



## ASX& MEDIA RELEASE

### Peplin to present at the 2008 Thomas Weisel Partners Healthcare Conference

**EMERYVILLE, California and BRISBANE, Australia, 4 September 2008: Peplin, Inc.** (ASX:PLI) announced that Chief Commercial Officer George Mahaffey will present at the Thomas Weisel Partners Annual Healthcare Conference at the Four Seasons Hotel in Boston, MA on Thursday, September 4 at 11.30am US Eastern Standard Time (1.30 am on Friday, September 5 AEST). A live webcast of the presentation will be available at <http://www.veracast.com/webcasts/twp/healthcare08/98115341.cfm> or via Peplin's website at [www.peplin.com](http://www.peplin.com).

An archive of the webcast will be available on our website [www.peplin.com](http://www.peplin.com) for replay for thirty days following the live presentation. A copy of the presentation material is attached to this release.

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#### ABOUT PEPLIN

Peplin is a development stage specialty pharmaceutical company focused on advancing and commercializing innovative medical dermatology products. Peplin is currently developing PEP005 (ingenol mebutate), which is the first in a new class of compounds and which is derived from the sap of *Euphorbia peplus*, or *E. peplus*, a rapidly growing, readily available plant commonly referred to as petty spurge or radium weed. *E. peplus* has a long history of traditional use for a variety of conditions, including the topical self-treatment of various skin disorders, including skin cancer and pre-cancerous skin lesions. Peplin's lead product candidate is a patient-applied topical gel containing ingenol mebutate, a compound the use of which Peplin has patented for the treatment of actinic keratosis, or AK. This product candidate is currently in Phase II clinical trials and is referred to as PEP005 (ingenol mebutate) Gel.

#### FORWARD LOOKING STATEMENTS

This press release contains "forward-looking statements" as defined under U.S. federal securities laws, including, but not limited to, Peplin's clinical development plan referred to herein. These forward-looking statements can be identified through the use of words such as "anticipates," "expects," "intends," "plans," "believes," "seeks,"

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"estimates," "may," "will," and variations of these words or similar expressions. Forward looking statements are based on management's current, preliminary expectations and actual results could differ materially as a result of various risks and uncertainties, including, but not limited to, delays in the completion of clinical trials resulting from, among other things, ambiguous or negative interim results, failure to close the acquisition of Neosil, Inc., unforeseen safety issues, failure to conduct the clinical trials in accordance with regulatory requirements or clinical protocols, suspension or termination of a clinical trial by the FDA or other regulatory authorities, failure to obtain the stockholder approval necessary to approve the pending private placement, lack of adequate funding to continue a clinical trial and other important factors disclosed from time to time in Peplin's disclosures to the ASX. Forward-looking statements speak only as of the date they were made. No undue reliance should be placed on any forward-looking statements. Such information is subject to change, and we undertake no obligation to update such statements.



# Innovation in Dermatology

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Developing the next generation of dermatology products  
to treat serious skin diseases

George Mahaffey  
Chief Commercial Officer

[www.peplin.com](http://www.peplin.com)

# Forward looking statements

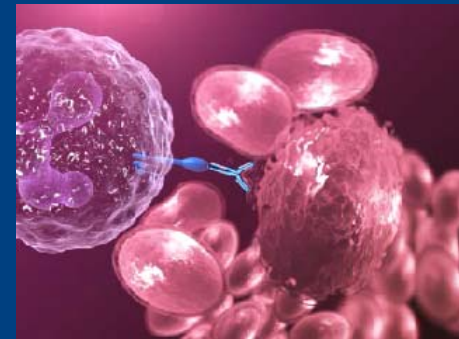
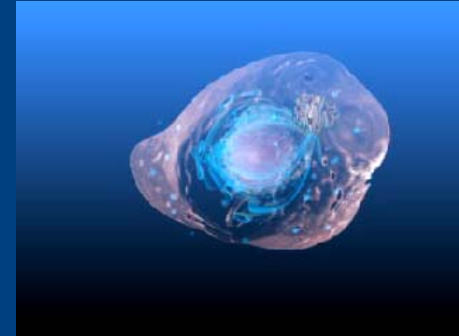
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This presentation contains "forward-looking statements" as defined under the U.S. federal securities laws including, but not limited to, statements regarding Peplin's future clinical development program. Actual events could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including but not limited to: adverse changes in general economic or market conditions, the inability to manage successfully and complete the offering, including the ability to retain and attract key employees, the risk that the offering may not occur in its expected timeframe or at all, and other one-time events and other important factors disclosed previously and from time to time in Peplin's filings with the U.S. Securities and Exchange Commission and the Company's disclosures to the ASX. Peplin and the Company disclaim any obligation to update any such forward-looking statements after the date of this presentation.

