

CLINUVEL AGM GROWTH 2020

Melbourne, 28 November 2017



CLINUVEL PHARMACEUTICALS
MANAGEMENT PRESENTATION
ASX: CUV
ADR: CLVLY
XETRA: UR9

Today's discussion outlines the CLINUVEL Board's objectives to lead the growth of the Group by 2020. The emphasis today is on the strategic direction of the Group towards growth by 2020. Audiences unfamiliar with CLINUVEL are encouraged to review the website at www.clinuvel.com.

Three elements have dictated CLINUVEL's Board strategic considerations. CLINUVEL intends:

- to maintain "situational awareness";
- to leverage the melanocortin technology (SCENESSE®)/knowledge; and
- to lend more visibility to the CLINUVEL brand.

The audience is asked to keep these three elements in mind when travelling into the future of the CLINUVEL Group.

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, 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 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; 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 2017 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.

You are advised to read the Safe Harbour Statement.

Contents

- 1 Corporate Value
- 2 Financials
- 3 FDA
- 4 SCENESSE® EU Market Access & Reimbursement
- 5 Growth 2020
- 6 Milestones
- 7 SCENESSE® in EPP

Index of the seven topics to be covered today which eventually will lead to the audience's understanding of CLINUVEL's objectives and the Group's intentions by 2020, pending regulatory clearances and upcoming legislative changes in EU-US-Asia, and drug safety aspects.

Corporate Value

CLINUVEL's success today is owed to physicians, patients and all who have contributed. In retrospect, one can distinguish in the value of CLINUVEL two key elements:

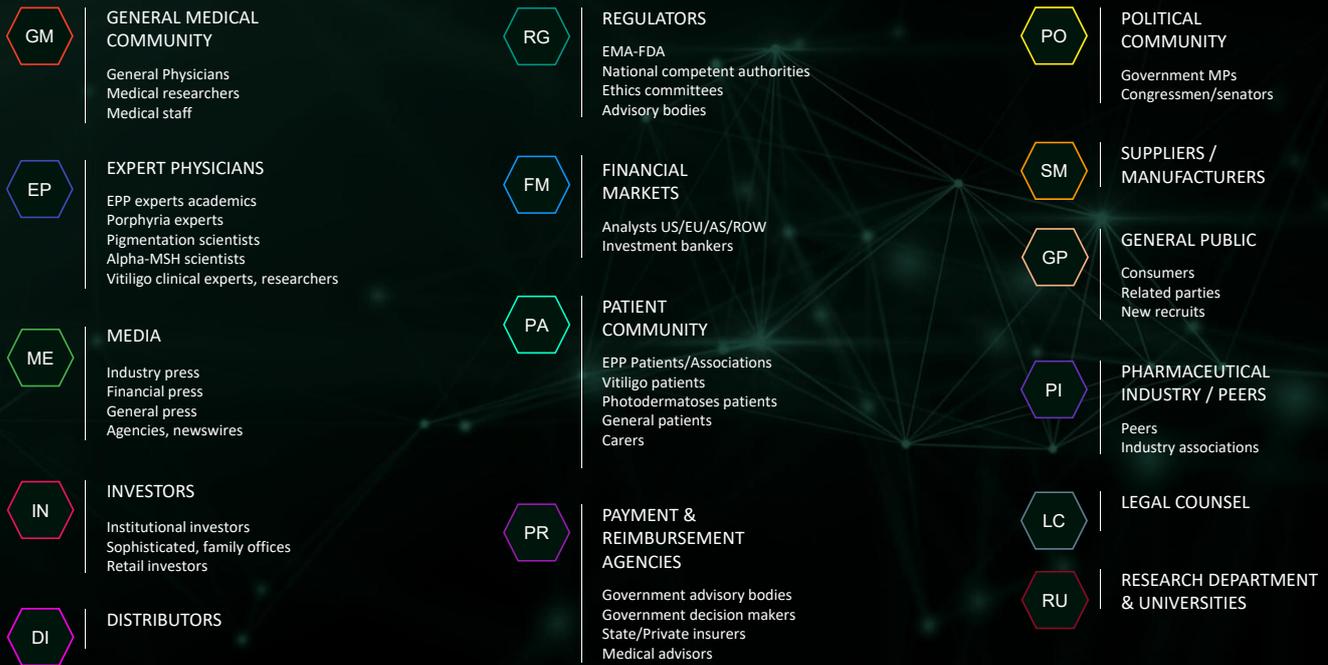
1. consistency in its communication to a wide variety of stakeholders;
2. follow through on its corporate actions.

The CLINUVEL team has *consistently communicated during 12 years* to a variety of stakeholders a persistent objective to develop SCENESSE® for erythropoietic protoporphyria [EPP] patients, who are from birth onwards lifelong condemned to an indoor existence, leading to social deprivation. SCENESSE® is licensed in Europe for the prevention of phototoxicity in adult patients with EPP.

The genetic condition EPP (FECH deficiency) affects patients' choices in life, their career choices during formative adolescent years and often choice of partners and family. FECH deficiencies lead to an accumulation and storage of the phototoxic molecule protoporphyrin IX in the skin, liver and gallbladder. Importantly, EPP is a unique disorder, *not comparable to any other affliction*, in that patients are phototoxic or intolerant to light emitted along the visible spectrum and originating from light sources, including LEDs, laptops, reflective surfaces, and the sun. Hence conventional therapies and topical sunscreens do not protect these patients, since the emitted **visible** light affects the accumulated protoporphyrin molecules and excites these to a higher state causing oxidative damage.

The second element of achievement lies in *following through corporate actions and objectives*.

