medicinal photoprotection

Melbourne, 23rd April 2009, 4:30pm

Dr D Wright, VP Scientific Affairs
Dr H Agersborg, CSO
Dr Ph Wolgen, CEO

Clinuvel

Safe harbor statement

Clinuvel is an Australian biopharmaceutical company focused on developing its leading drug candidate, afamelanotide, for a range of UV- related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks.

Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward looking statements), investors should note the following:

- actual results may and often will differ materially from these forward looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development program for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development program for afamelanotide is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place.

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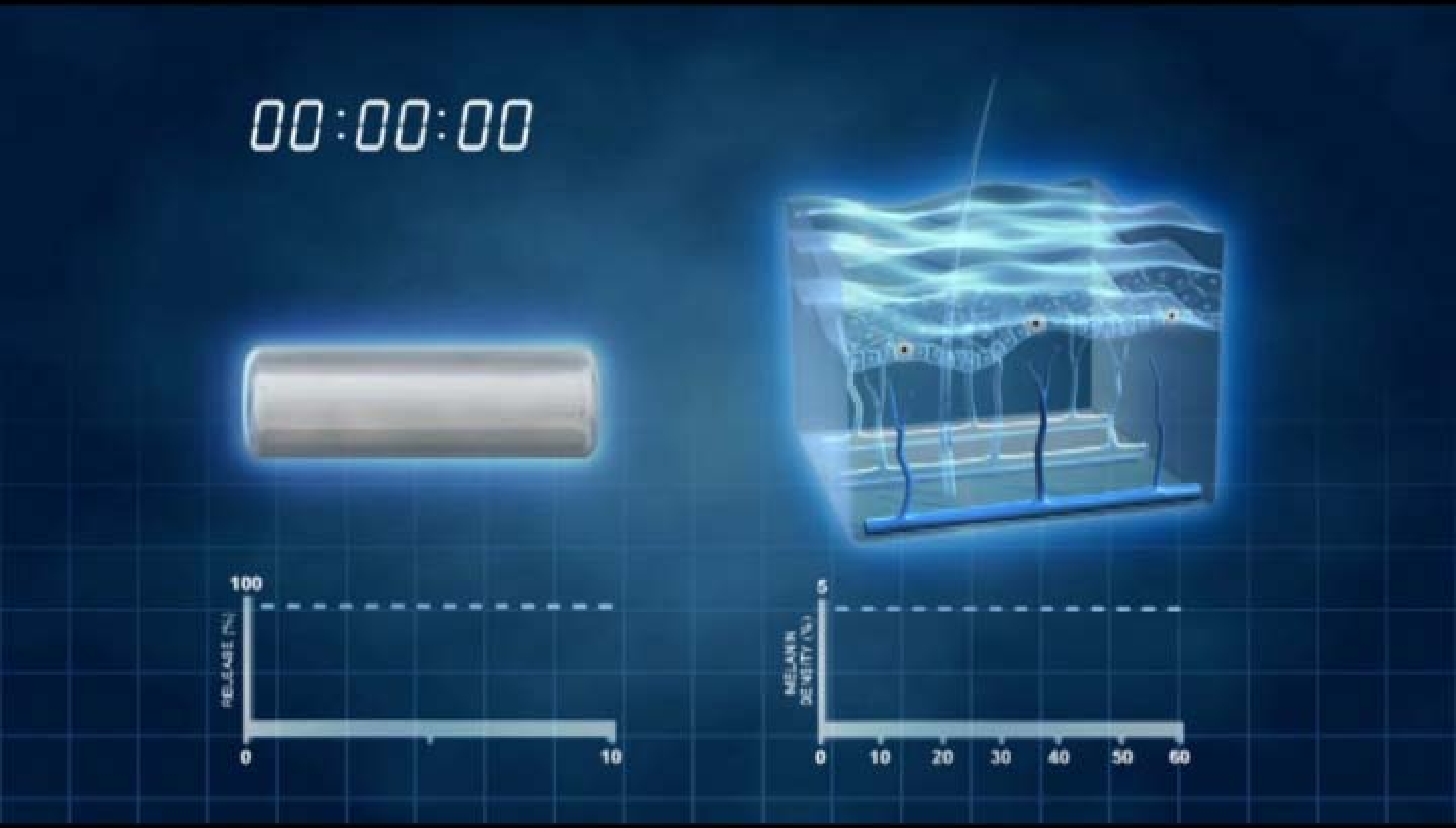
Clinuvel Pharmaceuticals Ltd

