



Novogen Limited

An emerging oncology drug
developer with two clinical-stage
programs

April 2017

 ASX NRT

 Nasdaq NVGN

Forward-Looking Statements

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Corporate Overview | Novogen's Transformation

Enhanced Pipeline

GDC-0084 in-licensed from Genentech in October 2016

- Under development for Glioblastoma (primary brain cancer)
- Completed phase I human trial in 47 patients
- Phase II human trial to start in 2017
- Open IND with US FDA, strong IP protection, and premanufactured API

TRXE-002-1 developed from pre-existing Novogen research

- Under development for ovarian cancer
- Phase I human trial currently underway in Australia and US

Strengthened Team

New senior management with extensive international industry experience

Global Scientific Advisory Board of eminent cancer research specialists

Focused Strategy

Accessing the best global innovation available

- Bring in programs with some of the risky, time-consuming work already done
- Partner with big pharma for expensive and labour-intensive late-stage development and commercialisation

Management | Experienced New Management Team



Dr James Garner

Chief Executive Officer & Managing Director

Physician / MBA; Extensive pharma drug 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



PiperJaffray



Kate Hill

Company Secretary

Chartered accountant, and former audit partner at Deloitte

Deloitte.

Expertise | Global Scientific Advisory Board

**Professor Sir
Murray Brennan**



New York



Memorial Sloan Kettering
Cancer Center

- Chairman Emeritus of Department of Surgery at MSKCC
- Former Vice President of American College of Surgeons

**Dr Karen
Ferrante**



Boston



- Former Chief Medical Officer at Millennium
- Contributed to multiple novel cancer therapies including Velcade® (bortezomib)

**Professor
Peter Gunning**



Sydney



- Head of School of Medical Sciences at UNSW
- Extensively published cancer researcher and academic

**Professor
Alex Matter**

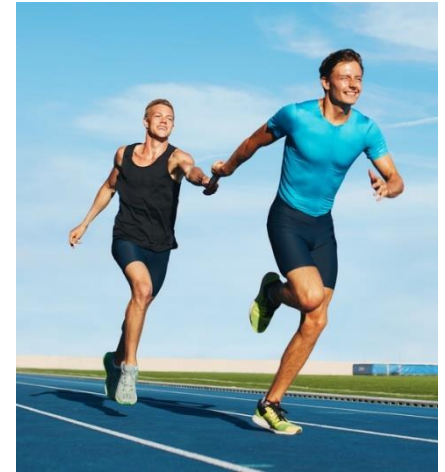
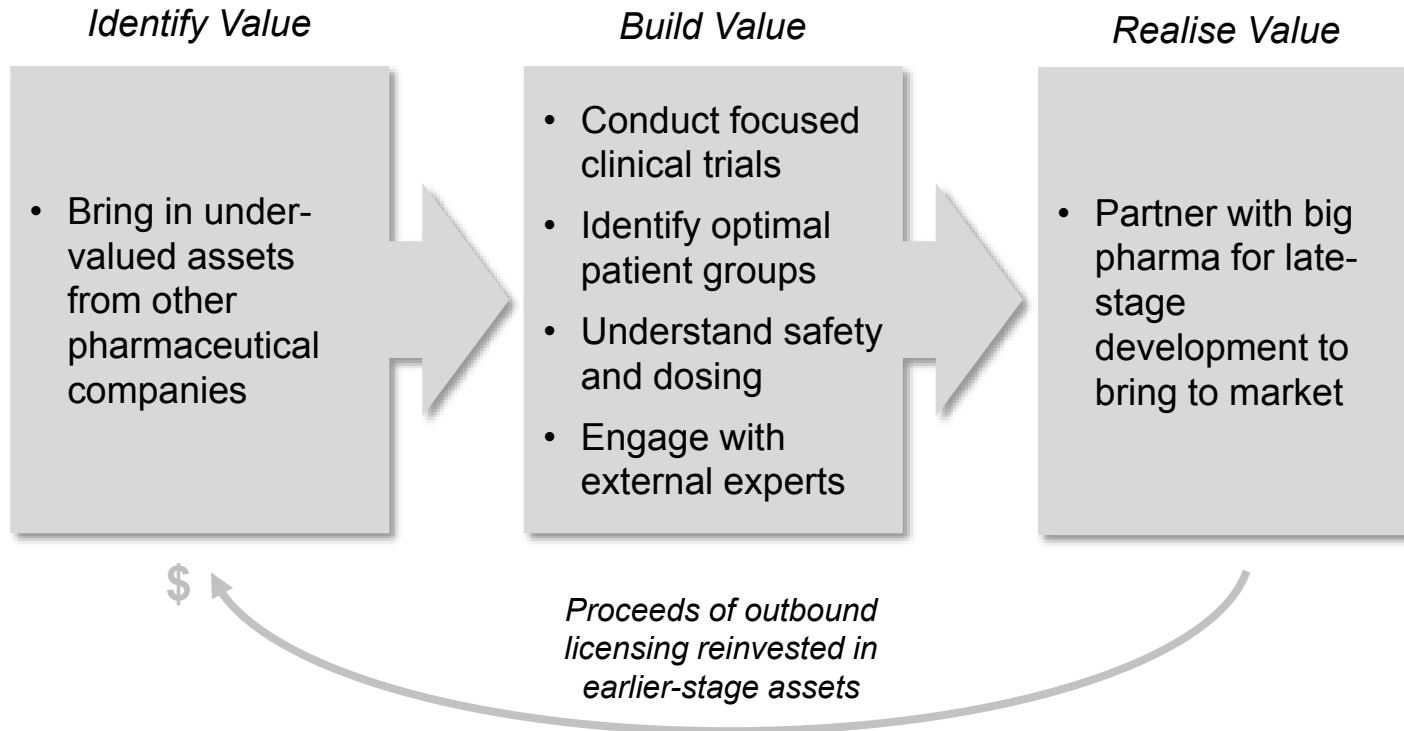


