CLINUVEL

ASX ANNOUNCEMENT

Twilight Event – Briefing

Melbourne, Australia, 29 June 2023	ASX:	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

CLINUVEL presented during a Twilight Briefing, after the close of market yesterday. Organised by Monsoon Communication, a slide deck of the Twilight Briefing is appended.

– END –

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; BÖRSE FRANKFURT: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

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

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 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 2022 Annual Report. Forward-looking statements speak only as of the date on which they are

made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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Unfolding

28 June 2023

Twilight Briefing Melbourne

Hosted by Monsoon Communications

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Value

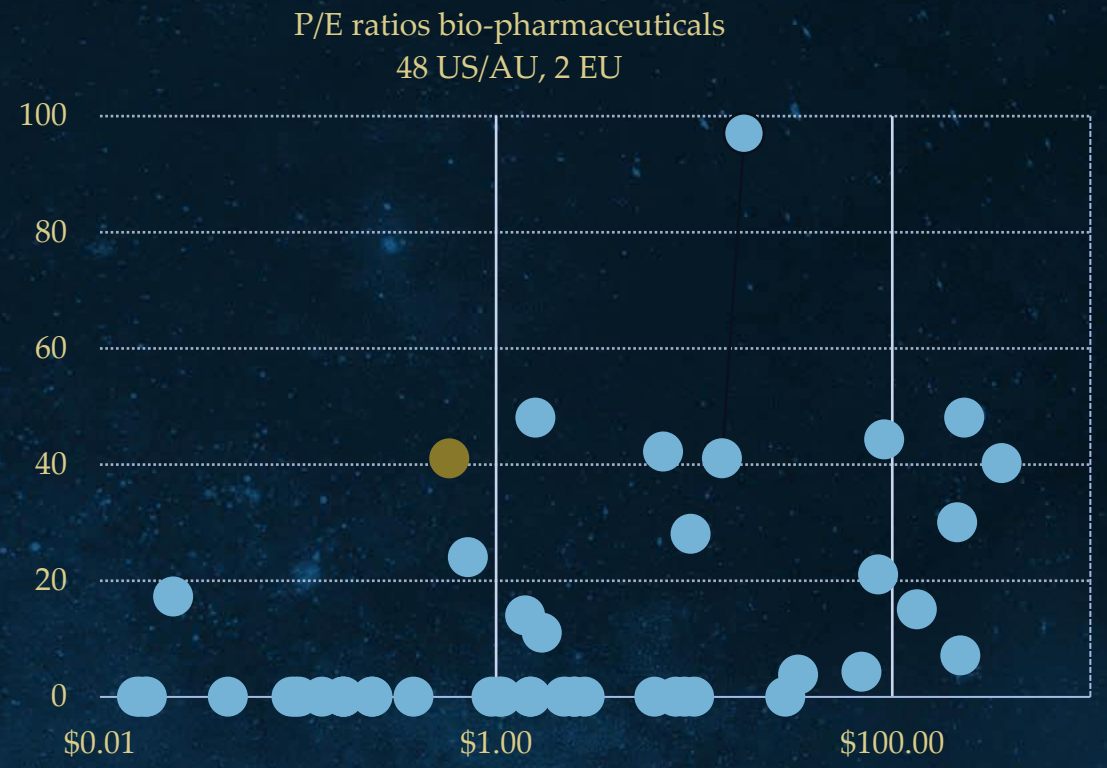
Valuing bio-pharmaceuticals

50 bio-pharmaceutical (48 US/AU, 2 EU)

TIC	P/E
NVO	40.2
AZN	48
PFE	7.1
NVS	30
CSL	44.3
SNY	15
REGN	21
GSK	4.3
BAX	-
BION	3.8
IMM	-
ITCI	-
ALNY	-
AXSM	-
PHAR	24
OCEA	-
SPL	-
PXS	17.2

