A clinical-stage drug development company

Corporate Update – Interim study update

Wednesday 12 October 2016
Quick overview

Key Assets

**Who we are:** A clinical-stage drug development company focused on discovering and developing new therapeutic treatments identified using our proprietary drug discovery platform.

**Lead Program:** DMX-200 currently in Phase II clinical trial for Chronic Kidney Disease (CKD) and US Orphan Drug Designation for Focal Segmental Glomerulosclerosis (FSGS).

- Pre IND meeting with FDA held 29th June 2016
- Therapeutic use patent **granted** in USA 19th April 2016
- **Positive** interim Phase 2 safety data announced Oct 2016

**Discovery Platform:** Receptor-HIT technology to identify clinical opportunities from drug-receptor interactions, and potential revenue generation.

**Leadership:** Commercially focused and experienced board and management with a record of hitting milestones and creating significant shareholder value.

Corporate Snapshot

<table>
<thead>
<tr>
<th>ASX Code:</th>
<th>DXB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share Price (10 Oct):</td>
<td>$.01</td>
</tr>
<tr>
<td>Market cap:</td>
<td>$16.5m</td>
</tr>
<tr>
<td>Cash (30 Jun 16):</td>
<td>$2.0m</td>
</tr>
<tr>
<td>Shares on issue:</td>
<td>1,497m</td>
</tr>
<tr>
<td>Performance Shares:</td>
<td>75m</td>
</tr>
<tr>
<td>Options:</td>
<td>98.7m</td>
</tr>
</tbody>
</table>

Top Shareholders

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr. Peter Meurs</td>
<td>21.19</td>
</tr>
<tr>
<td>Yodambao Pty Ltd</td>
<td>4.71</td>
</tr>
<tr>
<td>Mrs Wishney Sritharan Krishnarajah</td>
<td>3.41</td>
</tr>
<tr>
<td>J&amp;L Peterson</td>
<td>2.87</td>
</tr>
<tr>
<td>White Family</td>
<td>2.70</td>
</tr>
<tr>
<td>SRV Custodians Pty Ltd</td>
<td>2.53</td>
</tr>
<tr>
<td>Pfleger Family</td>
<td>2.08</td>
</tr>
<tr>
<td>Jampaso Pty Ltd (Williams Family)</td>
<td>1.85</td>
</tr>
<tr>
<td>Yodambao Investment</td>
<td>1.54</td>
</tr>
<tr>
<td>JGC Super Pty Ltd</td>
<td>1.43</td>
</tr>
</tbody>
</table>
DMX-200 – Why kidneys?

Dimerix identified DMX-200 using Receptor-HIT

- Published pre-clinical data show significant reduction in proteinuria when both receptors are targeted.
- **Standard of care treatment** for CKD is angiotensin receptor blocker (ARB) or ACE inhibitor (ACEi).
- DMX-200 is **adjunct** (NOT combination) therapy comprising *Irbesartan* + *Propagermanium*.

**Both receptors expressed in the kidney**

- **Irbesartan (Irb)**
  - Off-patent blockbuster treatment of high blood pressure

- **Propagermanium (PPG)**
  - Available for use as an anti-inflammatory agent – CCR2 mediated
Chronic Kidney Disease (CKD) – the big opportunity

- A global unmet medical need leading to kidney failure, cardiovascular disease and premature death
  - Estimated 26 million people in the US
  - Estimated US$2.6 billion spent in the US each year, mainly on late stage therapies due to lack of early stage treatment options

The Orphan Pathway

- Enables shorter trials with fewer patients and cost benefits
- Registration brings seven years of exclusivity in the US market

DMX-200 secured orphan drug designation for Focal Segmental Glomerulosclerosis (FSGS)

- Scarring of kidney (glomerulus)
- Leakage of blood and protein
- Serious and chronic disease leading to kidney failure
- Current therapy:
  - Steroids – serious side effects, resistance and non-response is common
  - Followed by a cocktail of off-label treatments

Source: kidneyfailurewe.com
FSGS renal survival rates

Cumulative percentage renal survival in primary FSGS
Percent survival; From: Nephrol Dial Transplant (1999) 14 [Suppl. 3]: 68-73

Non Nephrotic Proteinuria:
0.3–3 g protein/day
(PCR – 30-300 mg/mmol)

Nephrotic proteinuria:
>[3-3.5] g protein/day
(PCR > 300-350 mg/mmol)

Massive proteinuria:
>14 g protein/day
(PCR >1,400 mg/mmol)

i.e. a reduction in proteinuria has a profound effect on renal survival
DMX-200 Phase II (Part A) Interim Data