Singapore



- Former head of oncology research at Novartis
- Led team that discovered Gleevec® (imatinib), one of the first targeted therapies for cancer

Strategy | Accelerating Value Realisation

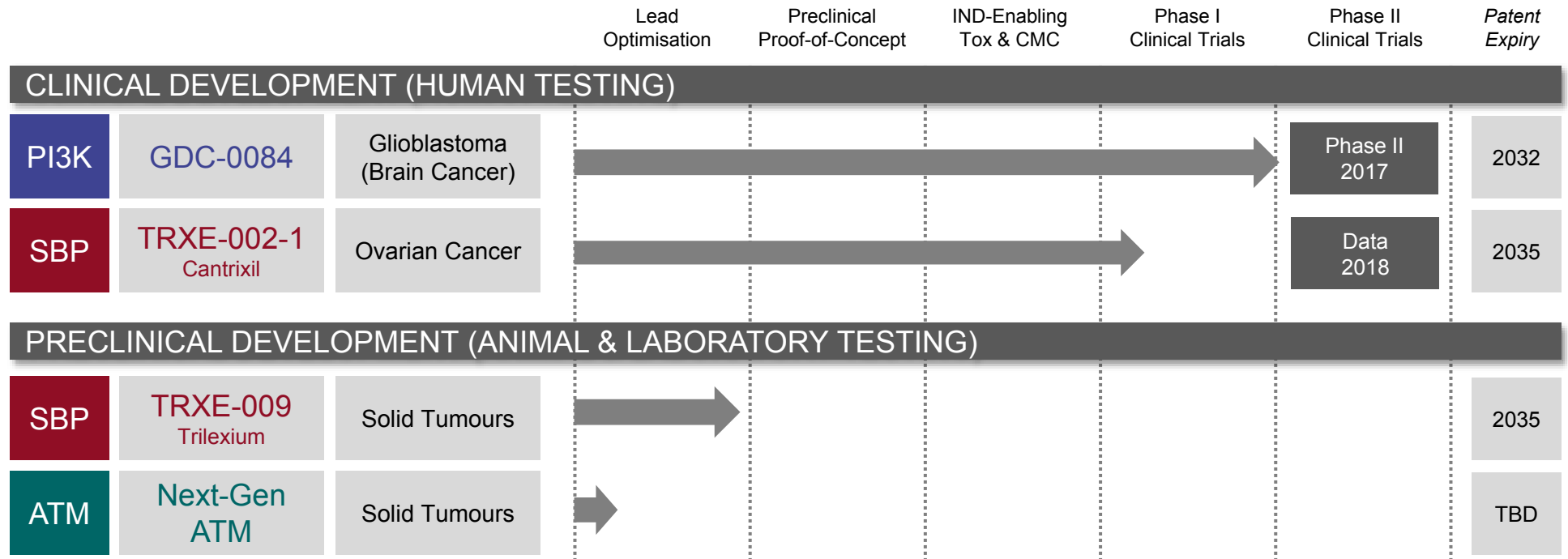


Reduce cycle time: 2-4 years to get to value inflection

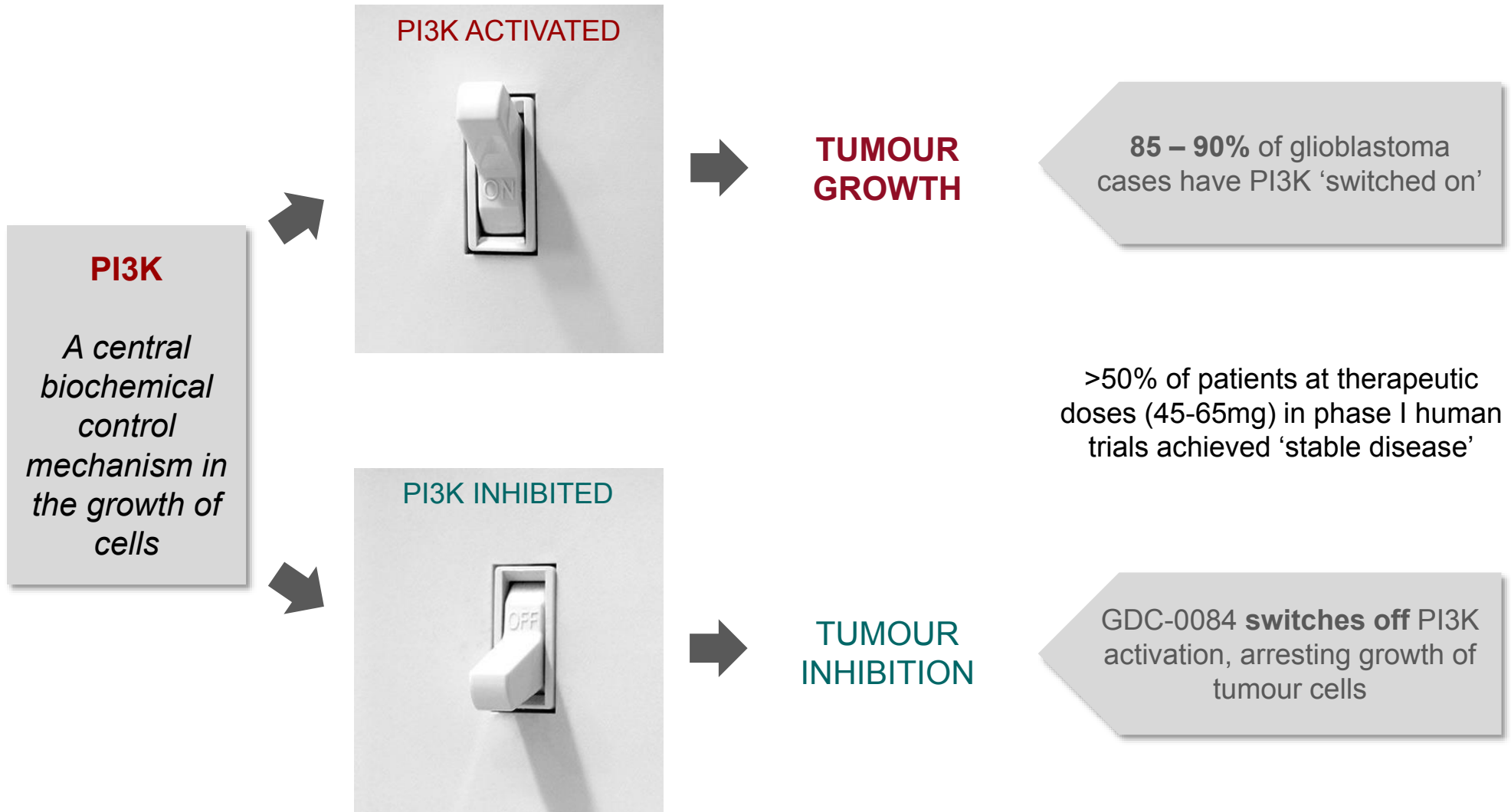
Improve portfolio strength: access the best global innovation

Mitigate risk: bring in assets which already partially de-risked

Portfolio | Diversified Pipeline – Two Assets in Human Trials



GDC-0084 | How it Works



Comparators | US-based PI3K Companies

Other companies focused on the PI3K technology have achieved value recognition in the market



