



**NeuroDiscovery**

**NeuroDiscovery**

**Acquisition of Enigma Therapeutics**

*A UK Cancer Therapy Company*



## Post Acquisition and Settlement

### Corporate Overview

ASX Code:	NDL
Share Price:	\$0.025
Market cap:	\$5.8m
Cash:	<b>\$3.5m</b>
Shares on issue:	232m
Unlisted Options:	28m

### Board of Directors

Dr Roger Aston Executive Chairman	Former CEO of Peptech, Founder of PsiMedica and former CEO of Mayne Pharma
Mr David McAuliffe Executive Director	Founder of PsiMedica, PolyNovo Biomaterials, NeuroDiscovery and JDS BioPharma
Mr Simon O'Loughlin Non-executive Director	Involvement with numerous listed public companies

### Major Shareholders

Board, Management and Founders ~50%

### Assets

100% of Enigma Therapeutics	Extensive patent family Potentially Phase III trial ready Potential CE Mark application
NSL-043	Licensed to Chinese Pharma Phase II ready Retains interest thru Sosei
NSL-101	Completed Phase II Seeking partner



## Enigma Therapeutics: Summary

- Technology originates from QinetiQ and pSivida Corp.
  - Over 10 years of significant investment in patents, preclinical / clinical trials and manufacturing
- Exclusive global rights to BrachySil (to be re named Oncosil) for cancer secured from pSivida Corp subsidiary
- Technology potentially ready for a Phase III trial in pancreatic cancer and CE Mark authorisation in Europe
- A management team highly experienced in oncology and commercialisation
- Patented intellectual property and extensive knowhow



## Oncosil: The Product

- **Conducted four clinical trials** in liver cancer (Phase I/II and Phase II) and pancreatic cancer (Phase IIa and IIb) in Singapore and UK with encouraging results on tolerability, safety and potential efficacy
- **Classed as a medical device** not a pharmaceutical meaning a potentially shorter and less costly regulatory path
- Comprises pure beta-emitter  $^{32}\text{P}$  or another approved radioisotope embedded in licensed medical device
- Delivers localised beta radiation by endoscopic needle insertion directly into tumor
- Prolonged and sustained localized radiation following single administration
- **GMP compliant manufacturing** and logistics already known
- Potential use in other solid tumors



## Oncosil: The Product (2)

### **Convenience**

- The treatment is an outpatient single visit or overnight stay
- Hospital radio-pharmacies prepare the device prior to use
- 30 minute endoscopic needle insertion by skilled gastrointestinal oncologists, radiologists, radiation oncologists or surgeons

### **Cost effectiveness**

- Only 1-2 treatments per patient
- High gross margins due to cost of raw materials in relation to expected sales price (expected to be ~ \$10-12k per treatment)



## Pancreatic Cancer

### Unmet Clinical Need

- >230,000 pancreatic cancer incidence pa world wide
- Median survival 4-6 months and +5 year survival is <5%
- Severe abdominal and back pain is a significant complication in patients who develop pancreatic cancer
- Approx. 45,000 new patients diagnosed with pancreatic cancer in the US each year
- World market for pancreatic drugs is projected to exceed \$1.2b by 2015

### Current Treatment

- Gemcitabine (Roche) is the standard treatment with median survival < 6 months
- Side effects include: fever, fatigue, vomiting, hair loss, mouth sores and diarrhea
- Erlotinib (Roche) is currently the last line therapy
- “Whipple” surgery is applicable in only 10-20% of cases and has 5-15% mortality rate
- Generic chemotherapy drugs include 5 fluoro-uracil (5FU) and leukovirin (LV)
- External beam radiation therapy is delivered daily over a 6 week period



## Results of Phase IIa Clinical Trial in Pancreatic Cancer

### **Study Design:**

A fixed dose study in 17 patients with pancreatic cancer

- Dose: a single intra-tumoral implantation of Oncosil (100 Gy)
- Gemcitabine commenced within 2 weeks prior to implantation, or within three days following implantation
- Patients were followed for safety for up to 24 weeks, with assessments of response at weeks 8, 16 and 24

