

CLINUVEL

NEW OPPORTUNITIES

Skin & Brain

Bioshares 18th Biotech Summit | Fremantle, 12 July 2024 | Lachlan Hay

ASX: CUV | **Börse Frankfurt: UR9** | **ADR Level 1: CLVLY**

Forward-looking statement

CLINUVEL GROUP

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), CYACÊLLE, 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®, CYACÊLLE, 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 2023 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.

CLINUVEL: addressing unmet need with melanocortins



SCENESSE® (afamelanotide) first-in-class (EMA & FDA)

- Orphan indication porphyria (EPP), absolute light intolerance
- Commercialised, direct distribution

>A\$330m in revenues since launch (Jun '16-Dec '23)

- 42% CAGR FY2017-FY2023
- 7 years of profitability

Pipeline with TAM >US\$44bn | Penetration >\$2bn

- Peptides for skin and brain
- Pharmaceuticals & PhotoCosmetics

COMMERCIALISING NOVEL TECHNOLOGY

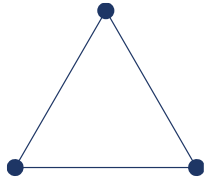
Decision Making

Focus vs Diversification

Designing and executing a novel program

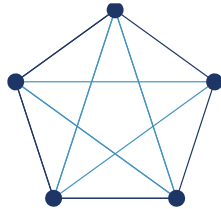
	FOCUS	DIVERSIFICATION
Indications / “pipes”	1-2	Multiple
Capital requirements	Lower (CUV: A\$150m, industry US\$1-2bn)	Higher
Manpower	Super specialised, in-house	Generalists & specialists, in-house & outsource
Timelines	Variable	Variable, likely longer
Clinical stakeholders	Dozens	100s-1000s
Market valuation	Binary – single ‘shot on goal’	After PoC, value across pipeline

Building networks – focus then diversification



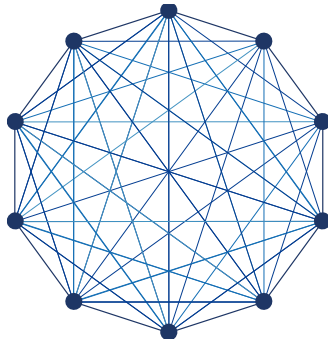
2005-08

focus EPP, social media,
clinical expert network



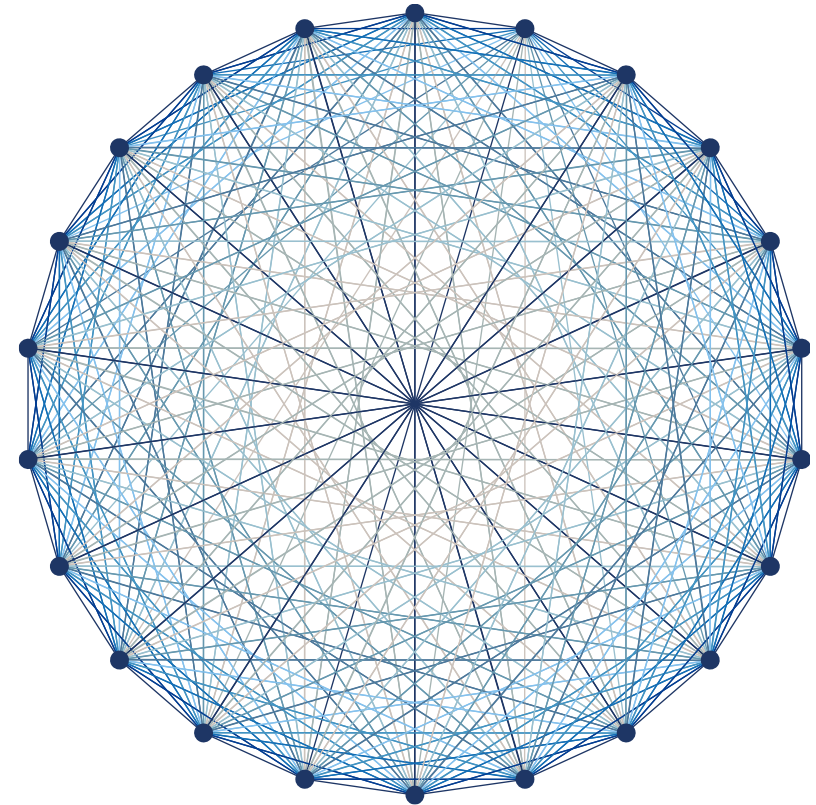
2009-15

clinical program, commercial
PoC, strengthen and
grow modestly



2016-24

establish prescriber network, long-term safety, widespread
medical acceptance of innovation, diversified pipeline

