



Novogen Limited

Presentation to Annual General Meeting of Shareholders

Dr James Garner
Chief Executive Officer

Sydney, NSW

16 November 2016

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.

Novogen is a biotech company dedicated to driving sustainable, long-term growth in shareholder value

Focus on unmet medical need

Pipeline of novel therapies, targeting oncology patients poorly served by existing treatment options

Financially sound

Listed on ASX and NASDAQ, with ample cash runway to drive forward existing pipeline

Clinical stage

Two clinical stage programs: GDC-0084 and Cantrixil, with rich newsflow over next 12-18 months

Strong management and Board

Lean team of internationally-experienced pharma executives, overseen by seasoned Board

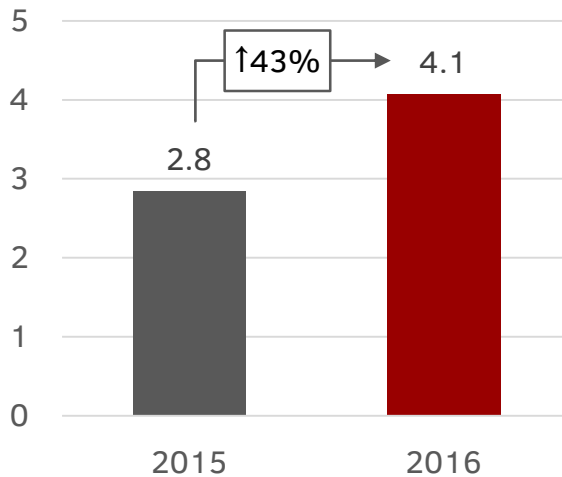
2016 has been a transformative year for Novogen



Novogen is financially efficient, with increasing expenditure reflecting progression of the pipeline

Revenue

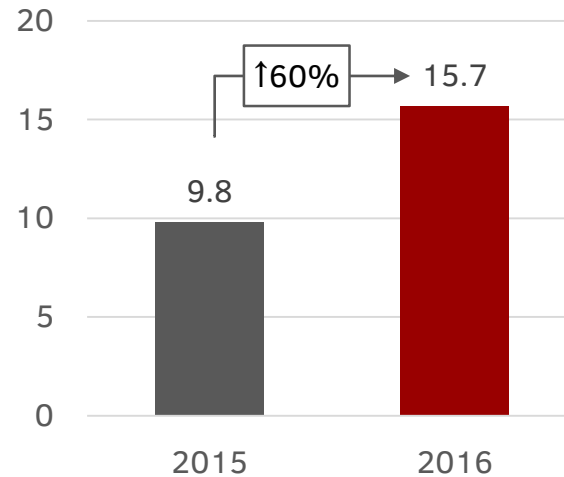
Revenue (AU\$, M)



- Optimised utilisation of R&D Tax Rebate scheme
- Careful management of cash resources and forex risk

Operating Expenditure

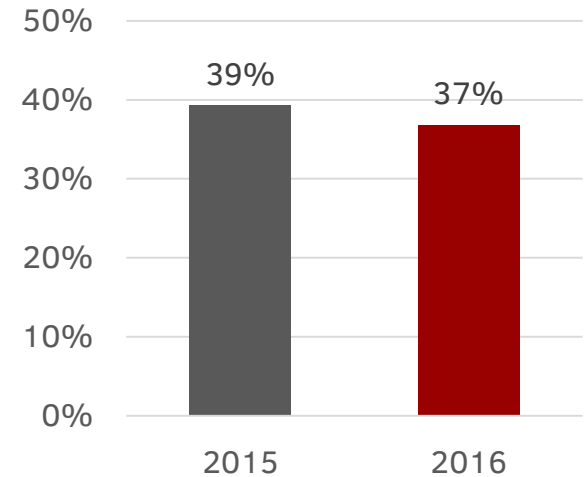
Expenditure (AU\$, M)



- Increased expenditure reflects IND-enabling work and larger-scale manufacture for Cantrixil and Anisina

