

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on
issue:

483 M

Board of Directors

Mr Iain Ross

Chairman
Non-Executive Director

Mr Bryce Carmine

Non-Executive Director

Mr Steven Coffey

Non-Executive Director

Dr James Garner

Chief Executive Officer
Managing Director

MARKET RELEASE

11 September 2017

NOVOGEN PRESENTS AT RODMAN & RENSHAW CONFERENCE

Sydney, 11 September 2017 – Australian oncology-focused biotechnology company Novogen Ltd (ASX: NRT; NASDAQ: NVGN) is pleased to release the presentation that CEO, Dr James Garner will be presenting at the Rodman & Renshaw 19th Annual Global Investment Conference being held in New York.

Dr James Garner will be presenting in New York at the Lotte New York Palace Hotel on Monday 11 September at 9:35 am, EDT.

ENDS

About Novogen Limited

Novogen Limited (ASX: NRT; NASDAQ: NVGN) is an emerging oncology-focused biotechnology company, based in Sydney, Australia. Novogen has a portfolio of development candidates, diversified across several distinct technologies, with the potential to yield first-in-class and best-in-class agents in a range of oncology indications.

The lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme. Licensed from Genentech in late 2016, GDC-0084 is anticipated to enter phase II clinical trials in 2017. A second clinical program, TRXE-002-01 (Cantrixil) commenced a phase I clinical trial in ovarian cancer in December 2016. In addition, the company has several preclinical programs in active development, the largest of which is substantially funded by a CRC-P grant from the Australian Federal Government.

For more information, please visit: www.novogen.com



Novogen Limited

An emerging oncology drug
developer with two clinical-stage
programs

 ASX NRT

 Nasdaq NVGN

September 2017

Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of the “safe-harbor” provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements, including changes from anticipated levels of customer acceptance of existing and new products and services and other factors. Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. The Company has no obligation to sales, future international, national or regional economic and competitive conditions, changes in relationships with customers, access to capital, difficulties in developing and marketing new products and services, marketing existing products and services update the forward-looking information contained in this presentation.