TIC	P/E
INCY	41
BMRN	97
SRPT	-
REC	28
JAZZ	-
ROIV	-
EXEL	42.2
BBIO	-
DICE	-
IRWD	11
NEU	-
MSB	-
CPRX	14
ALM	48
AGIO	-

TIC	P/E
RYTM	-
ANIP	-
CUV	**41**
MNK	-
PTN	-
PTX	-
RAC	-
PAR	-
IMU	-
CYN	-
FENC	-
OPT	-
ABEO	-
AKTX	-
CLLS	-
NKTR	
ACOR	



Nasdaq '22	Bio-pharmaceuticals	Profitable
Main board	798	67(8.4%)
NBI	274	25(9.1%)
ASX	91	3(3.2%)

Ref: *NY Stern PE pharmaceutical drugs | Curr=26, TTMPE=17, FWDPE=14 (Jan '23)*
CLINUVEL Strategic Update V, September 2022

CLINUVEL valuation

Differentiation

Date/period	Activity	P/E	Share Price
22 Sep 2014	EMA appr	-	4.90
09 Oct 2019	FDA appr	120	45.00
16 Mar 2020	US distrib	36	13.62
23 Sep 2021	dividends	87	43.58
30 Jan 2023	HY'22	67	28.29
23 Jun 2023	prior to FYE	41	17.42

Institutions	Jun 2022	Dec 2022	May 2023
Moelis	$23.14	$17.56	$23.21
Wilsons	$30.50	$23.53	$30.07
Jefferies	$32.00	$36.90	$37.30
BioShares	Buy	Buy	Accumulate

US fund:

"We don't usually meet profitable pharmaceutical companies, great story…"

US Inst. shareholder:

"…only through live events do we realize how much patience and long-term planning CUV does… we couldn't fully appreciate from Newsletters…"

US Inst. shareholder:

"CUV's dual strategy is unusual but most attractive, we invest in owner operated companies with a niche…"

AU Inst. shareholder:

"We have been following the story for years, an example for the sector, we invested in 2023 in CUV for its consistency…"

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Pipeline

Clinical pipeline skin-brain

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

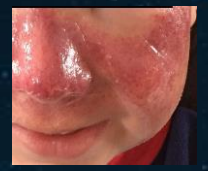
	Products	Indication	Age group	Phase I	Phase II	Phase III	Commercial
	SCENESSE®	EPP[1]	adults	→	→	→	EEA-US →
1	**SCENESSE®**	EPP[1]	adolescents			regulatory interaction, update '23 →	
2	**SCENESSE®**	VP[1]	adults	→	→	read out '24 (CUV040)	
3	**SCENESSE®**	XP[1]	>15 yrs	→	→	read out '23/'24 (CUV156-151-152-154)	
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**		

Pharmacovigilance over decades has been the 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

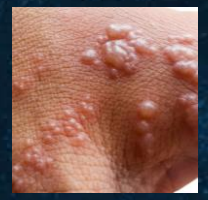
Clinical programs afamelanotide

Erythropoietic Protoporphyria (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
Pep[1]: 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
Pep[1]: TVASI50
Sec[1]: 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
Pep[1]: reduction photoproducts
Sec[1]: assisted DNA repair

Arterial Ischaemic Stroke (AIS)

Unmet need, > branch A2-M2-PS
Ph II: n=12 (CUV803) - ongoing
Pep[1]: safety
Sec[1]: increased CBF, decrease penumbra