ASX: CUV
Xetra: UR9
ADR: CLVLY

- Afamelanotide: Medicinal photoprotection
  First-in-class drug
- Completion Phase III 2009 + MAA
- foster Australian value investment 55:45%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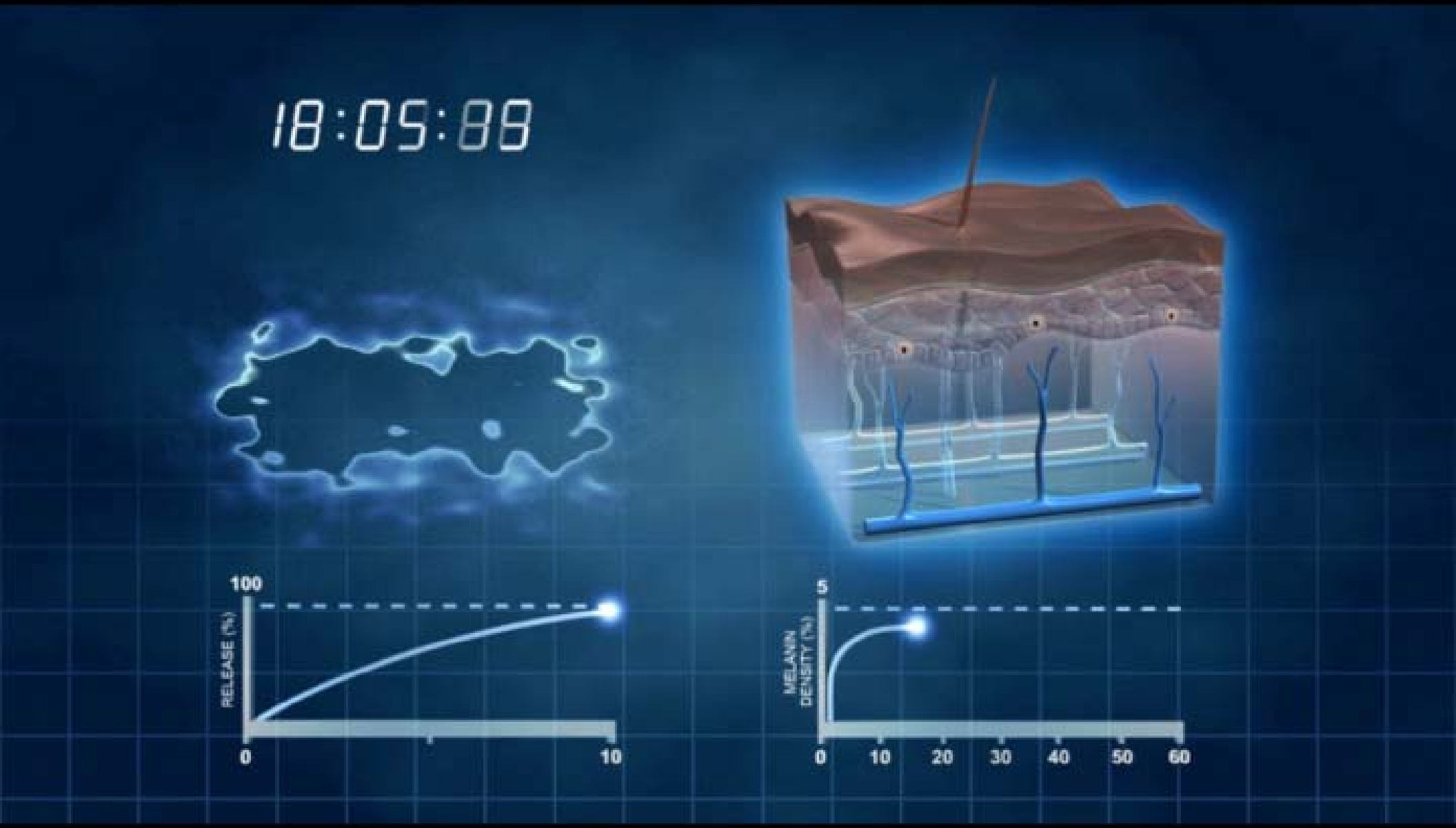
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RELEASE (%)
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MELANIN DENSITY (%)
