

NOVOGEN



Novogen Corporate Structure

Novogen Limited NVGN

Pharmaceutical

- Novogen Research Pty Ltd:
Australia
USA

Marshall Edwards, Inc. MSHL

- Anti-cancer company conducting clinical trials of Phenoxodiol
- LSE AIM (MSH)
NASDAQ (MSHL)

Consumer Products

- OTC Division:
 - Australia
 - UK
 - USA
 - Canada
 - Netherlands
- + Production

Glycotex, Inc.

- Glucan wound healing technologies
- S1 Registration Statement lodged with SEC



Business Context

- ✿ Novel science leading to outstanding commercial opportunities
- ✿ Consumer products based on plant isoflavone technology
- ✿ Drug development program underpinned by substantial science developed over many years
- ✿ The library of compounds reveal a multi-function approach to significant diseases
- ✿ Clinical development of anti-cancer compounds within Marshall Edwards Inc
- ✿ Clinical development of wound healing compound within Glycotex, Inc.



Business Context

- ✿ World Patent applications surround all products and compounds

Novogen Group Patents

29 patent families

271 patent applications

of which

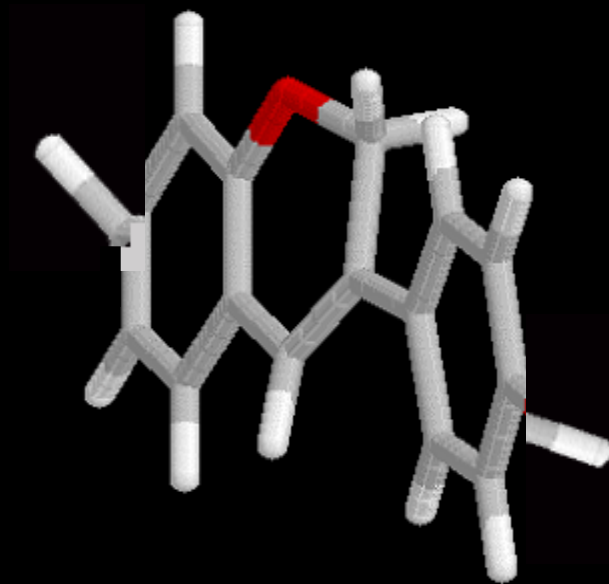
45 patents now issued

218 now being pursued



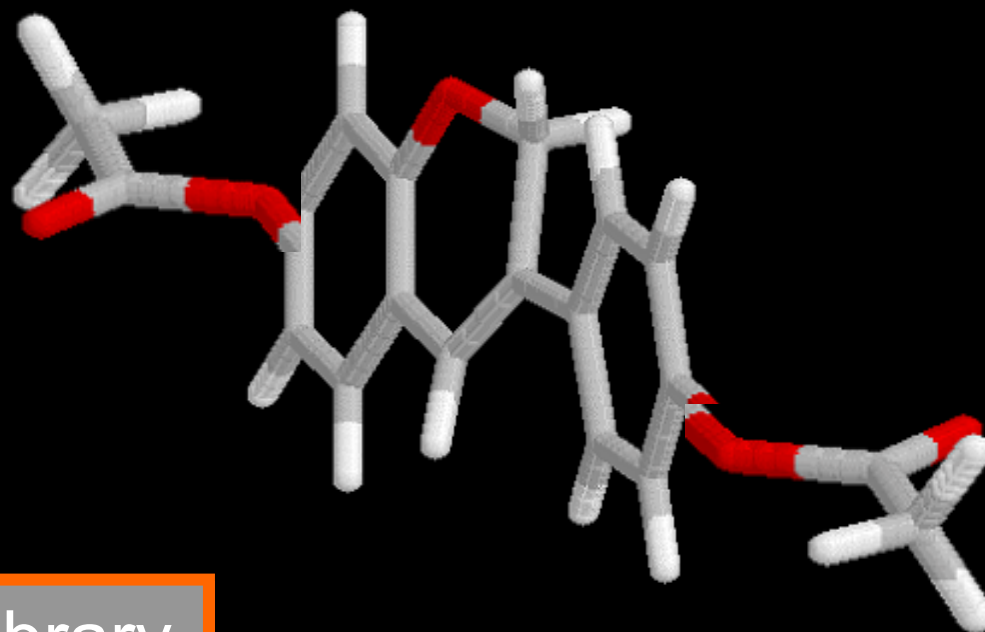
	Preclinical	Phase I	Phase II	Phase III	Target
Cardiovascular					
<i>trans</i> -NV-04	→		→		Anti-atherosclerotic, peripheral vascular dilatation
NV-27	→				
Anti-inflammatory					
NV-07 α	→			→	Anti-ageing
NV-52	→		→		Inflammatory disease
Oncology					
Phenoxodiol	→				Ovarian, prostate, cervical, renal cancers
NV-196	→		→		Cholangiocarcinoma, pancreatic cancer
NV-128	→				Lung, breast cancer
NV-5063	→				Colorectal cancer, leukemia
Wound healing					
Glucoprime	→				Wound healing