# Peplin highlights

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- Breakthrough treatment for actinic keratosis and skin cancers
  - Novel mechanisms of action
- Compelling Phase II results
- Phase III study planned for 3Q08 and conducted under a Special Protocol Assessment (SPA)
- Strong intellectual property



# Euphorbia peplus

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- Common plant
- European origin
- Early 1800's sap used topically to treat dermatological conditions
  - warts, corns, waxy growths, skin cancers
- Also used orally
  - Purgative, cancer of the stomach, liver and uterus
- Effective home remedy to treat skin cancers <sup>(1)</sup>

1) *Australasian Journal of Dermatology*, 1988

# Peplin history

1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008

Peplin founded to explore the folklore observation of anti-cancer activity of the sap of *Euphorbia peplus*

- Documented the sap's anti-cancer activity in human skin cancers
- Pursued activity-guided fractionation to identify key active ingredient

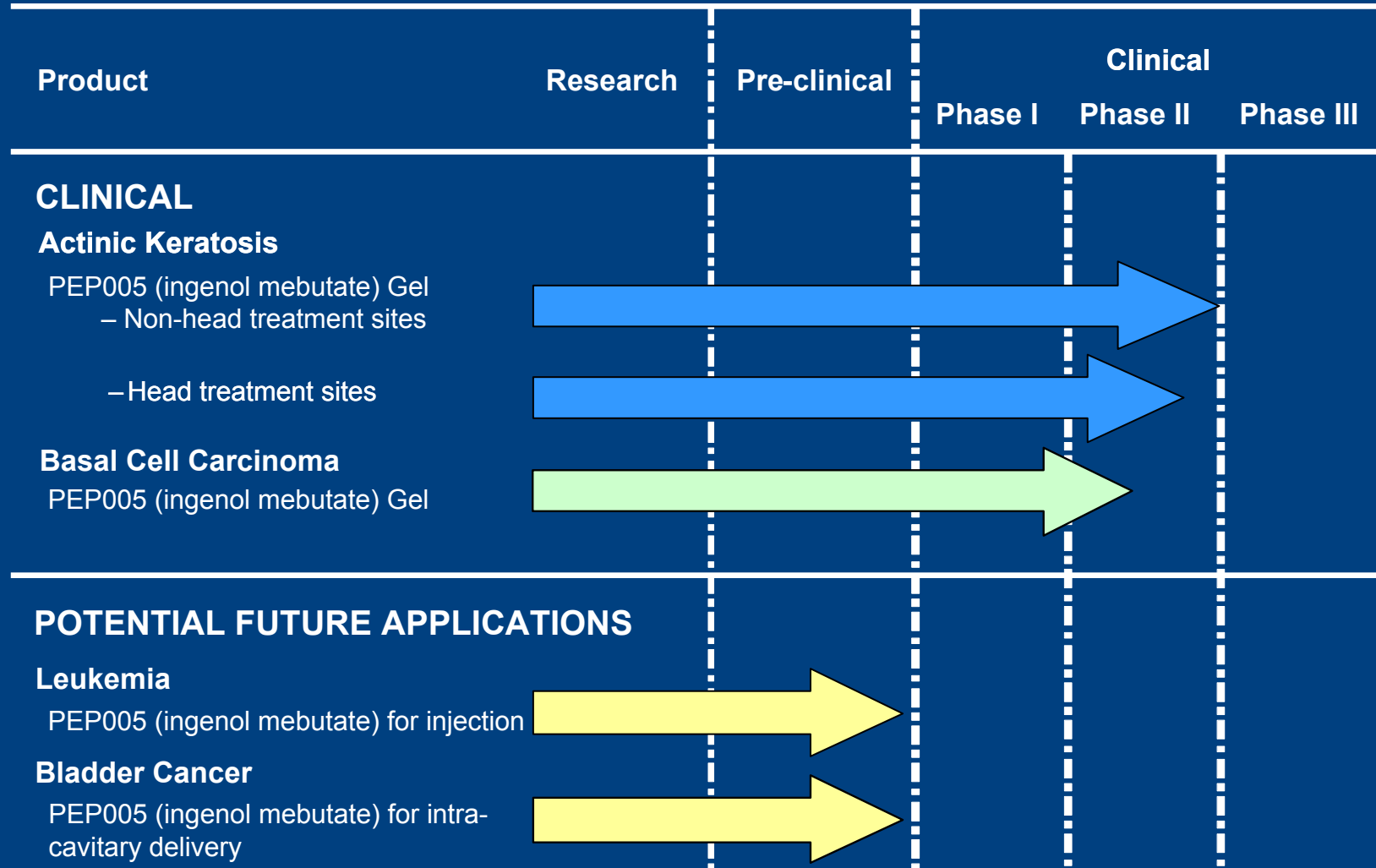
Selected PEP005 as lead candidate for its

