

### **Disclaimer**



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# **Capital Structure**



| Company location      | Melbourne, Australia |
|-----------------------|----------------------|
| ASX code              | VHL                  |
| Shares on issue       | 920 M                |
| Unlisted options      | 87.7 M               |
| Share price           | 0.7c                 |
| Market capitalisation | \$6.4 M              |
| Cash                  | \$4.0 M              |

## **Summary**



- Recent acquisition of GGTI-2418 oncology product from Yale University
- Phase 2 trials in multiple myeloma/breast cancer can commence within
   12 months
- High efficacy in mouse models of cancer
- Phase 1 human trials on advanced cancer patients
  - GGTI-2418 well tolerated with nausea as main adverse event.
  - Stable disease achieved in 4/13 cancer patients
- Outstanding scientific provenance from Yale University & prestigious
   Moffitt Cancer Center
- Market cap \$6.4m, cash \$4m makes Virax (VHL) the best value biotech on the ASX

## **Pathway Acquisition**



- Novel cancer drug which blocks an important cancer growth signal (inhibits Geranyl-Geranyl Transferase 1)
- \$10+ million spent on Pathway technology to date
- Completed Phase 1 trial in 13 patients with different cancers drug shown to be safe and well tolerated with 4 responses (stable disease) in a heavily-pretreated patient population
- GMP manufactured drug substance & product available
- Strong IP position patent life to 2025 with further enhancements available including companion diagnostic
- Full scientific support ongoing with Lee Moffitt Cancer Center & Albert Einstein Cancer Center







## **Outstanding Scientific Provenance**





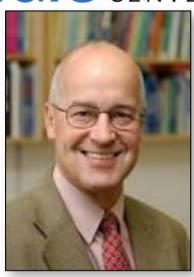


Prof. Said Sebti
Chair of the Dept. of Drug Discovery
Moffitt Cancer Center, Florida

#### **Moffitt Cancer Center**

- 3<sup>rd</sup> biggest cancer centre in the US
- Outstanding leader in developing new cancer treatments

# Yale cancer center



Prof. Andrew Hamilton
Formerly Provost of Yale University,
now Vice-Chancellor of University
of Oxford



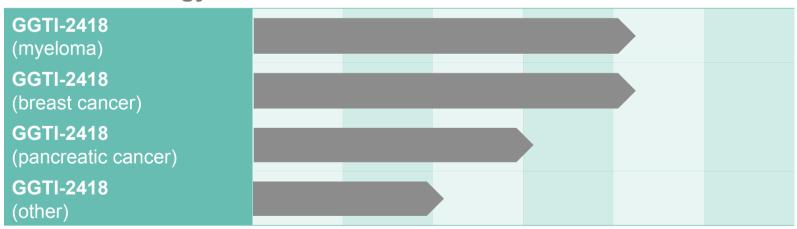
## **Pipeline of products**



### **Co-X-GENE Platform**

|                                | Discovery | Screening | Pre-clinical | Phase I | Phase II | Phase III |
|--------------------------------|-----------|-----------|--------------|---------|----------|-----------|
| TG-4010 (NSC lung cancer)*     |           |           |              |         |          |           |
| TG-4001 (mouth/throat cancer)† |           |           |              |         |          |           |
| Other                          |           |           |              |         |          |           |

### **GGTI Technology**



<sup>\*</sup>Program owned and undertaken by Transgene SA using Virax's Co-X GENE technology under licence

<sup>†</sup>Program owned and undertaken by Transgene SA in collaboration with EORTC (European Organisation for Research & Treatment of Cancer) using Virax's Co-X GENE technology under licence

### **Clinical Validation of Co-X-Gene**



### In partnership with Transgene SA, France

- >> TG4010 (MUC1 targeted IL-2 immunotherapy)
  - Positive phase IIb results in the 'TIME' trial of NSCLC (non small cell lung cancer) – increase in PFS in biomarker selected population
  - Progressing into Phase III study
- » TG4001 (E6/E7 targeted IL-2 immunotherapy)
  - Being developed for oropharyngeal cancer following infection with HPV (human papilloma virus)
  - In collaboration with EORTC (European Organisation for Research and Treatment of Cancer)

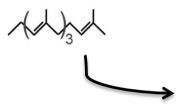
Currently undertaking a review commercial opportunities for Co-X-Gene