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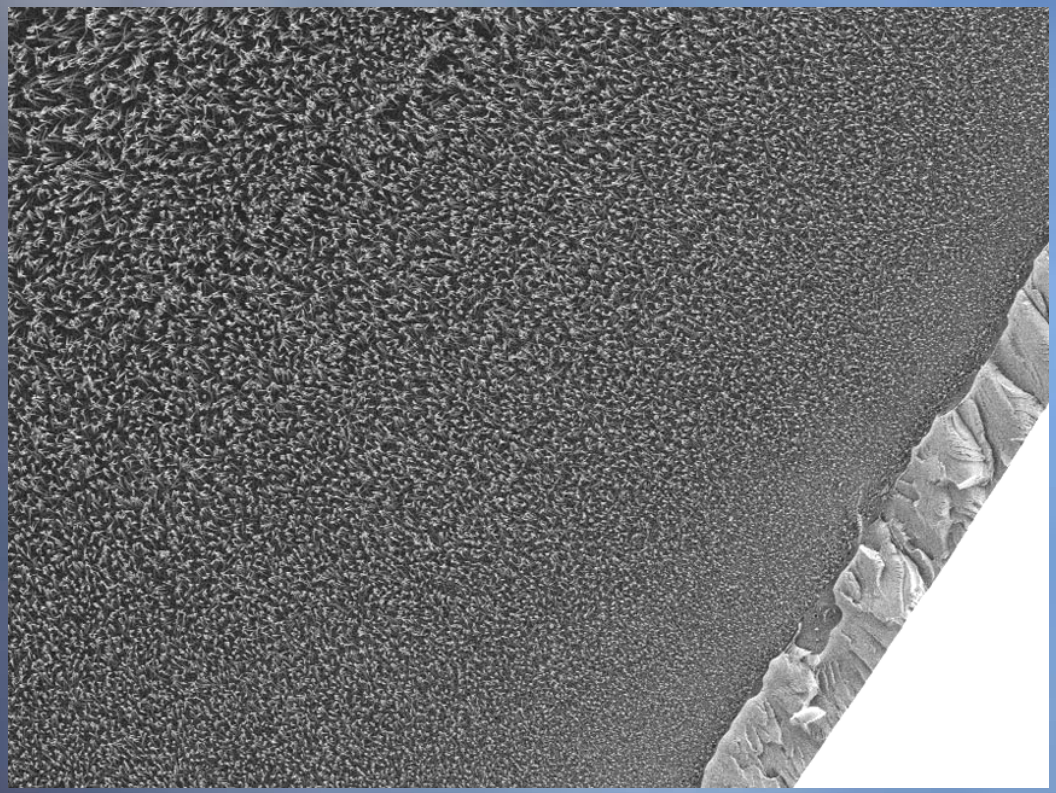
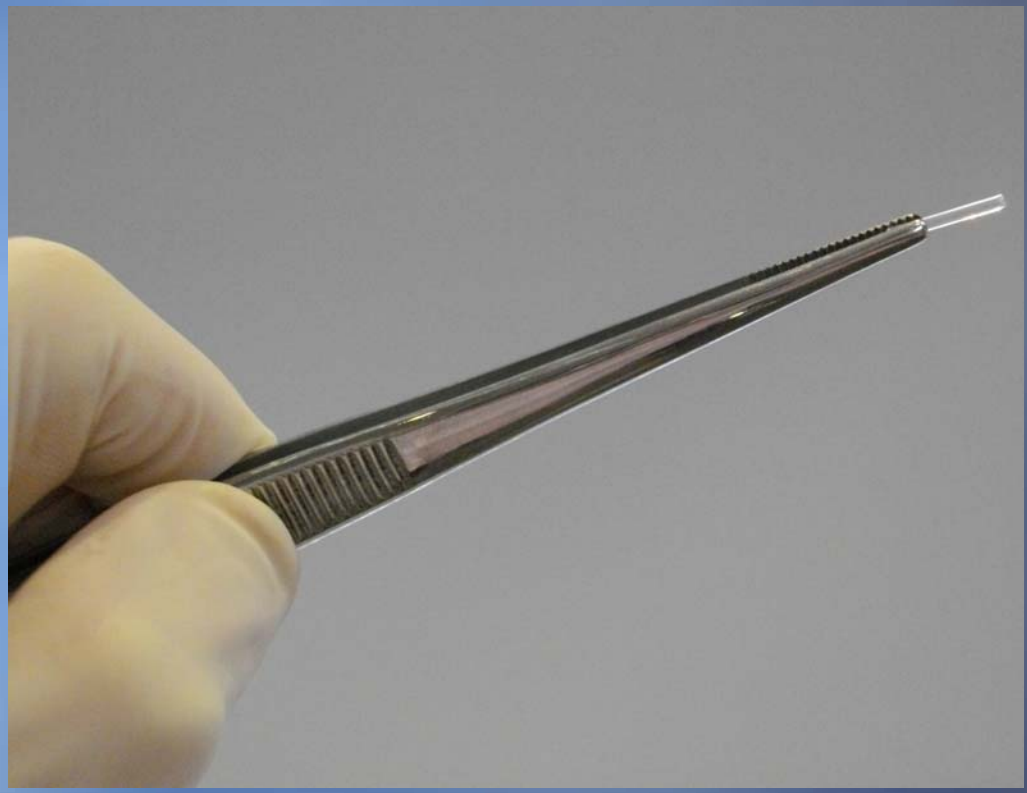
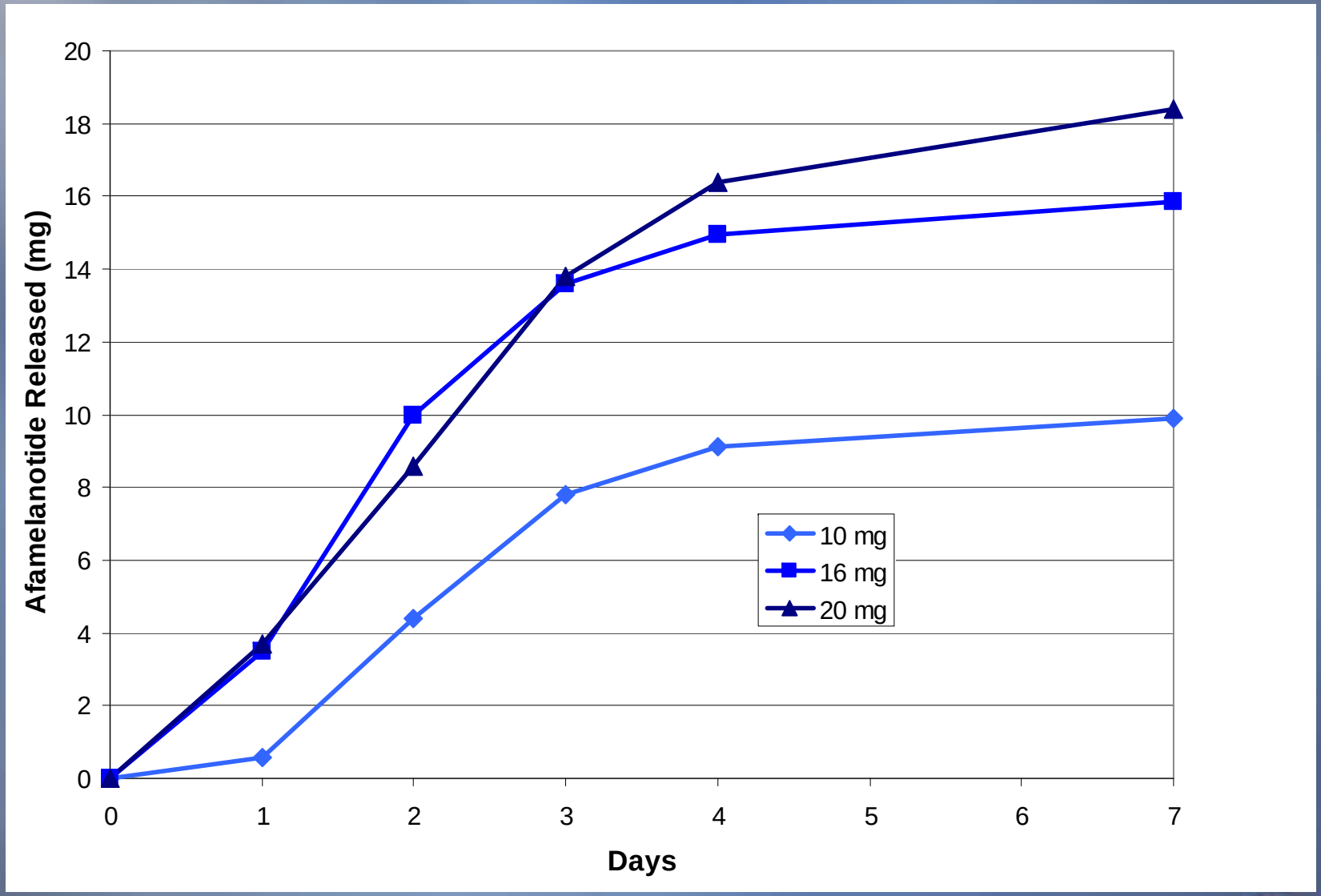
Chemistry, Manufacturing, Controls