CLINUVEL Stakeholders

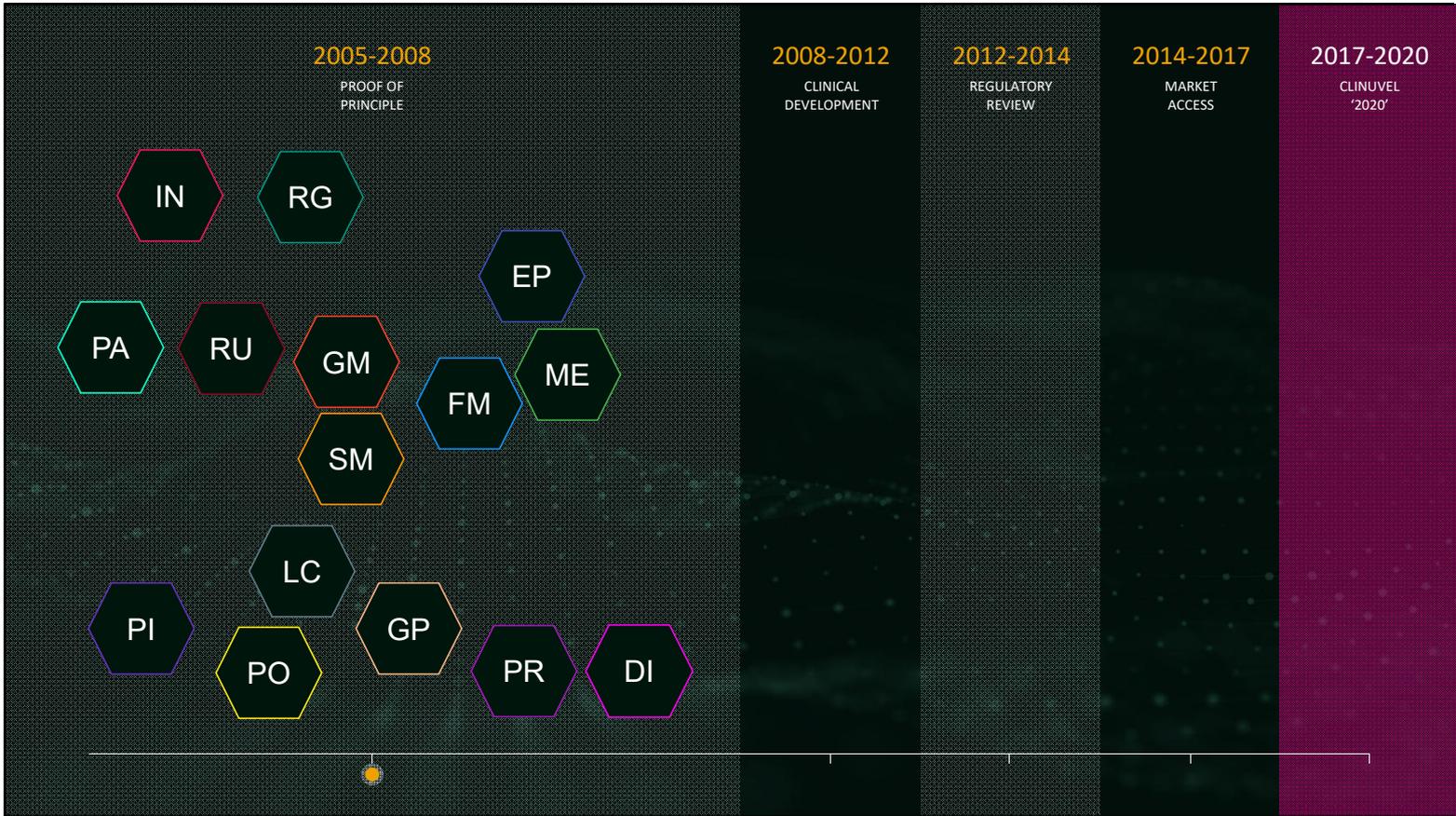


CLINUVEL transmits messages simultaneously to 15 different stakeholder groups, and in today's world, consistency of messages is required.

Some of these stakeholders are unique to CLINUVEL. Obviously, the various stakeholders have different objectives, incentives and interests.

Examples are given how the interests of stakeholders may be misaligned. In an indefectible system, all CLINUVEL stakeholders ought to have common objectives.

The 15 stakeholders can be further differentiated in 40 various subgroups, abbreviated in each hexagon shown.



In sectioning the five temporal corridors from 2005 to 2020, CLINUVEL has varied its communication channels as time passed to address the key stakeholders who are most relevant to each period. Illustrated on the slide is an example of the hierarchy of audiences addressed by our communication teams both inhouse and with local agencies during these years.

2005-2008

PROOF OF PRINCIPLE

2008-2012

CLINICAL DEVELOPMENT

2012-2014

REGULATORY REVIEW

2014-2017

MARKET ACCESS

2017-2020

CLINUVEL '2020'



From 2008 to 2012, *the years of clinical development*, obviously patient associations, research institutes, universities, regulatory authorities, expert physicians, and newly attracted investors required primary attention and communication through CLINUVEL's public channels.

2005-2008

PROOF OF
PRINCIPLE

2008-2012

CLINICAL
DEVELOPMENT

2012-2014

REGULATORY
REVIEW

2014-2017

MARKET
ACCESS

2017-2020

CLINUVEL
'2020'



During 2012 to 2014, *the years of European regulatory review*, the longest in the history of the EMA, it became apparent that the regulators required consistent communication.

2005-2008

PROOF OF
PRINCIPLE

2008-2012

CLINICAL
DEVELOPMENT

2012-2014

REGULATORY
REVIEW

2014-2017

MARKET
ACCESS

2017-2020

CLINUVEL
'2020'



During 2014 to 2017, *the years of approval and gaining market access*, we learned an entirely new phenomenon: uncurated news flow and content consumption.

2005-2008

PROOF OF PRINCIPLE

2008-2012

CLINICAL DEVELOPMENT

2012-2014

REGULATORY REVIEW

2014-2017

MARKET ACCESS

2017-2020

CLINUVEL '2020'

Media Coverage 2005 - Present

Media	Number of Titles
Industry	679
Magazine	36
Newspaper	326
Online	245
TV	60
Wire	123
Grand Total	1469

Online Traffic

Website visits (since 2008)	1,867,599
YouTube video views (since 2009)	1,058,609



The global attention for CLINUVEL has surpassed many of its peers. Over the past 12 years, we have seen in total 60 TV programs on SCENESSE®, 627 industry publications, 326 newspaper articles, and over one million YouTube hits on the Company’s channel. The tables illustrate the sheer amount of news flow surrounding CLINUVEL, an emerging pharmaceutical company with novel technology applicable in a universe of diseases. Most of the information on the Company is openly available.

2005-2008

PROOF OF PRINCIPLE

2008-2012

CLINICAL DEVELOPMENT

2012-2014

REGULATORY REVIEW

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MARKET ACCESS

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CLINUVEL '2020'

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Corporate value in 2017 and most certainly by 2020 will rest on consistent and measured communication, and our ability to follow through our objectives, whereby we will remain aware of how selective information on CLINUVEL can be used.

2

Financials

The Company has consistently sought to review its financial position at Annual General Meetings, with readers encouraged to follow the thought process since 2006.

Register analysis – CLINUVEL¹

Institutions	44.37%
Brokers	3.61%
Related parties	9.03%
ADRs ²	11.54%
Other	16.25%
Below threshold of analysis	15.19%

¹ As at 15 September 2017

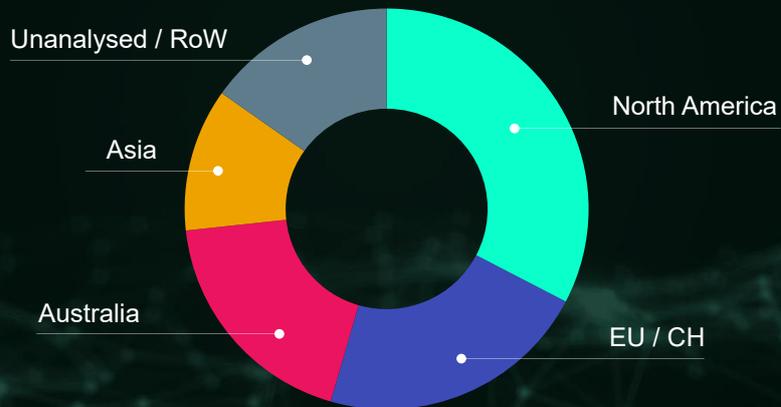
² Sponsored American Depository Receipt, CLVLY

The analysis of CLINUVEL's share register is of importance to comprehend the changing audiences the Company attracts, the institutional level of interest, and the other positions over time.

