

# Photoprotection

Afamelanotide 16mg

ASX:	CUV
XETRA-DAX:	UR9
ADR 1:	CLVLY

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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# Our journey/strategy

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# Clinuvel



DAYS

HOURS

MINUTES

SECONDS

1471

23:59

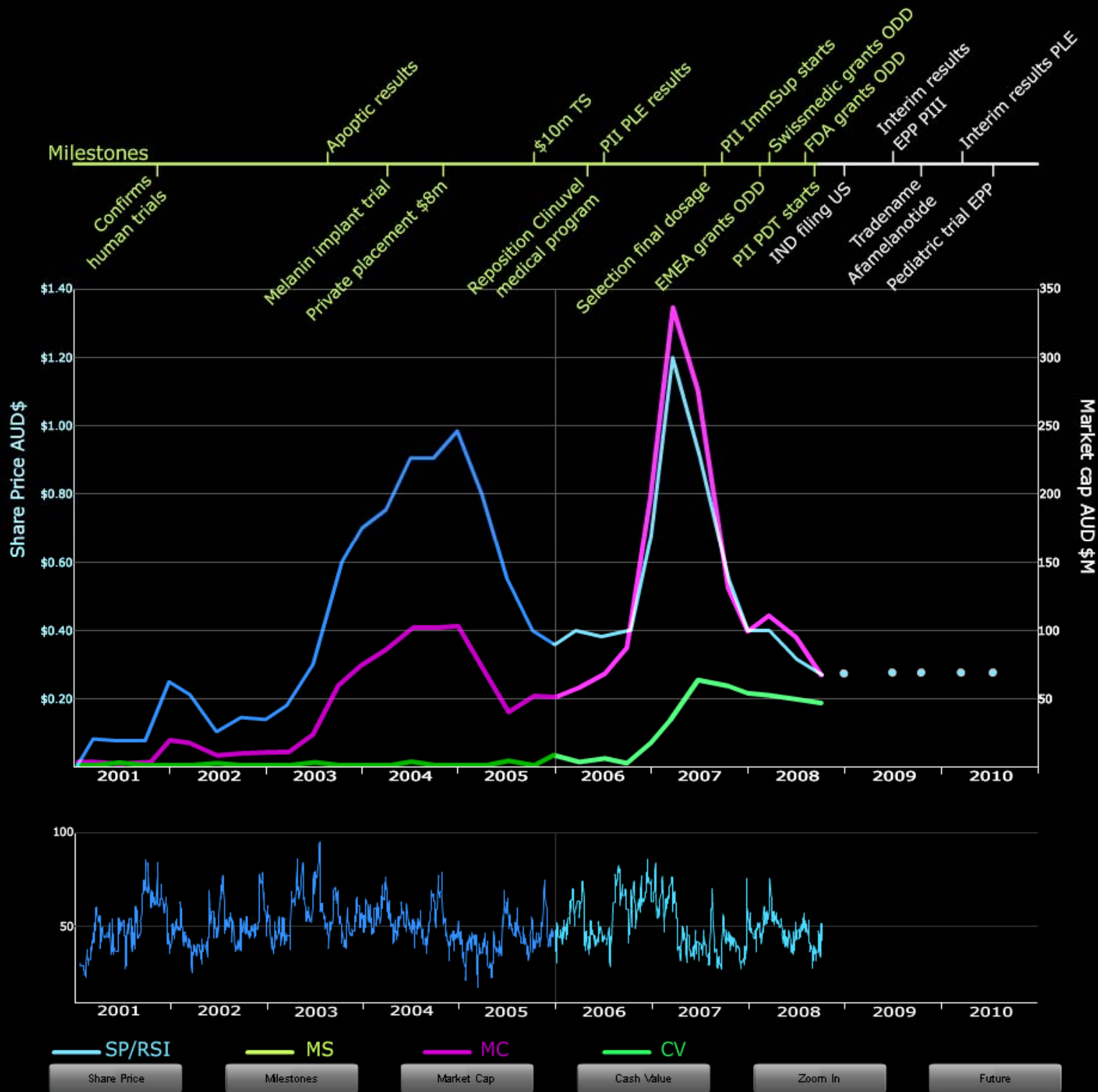
57

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800-295-0220

# Clinuvel's Domain: Photoprotection



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# Positioning CUV



OUR SITES: [corporate.clinuvel.com](http://corporate.clinuvel.com) | [photoprotection.clinuvel.com](http://photoprotection.clinuvel.com) | [clinuvel.com](http://clinuvel.com)

## Clinuvel Photoprotection Skin Intelligence

Dermatology

Sunburn

UV and Light

Skin Pigmentation

Xptise

### Intelligence on Skin, Melanin, UV and Light.

3 levels of knowledge [general, professional, academic]

**Photoprotection** (*n*) - the provision of protection from light and ultraviolet radiation. Melanin and sunscreens both provide photoprotection to human skin.

