering to this vision the Group has never been in a better financial and operational position as it is today.

As far as the stock price is concerned, time will provide a solution for the secular trend of this stock to continue on the basis of new indications, results and expansion.

16. PLANNING 2021 & CONCLUSION

The past year has been eventful and with plenty of progress and news flow from the Company, the calendar year 2021 is abundant in further milestones.

I share with you our internal planning – which could change due to unforeseen circumstances – but this very well summarises the objectives our team is working on.

There are various other pieces of news which will come to you, however we have taken nine prominent events to illustrate how we plan the year ahead and which aim to generate further value.

In conclusion, CLINUVEL's Strategic Update provided on 29 October and the rationale and implementation of strategy discussed today would make the Group a diversified operation.

New to shareholders is our unfolding of the stroke program, but specifically the DNA Repair trials in XP and in Caucasian individuals, which we are finally able to progress.

With excitement we have all lived towards a triptych strategy coming from melanogenesis to systemic photoprotection to DNA Repair, it was logical but time sensitive.

In three, we have also split the Group having now Pharmaceuticals, Healthcare Solutions and Communications, Branding and Marketing Divisions.

Amidst all the gloom in the world, I leave you now knowing that CLINUVEL has never been in a better financial and operational position.

17. THANK YOU

First, it would be inattentive and unjust not to publicly thank Mr Brock McKenzie, audit partner at Grant Thornton for the past five years of overseeing our financial audits; our sincere appreciation and we are sorry to see you go.

Second, I thank the senior partners of ABL, Mr Jeremy Leibler and Mr Leon Zwier who continue to serve the Company by overseeing governance and corporate strategy.

It leaves me with final words of immense gratitude to a thoughtful and disciplined Board of Directors and esteemed staff, for an exceptional year under tragic conditions.

I appreciated your attention today, and I hope we can see each other in person next year. I now turn to the Chairman Mr Blijdorp.

- End -

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (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.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair and acute or life-threatening conditions. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014, the US Food and Drug Administration in 2019 and the Australian Therapeutic Goods Administration in 2020 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information please go to http://www.clinuvel.com.

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 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 2020 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.

www.clinuvel.com
Level 11 T +61 3 9660 4900
535 Bourke Street F +61 3 9660 4999
Melbourne, Victoria, Australia, 3000

CLINUVEL

Annual General Meeting

First Virtual Meeting

CLINUVEL Group
11 November 2020

P Wolgen
Managing Director

ASX:	CUV
Level 1 ADR (Nasdaq International Designation):	CLVLY
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Legal Notice

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CLINUVEL Group

Functional divisions

Healthcare Solutions

Pharmaceuticals

Communications/ Branding/Marketing

Research, Development & Innovation Centre
VALLAURIX [SG]

I Pharmaceuticals Core Business

I	SCENESSE®
II	SCENESSE® ENFANCE
III	PRÉNUMBRA®
IV	Phimelanotide
V	CUV9900

CLINUVEL works towards a portfolio of minimum five prescription products currently targeting four patient populations.

Pipeline pharmaceutical program 2021

* Phase II read out expected 2021, pending COVID

II Healthcare Solutions

Validation of non-prescription products
originates
from active pharmaceutical ingredients