Register analysis – CLINUVEL¹

Institutions	44.37%
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Geographical distribution¹



¹ As at 15 September 2017

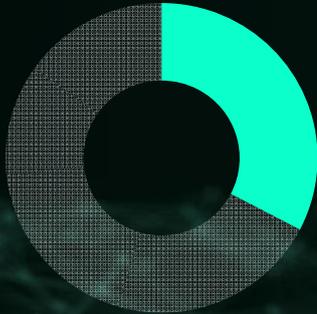
² Sponsored American Depositary Receipt, CLVLY

When looking at the geographical distribution we have seen an increase of holdings from Asia and North America, with the EU and Switzerland (CH) slightly on the rise.

Register analysis – CLINUVEL¹

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Geographical distribution¹



North America

ADRs² CLVLY as % of total CLINUVEL holdings



¹ As at 15 September 2017

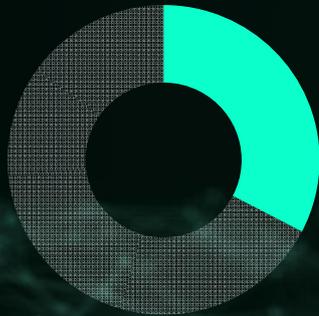
² Sponsored American Depository Receipt, CLVLY

In analysing the number of American Depository Receipts (ADRs) traded and newly issued, the Company gains some insight as to the interest for the CLINUVEL story from North America. Since the Nasdaq International Designation an increase in sponsored ADRs (CLVLY) has been seen, now at 11.46% of the entire Company.

Register analysis – CLINUVEL¹

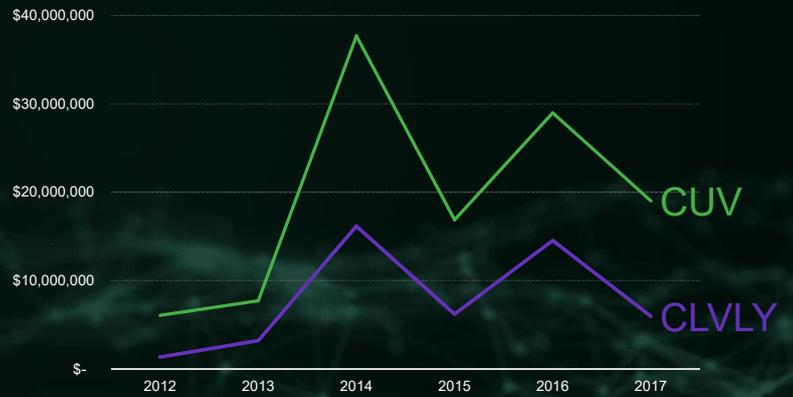
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Geographical distribution¹



North America

Traded value (A\$)



¹ As at 15 September 2017

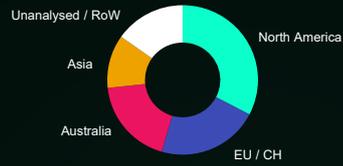
² Sponsored American Depository Receipt, CLVLY

Of most interest is the analysis of the value of the sponsored ADRs.

Register analysis – CLINUVEL¹

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Register: Geographical breakdown¹



Shares on Issue

47,735,227

12 month low-high

A\$5.91-\$9.44

12 month traded volume

4,771,470

MCAP

A\$437m

Dilution 2005-17

187%

Investment to date 2001-17

A\$172m

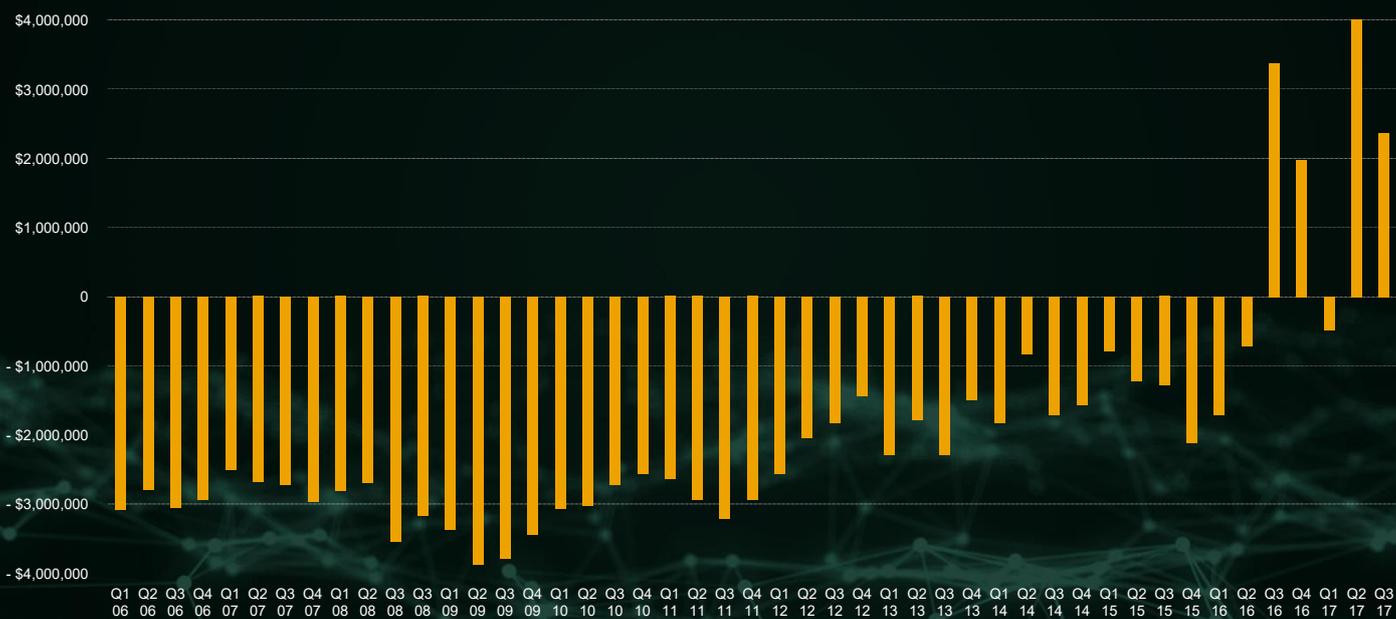
¹ As at 15 September 2017

² Sponsored American Depository Receipt, CLVLY

Currently there are 47,735,227 ordinary shares on issue, and no dilution has occurred since last year. The viewer is shown that the percentage of dilution is 187% over 12 years, a metric the finance team closely monitors.