- Pre-clinical pharmacology
- Toxicology
- Purification and formulation technology

INDs filed for AK and BCC

Company headquarters moved from Australia to US

# Product pipeline



# Investment thesis

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- Large market for actinic keratosis and other skin diseases
- High level of patient dissatisfaction with current therapies
  - Long treatment durations
  - Poor patient compliance
  - Local side effects during extended treatment
- Novel, late stage product with compelling, consistent clinical trial results
- Strong intellectual property
- Strong financial position

# Actinic keratosis (AK)



- Caused by accumulated sun damage
- Can unpredictably transition to Squamous Cell Carcinoma (SCC)
  - 1,300 to 2,300 US deaths per year<sup>(1)</sup>
  - Expensive and difficult treatment
- Affects more than 58 million Americans<sup>(2)</sup>, increasing with age
- 5.6 million office visits annually<sup>(3)</sup>
  - 8.2 million office visit estimates have been published <sup>(2)</sup>
- \$1.2 billion annual direct cost in US<sup>(2)</sup>
- 25% of all treatments involve topical therapies<sup>(4)</sup>
- 67% of cases had prior AK diagnosis<sup>(4)</sup>

1) *Dermatol Surg* 2007;33:1099-1101

2) Source: Lewin Group, *The Burden of Skin Diseases 2005*

3) US office visits for AK, NAMCS database (Aug. for 2001-2005)

4) *Journal of Dermatological Treatment*, 2006; 17: 162-166

# In-office procedures

## Approach

## Major benefits

## Major short-comings

### **Cryotherapy** (liquid nitrogen)

- Quick and inexpensive
- Historically attractive reimbursement
- Well established modality

- Only discrete lesions
- Short term localized pain and irritation
- Potential long term scarring
- 1 year recurrence rate of 72% <sup>(1)</sup>
- Declining reimbursement <sup>(3)</sup>

### **Levulan Kerastick<sup>(2)</sup>** (aminolevulinic acid HCl)

- Single topical application

- Irradiation 14 to 18 hours later
- Burning and stinging
- Requirement for dedicated equipment
- Unattractive reimbursement

1) *British Journal of Dermatology* 2007; 157 (Suppl. 2): 34-40

2) *Product Full Prescribing Information*

3) *2008 CMS Medicare Fee Schedule*

# Topical treatments<sup>(1)</sup>

*Long durations of treatment*

Product	Course	Efficacy: Complete clearance	AWP Cost /Tx <sup>(3)</sup>	Short-comings
<b>Aldara</b> <sup>®</sup> (imiquimod 5%)	2x/wk for 16 wks	45%	\$756	Erythema, flaking/ scaling/dryness, scabbing/crusting
<b>Carac</b> <sup>®</sup> (fluorouracil cream 0.5%)	1x/d for 4 wks	48%	\$150	Erythema, dryness, burning, erosion, pain
<b>Efudex</b> <sup>®</sup> (fluorouracil cream 5%)	2x/day for 4 wks	~50% <sup>(2)</sup>	\$573	Burning, crusting, contact dermatitis, erosion, erythema
<b>Solaraze</b> <sup>®</sup> (diclofenac sodium 3%)	2x/day for 30- 90 days	14 - 47%	\$714	Contact dermatitis, rash, dry skin/ scaling