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

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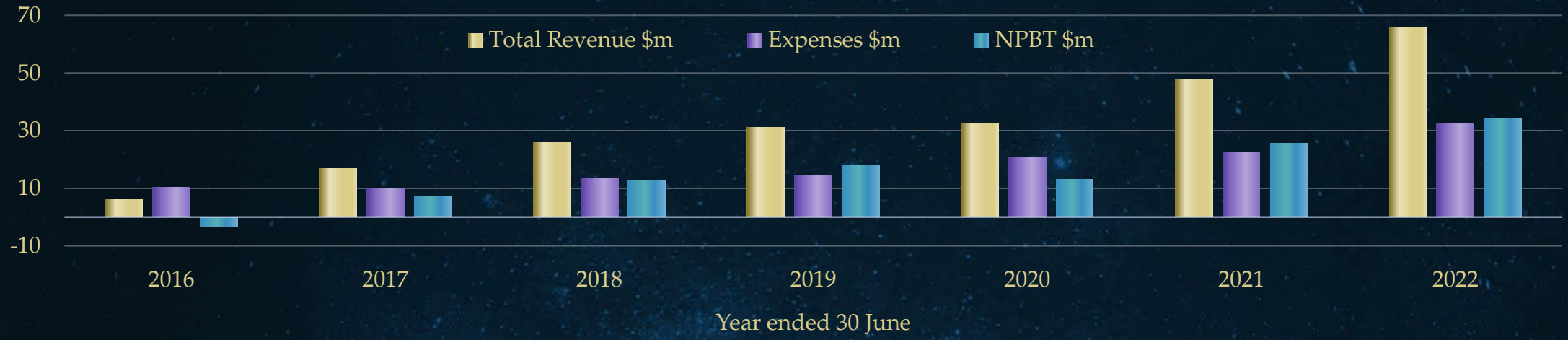
Finance

Financial performance 2005 – 2023



Discipline 2005 – 2023	
Financing	debt-free
Equity	minimal 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)

FYE 23 RESULTS:
4th week August

All figures in A$

Financing

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

I PHARMACEUTICALS		
SCENESSE®	- expanded use in	XP, vitiligo, VP
PRÉNUMBRA®	- 2nd gen. afamelanotide	AIS
NEURACTHEL®	- ACTH	CNS disorders
II PHOTOCOSMETICS		
CYACÊLLE	- polychromatic screens	highest risk populations
2nd product line	- DNA skin repair	
3rd product line	- risk-free tanning	fair, freckled, blond/ red hair, blue eyes
III MANUFACTURING		
In-house facilities	- next generation controlled-release	
	- parenteral formulations	
	- transdermal formulations	

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Photocosmetics

From photomedicine to photocosmetics?

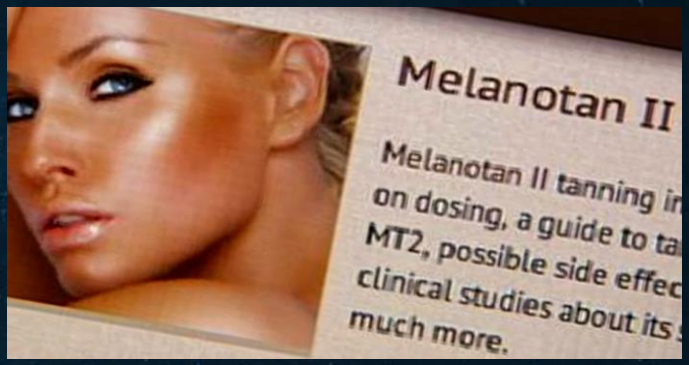
MELANOCORTINS IN PHOTOMEDICINE

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

Origin mass **demand** *for melanogenesis*

- history MELANOTAN-EPITAN 1980–2005
- ± $50m counterfeit self-injectable tanning products
- SCENESSE® no off-label permitted
- clinical results photomedicine CUV 2005–2023

COUNTERFEITS



MELANOCORTINS ACTIVATE MELANOGENESIS

ACTH

↓

AFAMELANOTIDE

↓

PARVYS/PHI-MELANOTIDE

Targeted
Technology
Translation

From photomedicine to photocosmetics?