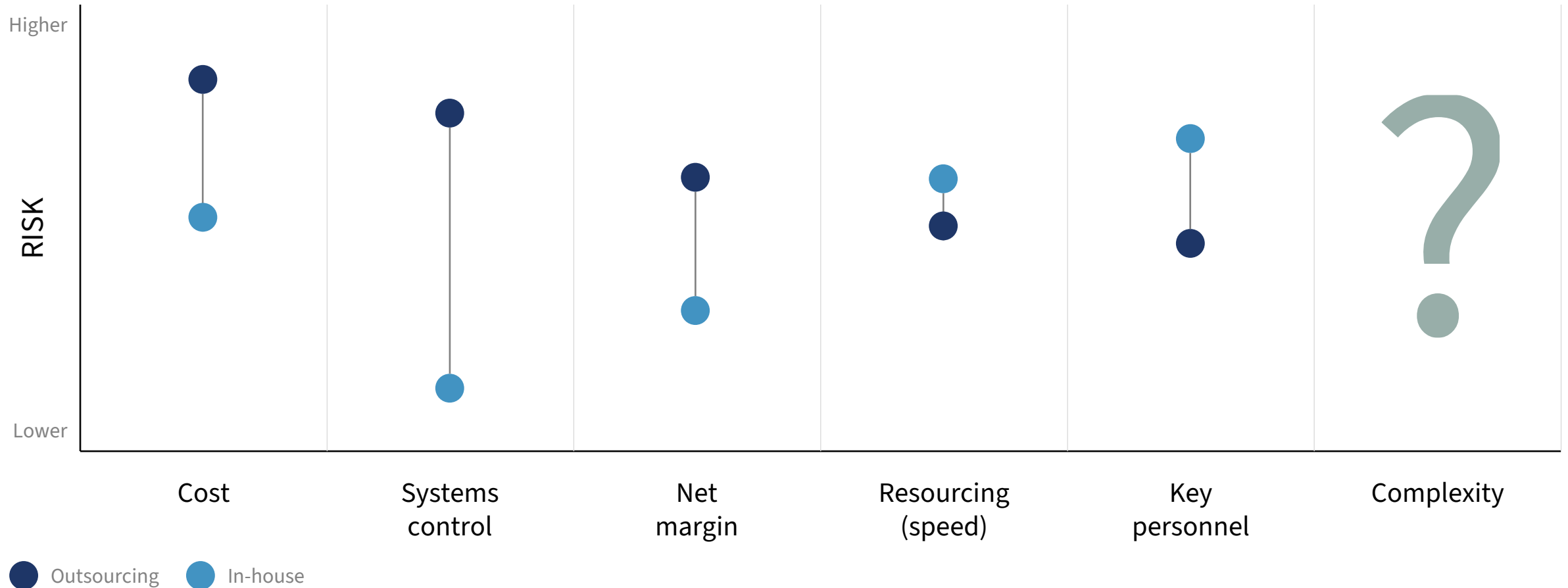


2025 onwards

building a global brand

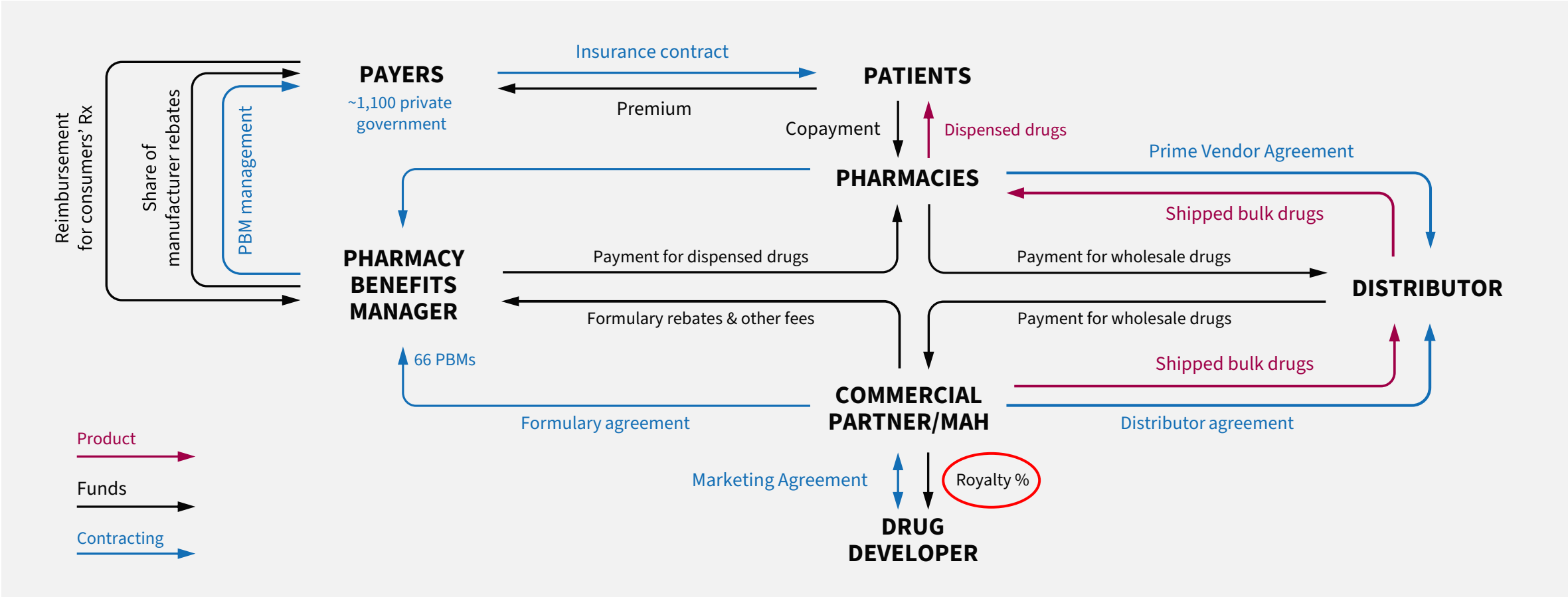
Risk Management

Outsourcing vs In-house



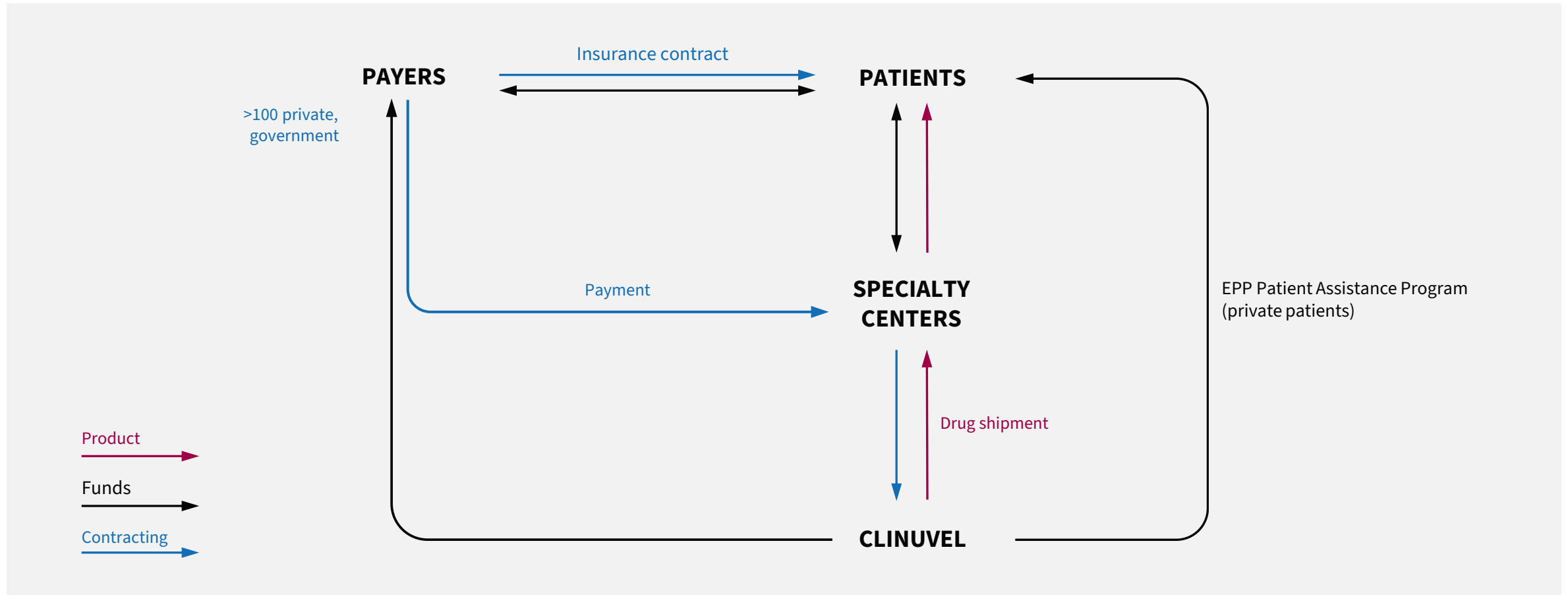
Traditional US commercial model

After US\$0.6-2bn invested, 95% failure rate



Source: adapted from US Assistant Secretary for Planning and Evaluation (ASPE) / Fein (2016).

CLINUVEL's US commercial model



US Commercial Infrastructure

Direct Distribution 2019–2024



In-house commercial team

- Director, Nth American Operations
- Financial specialists
- VA-Medicare-Medicaid
- Patient liaison
- Executive support
- Finance support
- Pharmacovigilance
- Quality Assurance / distribution



Logistics

- DC – cold storage
- labelling / packaging
- QA
- product release

Shipping

- cold transportation
- direct supply
- US medical centers



Medical centers

- orders
- pharmacy storage
- Rx filled
- direct contact

<\$5m p/a

WHAT'S NEXT?

Clinical Development

Melanocortins for skin and brain

Afamelanotide (α -MSH analogue)

SCENESSE[®] & PRÉNUMBRA[®]

- Photoprotective
- Assist DNA repair
- Anti-oxidative
- Anti-oncotic
- Melanogenesis (*bronzing, repigmentation*)



Adrenocorticotrophic hormone (ACTH)

NEURACTHEL[®]