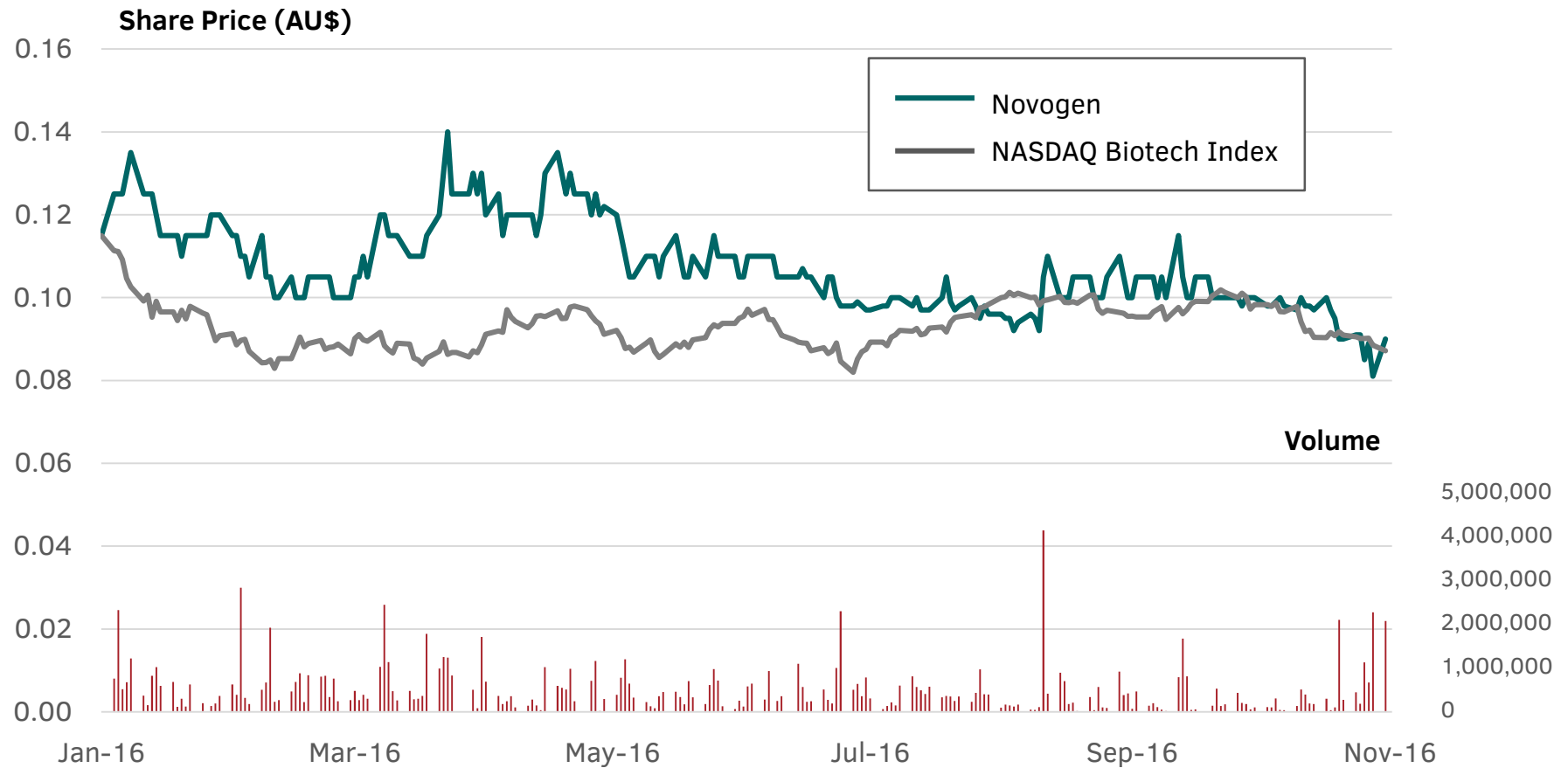
G&A / Total Expenditure

G&A / Total Expenditure (%)