- Study is on schedule and recruiting across four sites
- A total 21 of 30 participants dosed at end of Q3 2016
- Interim data shows DMX-200 well tolerated with encouraging safety profile
- All participants on stable irbesartan dose prior to start of treatment
- Participants dose of propagermanium escalated from 30 mg per day to a maximum of 240 mg per day
- Proteinuria measurement used was protein creatinine ratio (PCR) in mg/mol
- Three out of 11 participants (27%) who reached mid point (90 mg) show a ~ 50% reduction or greater in proteinuria over and above standard of care
- One participant achieved a 66% reduction in proteinuria at 90 mg dose
- Total participant exposure at end Q3 2016 was 67 months (5.5 years)
Phase II asset, sparsentan, for treating FSGS – a dual angiotensin endothelin receptor blocker

Patients removed from Standard of Care treatment 2 weeks prior to dosing

Top line positive data showing improved proteinuria compared with standard of care (irbesartan) at 8 weeks

Standard of Care (irbesartan) reduced total protein urine excretion per day by 19% and sparsentan by 47.4%

NASDAQ Listed: RTRX, Market cap: ~US$817 million

Completed Phase II for CCX140 in diabetic nephropathy – a CCR2 antagonist

Significant improvement in proteinuria on background of standard of care (ACE Inhibitor or ARB)

Measured urine albumin creatinine ratio (ACR) change from baseline by 16% over “placebo” (standard of care) at best dose (geometric mean reduction at 12 weeks of 24%)

NASDAQ Listed: CCXI, Market Cap: ~US$215 million
Australian Phase II study

- **Part A**: Interim: confirmed safety and signs of efficacy: Reporting mid 2017
- **Part B**: Efficacy of optimal dose(s): Commencing 2017

US Investigation New Drug (IND) application

- Initial pharmacokinetic (PK) study
- Comparison of current three times daily version with extended release formulation

Phase 3 Development for FSGS – FDA Pre-IND meeting outcomes

- **Agreed** development as an *adjunct* (not combination) therapy
- **Primary endpoint** discussions positive:

  “A substantial change in proteinuria in patients with marked proteinuria at baseline may be an acceptable endpoint for traditional or accelerated approval…”

Potential for a *single* Phase 3 pivotal study
Outlook for next 12–18 months

DMX-200 Program

• Complete recruitment for Phase 2 Part A – Q4 2016
• Complete extended release formulation for propagermanium - 1H 2017
• Report Phase 2 dose escalation trial - mid 2017
• Open IND for PK study – mid 2017
• Commence Phase 2 Part B – 2H 2017

DMX-250 Program

• Further pre-clinical studies for NASH program

Platform Technology

• Potential indications include diabetic retinopathy, cancer fatigue and multiple sclerosis
• Research collaborations and assay licensing opportunities
Further Information

Kathy Harrison, General Manager
+61 419 359 149
kathy.harrison@dimerix.com

James Williams, Executive Chairman
+61 409 050 519
james@dimerix.com

Dimerix Limited
ACN 001 285 230
www.dimerix.com
## Experienced board and management

### Executive Chairman:

**Dr James Williams**  
*BSc(Hons), PhD, MBA, GAICD*

- 15 years experience starting, funding, running and exiting biotechnology companies
- Co-founder of Dimerix and iCeutica (acquired in 2011 and now with 3 FDA drug approvals)
- Co-founder and Investment Director of Yuuwa Capital ($40M venture capital fund)

### General Manager:

**Ms Kathy Harrison**  
*MSc, Cert.Gov.(Prac), FIPTA*

- 20 years experience in Biotech: AMRAD, Cytopia Research Pty Ltd, Phosphagenics Limited
- Registered Patent and Trademark Attorney

### Director:

**Dr Sonia Poli**  
*MSc, PhD*

- Former Senior Management at Hoffman la Roche and Executive at Addex Therapeutics (Switzerland)
- 20 years international experience in small molecule drug design, optimization and clinical development
- Expertise encompassing multiple therapeutic areas

### Director:

**Dr Liz Jazwinska**  
*PhD, MBA, GAICD*

- 25 years experience in R&D management and drug portfolio business development
- Led Asia Pacific Partnering Group at Johnson and Johnson Research
- Director Industry Engagement at Institute of Medical Biology, A*STAR, Singapore

### Director:

**Mr David Franklyn**  
*BEcon*

- Experienced Director of ASX-listed companies in a variety of sectors
- Extensive experience in financial analysis, corporate advice, business management and IR
- Managing Director of Village National Holdings Limited