#### Featured topics

Skin Conditions

Skin Pigmentation

Q and As

About

- ▶ [Actinic Keratosis \(AK\)](#) - precancerous lesions of the skin
- ▶ [Squamous Cell Carcinoma \(SCC\)](#) - malignant tumour of the skin
- ▶ [Erythropoietic Protoporphyrin \(EPP\)](#) - a rare inherited metabolic disorder of the heme pathway
- ▶ [Polymorphous Light Eruption \(PLE\)](#) - a distressing seasonal skin condition likened to sun poisoning
- ▶ [Photodynamic Therapy \(PDT\) and Phototoxicity](#) - phototoxicity after PDT treatment
- ▶ [Solar Urticaria \(SU\)](#) - anaphylactic reaction to sun

#### Latest headlines worldwide

Skin Cancer

EPP

PLE

PDT

SU

Vitiligo

- |  |                    |            |
|--|--------------------|------------|
| ▶ <a href="#">Looking at skin cancer: What you need to know</a>                                  | 3News NZ           | 27/10/2008 |
| ▶ <a href="#">Being Snow White can be dangerous</a>  | New Straits Times  | 26/10/2008 |
| ▶ <a href="#">60,000 Nigerian Albinos Have Severe Skin Cancer</a>                                | Saturday Tribune   | 25/10/2008 |
| ▶ <a href="#">Chronic Inflammation Can Help Nurture Skin Cancer, Study Shows</a>                 | Medical News Today | 22/10/2008 |
| ▶ <a href="#">Link Between T Cell Response To New Melanoma Antigen And Relapse-Free Survival</a> | Medical News Today | 21/10/2008 |

About the Site

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### Xptise

The next dimension of knowledge

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#### Xptise Discussions

- ▶ [7th World Congress on Melanoma, Austria 2009](#)
- ▶ [Porphyria In Touch Meetings - USA](#)
- ▶ [Porphyria Association Inc \(Australia\) AGM](#)
- ▶ [More...](#)

#### Xptise Q & As

- ▶ [What are other common terms for AKs? Do you mean moles or sunspots or dry rough crusty patches?](#)
- ▶ [I am extremely susceptible to sunburn and can burn by being in the sun for as little as 5 minutes. What advice can you give me?](#)
- ▶ [How long can I spend in the](#)

# Quantitative Analysis Clinuvel



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## Technological/ Clinical

## Regulatory

## Business

## Acid Test

	2005			2006			2007			2008			2009			DF
	-1	1	2	-1	1	2	-1	1	2	-1	1	2	-1	1	2	30%
Safety in animals, toxicology SDT/MDT		•			•			•				✓			✓	
Safety in humans, SDT			✓			✓			✓			✓			✓	
Formulation ST, possible		•			•			•			•			•		
CMC	x			x				•			•			•		
Manufacturing, tech, scale, COGS		•			•			•			•			•	→	
Delivery, acceptable/optimum		•			•			•			•			•		
Safety in humans, LT		•			•			•			•			•		
<b>Score</b>			6			7			11			13			14	12.7
Regulatory, ROW strategy	x				•			•			•			•		
Regulatory, US strategy	x				•			•			•			•		
First acknowledgement (ROW:ODD)	x			x			x				•			•		✓
First acknowledgement (FDA:ODD)	x			x			x				•			•		✓
Multiple reg pathways	x			x			x			x				•	→	
IND	x			x			x			x				•	→	
Approvals(MEC/REG)-EMEA/SwM/TGA		•			•			•			•			•		✓
SPA, Phase II	x			x				•			•			•		
End-of-Phase II	x			x			x			x			x			
<b>Score</b>			-7			-3			-1			6			12	9.4
Board			✓		•			•			•			•		
Mgt, key personnel		•			•			•			•			•		✓
Cash, funding [24m]	x				•			•			•			•		✓
IP, filings, oppositions, grants		•			•			•			•			•	→	
Execution, magn, timely, quality		•			•		✓		•		•		✓		•	✓
Visibility, brandequity	x			x			x				•			•		
Exit, collaborations, partnerships, MBO	x			x			x			x			x			
<b>Score</b>			2			4			5			8			9	7.7
Burn Rate (proj vs real time)	x			x				•			•			•		✓
InterimResults Phase III	x			x			x				•		x	→		
Demand: physicians,patients, branding		•			•			•			•			•		✓
Industry forces/mkts/legislation	x				•			•			•			•		
Propensity to change (mgt)			✓	x			x				•		x	→		
Potential to expand/M&A	x			x			x			x			x	→		
Focus,execution		•			•		✓		•		•		✓		•	✓
Composition Share Register	x			x			x				•			•		
Phase III results	x			x			x			x			x	→		
MAA, any markets	x			x			x			x			x			
<b>Score</b>			-3			-3			0			3			12	10.5
<b>Total Score</b>			-2			5			15			30			47	40