1) *Product Full Prescribing Information*

2) *Supplement to The Journal of Family Practice, May 2006*

3) *Redbook, August 2008*

# The Peplin solution

## PEP005 (ingenol mebutate) Gel for AK: Product Profile

Description	Patient applied topical gel	
Packaging	Two or three single use mini-tubes	
Course of therapy	Once-a-day for two or three consecutive days	
Side effect profile	Localized erythema, flaking or scaling, crusting, vesicles and swelling. Peaks in 3-8 days, resolves in 2-4 weeks	

Treatment area	Non-head (2 day)	Head (2 or 3 day)
Concentration	0.05% (PEP005 Gel)	0.005%-0.015% (PEP005 Gel)

# PEP005 (ingenol mebutate) Gel for AK

## Strong clinical data

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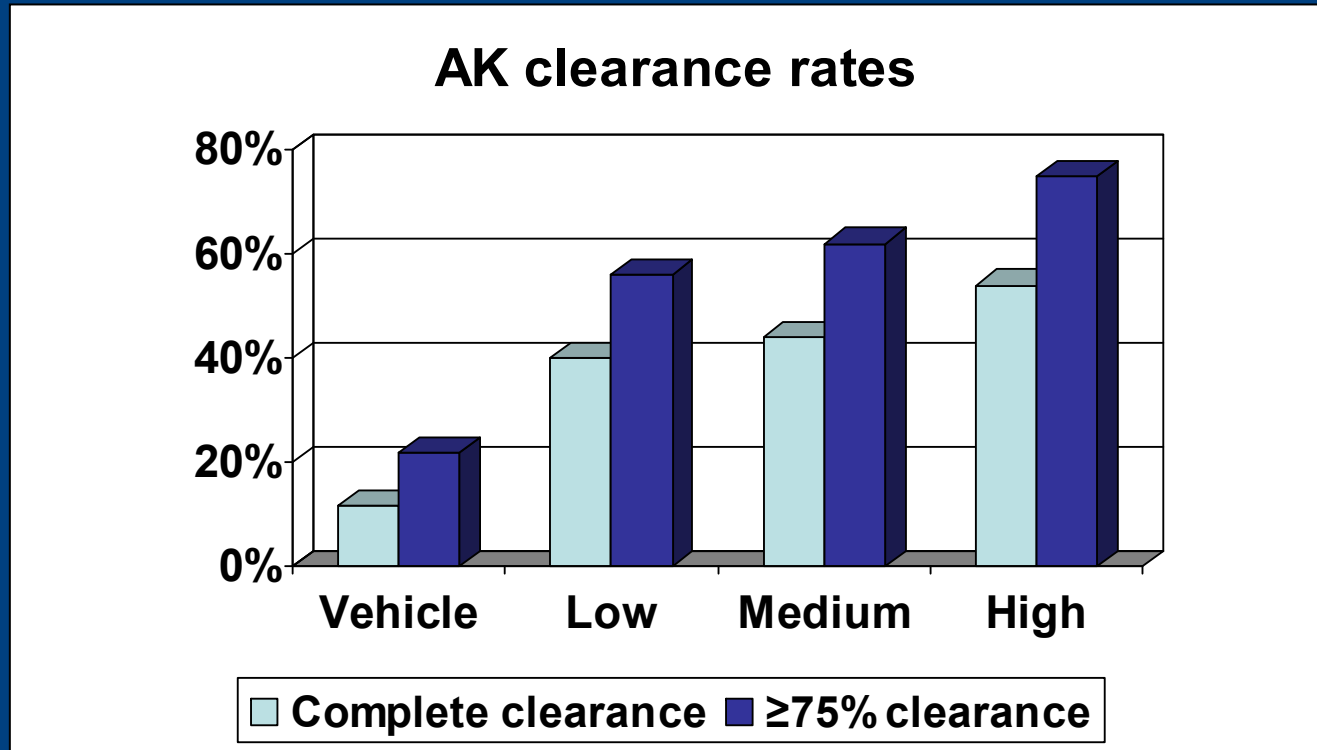
- IND filed June 2004
- Six AK trials (2005-2007)
  - Single dose phase I (lesion-directed)
  - Two dose phase IIa (lesion-directed)
  - Two dose phase IIa (field-directed therapy-body)
  - 2 and 3 day phase IIa/b (field-directed-body)
  - 2 and 3 day phase IIa/b (field-directed-face)
- Significant AK safety database
  - >400 subject exposures to drug
- Two key clinical trials
  - PEP005-006: treatment sites on body and scalp
  - PEP005-007: treatment sites on face and face/scalp