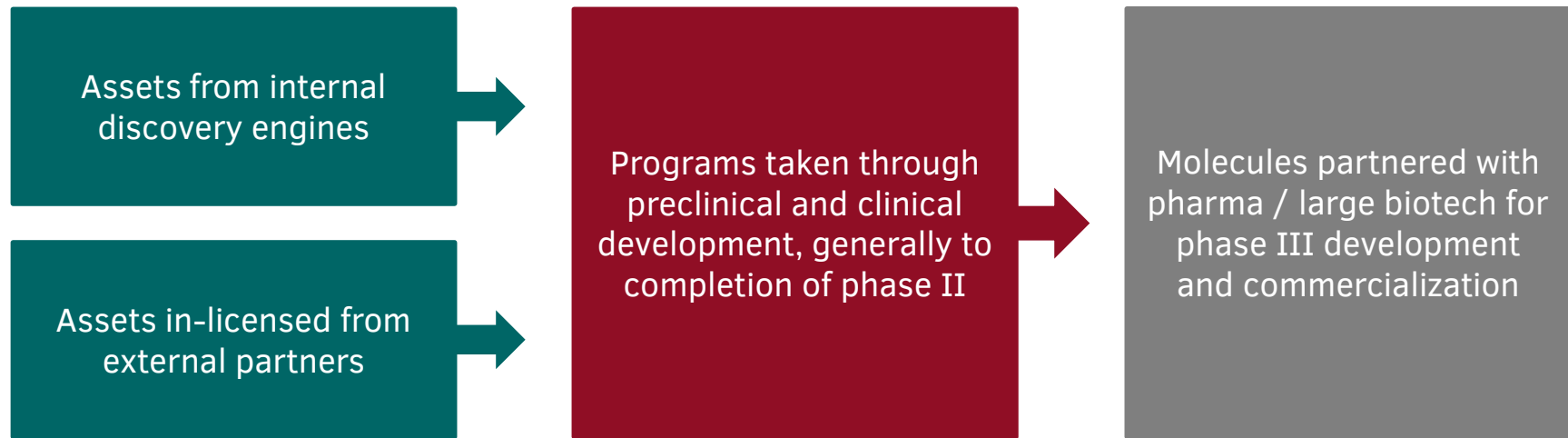
- Improved operating efficiency results in a greater proportion of capital being devoted to R&D

Stock price performance, while disappointing, has been consistent with other companies in the biotech sector



Source: ASX; Yahoo Finance

Novogen has focused on oncology, with a clear strategy for building and managing a high-value portfolio



Novogen has built a strong management team with international experience in big pharma



Dr James Garner

Chief Executive Officer & Managing Director

Physician / MBA; Extensive pharma drug development experience



Dr David Brown

Chief Scientific Officer

Twenty years of drug discovery and development experience



Dr Gordon Hirsch

Chief Medical Officer

Physician / MBA; Twenty years of pharmaceutical industry experience



Dr Peng Leong

Chief Business Officer

Eighteen years of business development and investment banking experience



Dr Andrew Heaton

VP, Drug Discovery

Twenty years of medicinal chemistry experience



Cristyn Humphreys

Chief Financial Officer

Chartered accountant with twenty years of experience in corporate roles

Our newly-appointed Scientific Advisory Board brings global expertise and experience to Novogen