Long-term use
provided confidence in
SAFETY

Pathway to DNA Repair products

CLINUVEL's melanocortins

universal care benefiting all

Healthcare Solutions

Dermocosmetics

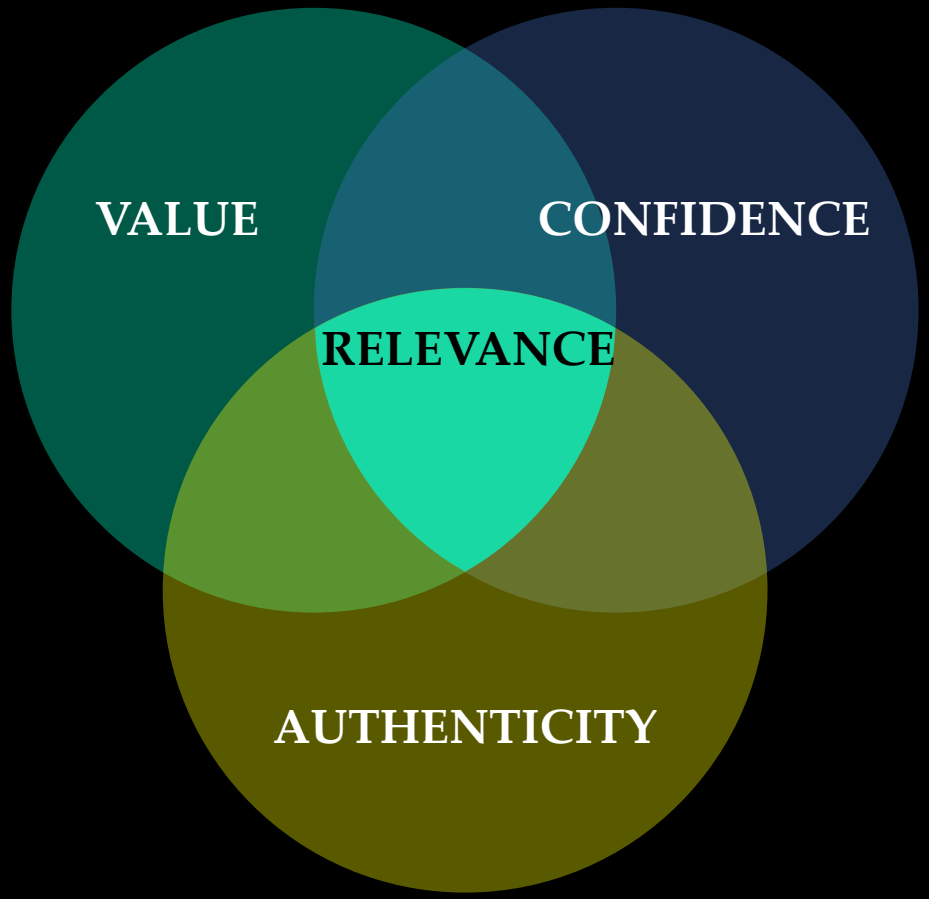
Product Line 1A	*Product Line 1B*	*Product Line 2*	*Product Line 3*
Market Entry *Polychromatic Protection*	*Market Entry* *Polychromatic Protection* *Line Extensions*	*Parvysmelanotide* *DNA Repair*	*Line Extensions* *Complementary in vitiligo, depigmentation*