ACTH

AFAMELANOTIDE

PARVYS/PHI-MELANOTIDE

+/- 43 y data – photomedicine

"photocosmetics"

Transdermal, leave-on product lines

1. CYACÊLLE polychromatic range
2. DNA assisted repair
3. melanogenic (sun-free bronzing products)

MARKETING = GLOBAL COMMUNICATION

1. in-house Communications, Branding, Marketing team (25)
2. global program
3. marketing budget
4. Targeted Digital Marketing

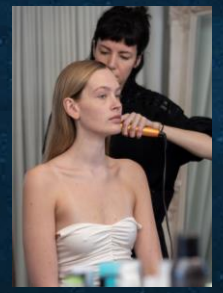
CONTENT GENERATION

Transformational program

Pharmaceuticals → Science - evidence based **trust-longevity** → Strategy melanocortins in **photocosmetics** → In-house CBM division +/- 25

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

1	Social media	- Direct branding - Performance marketing
2	CUVA program	- User-generated content - 60: 900K followers
3	CUVIP program	- Cyclical program - 10: >5 M followers
4	Global events	- Pilots, commercial launches - Large scale launch events
5	Television/YouTube	- Prime time presentations - Themed
6	Press/industry	- Editorial introductions - Cosmetic/dermatology
7	Partnership events	- Identified audience - Common concerns/risks
8	Conferences/fairs	- Product presentations - Invited clientele
9	IR program	- Conferences/NDRs - Soirées/panels



Conclusion

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

"pre-emption – resourceful – longitudinal"

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Thank you for your interest

Appreciation to Monsoon

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

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Questions received and addressed

Competition in orphan diseases and SCENESSE®

Segmentation vitiligo: how does SCENESSE® fit into future treatment?

Catalysts for 2023

How to view competition in orphan diseases?

Where is SCENESSE® on pareto curve?