**Professor Sir
Murray Brennan**



**Dr Karen
Ferrante**



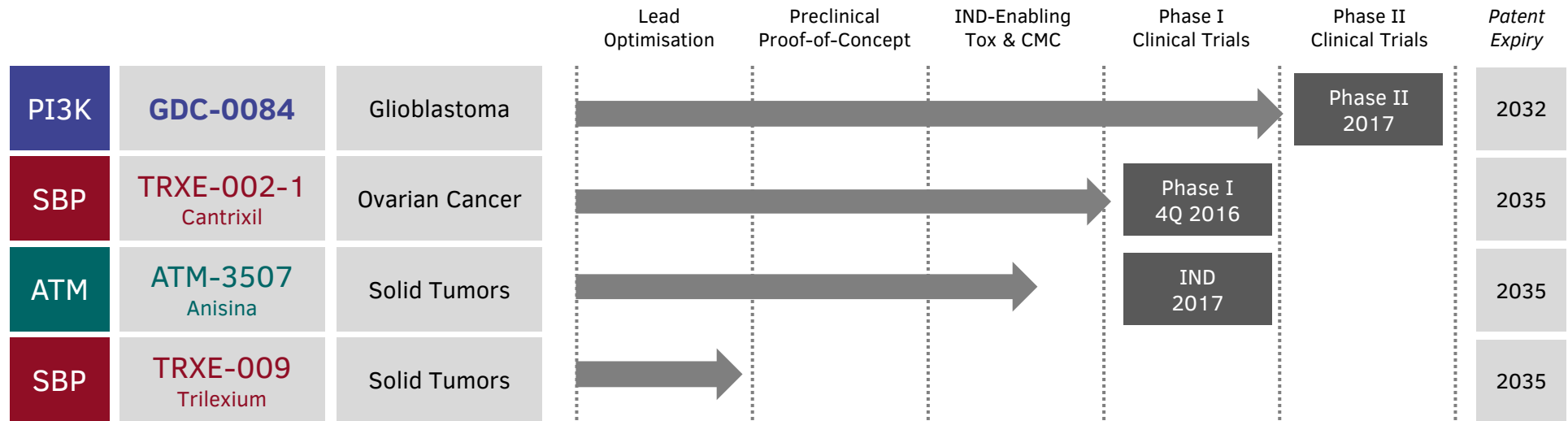
**Professor
Peter Gunning**



**Professor
Alex Matter**



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



PI3K Technology	Brain-penetrant PI3K inhibitor with some mTOR activity, targeting PI3K / Akt / mTOR pathway, which is shown to be upregulated in majority of GBM cases and many other tumor types
ATM Technology	First-in-class program targeting cancer-specific tropomyosin isoform in cytoskeletal microfilaments of cancer cells, leading to apoptosis
SBP Technology	First-in-class program based on earlier clinically-validated isoflavone chemotype (e.g. phenoxidiol, MEI Pharma), but with distinct IP space and greater preclinical activity

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

Presentation

- Usually presents with non-specific symptoms (e.g. headaches, nausea)
- Rapid clinical progression to permanent neurological defect and coma

Epidemiology

- Approximately 12,500 incident cases per annum in United States
- Limited understanding of causes and risk factors
- Generally more common in people >50 years of age, and slightly more common in males

Prognosis

- Median survival following diagnosis = 12-15 months with best available treatment (~3 months without treatment)
- 5-year survival rate = 3-5%
- Limited improvement in prognosis over last 15-20 years