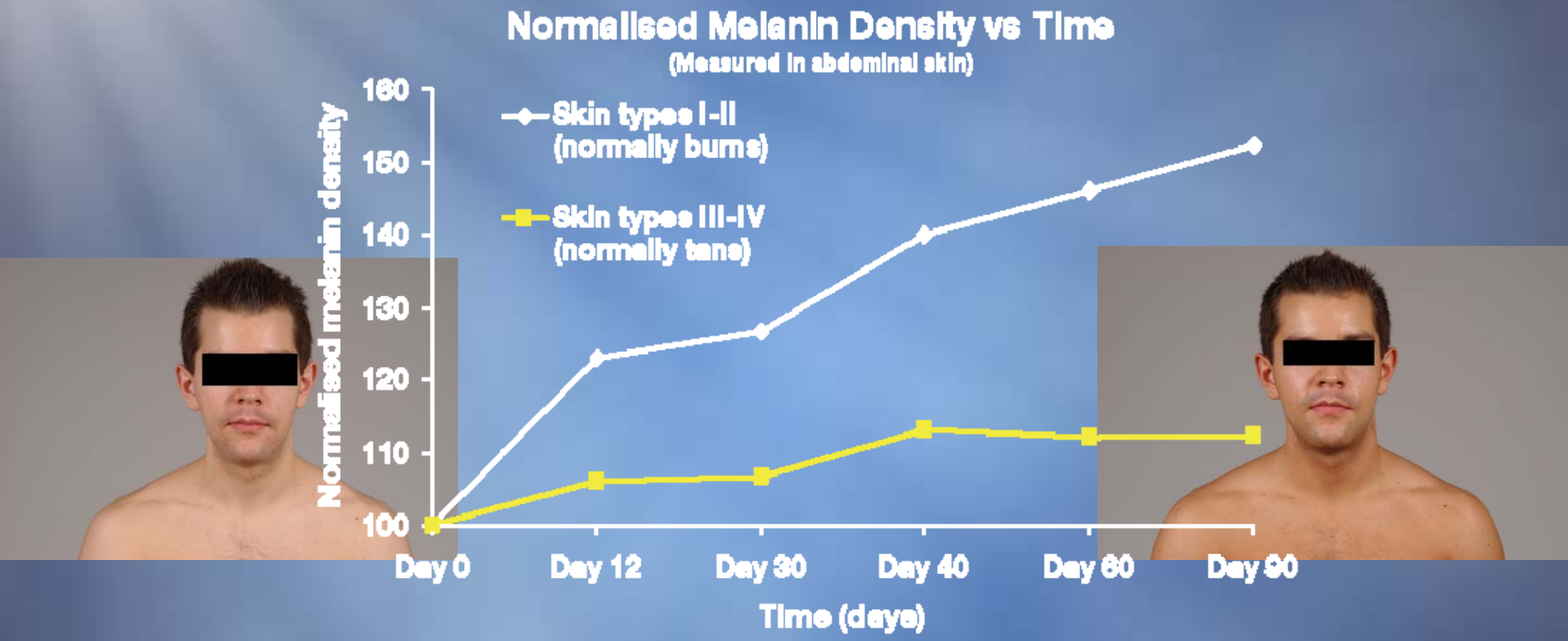




Implant Release Profiles



Afamelanotide increases melanin density



Photoprotection to fair skin (Fitzpatrick type 1 and 2)
Drug released over 7 to 10 days
Melanin increased for 60 days

Am J Epidemiol, 2002; J Inv Dermatol, 2006; NEJM, 2009

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EPP - Photoprotection

- Genetic disease: deficiency of ferrochelatase
- Absolute sun intolerance: **phototoxicity**
- Childhood: misdiagnosis, misery (and for parents)
- Adult patients: adaptive behaviour (sun avoidance)
- Clinical protocols: 1 or 2 endpoints

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Orphan Disease(s) = Rare Disease(s)

- Incidence: < 200,000 (US), < 5 in 10,000 (EU)
- Severe disorders: porphyrias
- Lack of current effective therapy: photoprotection
- 2008 Orphan Drug Designation:
  - EMEA
  - SwissMedic
  - FDA
  - TGA (pending)

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CUV Integrated Clinical Program
e.g. EPP (porphyria)

- 5,000 registered patients
- 11 countries
- Intense program management – online/offline
- Networks – patients and physicians

Clinical Data

Liquid 1,700 doses in 137 subjects
Implant 450 doses in 324 subjects
Currently 190 patients

Phase II	Study # 008 n = 45	p < 0.0001 MD: p < 0.03	2005
Phase I	Studies # 006-007-009 n = 28	MD: p < 0.05	2006 Confirmatory PK, final dose and formulation
Phase IIb PLE	Study #012 n = 26	p = 0.01	2006
Phase II EPP	Study #010 n = 5	p = 0.007 MD: p = 0.0043	2007
Phase III EPP	Study #017 n = 101	Reduce # and severity of reactions	2007
			2008 ODD status granted for EPP
Total n = 205	Interim results n = 14	p < 0.001 MD: p = 0.048	Jan 2009
Orphan disease	Study #017 full result n =101		Nov 2009