- Anti-inflammatory
- Immune modulation



Clinical development determinations

Severe or life-threatening disorders | Unmet medical need, no alternative

Academic/clinician support | Feasibility of clinical program | Reimbursable

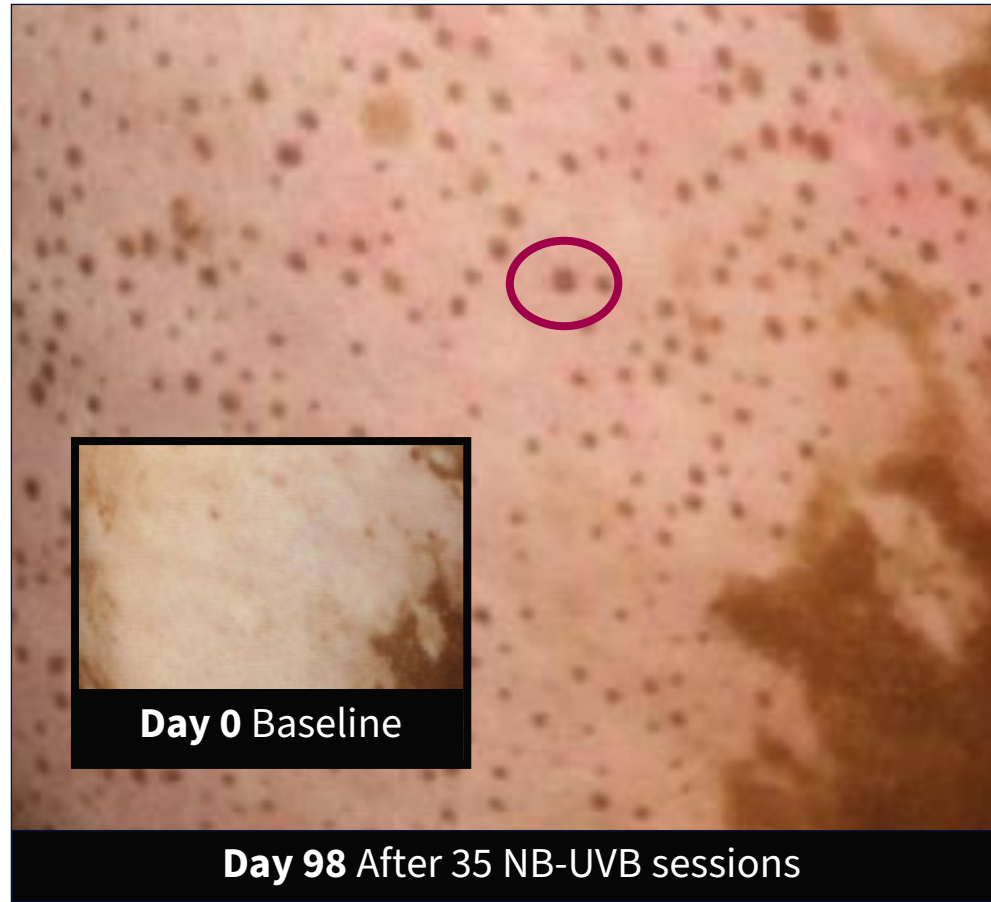
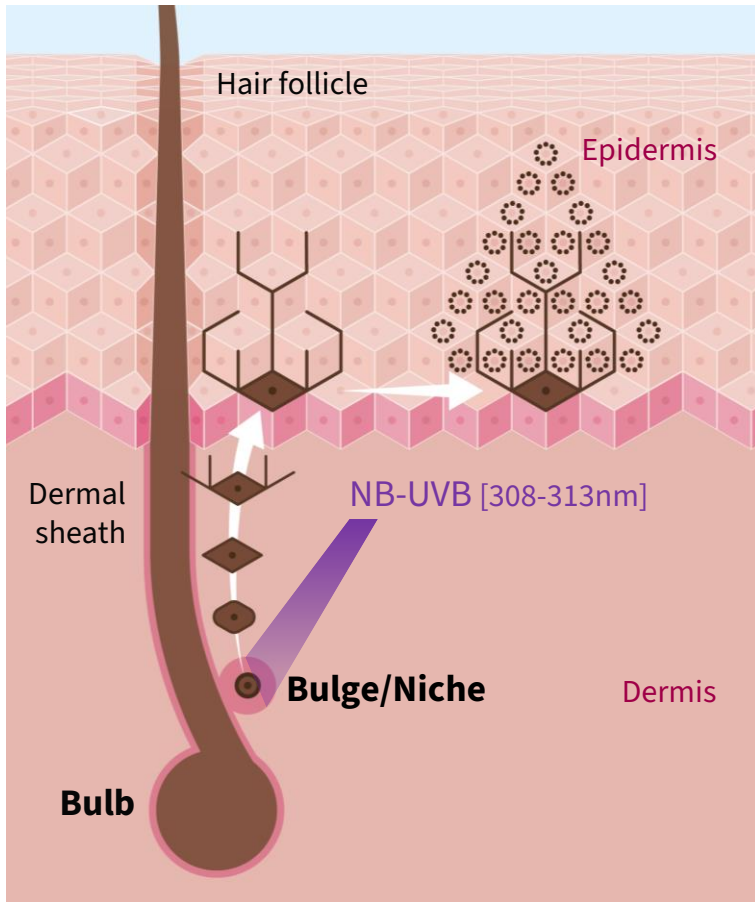
Pharmaceutical Pipeline