# PEP005-006 Study design

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- Treatment location: body and scalp
- Multi-center, double blind, double dummy, randomized, vehicle controlled
- Three active arms with a vehicle control
  - Randomized 222
  - Modified intent to treat population
    - Vehicle 60
    - 0.025% D1,2,3 (Low) 50
    - 0.05% DV,2,3 (Medium vehicle D1) 55
    - 0.05% D1,2,3 (High) 57
- Evaluating safety and efficacy
- Patients with 4-8 AK lesions in a 25 cm<sup>2</sup> treatment area on the arm, shoulder, chest, back or scalp

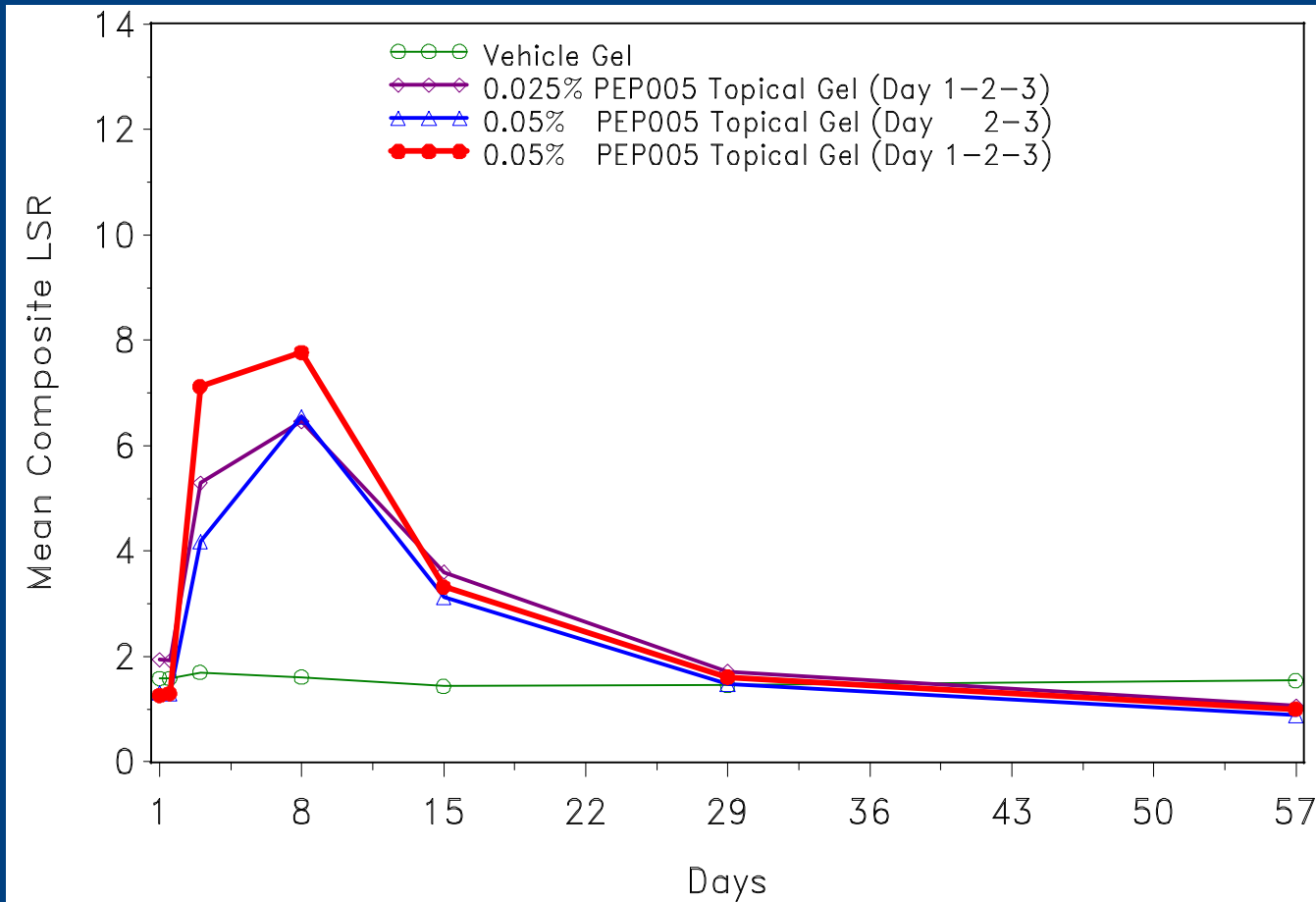
# PEP005-006 Efficacy results



Medium strength data	0.05% (Two days) N=55	Vehicle N=60	P-value
Complete clearance rate	44%	12%	0.0001
Partial clearance rate	62%	22%	<0.0001