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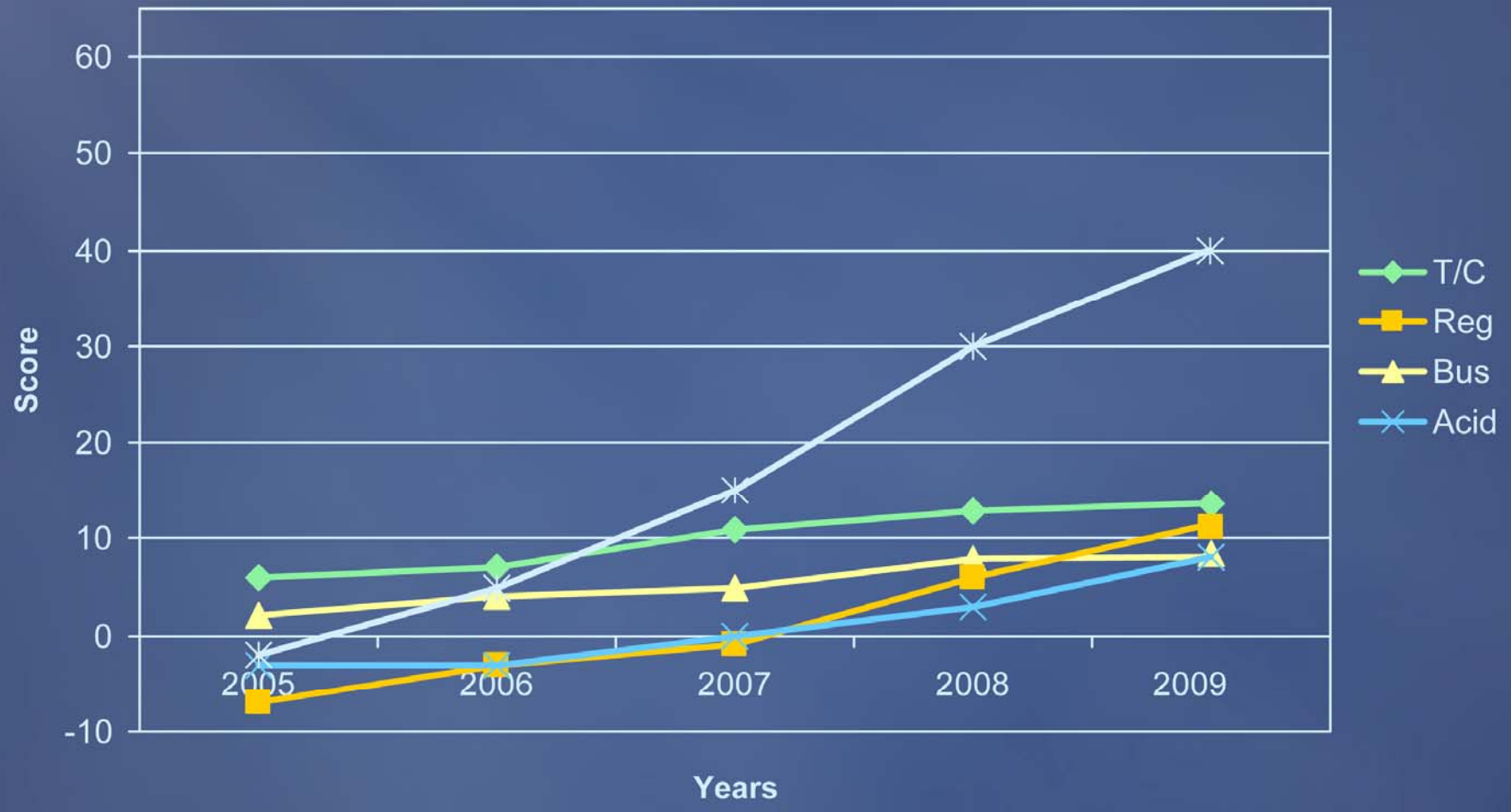
