

Clinuvel Pharmaceuticals

SCENESSE® European pre-marketing phase

*Corporate Update
January 2013*

Darren Keamy, CFO
Philippe Wolgen, CEO

ASX:	CUV
XETRA-DAX:	UR9
ADR:	CLVLY



Safe harbor

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, will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place.

Key personnel

Mr Stan McLiesh, BEd

Non-Executive Chairman, >30 yrs pharma experience – commercialisation, M&A

Mrs Brenda Shanahan, Mr Jack Wood, Mr Elie Ishag

Non-Executive Directors, broad background in finance, healthcare, pharma deal making

Dr Philippe Wolgen, MD, MBA

Chief Executive Officer & Managing Director, background finance, healthcare analyst and qualified surgeon

Dr Dennis Wright, MSc, PhD

Acting CSO, responsible for scientific affairs worldwide

Mr Darren Keamy, BCom, CPA

CFO, Company Sec, experienced CPA to public companies

Dr Nicoletta Muner, BPharm (Hons)

MPharmSci

Director, Global regulatory affairs, >15 yrs EU

Ms Daniela Schaefer

VP Global Business Development, >15 yrs banking/ investment experience

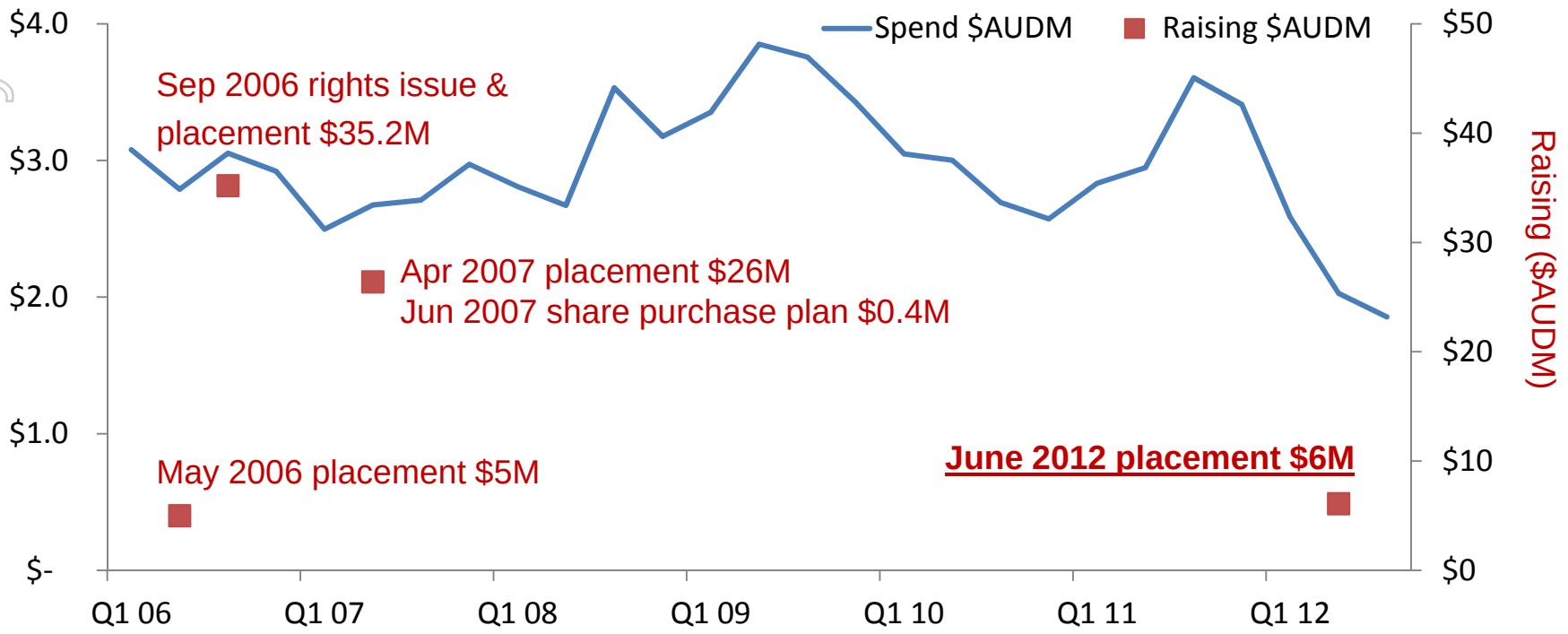
Development cycle & milestones '06-'12



	Clinical & Regulatory	Finance	Commercial
2006	EU Ph II EPP results	A\$67m raised	New management
2007	EU Ph III ¹ EPP starts Final dose selected		
2008	FDA, EMA, Swiss ODDs		
2009	FDA allows IND; Interim EU Ph III ¹ EPP results		
2010	FDA allows EPP Ph II; Final EU Ph III ¹ EPP results		SCENESSE® brand approval; Italian program starts; Manufacturing partner secured
2011	FDA allows vitiligo Ph II; Pre-clinical program completed; US Ph II, EU Ph III ² results	Share consolidation	
2012	US Ph II vitiligo results	Placement A\$6M	Swiss program starts