## **Method of Action – GGTI-2418**

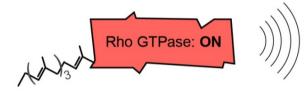


#### Geranylgeranyl

Or 'GG', is a type of 'lipid' (a fat or oil)



'Active' Rho GTPase needs an attached GG lipid to signal correctly

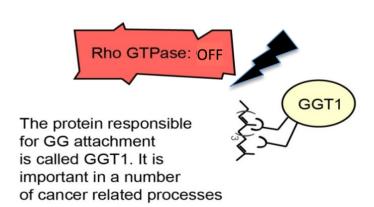


#### Various effects

Constantly transmitted 'growth' signal

Prevents tumour supressor proteins (which normally force sick cells to commit suicide) from working correctly

Patient develops cancer



#### **GGTI-2418**

The current drug candidate

GGTI-2418 targets GGT1 and prevents it from attaching GG lipids to proteins

By doing this it prevents the 'cancer causing' signal from being transmitted

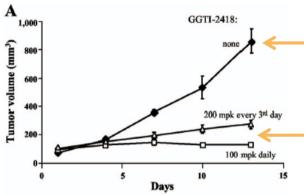
## **Compelling Pre-Clinical Results**



### **Mouse Study #1**

Small lung tumours were implanted into mice

Mice were injected with placebo or GGTI-2418

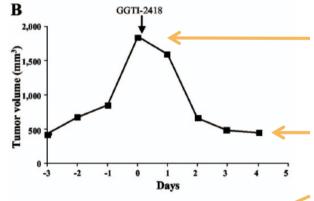


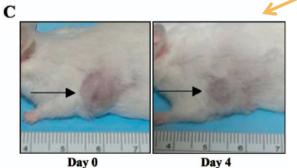
Tumors in placebo-treated mice grew to 8x their initial size after 2 weeks

By contrast, daily doses of GGTI-2418, or higher doses every 3<sup>rd</sup> day, dramatically slowed tumour growth

### Mouse Study #2

Used genetically modified mice with strong disposition to develop breast cancer
Graphs & images here show an example mouse from this study





Tumour rapidly grows, until daily treatments with GGTI-2418 begin at Day 0

After this the tumour shrinks, GGTI-2418 allows 'tumor suppressor' proteins such as p27 to reactivate

Easily seen in these pre- & posttreatment images of the affected mouse

When averaged across whole study GGTI-2418 caused 60% decrease in tumour size

# **Phase I Clinical Trial – Completed**



| No. of Patients   | 13   |
|-------------------|--|
| Trial Centers     | Indiana University & University of Pennsylvania  |
| Patient Inclusion | Patients with advanced-stage, treatment-refractory solid tumours for which standard treatments have failed or for whom standard therapies were not available   |
| Methods           | GGTI-2418 as a 30-min IV infusion on Days 1-5 every 21 days.   |
| Study Objectives  | <ul> <li>Determine dose limiting toxicity (DLT) &amp; maximum tolerated dose (MTD)</li> <li>Assess safety, tolerability and pharmacokinetics</li> <li>Observe clinical response &amp; explore correlative biomarkers predictive of GGTI-2418</li> </ul>  |
| Summary           | <ul> <li>GGTI-2418 is well tolerated with nausea as the main adverse event</li> <li>Elevation in Liver Function Test was identified as the dose limiting toxicity, with the LFTs returning to baseline upon discontinuation of GGTI-2418</li> <li>GGTI-2418 plasma concentrations were dose proportional &amp; far exceeded concentrations required for in-vitro inhibition of geranylgeryanly transferase I</li> <li>Stable disease achieved in four cancer patients</li> </ul> |





### Future studies - Phase 1b/2 Trial in Myeloma



- Multiple myeloma bone marrow cancer arising from plasma cells
- 24,000 new cases each year in the US, 1500 in Australia
- High mortality rate, large unmet medical need
- Phase 1b dose escalation stage in up to 18 patients to determine a safe & effective dose for Phase 2
- Phase 2 in combination with bortezomib (Velcade™) in up to 36 patients
- To be conducted at Moffitt Cancer Centre



### Future Studies - Phase 1b/2 Trial in Breast Cancer



- The most common cancer in American and Australian women.
- >200,000 new cases in US & >13,000 new cases in Australia each year
- Unmet medical need for advanced disease
- Phase 1b dose escalation stage to determine a safe & effective dose for Phase 2
- Phase 2 in combination with paclitaxel (Taxol™) in HER2 -neg
- Design to include p27 diagnostic to identify patients most likely to respond
- To be conducted at Albert Einstein Montefiore Medical Center