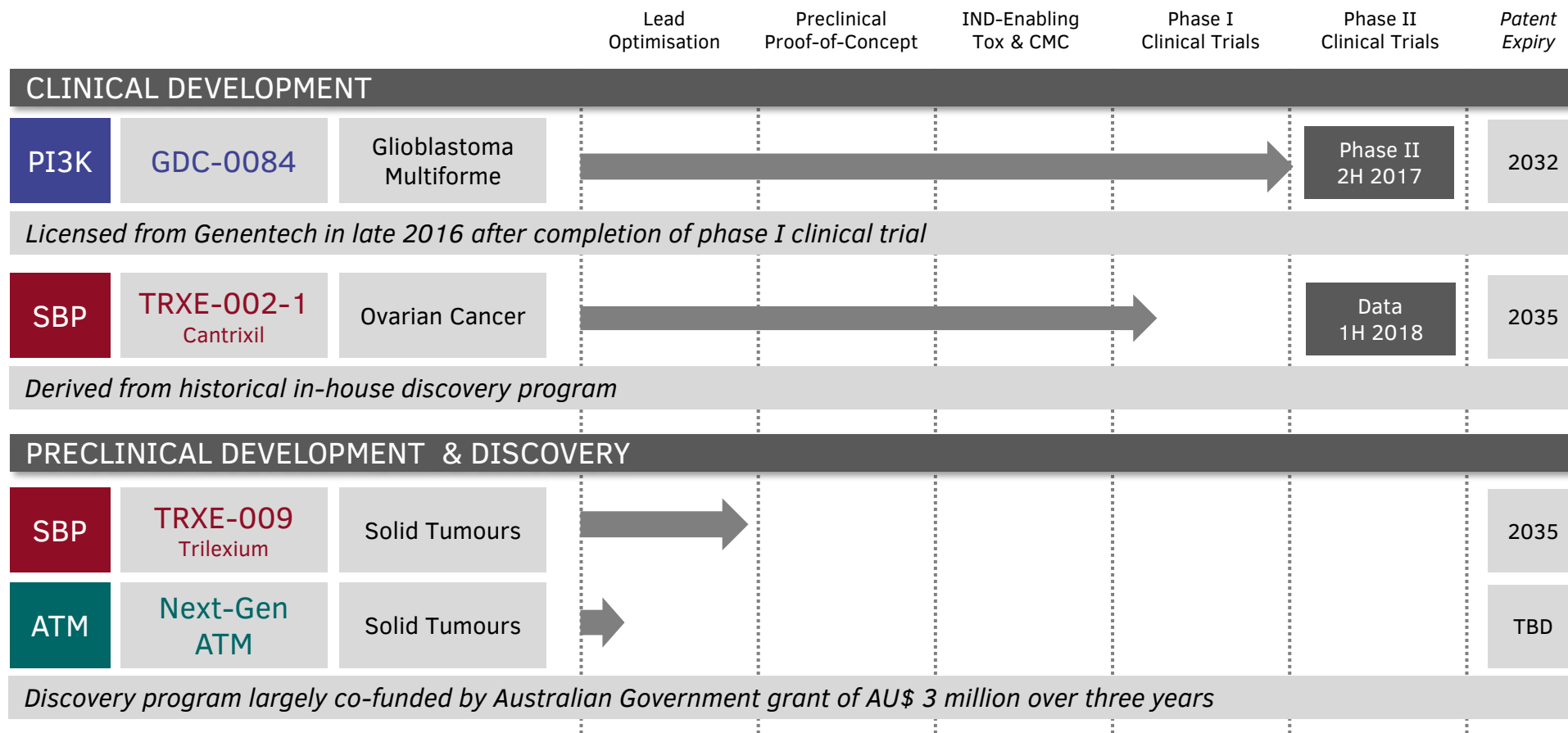
Executive Summary

- Novogen is an oncology-focused biotechnology company, listed on ASX and NASDAQ
- Lead asset is GDC-0084 for GBM, an orally-administered small molecule PI3K inhibitor licensed from Genentech
 - PI3K class is well-validated, with one commercial product on market: Zydelig (idelalisib) from Gilead
 - PI3K / Akt / mTOR pathway shown to be upregulated in 85-90% of GBM tumours
 - GDC-0084 well differentiated from class; able to cross blood-brain barrier
 - Genentech has successfully completed a large (n=47) phase I study in recurrent GBM patients, demonstrative a favourable safety profile and promising indications of clinical efficacy
 - GDC-0084 is ready to begin phase II studies in first-line GBM, with protocol concept developed, experienced clinical sites enthusiastic to participate, and 45kg of drug substance already manufactured and on hand
- Cantrixil, lead asset from in-house discovery programs, is currently in a phase I clinical trial in ovarian cancer in United States and Australia
- Company strategy is to build a diversified pipeline over the medium term by in-licensing undervalued assets that have been deprioritised by pharmaceutical companies and developing them to value inflection

Agenda

- Corporate Overview
- GDC-0084
- Cantrixil
- Investment Hypothesis

Novogen has a well-diversified portfolio of assets, stretching from preclinical to mid-stage clinical



A strong team brings international experience in big pharma and biotech

Management Team



Dr James Garner
Chief Executive Officer
& Executive Director

Physician / MBA; Extensive drug development experience



Dr Gordon Hirsch
Chief Medical Officer

Physician / MBA; 20 years of pharma industry experience



Dr Peng Leong
Chief Business Officer

18 years of BD and investment banking experience



Kate Hill
Company Secretary

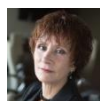
Chartered accountant, and former audit partner at Deloitte



Scientific Advisory Board



Professor Sir Murray Brennan
Emeritus Chairman of Cancer
Surgery at Memorial Sloan Kettering
Hospital, New York



Dr Karen Ferrante
Former Chief Medical Officer at
Millennium Pharmaceuticals



Professor Peter Gunning
Head of School of Medical Sciences
at University of New South Wales