EPP Ph III¹: CUV017 (EU & Aust) EPP Ph III²: CUV029 (EU)

Expenditures



Business Function	Spend % (2006-2012)
R&D (includes cost of clinical study and drug delivery programs, direct R&D staffing)	48%
Toxicology & Regulatory	13%
Business, Marketing & listing	5%
General operations	34%



Registry CUV

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- Top 20 own 68%
- Retail 51% : Non-Retail 49%
- Aus 44% : EU 28% : US/RoW 28%
- ADR: 8.7%
- Staff and management ownership interests 3%-4.3%

Clinical target: EPP

Erythropoietic protoporphyria (EPP) – absolute light intolerance

Est. global incidence: up to 11,000 assessable patients (4,000 EU/4,000 US)



Phototoxic reaction in EPP

- Rare (**'orphan'**) lifelong genetic disorder
- No effective treatment/preventative – unmet clinical need
- SCENESSE® safe, effective in Phase III trials as photoprotective
- 349 EPP patients evaluated, >146,300 days on drug, ~1500 doses
- 172 patients involved in compassionate use and Swiss/Italian programs

Commercial opportunity

- US\$50-100M p/a
- Orphan indication: exclusivity obtained (10 years EU, 7 years US)
- European Marketing Authorisation Application filed Feb 2012
- US Phase III results expected Q1/2 2013
- Agreed reimbursement programs underway in Italy, Switzerland

Clinical target: vitiligo

Vitiligo – acquired depigmentation disorder

Est. global incidence: 45 million patients



Depigmentation caused by vitiligo
Image: courtesy Pearl E Grimes MD

- Progressive, psychologically devastating disease
- No effective treatment to date
- SCENESSE® used as combination repigmentation therapy
- Phase IIa (CUV102) results excellent

Commercial opportunity

- >US\$500M p/a
- Strong patent protection
- No other systemic pharmaceuticals under development
- High level of support from medical, regulatory communities

Expenditure projections - 2013

Business Function	\$AUDM
R&D (includes cost of clinical study and drug delivery programs, direct R&D staffing)	\$4,843
Toxicology & Regulatory	\$1,053
Business, Marketing & listing	\$376
General operations	\$3,481
Total	\$9,753

Transitioning from R&D to commercial sales

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- First Marketing Authorisation Application (EPP) filed Feb 2012, decision expected Q1/Q2 2013
- EU reimbursement discussions underway
- High level physician and patient support
- Solo distribution vs partnership under consideration

Business model – self sufficiency vs outsourcing

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In-house capabilities

- Clinical trial development, execution and monitoring
- Data collation, analysis
- Small scale distribution – Italian + Swiss program
- Regulatory, ethics strategy & submissions
- Academic relations strong – patients, physicians, payors
- Communications, online

Italian/Swiss EPP program – distribution model

- Italian law allows prescription of SCENESSE® to EPP patients, reimbursement for supply by Italian government
- Swiss law allows prescription of SCENESSE® to EPP patients, reimbursement for supply by insurance companies
- Agreed pharmacoeconomic benefit with national reimbursement agency - €32,250/patient/per annum
- 24 month (2010-2012) sales A\$2.2m
- Identified patient population and physician network
- Distribution to patient population done in-house using same process established for clinical trials
- This model demonstrates Clinuvel's ability to market SCENESSE® for EPP

Future markets



Singapore/Asia

- Estimated >5M vitiligo patients
- National healthcare system
- High level NB-UVB penetration

USA - EPP

- 4,000 EPP patients

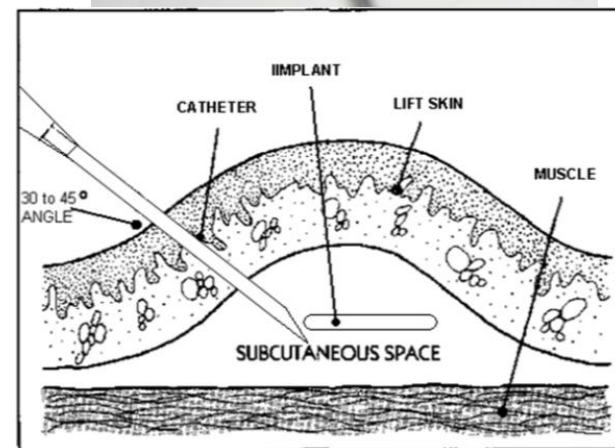
USA - vitiligo

- Up to 6M vitiligo patients
- Insurance coverage NB-UVB



SCENESSE® (afamelanotide)

- Activates melanin in skin to provide natural umbrella
- First-in-class drug (New Molecular Entity)
- An analogue of the naturally occurring melanocortin alpha-MSH
- Systemic photoprotection, repigmentation
- Patented injectable 16mg resorbable formulation
 - Size grain of rice
 - Controlled-release over 7-10 days
 - Physician administered
 - Protection for 60 days



Conclusions

- Unique drug with multiple indications
- EMA EPP filing outcome expected Q1/Q2 '13
- Safety profile SCENESSE® excellent
- Vitiligo phase II trial endpoints met
- Longevity: Clinuvel team kept intact for 7 years