Single asset company with one PI3K inhibitor in phase I human trials

US\$ 122 million
Market Cap



One PI3K inhibitor in phase II human trials, one other drug in phase III, and two in animal testing

US\$ 600 million
Market Cap



One PI3K inhibitor in phase II human trials

Acquired by big pharma in 2011 for
US\$ 375 million

GDC-0084 | What Makes it Different

One PI3K inhibitor is already a marketed drug, providing validation for the approach



GDC-0084 inhibits all the four main types of PI3K, whereas Zydelig mainly targets just one type

Others PI3K inhibitors are in human trials against a wide range of cancer types

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

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

Commentary

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

Claudia Fu

Show more

Abstract

While PI3K/AKT/mTOR pathway is a key signaling pathway in many types of cancer, including breast cancer, the role of this pathway in the development and progression of breast cancer is still unclear. This pathway is involved in many cellular processes, including cell growth, proliferation, and survival. In this review, we discuss the role of the PI3K/AKT/mTOR pathway in breast cancer and the potential of targeting this pathway as a therapeutic strategy.

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

Elisavet Papiol

Winship Cancer Institute of Emory University, Atlanta, GA, USA

Ruth O'Regan

roregan@emory.edu

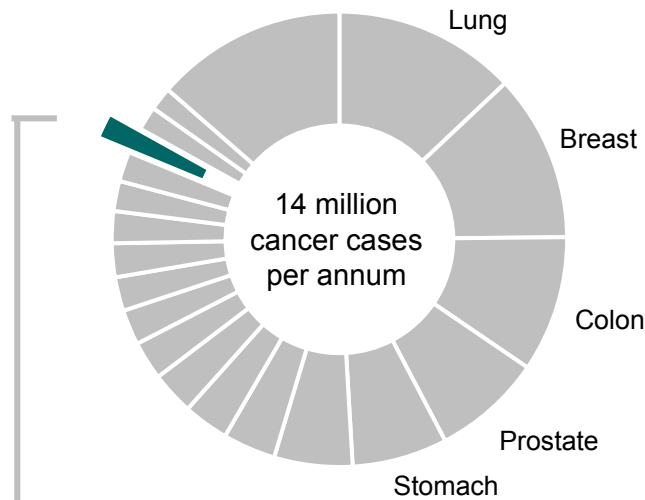
Winship Cancer Institute of Emory University, Atlanta, GA, USA

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 resistance to PI3K/AKT/mTOR inhibitors.

GDC-0084 is able to cross the blood-brain barrier, which most PI3K inhibitors cannot

GDC-0084 | Unmet Need in 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**

GDC-0084 | Promising Human Trial Data

Safety

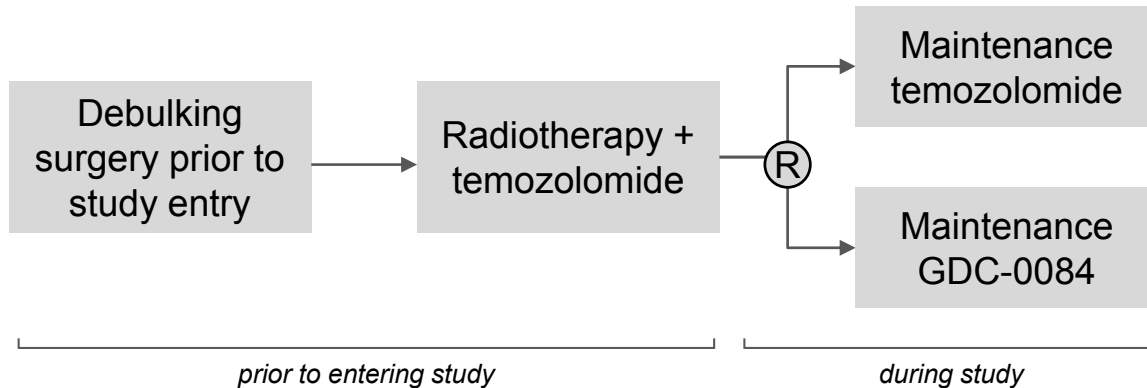
- Phase I safety trial conducted by Genentech
- 47 patients enrolled with advanced brain cancer
- Most common adverse events were mouth ulcers and increase in blood sugar (common effects of PI3K inhibitors)
- No evidence of liver, bone marrow, kidney toxicity, or mood disturbances
- Data presented at American Society for Clinical Oncology annual meeting in Chicago, June 2016