Professor Alex Matter
Former Global Head of Oncology
Research at Novartis



Board



Iain Ross
Chairman

Executive and Board roles in pharma and small biotech



Bryce Carmine
Deputy Chairman

36 years executive experience in Eli Lilly



Steven Coffey
Non-Executive Director

Chartered accountant with extensive governance experience



Dr James Garner
Chief Executive Officer
& Executive Director

Physician / MBA; Extensive drug development experience



Agenda

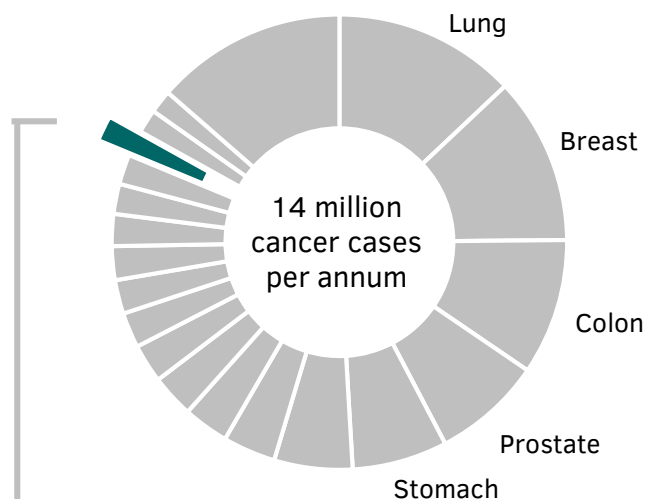
- Corporate Overview

- GDC-0084

- Cantrixil

- Investment Hypothesis

Glioblastoma Multiforme (GBM) is the most common form of primary brain cancer



Glioblastoma Multiforme

133,000 cases
per annum
worldwide

Indicative Market
Opportunity

US\$ 1 billion

**No clear
cause**
or strong risk
factors

**3-4
months**
untreated
survival

**12-15
months**
average
survival with
treatment

Any age,
but most
common in
60s

Five-year
survival
3 – 5%
(breast
cancer: 90%)

Most common drug treatment is temozolomide
(Temodar®), used after surgery and radiotherapy

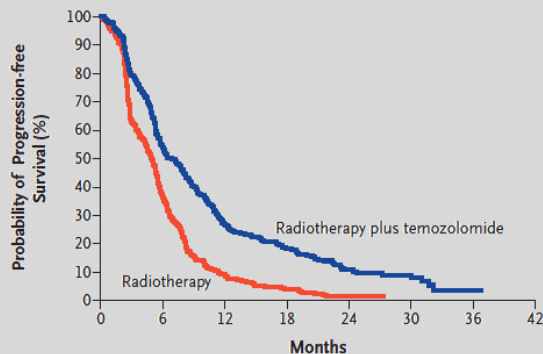
**Ineffective in approximately
two-thirds of patients**

Current GBM standard of care is ineffective in ~65% of patients

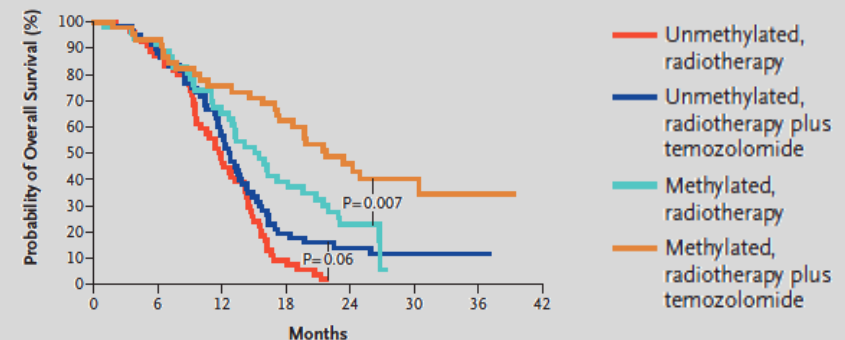
Standard
of Care
(‘Stupp
Regimen’)



Temozolomide is clearly efficacious...