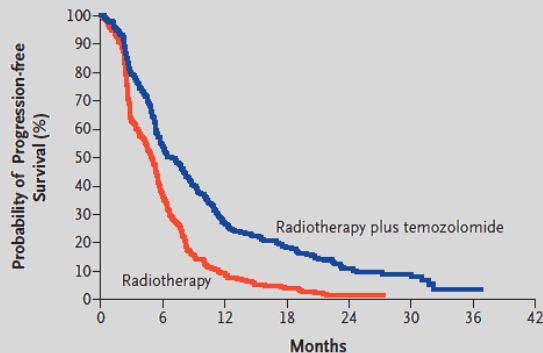
Source: GLOBOCAN 2012

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

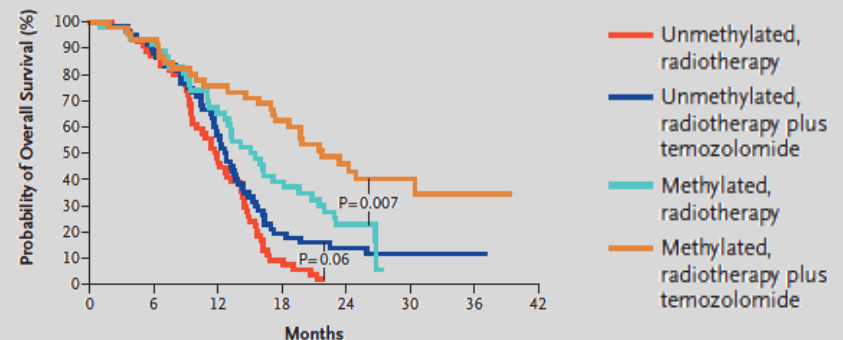
Standard
of Care
(‘Stupp
Regimen’)



Temozolomide is clearly efficacious...



...but only in ~35% of patients who are sensitive



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

PI3K inhibitors are well-validated, with one marketed product and extensive clinical data

Zydelig (idelalisib) on market



Other PI3K inhibitors in clinical trials

Review

Nature Reviews Clinical Oncology **10**, 143-153 (March 2013) | doi:10.1038/

Development of PI3K inhibitors: lessons learned from early clinical trials

Jordi Tabernero
Commentary
Targeting PI3K/AKT/mTOR pathway in non small cell lung cancer

The PI3K/AKT/mTOR pathway in breast cancer: targets, trials and biomarkers

Commentary

Claudia Fu
Show n

Abstract

While PI3K/AKT/mTOR pathway is a complicated intracellular pathway, which leads to cell growth and tumor proliferation and plays a significant role in endocrine resistance in breast cancer. Multiple compounds targeting this pathway are being evaluated in clinical trials. These agents are generally well tolerated and can be used in combination with targeted therapies, endocrine therapy or cytotoxic agents. The identification of subtypes of tumors more likely to respond to these therapeutics cannot be overemphasized, since breast cancer is a very heterogeneous malignancy. Activation of pathways such as KRAS and MEK can act as escape mechanisms that lead to

The PI3K/AKT/mTOR pathway in breast cancer: targets, trials and biomarkers

Elisavet Paplomata

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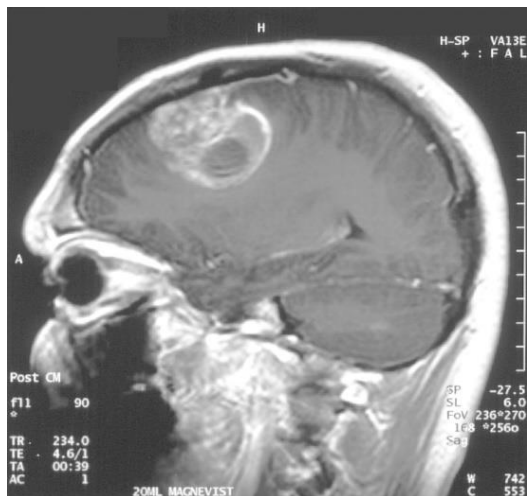
Abstract

The phosphoinositide 3 kinase (PI3K)/Akt/mammalian (or mechanistic) target of rapamycin (mTOR) pathway is a complicated intracellular pathway, which leads to cell growth and tumor proliferation and plays a significant role in endocrine resistance in breast cancer. Multiple compounds targeting this pathway are being evaluated in clinical trials. These agents are generally well tolerated and can be used in combination with targeted therapies, endocrine therapy or cytotoxic agents. The identification of subtypes of tumors more likely to respond to these therapeutics cannot be overemphasized, since breast cancer is a very heterogeneous malignancy. Activation of pathways such as KRAS and MEK can act as escape mechanisms that lead to

GDC-0084 differentiated from other PI3K inhibitors by:-

- Ability to cross blood-brain barrier
- Optimised balance of PI3K and mTOR activity