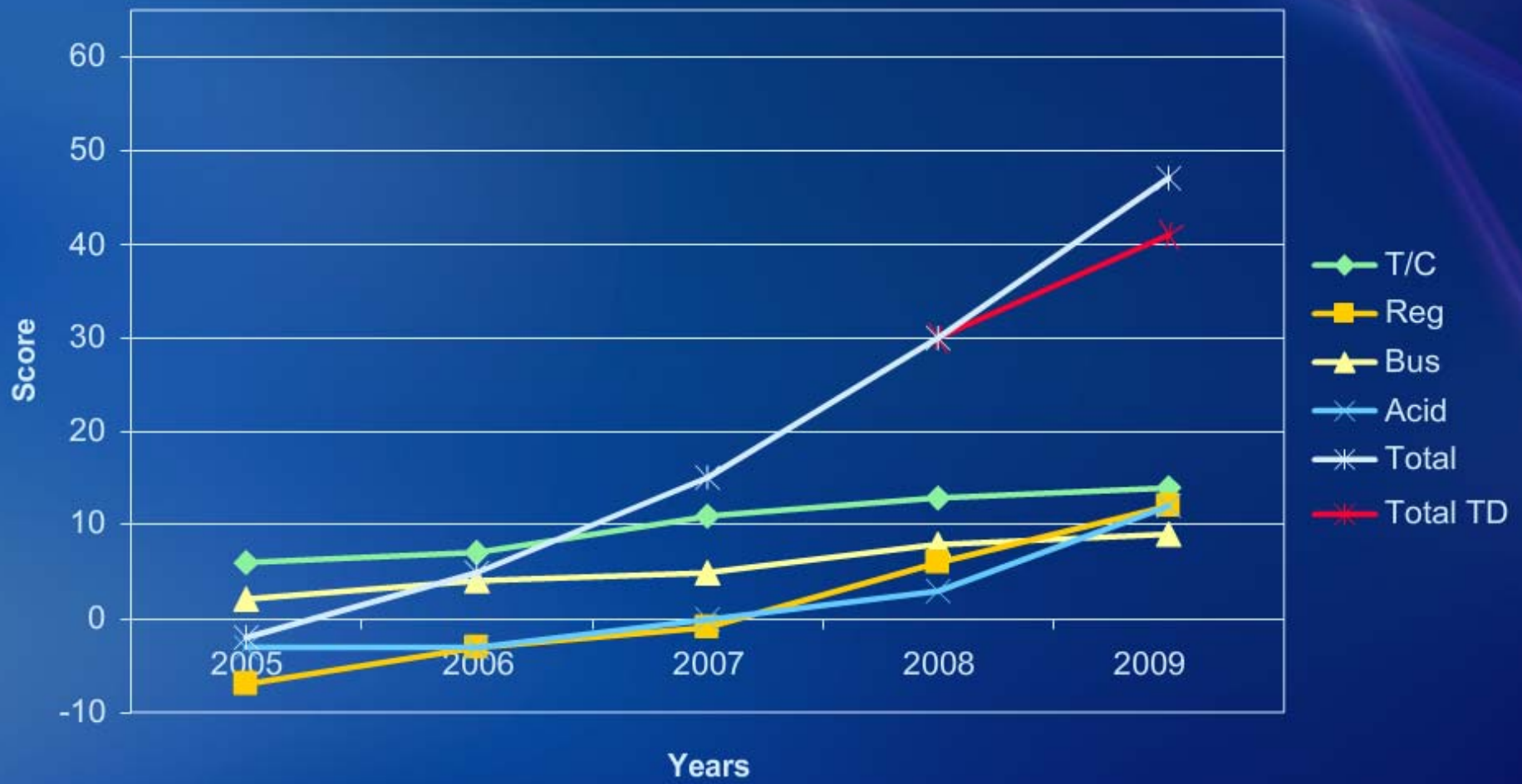
-1	Not yet achieved	✓
1	Progressing	•
2	Success	x



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# Clinuvel's Domain: Photoprotection



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## Macro Markets

- » US Market US\$500M
- » R&D: First entry to leadership
- » Competitive environment