...but only in ~35% with a methylated MGMT promotor



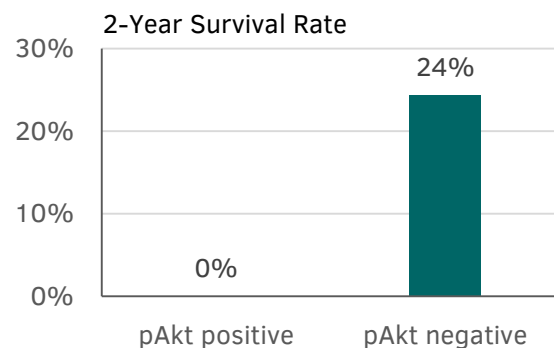
Source: ME Hegi, A-C Diserens, T Gorlia, et al. (2005). *N Engl J Med* 352:997-1003

The PI3K pathway is highly relevant to GBM; GDC-0084 is differentiated within the class

PI3K Activation in GBM

PI3K pathway upregulated in
~90% of GBM cases
per Cancer Genome Atlas¹

PI3K dysregulation is associated
with a worse prognosis²



PI3K Inhibitor Class is Diverse

Differentiation

GDC-0084 is a pan-PI3K inhibitor, active against all four isoforms (α β γ δ)

GDC-0084 is a dual PI3K / mTOR inhibitor

GDC-0084 penetrates the blood-brain barrier (1:1 brain / plasma ratio)

Rich preclinical data set supporting clinical development in GBM

Comparators

Idelalisib (Gilead) – δ
IPI-549 (Infinity) – γ
Umbalisib (TG) – δ

Taselisib (Genentech) – PI3K only

Buparsilib (Novartis) – also brain-penetrant but mood disturbances

Buparsilib (Novartis) – lead indication is breast cancer

Relevance

α & β isoforms likely more relevant to solid tumors

Dual mechanism reduces bypass signalling

Brain / plasma ratio ≥ 1 necessary, given diffuse nature of GBM

GDC-0084 developed from ground up as a GBM drug

¹CW Brennan et al, *Cell* (2013), 155(2):462-477; ²Y Suzuki, et al. *J Radiat Res* (2010), 51(3):343

Previous GBM failures are understood and can inform development of new therapies

Pharmacokinetic Failure

- Many small-molecule kinase inhibitors are not well brain-penetrant, and so reach insufficient concentration at the tumour

Tumour Genetics & Heterogeneity

- Many driver mutations for GBM, but few constitutive (e.g. EGFR disordered in ~40% of cases)
- Profound heterogeneity in the tumour, and rapid evolution

Compensatory Mechanisms

- Inhibition of some downstream targets may lead to upregulation elsewhere (e.g. pure mTOR inhibitors have been associated with *worse* clinical outcomes)

Immunological Environment

- Brain is 'immunologically privileged', with profoundly different set of immunological responses, so immuno-oncology therapies and cancer vaccines are likely to face hurdles

Clinical Trial Design

- Positioning in advanced treatment failures entails an extremely 'hard-to-treat' group with limited life expectancy, creating very high bar for new therapies
- Combination therapy tends to be limited by significant toxicity, and some monotherapies can be impeded by higher levels of toxicity in this population

Genentech's phase I study established a dose of 45mg and demonstrated acceptable safety