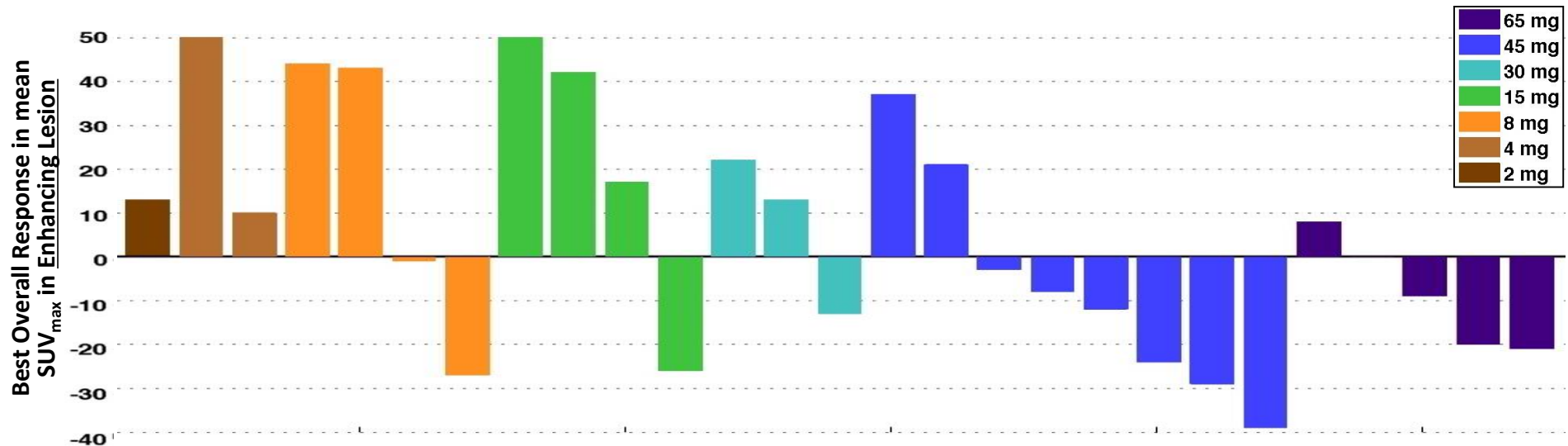
GDC-0084 has successfully completed a phase I study which established dose and safety profile



Phase I Study

- 47 patients enrolled at 4 centres (MD Anderson, UCLA, Dana-Farber, and Vall d'Hebron)
- Patients were grade 3 or 4 gliomas with at least one (and in most cases, several) lines of prior therapy
- 45mg established as Maximally Tolerated Dose (MTD) for phase II study
- Pharmacokinetic profile consistent with daily dosing
- Safety profile consistent with other PI3K inhibitors, with hyperglycemia and mucositis / stomatitis the most common adverse events
- Promising signals of pharmacodynamic response on FDG-PET, an exploratory radiological marker

GDC-0084 has shown promising efficacy signals on FDG-PET in phase I study population



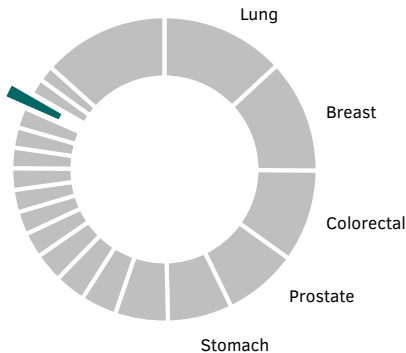
- *FDG-PET is an experimental imaging technology that shows the metabolic activity of a tumour*
- *7 / 27 patients (26%) had a metabolic partial response*