Phenolic drug scaffold (isoflavone derivative)



Low activity

Novogen proprietary synthesis builds an enhanced molecule



Novogen Library
now over 190
compounds

High activity



Cardiovascular

✿ **Cardiovascular disease** = hypertension, atherosclerosis

✿ ***trans* NV-04 pleiotropic effects (treats both indications):**
preclinical studies showed:

- reduced cholesterol deposition in arteries
- reduced atherogenic plaques
- improved endothelial function and vasodilation
- reduced cholesterol oxidation

Human trials

First Phase I complete

Second Phase I complete

Phase II study to address target indications,
(hypertension, arterial compliance)



Cardiovascular

Second Phase I trial complete...

- ✿ *Trans* NV-04 administered orally to 25 middle-aged men and women who were overweight and also suffered from at least two complications of fatness: abnormal blood fats, high blood glucose or raised blood pressure
- ✿ Double-blind, cross-over design, 5 weeks each phase
- ✿ Arterial stiffness significantly reduced
- ✿ Blood pressure (both systolic and diastolic) lowered significantly

R&D Pipeline...

- ✿ NV-27 pre clinical – improved anti-oxidant



Anti-inflammatory: NV-07 α topical

- ✿ Anti-ageing (especially photoageing) is a large cosmetic market
- ✿ NV-07 α positioned for topical therapy for after sun use to reverse effects of ageing and damage caused by long term sun exposure
- ✿ In pre-clinical studies:
 - reverses damage to skin caused by exposure to UV light
 - reduced wrinkling, reduced thickening of the skin
 - increased immune response = reduced skin cancer development
- ✿ Australian and US patents granted

Phase II human trials complete; licence negotiations continuing



Anti-inflammatory: NV-52

- ✿ Anti-inflammatory for inflammatory bowel disease (IBD)
 - Ulcerative Colitis
 - Crohn's disease
- ✿ Improved maintenance therapy remains unmet medical need
- ✿ NV-52 in mouse model of IBD: reduction in the occurrence and severity of clinical signs; reduced body weight loss; reduced time to recovery; reduction in colonic ulceration.

Pre-clinical complete;
Phase I human trial complete

- ✿ **Pipeline compounds:** in development for range of inflammatory diseases and pain relief



Oncology

Marshall Edwards, Inc.

Phenoxodiol

- ✿ Low toxicity demonstrated
- ✿ Phenoxodiol active in broad range of major cancers
- ✿ Current targets: ovarian, prostate, cervical and renal cancers
- ✿ Phase II human clinical trials in the US and Australia - Oral and IV dose forms



Oncology

Marshall Edwards, Inc.

Phenoxodiol

- On basis of current trial data, FDA approved Fast Track Status for
 - ovarian cancer refractory to chemotherapy – approved Nov.'04
 - hormone refractory prostate cancer – approved Jan.'05
- Protocols for pivotal studies submitted to trial sites
- For ovarian cancer, Phase III OVATURE study, CRO appointed, trial site selection in progress



Oncology

Marshall Edwards, Inc.

Trial Results

Phase I

- Trials in USA and Australia
- Trials were dose escalating and used drug bolus or IV
- 21 of the 63 patients over four phase I studies were stabilized.