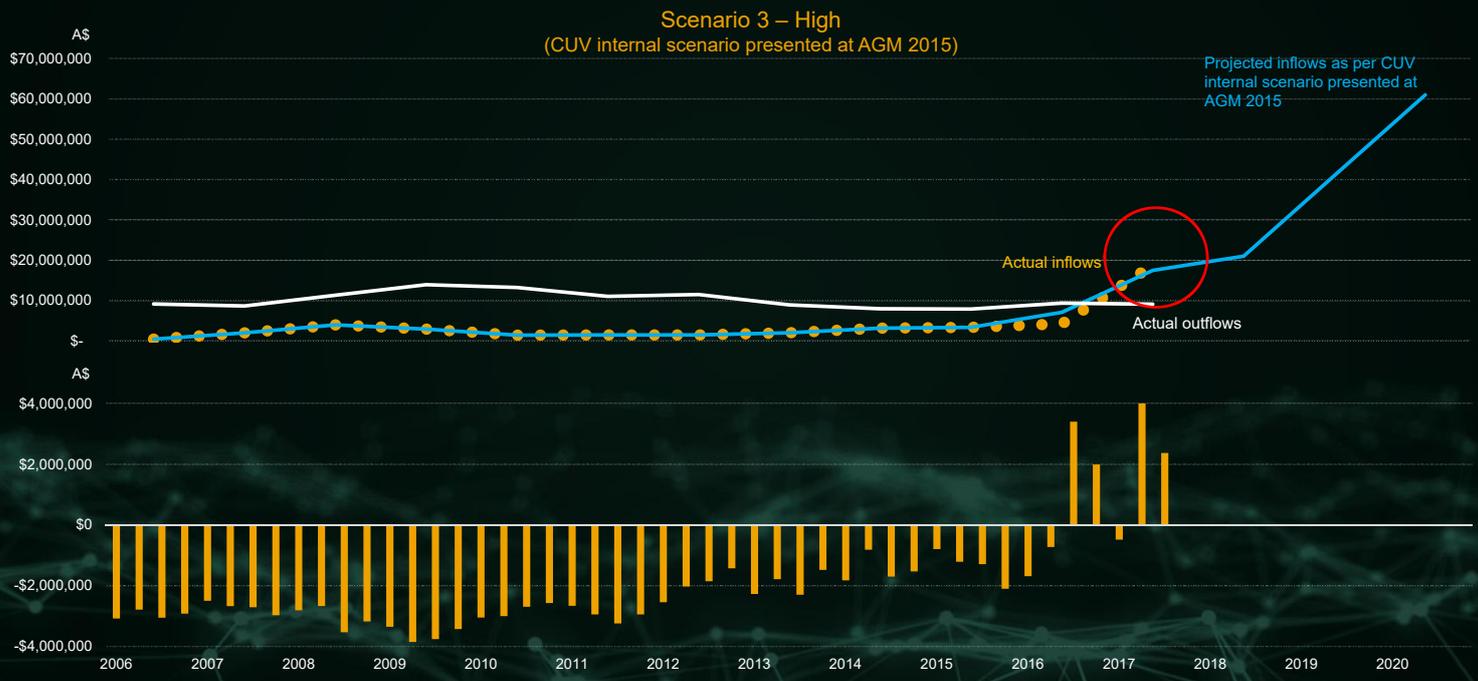
Quarterly Cashflow [2006 - 2017]

Cashflow per quarter AS

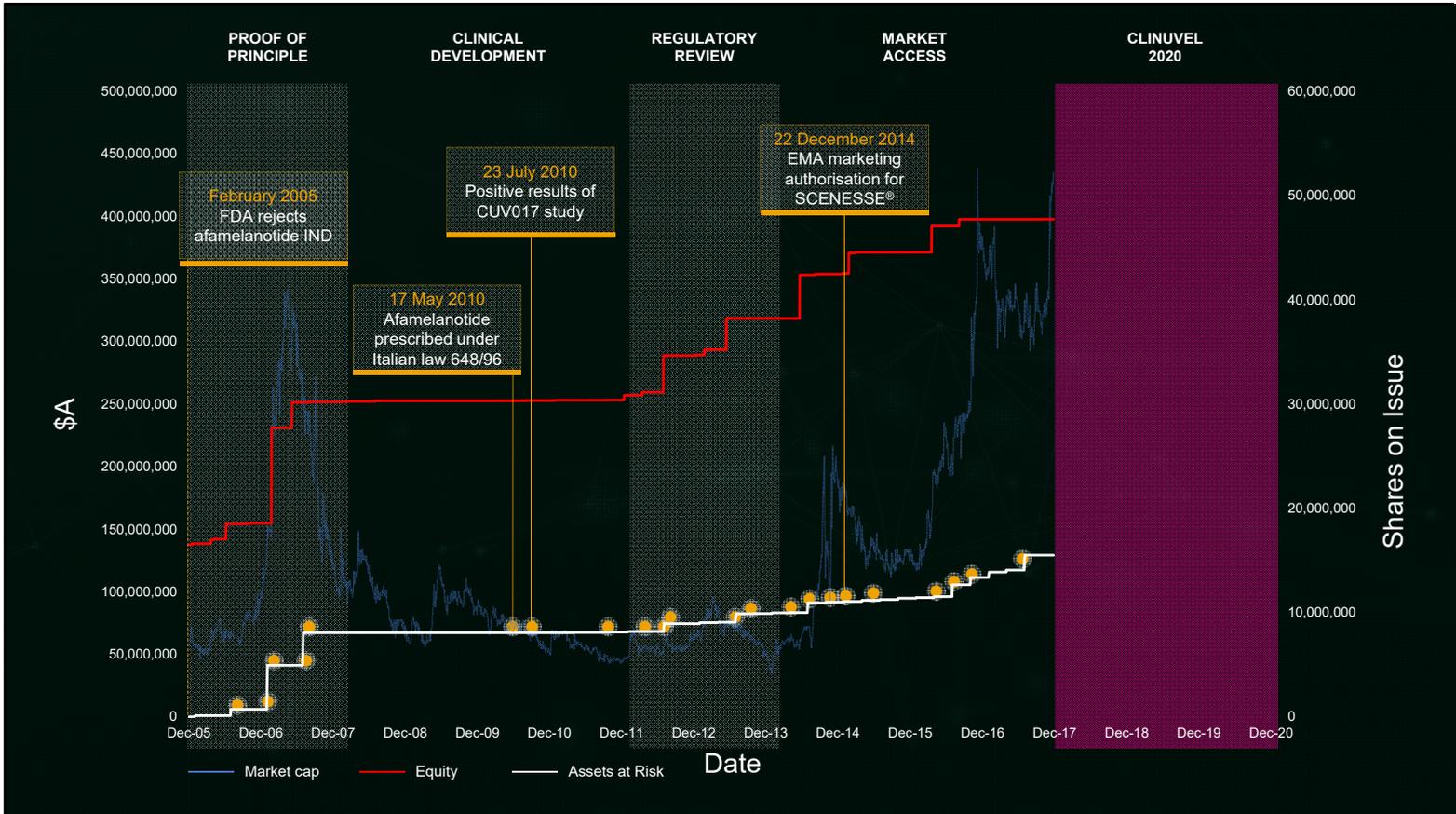


Illustrated is 47 quarters of cashflow since management started the SCENESSE® program. In 43 of these quarters the cashflows were negative, in four of the five most recent quarters CLINUVEL has become cash flow positive. An epitome has been the maiden profit posted by the Company at the end of FY2017.

Quarterly Cashflow [2006 - 2017]



CLINUVEL is currently not in the position to provide financial guidance, however as an expression of CLINUVEL's ambitions, it had shared three internal scenarios during the 2015 AGM. The audience is shown CLINUVEL's performance to date against the third, "High", scenario, tracked to 2020.



The white line highlights the hurdles the CLINUVEL team had to overcome to arrive at today's juncture. At quite a number of moments the team was at crossroads given the legacy of the Company, and had to surmount resistance. In many ways the white line symbolises the persistence of the team.