Ovarian cancer remains a disease of high unmet medical need

High Incidence

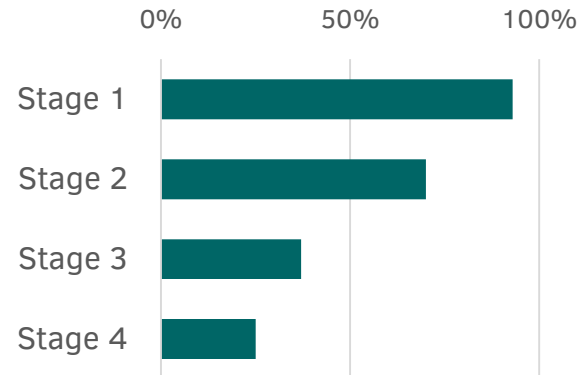
Ovarian Cancer

- 17th most common tumour worldwide
- 7th most common tumour in women
- ~240,000 new cases per annum
- 1.7% of all new cancer cases
- Overall lifetime risk is 1.6% for women
- Genetic cause (BRCA1 or BRCA2) in ~10% of cases
- More common in women who have not borne children
- 80% of cases occurring in women >50 years of age



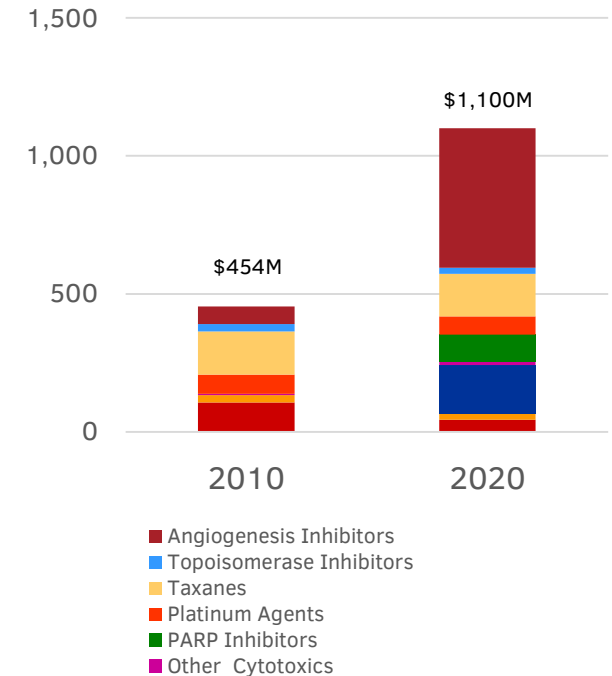
Poor Prognosis with Existing Therapies

Five-Year Survival



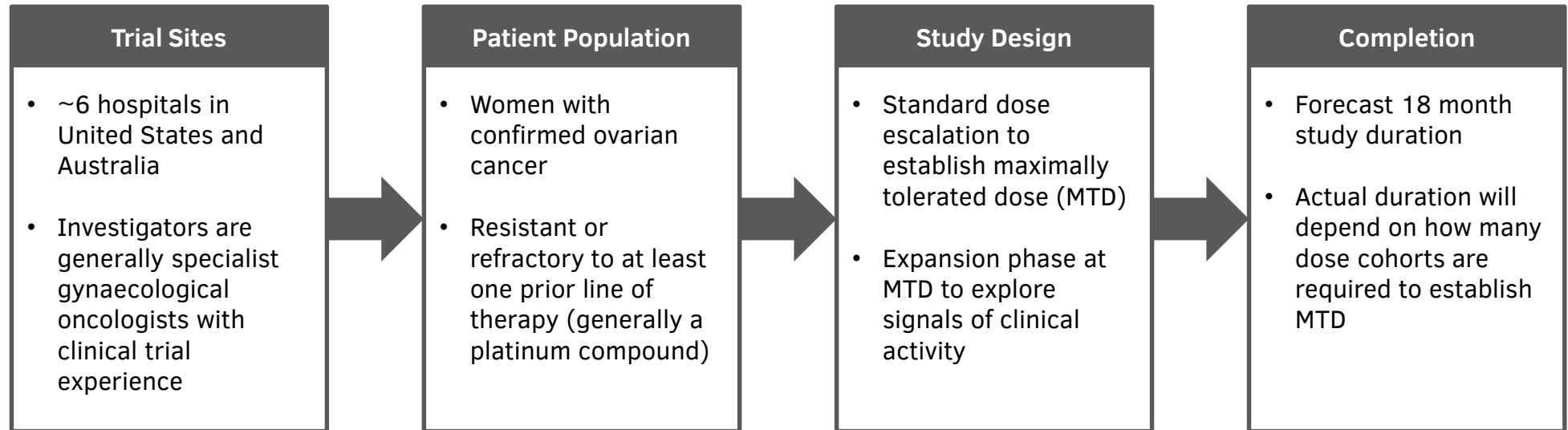
Growing and Evolving Market

Market Size (US\$,000)