Efficacy Signals

	GDC-0084	Comparison
Arresting Tumour Growth	40% Achieved 'stable disease'	21-52% in studies of Avastin in similar patients
Potentially Delaying Progression	21% Remained on study for >3 months	Median progression-free survival of 1 month
Slowing Tumour Activity	26% Showed 'metabolic partial response'	Potentially better predictor of clinical response than MRI

GDC-0084 | Phase II Study Starting 2H 2017

Phase II study design to target first-line patients, following surgery and radiotherapy



Patients in United States, Australia and other countries, under oversight of US Food & Drug Administration under an open IND

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

Commencement:
2H 2017
(Jul – Dec 2017)

Duration:
approx. **2.5 years**

Number of patients:
approx. **200**
(100 per arm)

Regulatory Strategy

- Study will be designed to provide robust evidence of clinical efficacy using progression-free survival (PFS) as primary endpoint
- FDA provides a mechanism for promising drugs in diseases with high unmet need to receive 'accelerated approval' prior to completion of a definitive phase III study. Avastin (bevacizumab) was approved for recurrent GBM in this way
- Novogen hopes to discuss potential for accelerated approval with FDA after completion of phase II

GDC-0084 | Longer-Term Expansion Opportunities

Novogen's Core Focus

Potential Opportunity for Future Partners

Glioblastoma

Metastatic brain
cancer

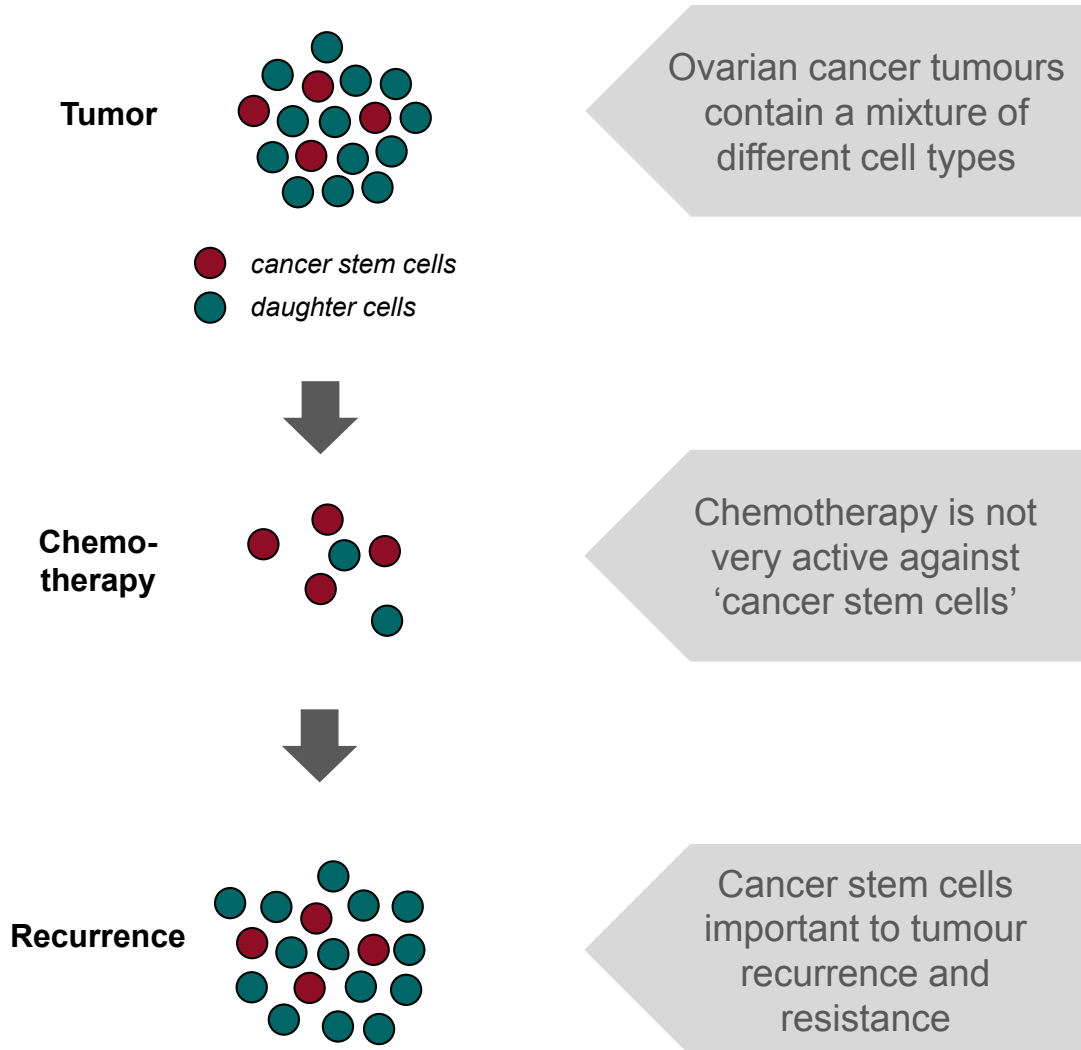
Other types of
cancer

- Best opportunity to run a focused clinical program
- Fastest path to market

- Up to 10 times as many patients as glioblastoma
- Potential to expand use of GDC-0084 after a successful launch in glioblastoma

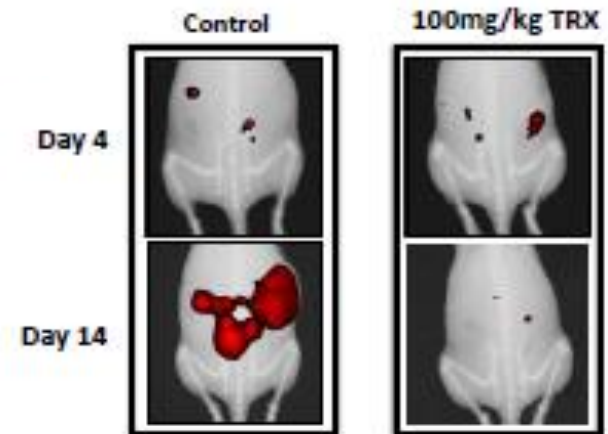
- 'Blue sky' potential
- PI3K inhibitors have potential to treat many types of cancer

TRXE-002-1 (Cantrixil) | How it Works



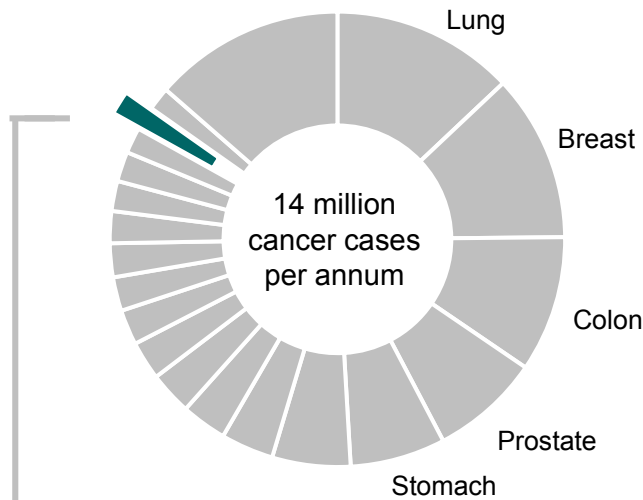
TRXE-002-1 is active against both regular cancer cells and cancer stem cells, and may therefore help to prevent recurrence