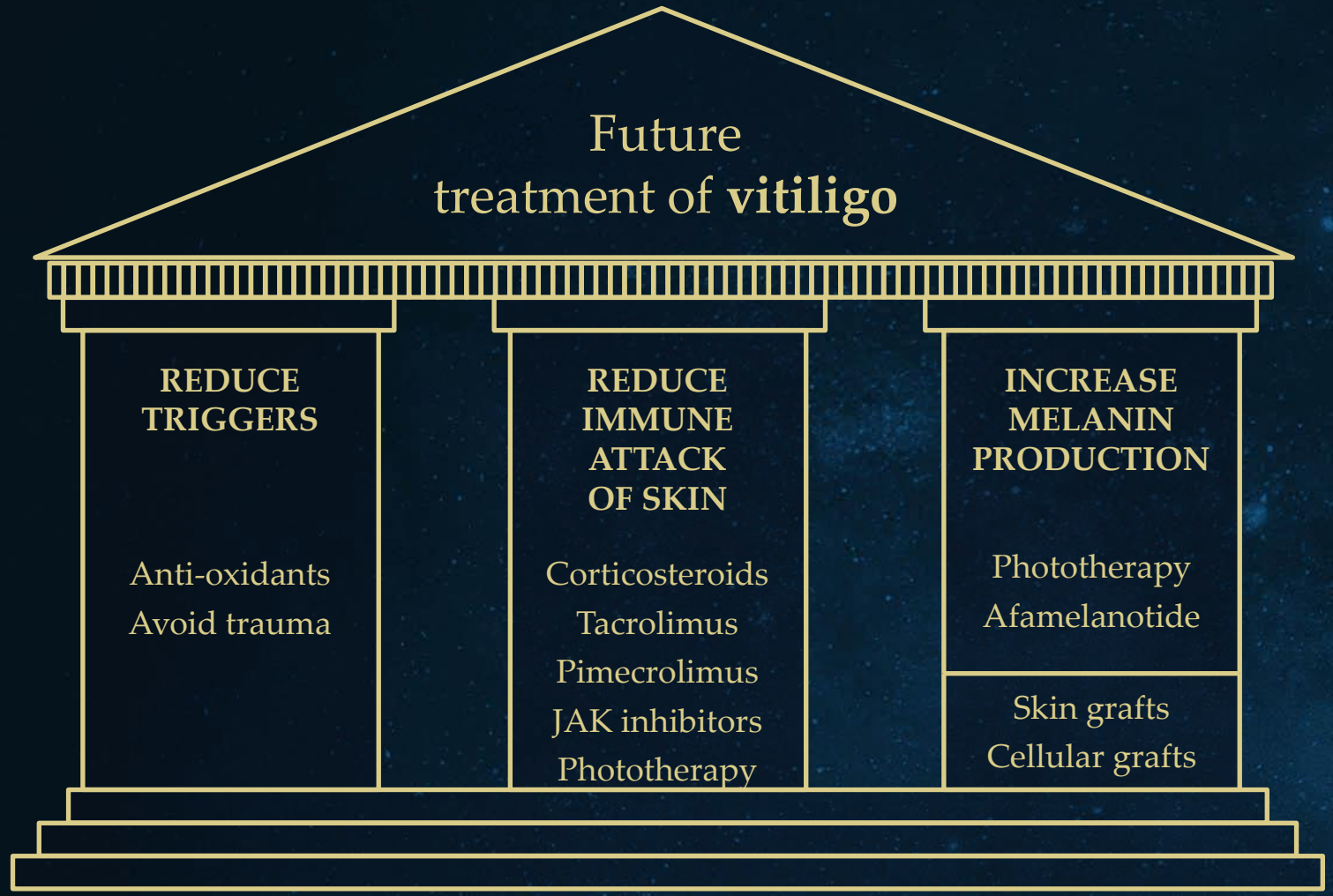
Example: market for hereditary angioedema (HAE; prevalence: 1:10-50k)				
Product	Therap. approach	FDA appr.	Sponsor	US$ "per HAE attack"[1–4]
CINRYZE	reconst. h-plasma	Oct 2008	Lev Pharma. (acq by ViroPharma $617M)	$15,108
BERINERT	C1 esterase inh.	Oct 2009	CSL-Behring	$14,668
KALBITOR	h-monocl. antibd	Dec 2009	DYAX Corp. (acq by Shire $5.9B)	$21,068
FIRAZYR	brdkin B2-rec ant	Aug 2011	Shire (acq by Takeda A$46B)	$14,806
RUCONEST	C1 est-recomb	Jul 2014	Pharming (MCAP A$1.1B)	$12,905
HAEGARDA	C1 esterase inh.	Jun 2017	CSL-Behring	$22,392
ORLADEYO	kallikrein inh.	Dec 2020	BioCryst Therapeutics (MCAP A$1.9B)	$37,208/month[5]

1. over time orphan diseases - attract new entrants
2. populations of addressable patients - being expanded
3. cost-effectiveness per treatment - in close range
4. cost-effectiveness - modelling
5. multiple actors - do not erode but increase value

[1] Front med Lau; [2] FDA, RX Pharma, AWP; [3] Avon-drug dev 2015; [4] ICER data 2020; [5] Rx GoodTher

Presented at AAD 2023 - Vitiligo Future Treatment

Global Vitiligo Foundation



Afamelanotide

1. non-immune suppressant
2. physiological response
3. activates eumelanin
4. icw NB-UVB differentiates stem cells
5. stabilizes eumelanin
6. < 4 weeks to 1st response
7. systemic = total body

JAK inhibitor(s)

1. immune-suppressant
2. non-physiological
3. not activating eumelanin
4. no effect on stem cells
5. repetitive use
6. long time to response
7. topical = area-specific

Catalysts 2023

SCENESSE®	use in adolescents	EMA outcome
Vitiligo	CUV105, n=150, TVASI50	start
XP	CUV151-156	read outs
VP	CUV040	1st results
AIS	CUV803	1st results
NEURACTHEL®		manufacturing
Photocosmetics		launch, e-commerce global launch event
FYE23		financial performance