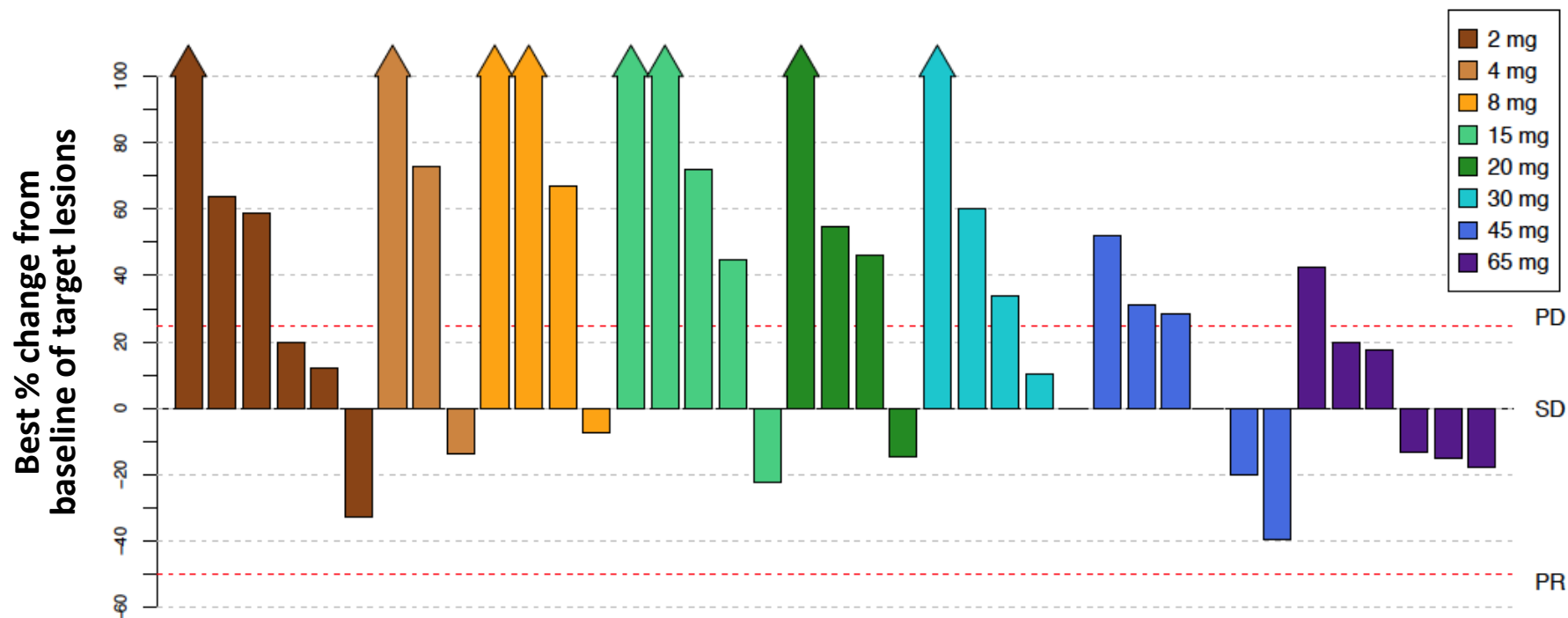
Safety

- Phase I safety trial conducted by Genentech
- 47 patients enrolled with advanced glioma (grade 3/4)
- Most common adverse events were oral mucositis and hyperglycemia (common effects of PI3K inhibitors)
- No evidence of liver, bone marrow, kidney toxicity, or mood disturbances
- Data presented at American Society for Clinical Oncology annual meeting in Chicago, June 2016

Efficacy Signals

GDC-0084**Arresting
Tumour
Growth****40%**Achieved
'stable disease'**Potentially
Delaying
Progression****21%**Remained on study
for >3 months**Slowing
Tumour
Metabolism****26%**Showed 'metabolic
partial response' on
FDG-PET

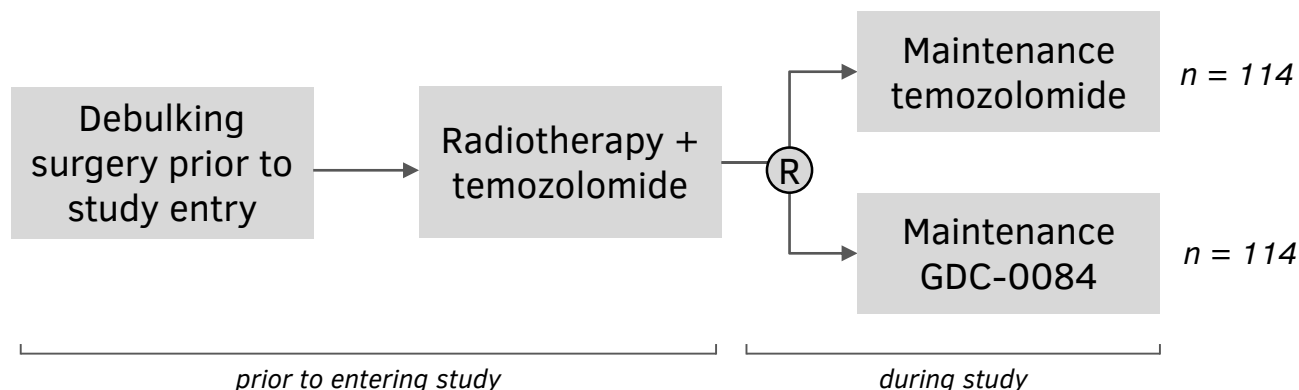
40% of patients achieved stable disease, with response increasing in higher doses