III Communications, Branding, Marketing

Effective communication is

the determinant

of commercial success in dermocosmetics



Connecting to audiences

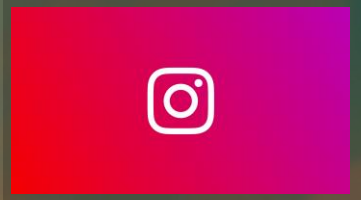
Rapidly changing media landscape

Localisation of content consumption

Paid & earned

Multi-channel dialogue: social, mobile, influencers, web

YouTube >2bn users per month

 >1bn users per month

TikTok >850m users per month

新浪微博 >300m users per month

 >2.7bn users/month

 >1bn users/month

Google 6.9bn searches/day

Baidu 百度 195m users/day

Strategy

I Melanogenesis

II Systemic photoprotection

III DNA Repair

1980 - technology forms the base

2005 - team forms a vision

2020 - execution of triptych

From medicinal therapies…

… to universal skin care products for DNA Repair

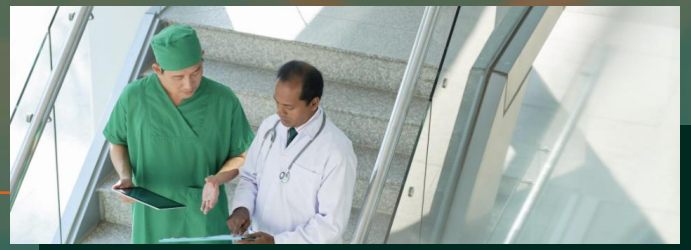
Technology Translation
DNA Repair

……secure tomorrow today……

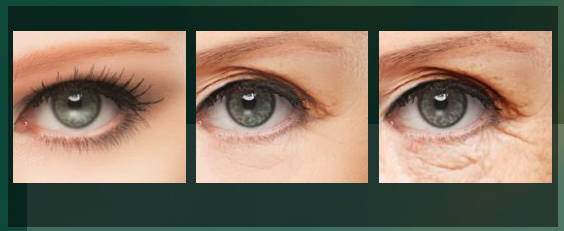
Pharmaceutical
[PRESCRIPTION ONLY]

SCENESSE®
SCENESSE® ENFANCE
PRÉNUMBRA®
Phimelanotide
CUV9900

Systemic repigmentation
Systemic photoprotection
Neurotrophic – anti-oncotic
DNA Repair



Awareness among medical community
- innovation and medical need



Healthcare Solutions

ProdLine: Parvysmelanotide

ProdLine: DNA Repair

Polychromatic protection
DNA Repair

Awareness to be raised among broad audience

Commercial update

94% treatment retention – EU

97% treatment retention – CH

SCENESSE® - world's first systemic photoprotective

Only approved therapy for adult EPP patients

Uniform net price maintained, unchanged since 2017 (no CPI increase)

SCENESSE® - systemic photoprotection in EPP

* Locations are approximate

USA: launched April 2020

- CUV changed strategy during COVID pandemic
- 28 Specialty Centers trained & accredited
- Treatment under Prior Authorization
- Savings Program for patients
- US patients starting third treatment dose

EEA: four years of post-marketing experience

- Standard of care in EPP Expert Centres
- First publication on long-term post-MA use confirms safety, effectiveness (Wensink et al)