Source: GLOBOCAN; Holschneider & Berek (2000), *Sem Surg Onc* 19(1):3-10; Decision Resources

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

Work continues at full pace with Anisina and Trilexium

Anisina (ATM-3507)

Current Status

- IND-enabling activities (CMC, toxicology, regulatory) well underway
- Final preclinical studies underway to optimise phase I clinical trial design
- Initiating GMP manufacture

Plans for 2017

- Submission of IND and initiation of phase I clinical study in 2H 2017

Trilexium (TRXE-009-1)

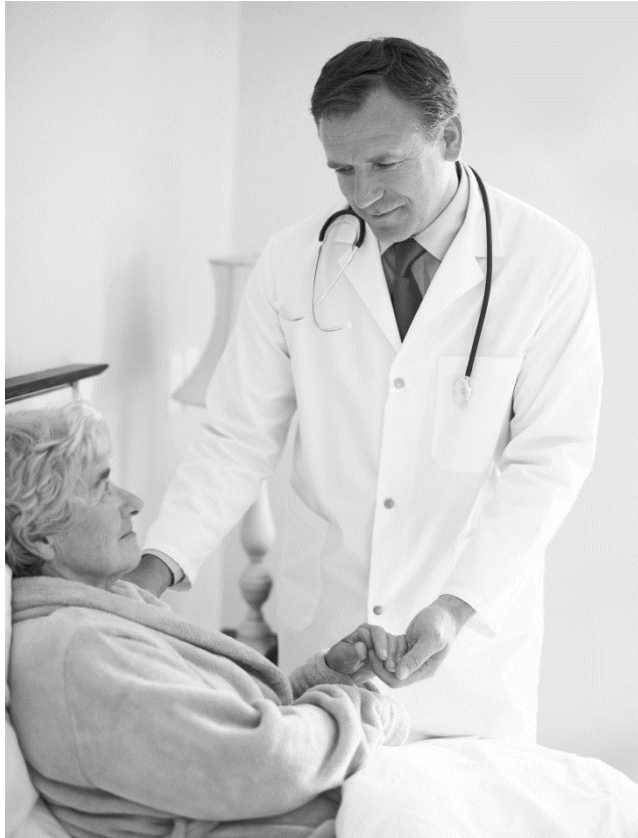
Current Status

- Preclinical development ongoing
 - Broad activity against multiple cancer types
 - High potential to combine with targeted therapies
- Development of a clinical formulation underway (intravenous liposomal formulation favoured)

Plans for 2017

- Initiation of IND-enabling activities in mid-2017

2017 will be an important year for Novogen, with a rich series of value-driving events



Key Milestones for 2017

IND submission and approval for Anisina

Initiation of Anisina phase I study

Initiation of GDC-0084 phase II study

Full recruitment of Cantrixil phase I study

Initiation of IND-enabling activities for Trilexium

Novogen now has a diversified portfolio and is positioned for growth



- **Focus on unmet need:** pipeline of novel therapies, targeting oncology patients, poorly served by existing treatment options
- **Building a sustainable model:** leveraging oncology expertise, developing commercially attractive, in-house and external assets
- **Diversified portfolio:**
 - Multiple assets in various stages of development – from pre-clinical through to phase II-ready
 - Across technologies / development platforms
- **Strong management and board:** lean team of internationally-experienced pharma executives
- **Financially sound:** listed on ASX and NASDAQ, with cash runway
- **News flow:** rich series of value-driving milestones over 12-18 months