CR / PR: 0
 SD: 19 (40%)
 PD: 26 (55%)

Disease stabilisation is consistent with a primarily cytostatic mechanism, and highly relevant for use in post-resection setting

First-line phase II study design is supported by preclinical data and KOL consultation



Approximately 60 sites in 5-6 countries

Will target patients who are resistant to temozolomide
(approximately two-thirds of glioblastoma patients)

Duration:

18 months recruitment
12 months follow-up

Number of patients:

approx. **228**
(114 per arm)

Regulatory Strategy

- Designed to provide robust evidence of clinical efficacy, using an endpoint, progression-free survival (PFS), that could potentially be approvable
- Goal is to seek accelerated approval prior to completion of a definitive phase III study. Avastin (bevacizumab) was approved for recurrent GBM in this way
- In the interim, Novogen aims special designations (ODD, FTD, etc.) to provide enhanced opportunities for regulatory engagement

Brain metastases from non-CNS tumors represent long-term upside potential

Overview

- Estimated 100,000 - 200,000 cases/year in US
- ~10-25% adult cancer patients develop symptomatic brain mets
- Lung, breast and melanoma represent the majority of brain mets
- Frequency of brain mets increasing with better systemic control and longer survival
- Few (if any) drugs available to treat brain metastasis

Example: Breast Cancer

- ~30-44% of metastatic HER2-positive metastatic breast cancer patients have brain metastases
- Brain metastases represent the cause of death in ~50% of HER2-positive breast cancer patients
- ~40-50% of breast cancer brain metastases have disordered PI3K pathway
- Therapies that are effective for the primary tumor (e.g. Herceptin) are often ineffective for brain metastases

Next Steps

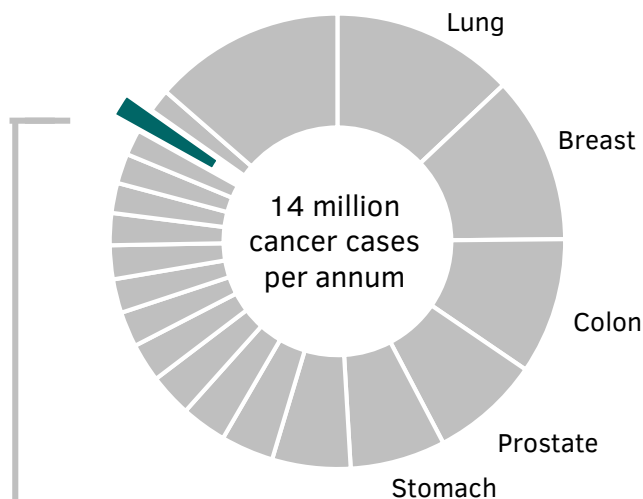
- Use GBM as a 'gateway indication', with the potential to explore registration post-phase II via accelerated approval / breakthrough designation, subject to clinical results
- Meanwhile, conduct preclinical exploration of brain metastases in partnership with identified researchers to demonstrate preclinical proof-of-concept and augment economic value of the asset

Source: E Lim & N Lim (2012). *Oncology*. 26(7):652-9; PK Brastianos, SL Carter, S Santagata, et al. (2015). *Discovery* 5:1164

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Ovarian cancer remains a disease of high unmet medical need



Ovarian Cancer

239,000 cases per annum worldwide

Indicative Market Opportunity

US\$ 1.5 billion

Cause of death for
1 in 100
women

>60%
of patients
have disease
spread at
diagnosis

10%
of cases are
primarily
genetic in
origin

80%
of patients
are over 50
years of age

Five-year
survival
45%
(breast
cancer: 90%)