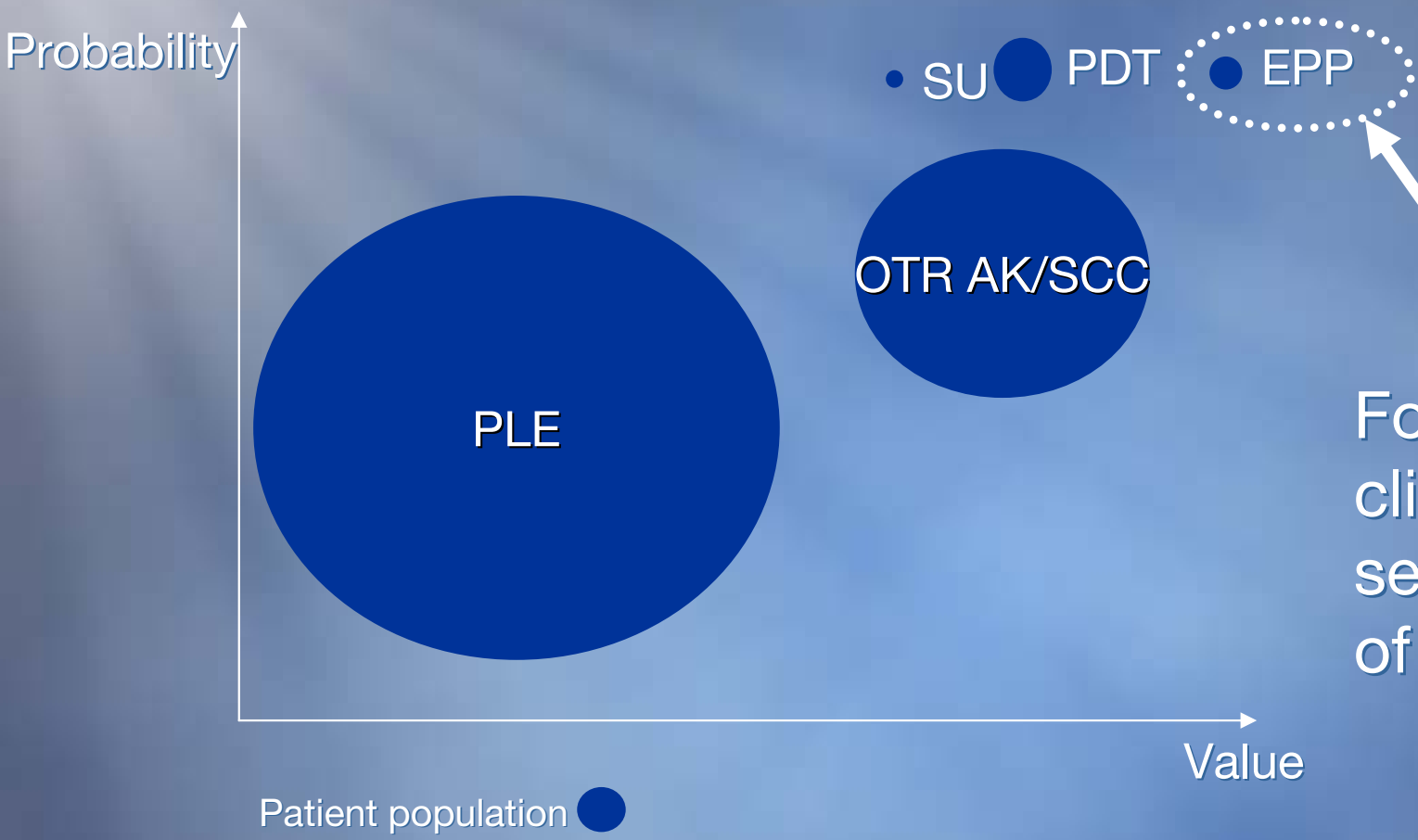
Quantitative Analysis Clinuvel