# **Valuation Anomaly**



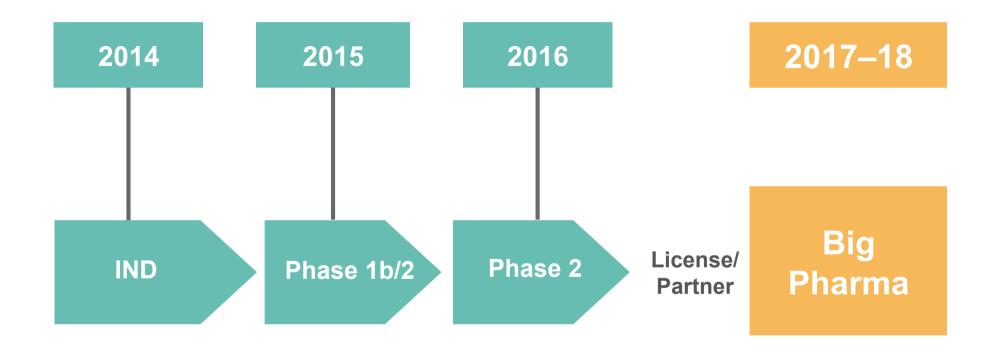
| Company  | Code                            | Market Cap<br>(\$m)                            | Phase of Development                         | Average<br>(\$m) |
|--|---------------------------------|--|--|------------------|
| Novogen<br>Cellmid<br>Phylogica  | NRT<br>CDY<br>PYC               | 25.0<br>18.3<br>32.1                           | Pre-clinical<br>Pre-clinical<br>Pre-clinical | 25.1             |
| Antisense Therapeutics Benitec Biopharma Circadian Technologies Patrys Biotron                   | ANP<br>BLT<br>CIR<br>PAB<br>BIT | 20.2<br>91.5<br>11.2<br>17.8<br>27.4           | <br> <br> <br> /  a<br> /  a                 | 33.6             |
| Viralytics Innate Immunotherapeutics Bionomics Prana Biotechnology Invion Neuren Pharmaceuticals | VLA IIL BNO PBT IVX NEU         | 24.4<br>45.6<br>185.6<br>81.2<br>40.7<br>124.0 | <br>  <br>  <br>  <br>                       | 83.6             |

Virax has two Phase 1b/2-ready programs in the first instance, with other indications to follow

As at 13 June 2014

## **Business Strategy & Exit**





### **Executive Leadership**



### **Rob Crombie – Managing Director**

18 years background in private & public markets in the UK & Australia with a strong business development track record in closing significant deals between biotechnology & pharmaceutical companies.

Formerly Head of Melbourne Operations at Arana Therapeutics & was instrumental in driving from start-up phase as EvoGenix through IPO to a \$318M cash sale to Cephalon (Teva Pharmaceuticals).



### Paul Hopper – Executive Director

20 years experience in international public company markets with a focus on start-up. Served as either Chairman, non-executive director or CEO of 14 public companies in the US, Australia & Asia.

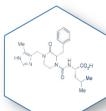
Advisor at Los Angeles-based Cappello Group where he is Head of the Life Sciences and Biotechnology Group responsible for mergers & acquisitions & capital raisings focusing on the biotech/life sciences sectors.

Executive Chairman of Imugene Ltd & Viralytics Ltd

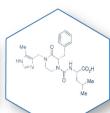


## Why Virax?

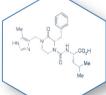




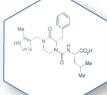
Lead GGTI-2418 First-in-class molecule with potential application across many cancers



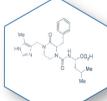
Strong support from Moffitt Cancer Centre & Albert Einstein University to run clinical trials



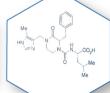
Huge multiple myeloma & breast cancer markets



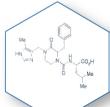
**GMP manufacturing completed – commercial scale-up available** 



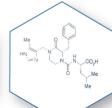
Phase 1 trial completed - safe & well tolerated



Robust IP with potential for further enhancements



Phase 2 trials in multiple myeloma & breast cancer can commence within 12 months



Modest valuation against ASX listed peer group