Mouse Model



Yale | Data courtesy of Prof Gil Mor, Yale University

TRXE-002-1 | Unmet Need in Ovarian Cancer



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

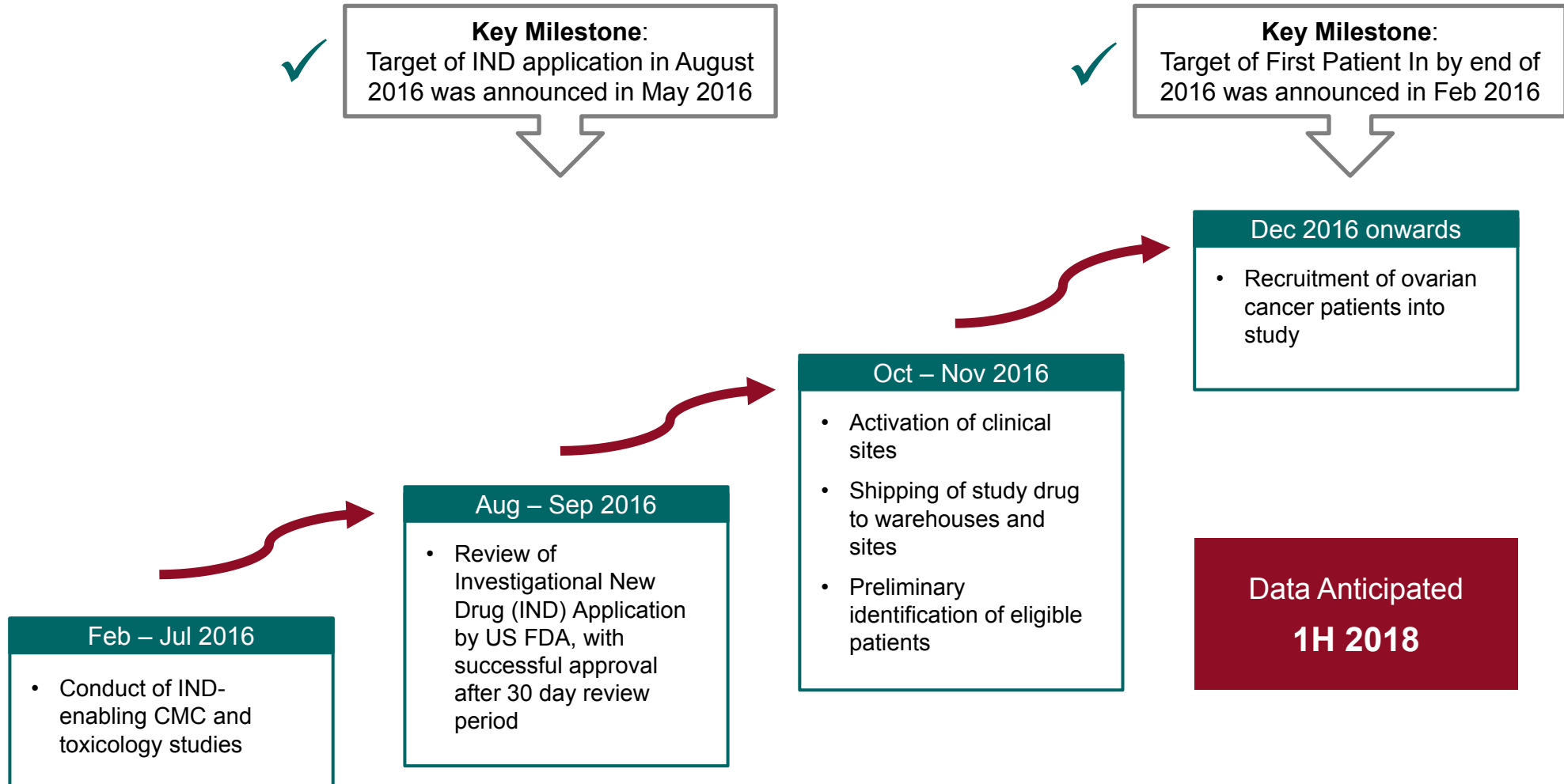
80%
of patients are
over 50 years
of age

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

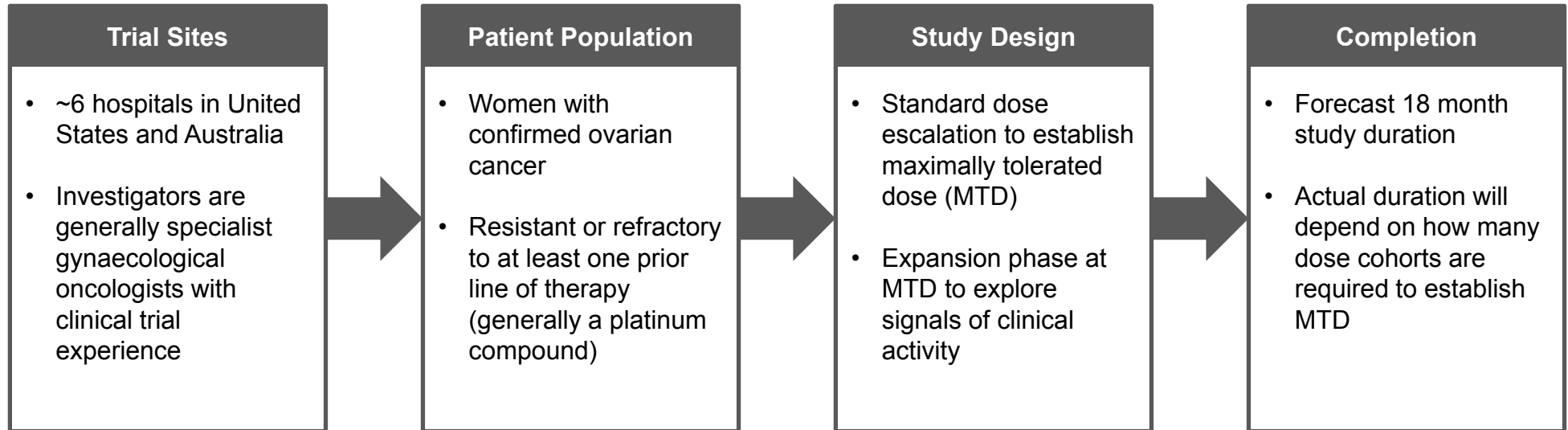
Chemotherapy only curative in ~20% of ovarian cancers