This slide also shows key milestones, with four events highlighted. In total, those represented by yellow markers are:

- 28 Nov 2005 – New CLINUVEL management structure
- 01 May 2006 – Private placement raises A\$5.0m
- 01 Nov 2006 – Raise of A\$35.2m via Rights Issue & Private Placement
- 22 Feb 2007 – Positive results of CUV010 study (Phase II EPP)
- 26 Apr 2007 – Completion of A\$26m Private Placement
- 17 May 2010 – Afamelanotide prescribed under Italian law 648/96
- 23 Jul 2010 – Positive results of CUV017 (Phase III EPP) study
- 03 Nov 2011 – Positive results of CUV030 (Phase II EPP) study
- 06 Feb 2012 – EMA marketing authorisation application for SCENESSE®
- 26 Apr 2012 – Swiss insurers first agree to reimburse SCENESSE®
- 24 Jun 2012 – Raise of A\$6.2m
- 06 May 2013 – Raise of A\$6.3m
- 11 Nov 2013 – Positive results of CUV039 (Phase III EPP) study
- 20 May 2014 – Raise of A\$6.9m
- 28 Jul 2014 – Hostile takeover bid from Retrophin
- 22 Dec 2014 – EMA marketing authorisation for SCENESSE®
- 02 July 2015 – NEJM publishes pivotal phase III SCENESSE® studies
- 15 May 2016 – Raise of A\$8.3m
- 22 Jun 2016 – SCENESSE® launched in Europe
- 09 Nov 2016 – Agreement with FDA on New Drug Application timelines
- 12 Apr 2017 – Agreement reached on German SCENESSE® pricing

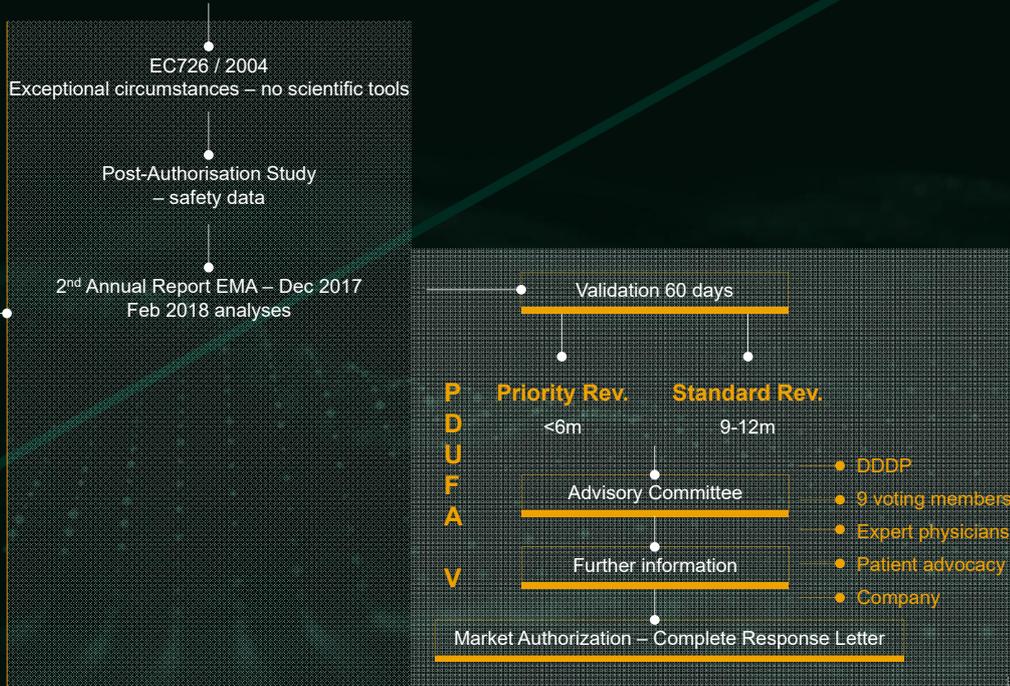
3

FDA



An overview of FDA milestones to date is given.

CLINICAL DATA



2017-18

The pathway of the FDA filing and rationale is explained. The possible outcomes are highlighted and are:

- Marketing Authorization;
- Complete Response Letter.

The process is described.

4

SCENESSE® EU Market Access & Reimbursement

CLINUVEL has established SCENESSE® as the standard of care for adult EPP patients in Europe. Work continues to enable access to the treatment for patients with an unmet medical need.

Media

A media excerpt is shown of a Swiss insurer and a patient representative debating unequal access to treatment, as well as the tripling of the price of the drug while the Company made the drug available to Swiss patients free of charge and at a subsidised level, while not posting profits during that period. The moderator concludes by stating that the treatment is meanwhile available in other countries. A still image of news clips is shown of the headlines on CLINUVEL and the distribution of SCENESSE®.

SCENESSE® EU Market Access & Reimbursement

22 Dec 2014

EMA – EC 726 / 2004 14 (8)

MA under 'Exceptional Circumstances'

- **1** Orphan product
- **2** No scientific instruments available to quantify effectiveness
- **3** Unethical to subject EPP patients to further clinical trials

2015-2022

EPP Pharmacovigilance

EPP Disease Registry

- **A** Safety data
- **B** Rate of continuity Rx
- **C** Inventory of Daily Activities

SCENESSE® was granted marketing authorisation by the EMA in 2014 under Exceptional Circumstances due to the unique nature of EPP and the lack of scientific tools available to quantify the disease or a treatment.

Since approval CLINUVEL's teams have established a compliant pharmacovigilance system to monitor drug safety, and the first ever international EPP disease registry to collect long term safety and effectiveness outcomes endpoints. Pseudonymised data are collected from patients receiving the drug at European EPP Expert Centres.

SCENESSE® EU Market Access & Reimbursement

Germany 2017

IQWIG

GBA

GKV (PKV) - AMNOG (§130 V SG)

- Clinical benefit
- Alternative Tx
- Comparable Tx
- Price setting

Court of Arbitration 31/03/17

- SCENESSE® reviewed by CoA
- EU price established
- No rebates payable
- GKV/PKV pay uniform EU price
- Treatment benefit unquantifiable

15/09/15

Outcomes CoA Germany (25)

- Retract from market **7/25 = 28%**
- Appeal final price setting **7/10 = 70%**

An example is given of the negotiations with the German government reimbursement body, GKV-Spitzenverband, which eventually led to a formal Court of Arbitration in March 2017. SCENESSE® is now the standard of care for EPP in Germany.

SCENESSE® Eligible expert centres in Europe

- 66.1% increase in patient treatments 2016 to 2017
- 5 US patients treated in 2017

SCENESSE® Uniform Price



¹No alternative effective therapy exists for SCENESSE®
²Price in Lauer-Taxe is published by IFA GmbH

There are 42 European EPP Expert Centres who have indicated a willingness to prescribe SCENESSE® for their patients.

Increasingly we have seen movement across borders as patients seek access to treatment, including five US patients who have received treatment in Europe in 2017.

CLINUVEL established a uniform price for SCENESSE® with all nations treated equally.

5

Growth 2020

CLINUVEL seeks sustainability. A number of key elements of sustainability are described as part of the foundations of the business.



EXPERTISE

- *financial management*
— structured project finance
- clinical – regulatory – PV – QA
- distribution – market access – pricing
- melanocortins – GCPR - physics / optics
- peptide chemistry – analytical
- endocrinology – haematology – gastroenterology – dermatology

There are key foundations now in place from which we are growing the Group.

Parts of the assets not found on the balance sheet but vital to the longevity of CLINUVEL reside in:

1. ability to maintain financial discipline;
2. ability to see through complexity.