Chemotherapy only curative in ~20% of ovarian cancers

More than half of patients with advanced disease will recur within 1-4 years

Cantrixil (TRX-E-002-1) is a novel small molecule optimized to kill tumor-initiating cells

First-in-class agent that kills the 'tumor-initiating cells' thought to be responsible for tumor recurrence and metastasis

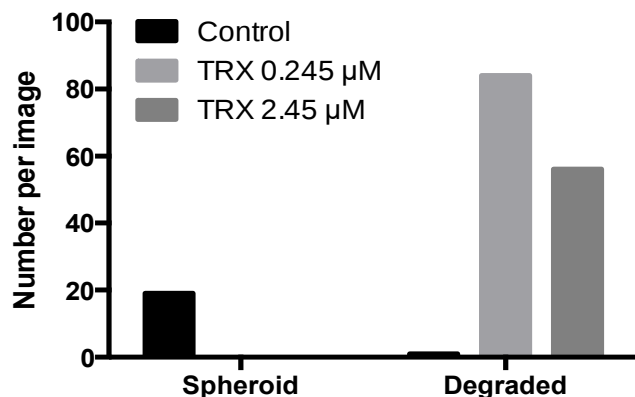
Potentiates the destruction of ovarian cancer stem cell spheroids which are linked to migration and enhanced chemo-resistance

Cantrixil kills chemo-resistant cancer cells resulting in improved survival compared to cisplatin alone in tumour-bearing athymic nude mice

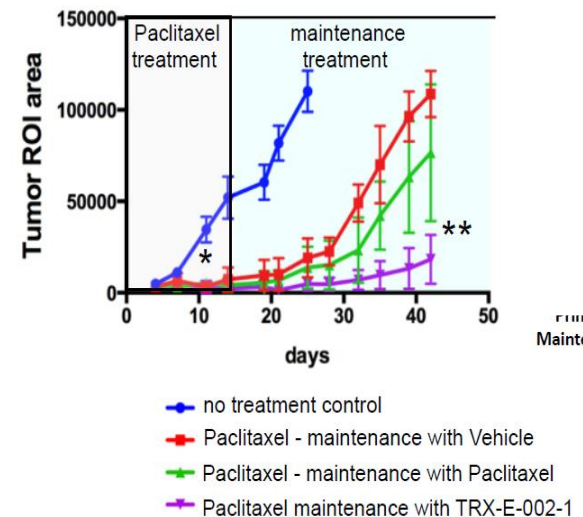
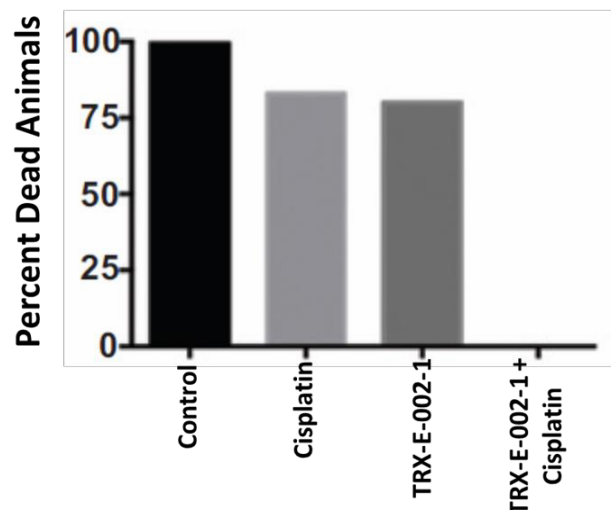
Prevents recurrence post-chemotherapy

Combination treatment of TRX-E-002-1 and paclitaxel reduces tumour recurrence in a model of disseminated, chemoresistant ovarian cancer