Total score: 40/66

Value proposition



Focus on greatest clinical need serving as a proof of concept

Condition	Treating Physicians	Population
EPP	Hematologists/Dermatologists	>5000
AK/SCC	Transplant Surgeons/Dermatologists	>10m
PDT	Oncologists/Gastroenterologists	>5000
SU	Photobiologists/Dermatologists	<5000
PLE	Dermatologists/GPs	10-15%

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Case study: Genzyme orphan drugs

Drug	Disease	Annual cost per patient	Incidence	Ph III trial size
Cerezyme	Gaucher disease	>$300,000	5000 worldwide	40
Fabrazyme	Fabry disease	~$180,000	5000 worldwide 0.25 per 10,000	56
Myozyme	Pompe disease	$200,000-300,000	~1000 worldwide	18
Aldurazyme	MPS 1	~$175,000	0.025 per 10,000	45
Clolar	Acute lymphoblastic leukaemia	$90,000	0.1 per 10,000	49
Gleevec	Chronic myeloid leukemia	$35,000-50,000	0.18-0.5 per 10,000	1225; 147

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Financials

- MCAP A$84M (FD=A$108M)
- A$39.48M reserves, A$1.2M burn rate (A$1.7M Q3'09)
- 15 yr development cycle - A$55M to date, A$93M
- 303M o/s (F/D 326M)
- 64% in 50 different holdings

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Summary

- Clinuvel is funded to market A$39.4M
- Afamelanotide - first-in-class drug
- Intense risk management
- Corporate development ongoing

“…where no one has gone before…”