## Macro Industry

- » Pharmaceutical/cosmoceutical: attractive
- » SME R&D success triggers M&A
- » New drugs drive value



## Micro Markets

- » Melanotide, preventative
- » first in class drug for phototoxicity (skin diseases)
- » eg Organ Transplant Recipients and Erythropoietin Deficiency
- » High demand, strong penetration, targeted markets
- » Developing a market → visibility/brand equity



## Micro Industry

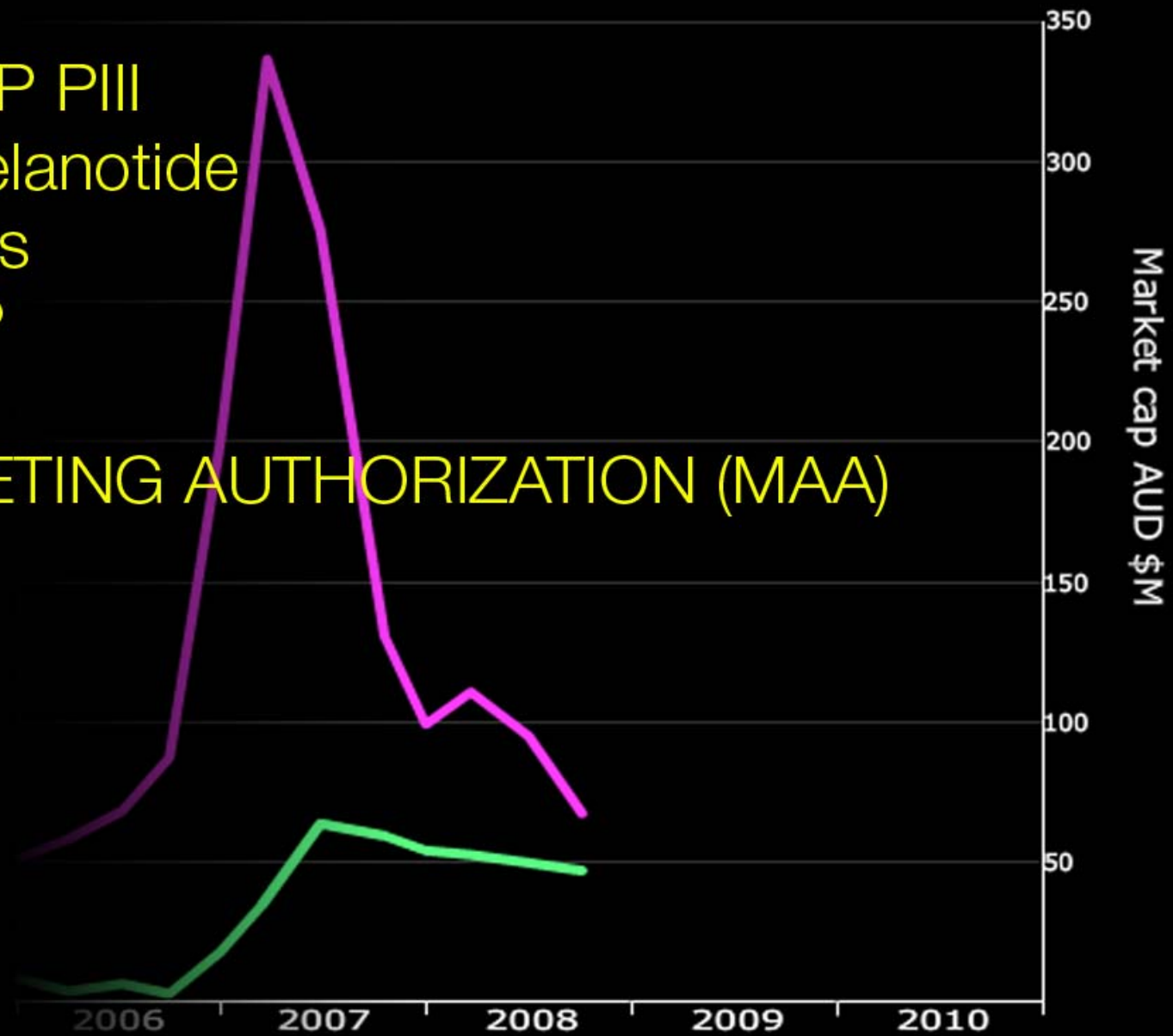
- » IP, know-how
- » Sustainability, competitive advantage
- » Industry collaboration, licensing deals and partnerships



...NEXT 12 MONTHS:

- »IND filing US
- »Interim results EPP PIII
- »Tradenname afamelanotide
- »Interim PLE results
- »Pediatric trial EPP

... towards MARKETING AUTHORIZATION (MAA)



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4 15 23:59 56

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