Number of spheroids after 48 hours of treatment with Cantrixil

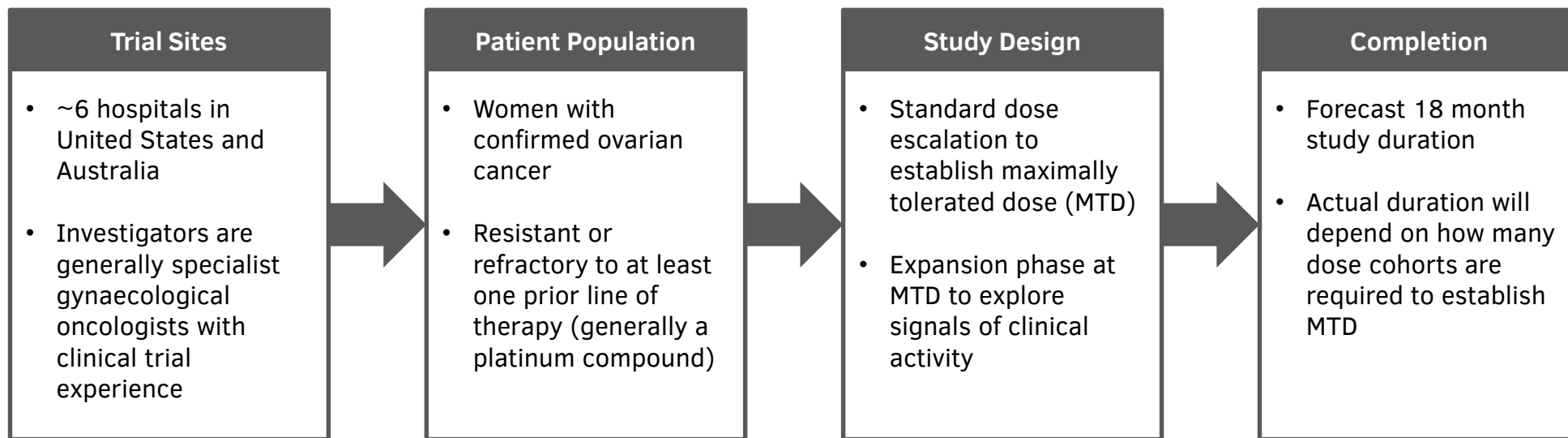


Survival benefit over 47 days of treatment compared with the respective monotherapy controls



Ref: Mol Can Ther; 15(6) June 2016

Phase I study is designed to establish safety and tolerability, and explore potential efficacy



Study performed under Investigational New Drug (IND) application with United States Food & Drug Administration (FDA) – provides careful validation and supports eventual product approval in United States

In addition to standard efficacy measures (via CT scan), study will measure exploratory biomarkers to seek signals of clinical activity

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Milestones and Newsflow

Calendar Year Basis

	2017	2018	2019	2020
GDC-0084	2H Phase I study publication 2H FDA meeting re: GBM phase II program 2H Initiation of GBM study	1H Planned FDA ODD approval 1H Potential exploratory clinical studies with partners	1H Initial data from GBM study	1H Data from FDG-PET subgroup of GBM study
Other Programs	2H Maximum Tolerated Dose (MTD) from TRXE-002-1 phase I study in ovarian cancer	1H Completion of TRXE-002-1 phase I study in ovarian cancer		2H Completion of ATM discovery program and potential progression to clinic

Financial Overview



* Adjusted for change in ASX / NASDAQ consolidation ratio on 14 July 2017

As at 30 June 2017

Cash at Bank ~US\$ 11.1 million	Debt Nil
Market Capitalisation	US\$ 16.2 million
Listing	ASX: NRT NASDAQ: NVGN (1:100 ratio)
Average Daily Volume	ASX: 0.1% /day NASDAQ: 0.2% /day
Average Daily Value	ASX: AU\$ 44K /day NASDAQ: US\$ 54K /day
Shares on Issue	483 million (35% US, 65% Australia)
Outstanding Options / Warrants	~60 million

Investment Summary

High-Quality Pipeline

- Lead asset in-licensed from Genentech after successful phase I

Clear Development Plans

- Multiple value-driving catalysts between now and 2Q 2019

Careful Risk Management

- Two active clinical programs providing diversification

Proven Team

- Board and management brings international big pharma experience

Sustainable Corporate Strategy

- Ambition to source additional assets and to aggressively seek partnering opportunities with big pharma