# PEP005-006 Safety

## Time course of local skin response



# PEP005-006 Patient satisfaction

At End of Study patients were asked impression of the treatment:

- Overall satisfaction
- Convenience of use
- Healing time
- Cosmetic outcome
- Comparison with prior treatment

Overall Level of Satisfaction [overall  $p < 0.0001$ ]

	Vehicle (N=60)	Low (N=50)	Medium (N=55)	High (N=57)
Mean	4.4	6.1	6.2	6.0
Median	4.0	7.0	7.0	7.0

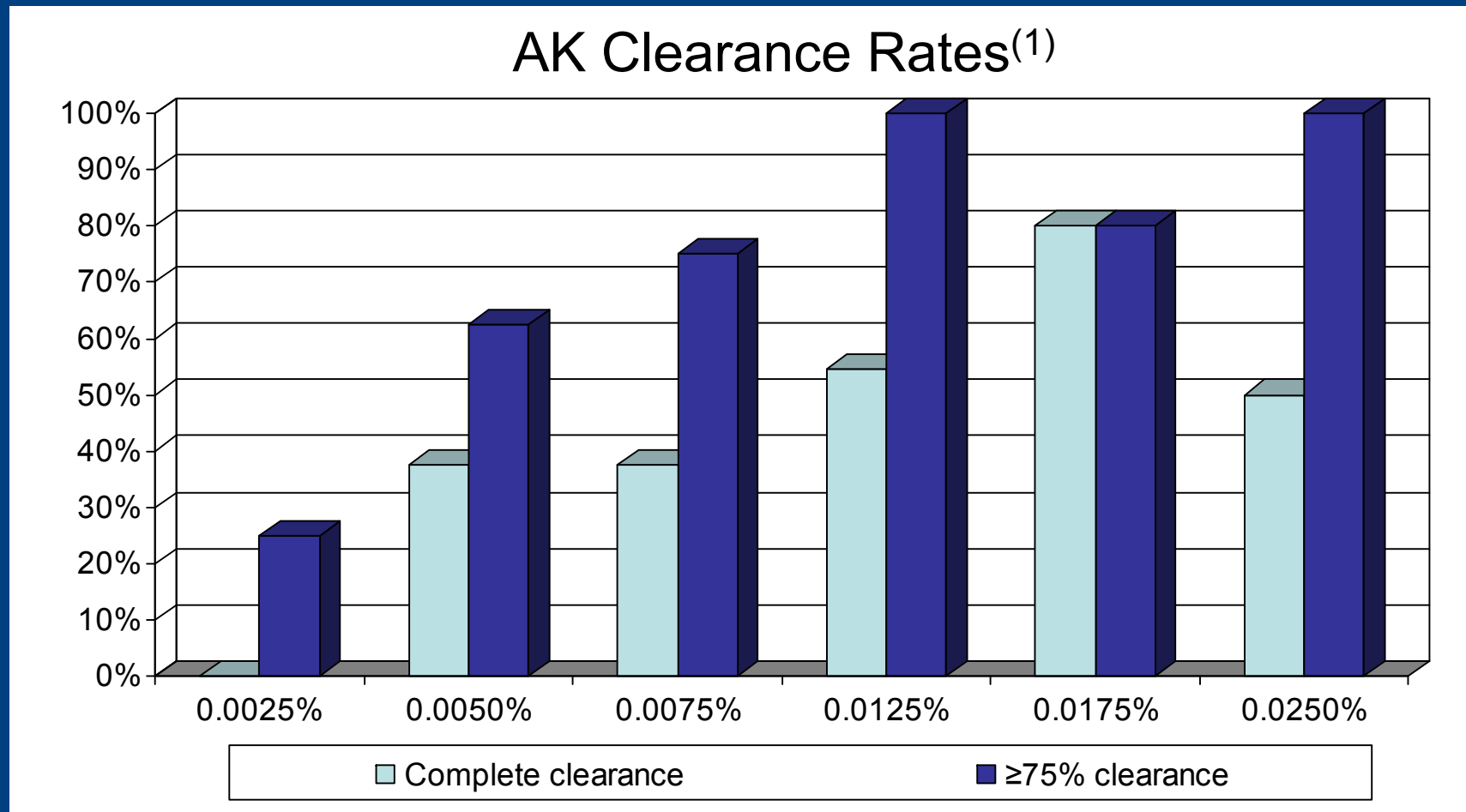
*All questions were answered using a 7-point scale where 1 = very negative and 7 = very positive*