The team has built a specific set of skills to progress SCENESSE® to market.

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Definitions:

GCPR: G-coupled protein receptors

PV: Pharmacovigilance

QA: Quality Assurance



COMMUNICATION – MEDIA STRATEGY

repositioning company

'branding' CLINUVEL
increase visibility

- medical community
- general public
- investment community

EXPERTISE

The elements 'timely visibility', and 'relevance to a widest possible audience', requires more work towards reaching:

- medical community
- general public
- investment community

and are part of the growth strategy.



FINANCIAL TARGETS

reinvest in R&D

• cross subsidise - ROCE

• increase assets

• ROE

COMMUNICATION - MEDIA

EXPERTISE

The Company seeks to reinvest in R&D.



VALUES-MISSION-VISION

- innovative solutions for complex medical problems
- translate scientific breakthroughs to commercial products
- attitude, respect, appreciation, knowledge-based culture
- *'persistence of objectives beyond what can be expected from staff'*

FINANCIAL TARGETS

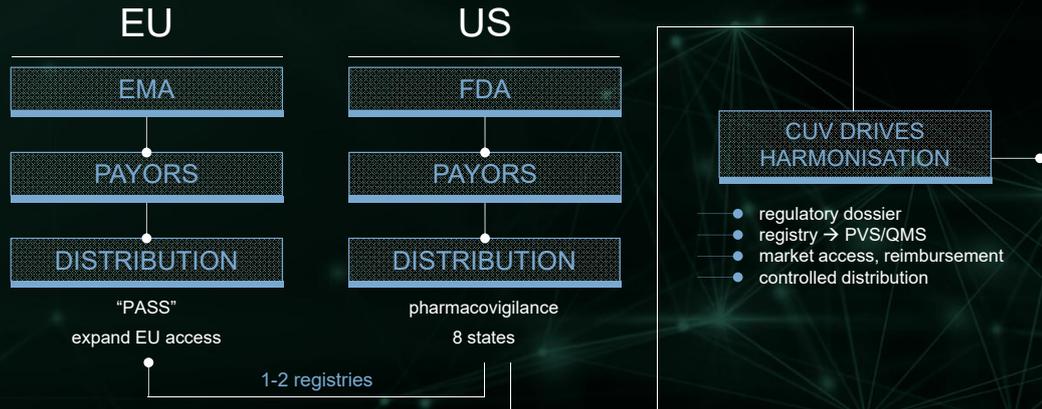
COMMUNICATION - MEDIA

EXPERTISE

There is a consistency across the Group which reflects our core values and what we expect from staff. By making these central tenets of operations we are best positioned to grow.



SCENESSE®



VALUES - VISION

FINANCIAL TARGETS

COMMUNICATION - MEDIA

EXPERTISE

The lead drug SCENESSE®, a systemic photoprotective agent, forms the basis for growth. A number of key learnings have been derived from the development of the drug and its path to marketing authorisation. While the EMA approval of SCENESSE® has taken some time to find a way to grant the drug marketing authorisation, the US does not yet have similar pathways, although regulatory reforms are under way. In many ways the SCENESSE® case drives harmonisation between the two leading agencies and, from a perspective of regulatory and cost efficiency, common and logical pathways make sense. CLINUVEL's sequential regulatory filings of clinical trial data and European data from conditions of use are a step towards facilitating similar scientific considerations by various agencies.

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Definitions:

EMA: European Medicines Agency

FDA: US Food and Drug Administration

SmPC: European Summary of Product Characteristics

Ph IIb/III: Phase IIb or III clinical trials

PVS: Pharmacovigilance System

QMS: Quality Management System



SCENESSE®

- EPP
- EPP US
- EPP Japan, Australia
- Label extension – ‘cutaneous porphyrias’
- Dosing increase 4 to 6 per annum
- New orphan indication – high unmet need
- Vitiligo Ph IIb/III US trials
- 1:140,000 prevalence
- +/- 500 known
- FDA orphan designation
- SmPC to be reviewed
- IP filed
- North America

VALUES - VISION

FINANCIAL TARGETS

COMMUNICATION - MEDIA

EXPERTISE

SCENESSE® once approved in the US will likely have several applications – *pending regulatory approval* – in:

1. EPP Europe (adults)
2. EPP USA (adults)
3. adult EPP patients across various jurisdictions where known patient populations exist (Australia-Japan)

through label extension in:

4. other cutaneous porphyrias (orphan indication)

through

5. an increase in prescription from 4 to 6 doses per annum
6. a third (new) orphan indication
7. vitiligo affecting North American patients of darker complexion (Fitzpatrick types IV-VI).



RESEARCH & DEVELOPMENT

CLINUVEL-VALLAURIX

ANALYTICAL LAB

- second laboratory Singapore - CUV

ANALYTICAL METHODS

- fully equipped, GLP
- maximum capacity

SMALL MOLECULES Rx

- CUV9900 —• topical Rx skin inflammatory D.
- VLRX001 —• DNA repair & regeneration.
- —• systemic, 2nd generation MC.

PAEDIATRIC PRODUCT

- SCENESSE® ENFANCE —• dosing < 18 years

SUSTAINABILITY

- PROPRIETARY TECHNOLOGY
- PRODUCT LIFECYCLE MGMT
- COMPETITIVE ADVANTAGE
- BARRIERS TO ENTRY
- “CUSTOMERS” DEMAND

EXPERIMENTAL LAB

- VALLAURIX joint venture

SCENESSE®

VALUES - VISION

FINANCIAL TARGETS

COMMUNICATION - MEDIA

EXPERTISE

Essential to long term growth is technological advancement via continuous research & development. CLINUVEL has a majority stake in an experimental laboratory in Singapore, where a number of novel projects are being progressed, and will lead to the clinical development of:

8. CUV9900

9. VLRX001

both as topical and second-generation melanocortin (MC) products.

Following the request by the regulatory authorities, the teams are also working on the development of 10. SCENESSE® ENFANCE for children diagnosed with EPP.

SCENESSE® ENFANCE will be evaluated for European and North American EPP patients.

Sustainability is being reiterated in light of the research and development.

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Definitions:

GLP: Good Laboratory Practice

MC: Melanocortin



GROWTH 2020

ACQUISITION(S)- LICENSING

- synergies – existing expertise
- same user base
- fully integrated
- profitable short-term

SCENESSE®

RESEARCH & DEVELOPMENT

VALUES - VISION

FINANCIAL TARGETS

COMMUNICATION - MEDIA

EXPERTISE

The Company will further expand through the licensing of a product and/or an acquisition. The objective is to increase the product offerings.