### **Results:**

- Analysis of patients demonstrated significant tumoricidal activity with a disease control rate of 82%
- Over the 24 week period of the trial, patients experienced an average reduction in pain of 35%, with a maximum reduction of 69% between weeks 8 and 11 following implant
- Median progression free survival was 121 days
- Median overall survival was 309 days or 10 months (cf. 5.7 months with gemcitabine)



## Results of Phase IIb Clinical Trial in Pancreatic Cancer

### **Study design:**

A dose escalating study in 6 patients with pancreatic cancer

- Ascending doses; a single intra-tumoural implantation of Oncosil (up to 400 Gy).
- Gemcitabine commenced within two weeks prior to implantation, or within three days following implantation
- Patients were followed for safety for up to 24 weeks, with assessments of response at weeks 8, 16 and 24

### **Results:**

- 400Gy is the optimal safe dose to be administered – no device related adverse events
- Tumor control rate of 100% - stabilisation of tumour growth





## Planned Phase III Clinical Trial in Pancreatic Cancer\*

### Study design:

- Open label study
  - 150 patients subject to statistical analysis and trial powering\*
  - First patient potentially treated in Qrt 3 2013\*
- CE Mark Application
  - Subject to regulator agreement, application may be submitted in 2013\*
- Single intra-tumoral implantation of Oncosil
- Gemcitabine commenced within two weeks prior to implantation, or within three days following implantation
- End points:
  - Survival (three months or greater beyond current therapy)
  - Safety
  - Quality of life – substantial pain relief

**\*Subject to discussions with relevant regulatory authorities which need to be re-initiated**



## Patents & Know How

- Multi-layered protection from multiple granted patents in US, EU, Japan and elsewhere
  - On therapeutic product
  - On manufacturing method
- Know-How, Expertise & Trade Secrets
  - Brachytherapy clinical trial management
  - Manufacturing & distribution logistics
  - Core technologies and full toxicology package
  - Detailed professional Market Research Data (Navigant Consulting Inc.)



## Phase II Oncology Deal Valuations

- Pfizer – Coley
  - Global licence for a TLR9 agonist in 2005 upfront US\$50m plus US\$455m in milestone
  - Pfizer acquired Coley for US\$164m in 2007
- Novartis – Antisoma
  - AS1404 (since discontinued) but deal was for US\$75m upfront plus milestones
- Genentech – Seattle Genetics
  - SGN-40 a humanised monoclonal antibody against CD40
  - Upfront of US\$60m and potential milestones of US\$800m and committed US\$20m in first 2 years



## Brachytherapy Landscape

Company	Mcap*	Brachy Sales
Sirtex Medical Ltd (ASX:SRX)	\$515m	\$82m
Biocompatibles (UK) Ltd - Takeover	\$21m	\$3m
C.R. Bard Inc. (NYSE:BCR)	\$6,000m	NA
Cytoc Corporation (Proxima Thera) - Takeover	\$160m	\$12.6m (04)
IsoRay (AMEX:ISR)	\$22m	\$2m
MDS Nordion (NYSE:NDZ)	C\$560m	C\$50m
Nucletron Corporation (Delft) - Private	NA	\$180m
Oncura & Theragenics – Takeover GE Healthcare	\$80m	\$16.7m (07)
Theragenics Corp (Nordion licensee)	\$110m	Royalty stream
Xoft, Inc. (Standard Img Inc.)	\$150m	\$1.75m (07)
NeuroDiscovery Ltd (ASX:NDL)	\$5.8	NA
* US\$1 = A\$1		

\* Approximate figures



## Value Drivers

- Acquisition of Enigma
- Appointment of experienced management and directors
- Commencement of potential Oncosil Phase III clinical trial
- Potential CE mark application submitted in 2013
- Oncosil clinical trial results
- Licensing of Oncosil for pancreatic cancer treatment
- Other potential clinical trials in other cancers
- Possible trade-sale linked to successful trial / licensing deal



## Disclaimer

NeuroDiscovery has prepared this presentation based on information available to it from Enigma Therapeutics. No representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained. To the maximum extent permitted by law, none of NeuroDiscovery, its directors, employees or agents, nor any other person accepts any liability including, without limitation, any liability arising from fault or negligence on the part of any of them or any other person, for any loss arising from the use of this presentation or its contents or otherwise arising in connection with it.