# PEP005-007 Study design

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- Treatment location: face and scalp
  - Face 78.4%
  - Face & Scalp 21.6%
- Open-label, multi-center, dose-escalation, cohort study
- 10-fold range of doses tested and 2-3 day applications
- End points:
  - Identify an optimal tolerated regime
  - Evaluate safety and efficacy
- 4 to 8 AK lesions in a 25 cm<sup>2</sup> treatment area on the face or face/scalp

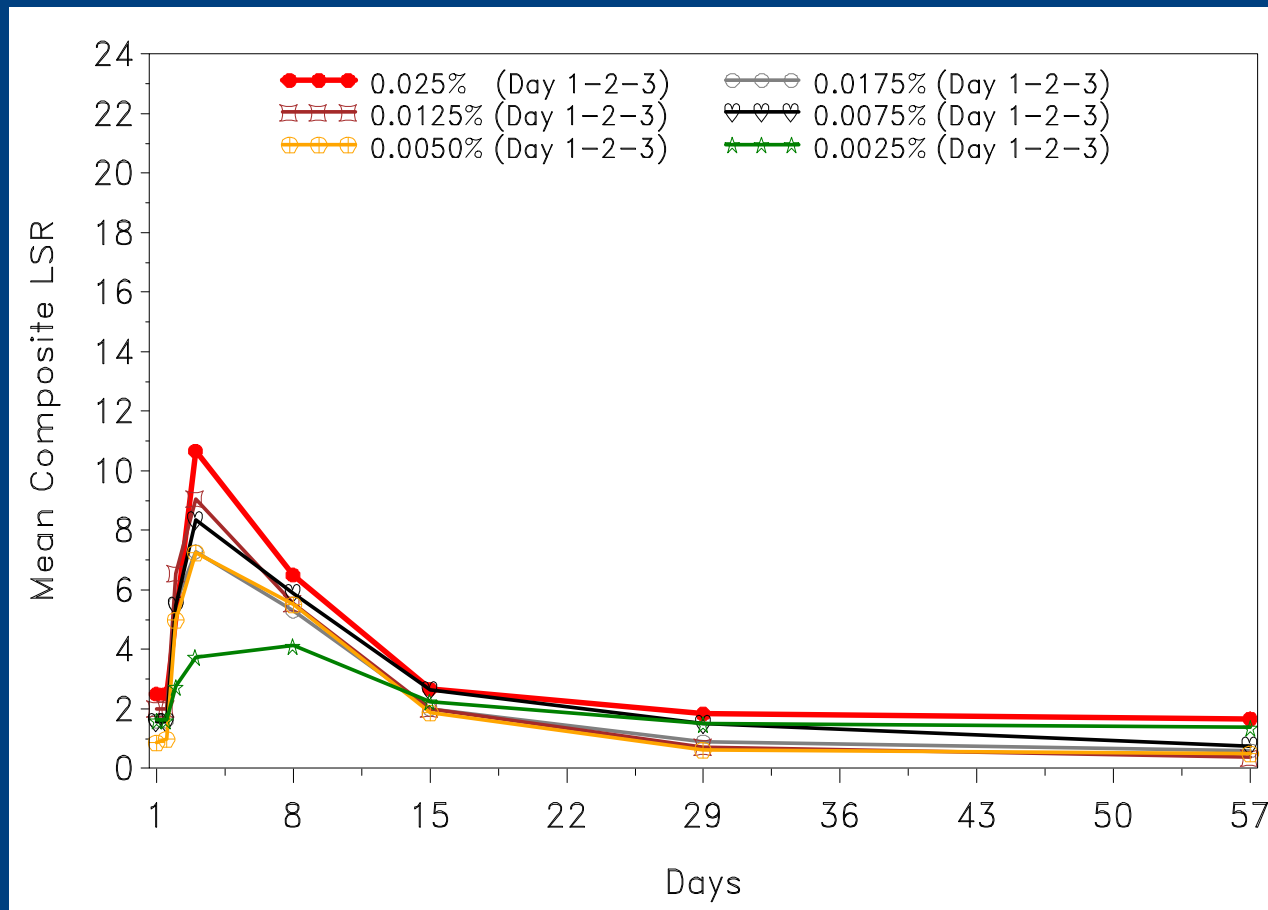
# PEP005-007 Efficacy results



1) Analysis of patient groups that were eligible to receive up to 3 days of dosing