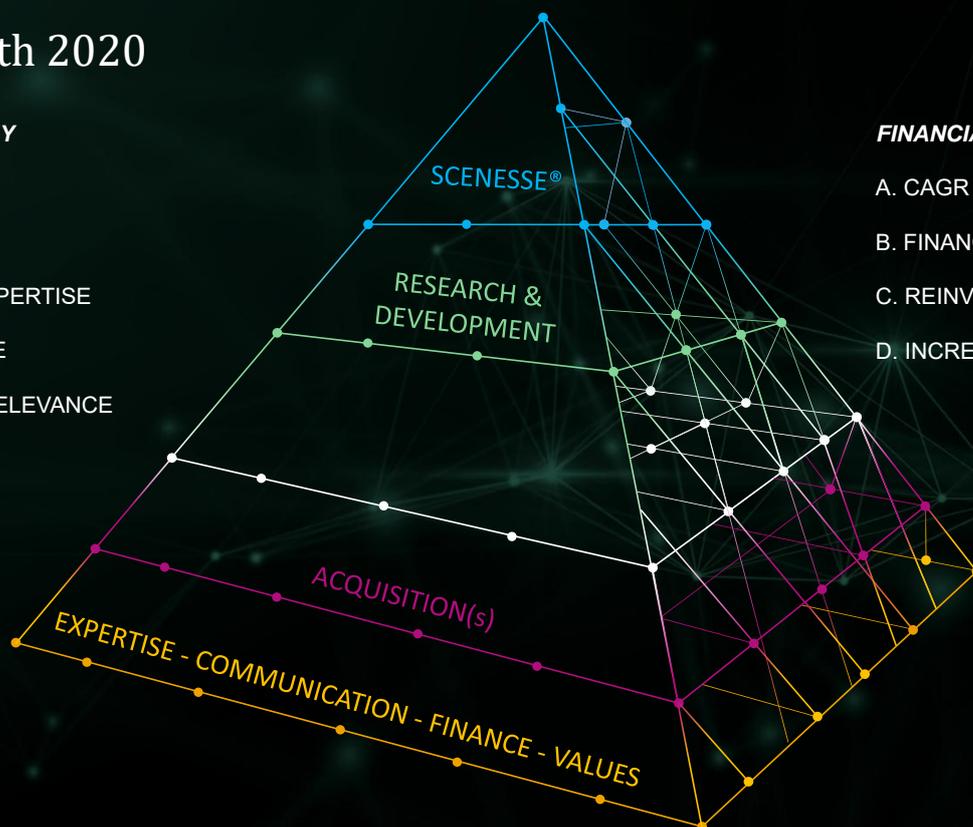
CUV Growth 2020

BUSINESS STRATEGY

- A. DIVERSIFY CUV
- B. SPREAD RISK
- C. USE/EXPAND EXPERTISE
- D. PRODUCT CYCLE
- E. MC INCREASE RELEVANCE
- F. LONGEVITY CUV

FINANCIAL STRATEGY

- A. CAGR
- B. FINANCE CONTROLLED GROWTH
- C. REINVEST IN R&D
- D. INCREASE RETURN ON EQUITY



The focus on melanocortins, financial management, execution, retention of talent, and the ability to persist towards a clear objective by the CLINUVEL team are all some of the key factors of success.

This complementary strategy to the pharmaceutical development will lend CLINUVEL greater visibility and relevance to a broad user base.

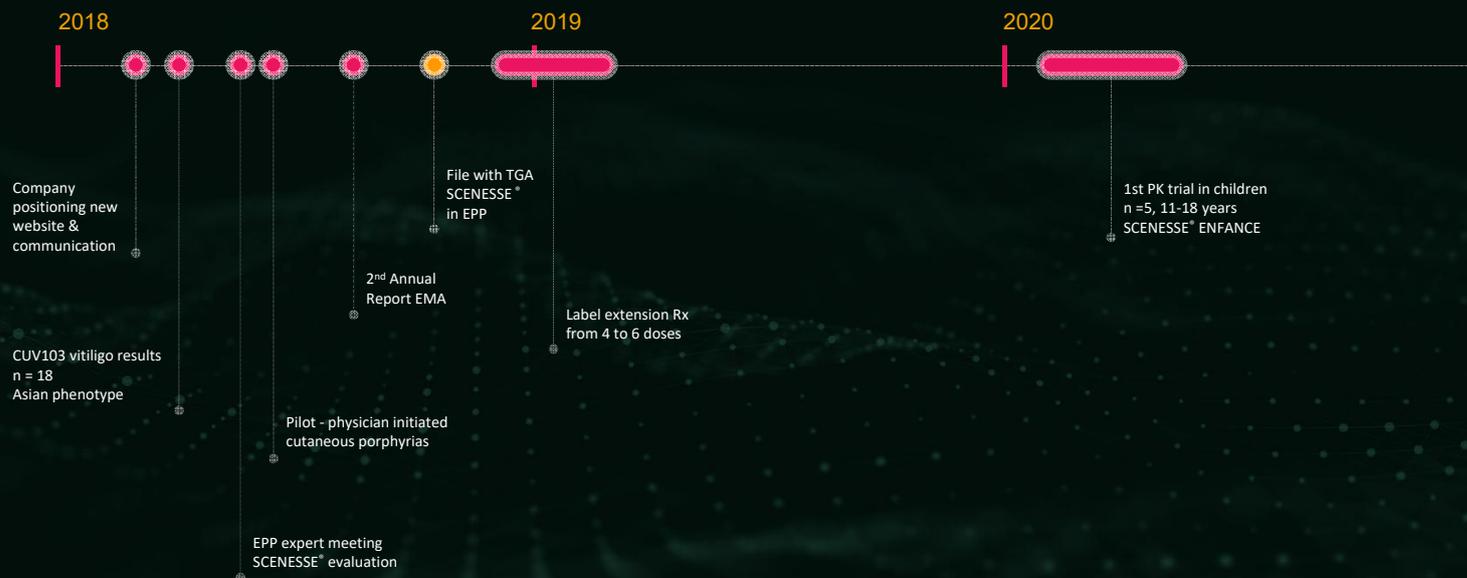
At the end of 2020 CLINUVEL will need to have transformed into a Group with greater diversification, product cycle management, addressing a paediatric population, greater product mix, reduction of asset risk and enhanced visibility among a general medical community, and a broad user base.

6

Milestones

All intended strategic considerations shared are subject to the ongoing safety of SCENESSE®, material changes to the CLINUVEL business due to unexpected events, and changes geopolitically, economically and force majeure. Timelines are given per continent.