	Preclinical	Phase I	Phase II	Phase III	Commercial
SKIN	SCENESSE ® (afamelanotide 16 mg) in adult EPP (EEA, UK, CH, USA, ISL, CAN, AUS)				
	SCENESSE ® (afamelanotide 16 mg) in adolescent EPP				
	SCENESSE ® (afamelanotide 16 mg) in adolescent and adult vitiligo				
	SCENESSE ® (afamelanotide 16 mg) in adolescent and adult XP				
	SCENESSE ® (afamelanotide 16 mg) in variegate porphyria				
	CUV9900 transdermal				
BRAIN	PRÉNUMBRA ® in arterial ischaemic stroke				
	PRÉNUMBRA ® in Parkinson's Disease				
	NEURACTHEL ® instant – IS, MS				
	NEURACTHEL ® modified release – CNS				

A close-up photograph of a woman with dark skin, showing significant vitiligo on her back and shoulder. The white patches are irregular and cover a large portion of her skin. She is looking slightly to the right of the camera with a neutral expression. The background is a plain, light gray.

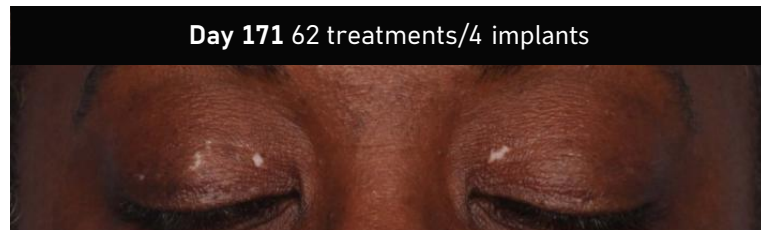
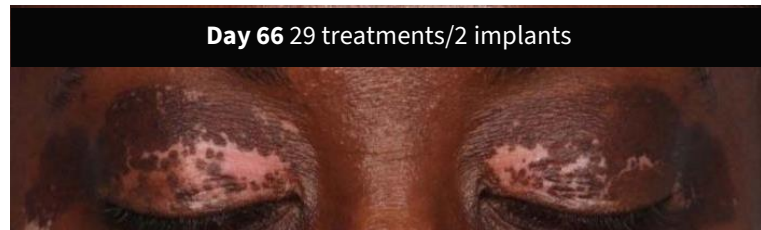
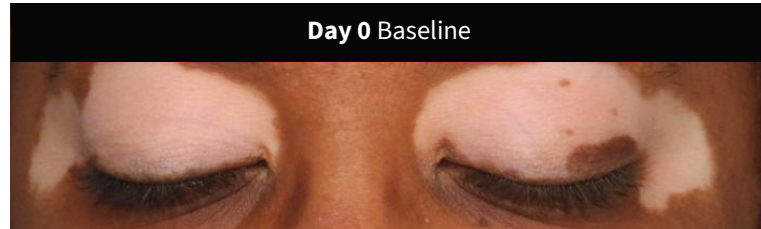
Afamelanotide
for vitiligo

NB-UVB – follicular repigmentation



NB-UVB differentiating follicular stem cells
Melanoblasts migrating, become fully functioning melanocytes
Afamelanotide acting as agonist to MC1R expressed