# PEP005-007 Safety

## Composite Local Skin Response (1)



1) Analysis of patient groups that were eligible to receive up to 3 days of dosing

# PEP005-007 Patient satisfaction

At End of Study patients were asked to provide their impression of the study treatment, questions included:

- Overall Satisfaction
- Healing time
- Cosmetic outcome
- Ease of use
- Comparison w/ prior treatment

## Overall Level of Satisfaction <sup>(1)</sup>

	0.025%	0.0175%	0.0125%	0.0075%	0.005%	0.0025%
	N=6	N=10	N=11	N=8	N=8	N=8
Average	6.5	6.6	6.9	6.8	6.5	6.4
Median	7.0	7.0	7.0	7.0	7.0	7.0

*7-point scale where 1 = very negative and 7 = very positive, 4 is neither positive nor negative*

1) Analysis of patient groups that were eligible to receive up to 3 days of dosing

# Non-melanoma skin cancer



- Most prevalent cancer worldwide
  - Basal cell carcinoma (BCC): 80%
  - Squamous cell carcinoma (SCC): 16%
- 1.2 million cases in US in 2004<sup>(1)</sup>
- US\$1.4 billion in 2004<sup>(1)</sup>
- Incidence: 3-8% worldwide increase annually since 1964<sup>(2)</sup>
- Gold standard is surgical excision

1) Source: Lewin Group *The Burden of Skin Diseases 2005*

2) *J Am Acad Dermatol* 2007; 56:125-43

# PEP005 (ingenol mebutate) Gel for BCC



- Tumor directed application
  - 1 or 2 treatments
  - Higher concentration than AK treatment
- Benefits over surgery
  - Reduced pain, scarring
  - Improved cosmesis
  - No sutures, infections
- Proof of concept in PEP005-003 study
  - 70% histology confirmed lesion clearance at 12 weeks ( $p=0.02$ ) with 2 day treatment of 0.05% PEP005
- Ongoing Phase IIa trial

# Milestones

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- Results Non-head AK Phase IIb trial July 2007
- Results Head AK Phase IIa trial Dec 2007
- Completion of SPA with FDA June 2008
- Initiate Head AK Phase IIb June 2008
- Early completion of Head AK Phase IIb Aug 2008
- Completed \$24m in financing Aug 2008
- Hire additional experienced management Aug 2008
- Initiate Non-head AK Phase III (REGION-I) Q3 2008
- Results Head AK Phase IIb Q1 2009
- Results Non-head AK Phase III (REGION-I) H1 2009

# Capital structure

Values in US dollars, unless otherwise stated <sup>(1)</sup>	30-Jun-08 (pro forma) <sup>(2)</sup>
Shares out. (Basic)	15.1 m
Warrants (options)	2.2 m
Employee options	<u>0.9 m</u>
Shares out. (Fully diluted)	18.3 m
Number of CDIs per share	20
Number of CDIs (Basic)	302.8 m
CDI price on ASX	A\$0.39 (\$0.38)
Market cap. (Basic)	\$113.5 m
Cash	\$56.0 m
Debt	<u>\$(13.8) m</u>
Technology value	\$71.3 m

1) Based on USD/AUD = [0.961]

2) Includes Neosil acquisition and Aug 2008 \$24m fundraising, subject to shareholder approval

# Balance sheet summary

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	30-Jun-08 (pro forma) <sup>(1)</sup>
	\$'000
Cash and cash equivalents	\$ 55,988
Property, plant & equipment	\$ 2,824
Other assets	\$ 8,021
<b>TOTAL ASSETS</b>	<b>\$ 66,833</b>
Liabilities	\$ 19,701
<b>NET ASSETS</b>	<b>\$ 47,132</b>

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1) Includes Neosil acquisition and Aug 2008 \$24m fundraising, subject to shareholder approval

# Investment thesis

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