Upcoming Milestones – Europe & Australia



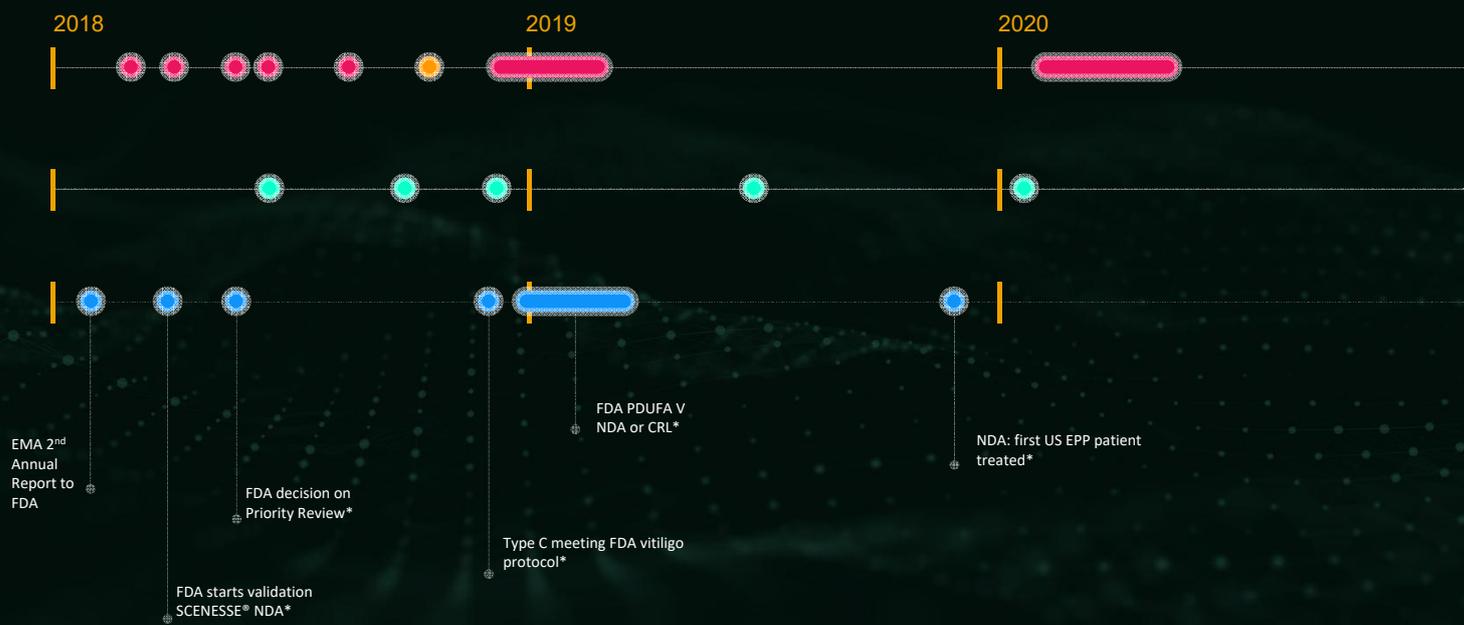
All intended strategic considerations shared are subject to the ongoing safety of SCENESSE[®], material changes to the CLINUVEL business due to unexpected events, and changes geopolitically, economically and force majeure. Timelines are given per continent.

Upcoming Milestones – Asia



All intended strategic considerations shared are subject to the ongoing safety of SCENESSE®, material changes to the CLINUVEL business due to unexpected events, and changes geopolitically, economically and force majeure. Timelines are given per continent.

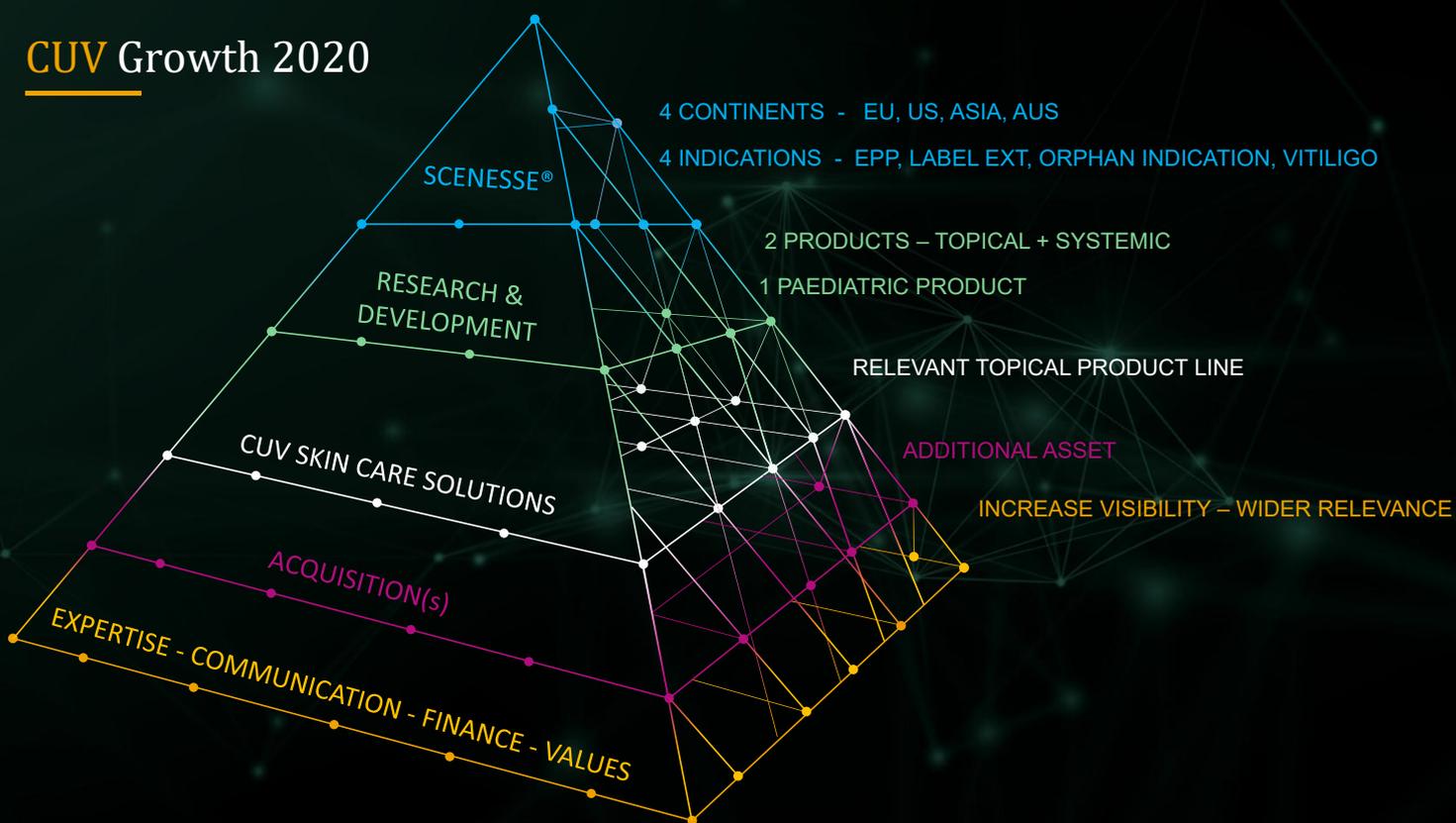
Upcoming Milestones – USA



All intended strategic considerations shared are subject to the ongoing safety of SCENESSE®, material changes to the CLINUVEL business due to unexpected events, and changes geopolitically, economically and force majeure. Timelines are given per continent.

* Possible scenarios shown.

CUV Growth 2020



As the slide shows, knowledge, expertise, and IP flowing downstream from the R&D on SCENESSE® and on clinical use lead to complementary products for a broader user base.

7

SCENESSE® in EPP

An overview of SCENESSE® in EPP is given for those unfamiliar with the Company's story.

SCENESSE® – Erythropoietic Protoporphyrin

Erythropoietic protoporphyria

- Gene defect: chromosome 18q21.3
- Burns, anaphylactoid reactions (phototoxicity)
- Lifelong light deprivation, nocturnal existence

“we have not been taken serious by society throughout our lives, now there is treatment available and we are noticed and given due attention”



SCENESSE® (afamelanotide 16mg)

- World's first systemic photoprotective drug
- EU approval for the prevention of phototoxicity in adult EPP patients
- Novel controlled release injectable subcutaneous formulation, once every two months



SCENESSE® is approved in Europe for the prevention of phototoxicity in adult patients with EPP. For more information, including copies of product information, please see CLINUVEL's website, www.clinuvel.com.

CLINUVEL would like to thank all of its Board of Directors, worldwide staff
and shareholders