CUV102 Phase II study results

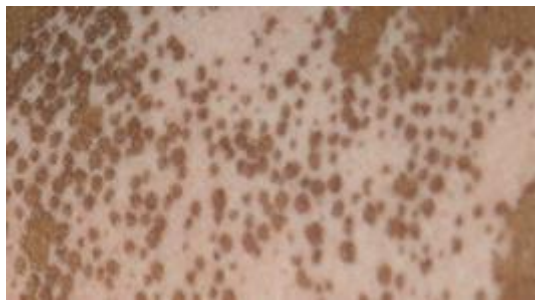


Vitiligo

Path to market



NB-UVB treatment



NB-UVB treatment + afamelanotide

CUV102 +NB-UVB n = 56



CUV103 +NB-UVB n = 21



CUV104 monotherapy n = 6



CUV105 +NB-UVB n = 200 **2024**

CUV107 +NB-UVB n = 200 **2024**

FDA submission¹ 2026

Step 1 >15,600 doses afamelanotide administered
 • Safety profile accepted

Step 2 NB-UVB combination
 • program planning resulted in savings \$75 – 145M

Step 3 **2022** FDA – precedent for NB-UVB as combination therapy

Step 4 **2022** Insurers providing reimbursement codes

Step 5 Project finance - clinical trials A\$77m

Step 6 **2023** Vitiligo Expert Panel

Step 7 **Train & accredit 120 US centres pre-marketing**

Total addressable market USA: US\$4.5bn

9% penetration of patients likely to seek treatment,
 years 1-2: US\$490-570m

Targeted Technology Translation

Targeted Technology Translation

PHOTOMEDICINE

TO

PhotoCosmetics

**ERYTHROPOIETIC
PROTOPORPHYRIA**

Intolerance to all types of light

1

**POLYCHROMATIC
PHOTOPROTECTION**

Advanced solar shield

XERODERMA PIGMENTOSUM

Severe photodamage and skin cancer

2

DNA REPAIR

Preserves and repairs the skin's DNA

VITILIGO

Loss of pigmentation in the skin

3

MELANOGENESIS

Activates pigmentation

Establishing a Brand

PHARMACEUTICAL

CORE TECHNOLOGY

melanocortins

INNOVATION

chemistry
formulations

DATA

safety
efficacy



PHOTOCOSMETIC

PHOTOPROTECTION

DNA ASSISTED REPAIR

SELF-BRONZING



Medical Community

Analysts

ASX

News Communiqués /
Bulletins

Patient experience

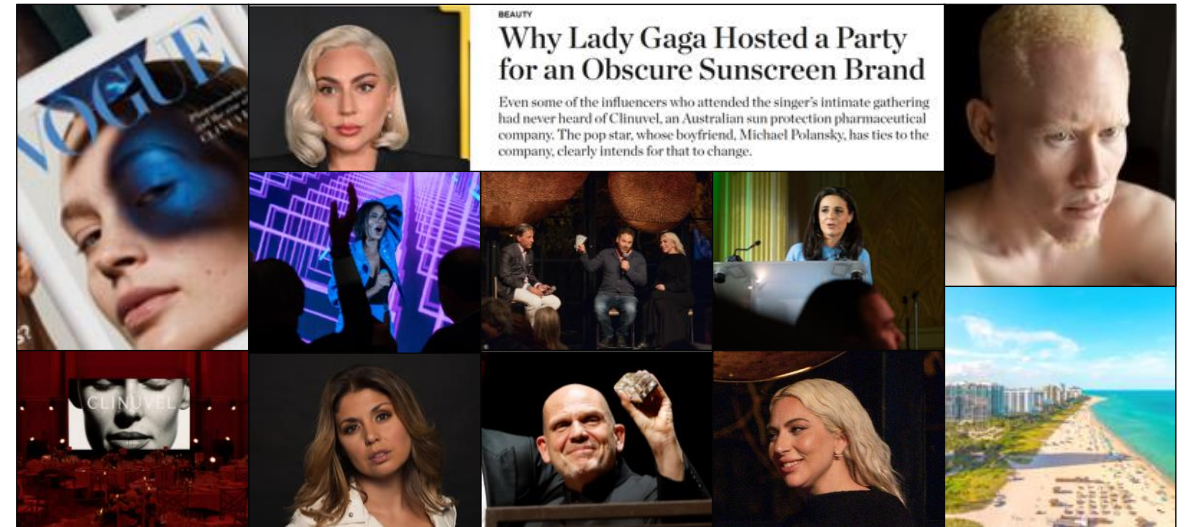
Malibu Event

3.4m Instagram

8,300 CUV Instagram

1,000% traffic increase

Target 5m CUV
database



CLINUVEL

A close-up photograph of a woman with vitiligo. She is looking slightly to the right of the camera with a neutral expression. Her skin is a mix of dark brown and white patches, particularly visible on her shoulder and upper arm. The background is a solid, dark grey color.

Q&A