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

TRXE-002-1 | Significant Progress in 12 Months



TRXE-002-1 | Human Clinical Trials Started in December 2016



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

Laboratory Research | Reprioritisation of ATM Projects

ATM-3507 (Anisina)



Next-Generation ATM Program

Program Terminated – April 2017

- Under development since 2013
- Novel approach to targeting the structural components of cancer cells, based on research from UNSW
- Animal studies showed unfavourable balance of activity and toxicity
- Funding and resources internally reallocated to other programs

Competitive CRC-P Grant Awarded – Feb 2017

- New approach to targeting structural components of cancer cells
- Aims to avoid challenges seen with older programs
- First drug development program to be awarded competitive CRC-P Grant by Federal Government
- Grant provides \$3 million of funding over three years, on top of \$1 million from Novogen

Milestones | Rich Series of Value-Driving Activities in 2017

GDC-0084 (phase II study in brain cancer)

Transfer of IND with US FDA



Transfer of responsibility for intellectual property



Completion of manufacture of capsules for trial

Consultation with FDA to confirm approach

Submission and approval of regulatory filings for study

Submission and approval of hospital ethics applications

Commencement of enrolment of patients ('First Patient In')

TRXE-002-1 (phase I study in ovarian cancer)

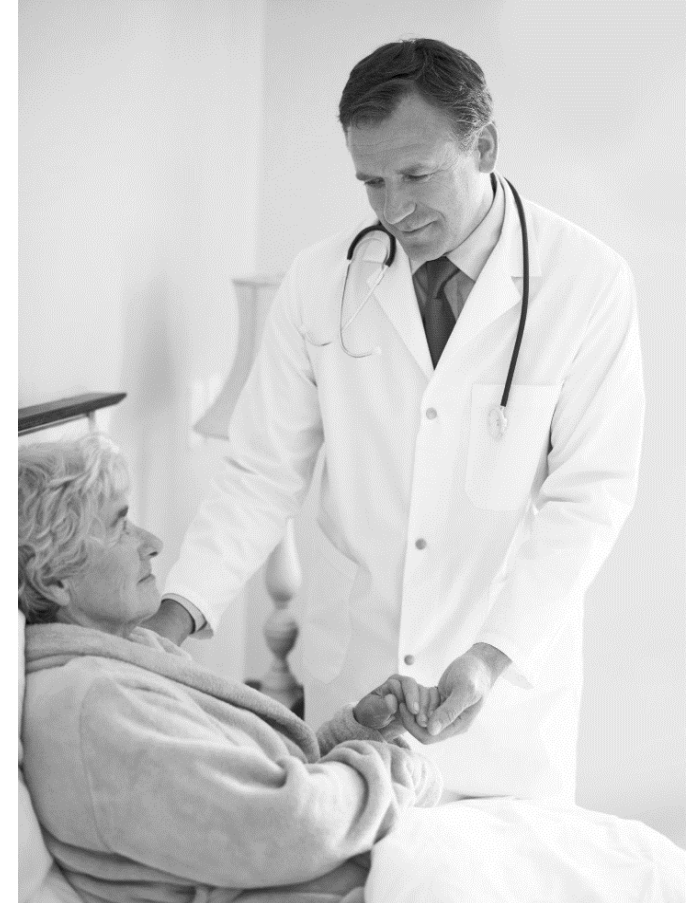
Completion of dose escalation phase

Granting of patents in US, EU, and other territories

Reporting of phase I data in 1H 2018

Next- Generation ATM Program

Commencement of work under grant





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