Oncology

Marshall Edwards, Inc.

Phase II

Chemoresistant Ovarian Cancer IV Dose Form

(Yale University, USA)

IV dose regime: patients with recurrent ovarian cancer resistant to standard chemotherapy; IV 1, 3, 10, 20 mg/kg dose x2 weekly for 12 weeks

40 patients total – study complete

Response measured by tumour mass, CA125



Oncology

Marshall Edwards, Inc.

Phase IIa

Chemoresistant Ovarian Cancer IV Dose Form

Preliminary results

- After 12 weeks, 10/40 patients remained stabilized
- In the first dose stratum (1 mg/kg), 6/7 patients alive (303 ± 15 days) after return to chemotherapy
- In the second dose stratum (3 mg/kg), 5/6 patients alive (268 ± 20 days) after return to chemotherapy



Oncology

Marshall Edwards, Inc.



“...it shows that for some women with very advanced ovarian cancers, that they have had about 18 months extra to their lives already, and many of those women are continuing to do very well indeed”

Professor Michael Quinn, Royal Women’s Hospital, Melbourne



Oncology

Marshall Edwards, Inc.

Phase IIa

Ovarian Cancer Combination Therapy

(Yale University Hospital, Royal Womens Hospital, Melbourne)

Multi-Center Study: Phenoxodiol as a Chemosensitizing Agent for Platinum and Taxane in Ovarian Cancer in Refractory/Resistant Patients

6 treatment groups –

IV phenoxodiol + paclitaxel

IV phenoxodiol + cisplatin

paclitaxel run-in then IV phenoxodiol + paclitaxel

cisplatin run-in then IV phenoxodiol + cisplatin

carboplatin run-in then IV phenoxodiol + carboplatin

carboplatin run-in then oral phenoxodiol + carboplatin

Fast Track by FDA on basis of preliminary data from this trial...

Phase IIa

Ovarian Cancer Combination Therapy

Preliminary Results Announced 10 May 2005:

- 27 subjects received PXD + cisplatin or PXD + paclitaxel.
- CR = 11%, PR = 22%, or SD = 44%
- Overall disease control rate = 77%
- The PXD and cisplatin or paclitaxel combinations were well tolerated, with no unexpected toxicities encountered
- Update to be presented at ECCO 13th European Cancer Conference, Paris November 2005



Oncology

Marshall Edwards, Inc.

Phase IIa

Prostate Cancer Oral Dose Form

(Monash Medical Centre, Sir Charles Gairdner Hospital, Aust.):

Oral Phenoxydiol in patients with late stage hormone-refractory prostate cancer

Doses: 20, 80, 200, and 400 mg

24 patients

- of the 12 patients treated with the two highest dose levels, 2 showed stabilization of PSA levels, 6 showed a decrease in PSA levels.
- two of these 6 responders showed a decline in PSA levels of >50%
- Update at AACR Philadelphia, November 05



Oncology

Marshall Edwards, Inc.

Phase I

Cervical SCC Oral Dose Form

(**Yale University Hospital**) Neoadjuvant study in squamous cell reproductive cancers

Data to be presented at AACR, Philadelphia, November 2005

Phase Ib

Renal Cancer Oral Dose Form

(**St George Hospital**), Phase Ib Safety and Preliminary Efficacy Study of Phenoxodiol (Oral Dosage Form) in combination with Cisplatin or Carboplatin.



Oncology Pipeline

Pipeline compounds

Clinical:

NV-196: Targets: cholangiocarcinoma, pancreatic cancer

Phase Ia - Bio-availability, Pharmacokinetic and Acute Safety (St. George Hospital, Sydney) in progress

Pre-clinical:

NV-5063: Targets leukaemia (esp. childhood), colorectal cancer

NV-128: Targets lung, breast cancer



Financial Strategy

- ✿ Group Cash at June 30 2005 \$US 36 M
- ✿ Cash Burn 04-05 (incl. share proceeds) \$US 8.5 M
- ✿ R&D Spend at June 30 2005 \$US 7.8 M pa
- ✿ Discovery
- ✿ R&D
- ✿ Manufacturing
- ✿ Clinical Trials
- ✿ Outlicensing