Financials

I Cost management

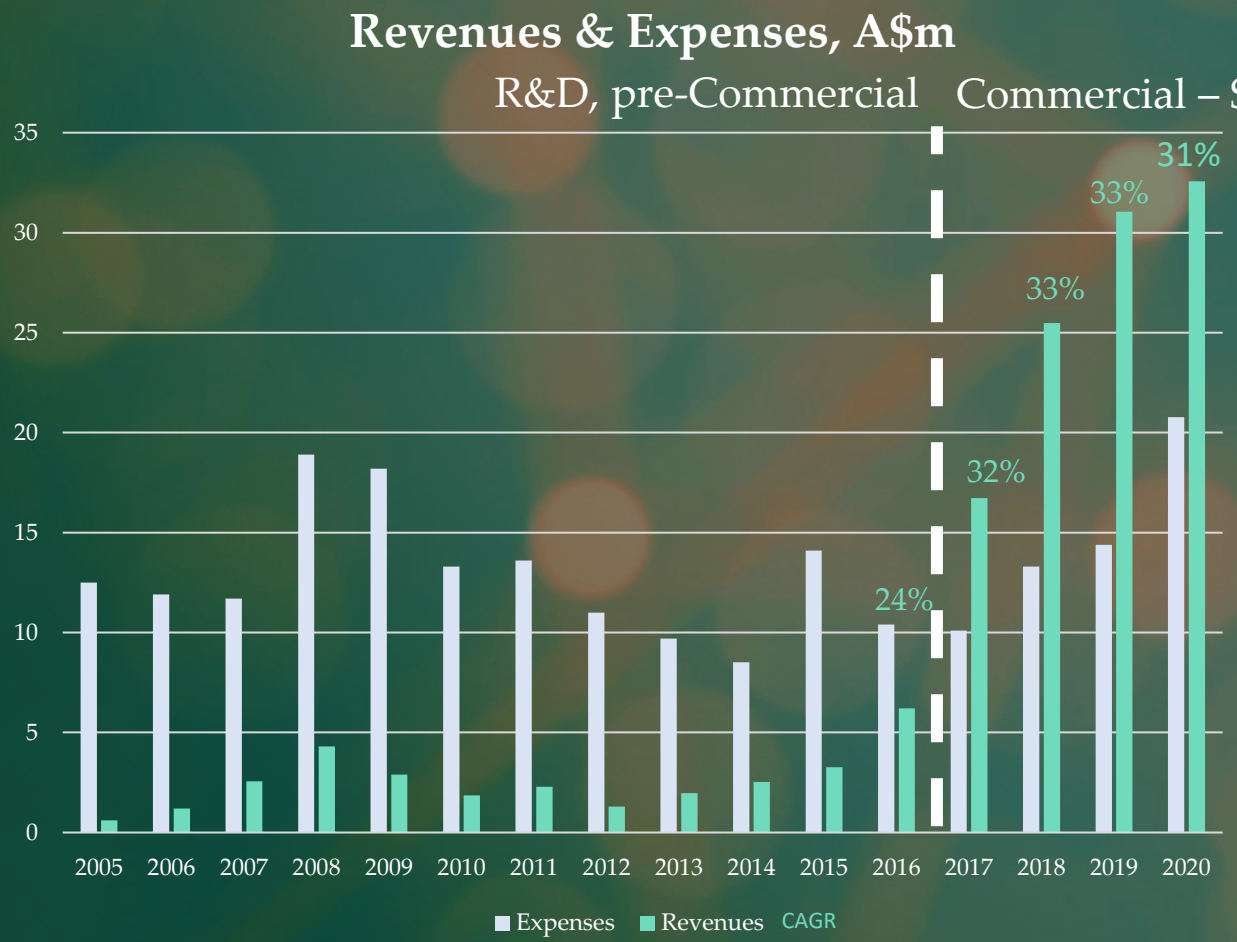
II Profitability

III Controlled expansion

John Brooks 1969
'Business Adventures'

"…….it doesn't matter if one has the perfect product, or great marketing… what you need is the right people to lead and run your company……"

Revenue growth

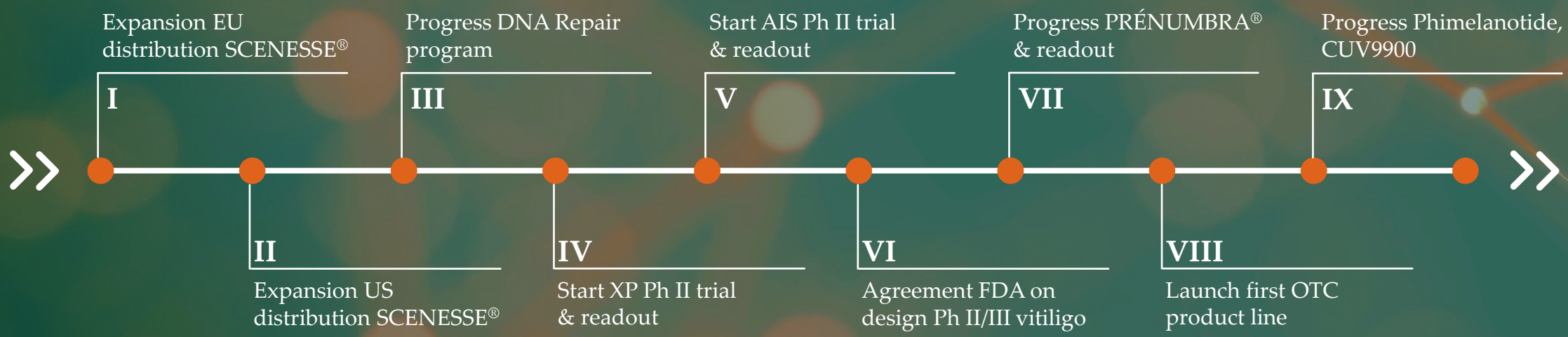


Financial Year 2019/20

- Revenues +4.9%
- NPAT A$16.6 M
- Cash reserves +23%
- Expenditures +44%

- Financial years ending 30 June
- CLINUVEL does not provide financial guidance for 2021

Planning 2021



Conclusion

- Diversified R&D under way
- Targeted Technology Translation – DNA Repair
- Financial strength established

CLINUVEL

Thank you

For your support & trust

CLINUVEL Group
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