

ASX:NRT

NASDAQ:NVGN

Novogen Ltd  
(Company)

ABN 37 063 259 754

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### Capital Structure

Ordinary Shares on  
issue:

483 M

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### Board of Directors

#### Mr John O'Connor

Chairman  
Non-Executive Director

#### Mr Bryce Carmine

Deputy Chairman  
Non-Executive Director

#### Dr James Garner

Chief Executive Officer  
Managing Director

#### Mr Ian Phillips MNZM

Non-Executive Director

#### Mr Iain Ross

Non-Executive Director

#### Mr Steven Coffey

Non-Executive Director

### MARKET RELEASE

21<sup>st</sup> February 2017

### NOVOGEN NEWSLETTER AND PRESENTATION

Sydney, 21<sup>st</sup> February 2017, Australian oncology-focused biotechnology company Novogen Ltd (ASX: NRT; NASDAQ: NVGN) is pleased to release its February 2017 investor newsletter which is attached with this cover note.

Investors are also invited to view a digital roadshow through which CEO, Dr James Garner discusses recent company developments and expected news flow in 2017. To view the digital roadshow, please copy and paste the following URL into your web browser:

<http://www.boardroom.services/novogenlimitedroadshow>

[ENDS]

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### 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 four development candidates, diversified across three distinct technologies, with the potential to yield first-in-class and best-in-class agents across 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. Three further molecules have been developed in-house from two proprietary drug discovery platforms (superbenzopyrans and anti-tropomyosins) to treat ovarian cancer and a range of solid tumours. Cantrixil, the most advanced of these, commenced a first-in-human clinical study in patients with ovarian cancer in late 2016, while Anisina and Trilexium are in preclinical development.

For more information, please visit: [www.novogen.com](http://www.novogen.com)

# NEWS LETTER

Welcome to the latest edition of our newsletter. Novogen has launched into 2017 after one of the most transformative years in its recent history.

We began 2016 as a preclinical stage company. In February, we stated that we would take our lead program, Cantrixil, into a phase 1 clinical trial by the end of 2016. This was an ambitious goal, since important parts of the critical chemistry, manufacturing, and control (CMC) work remained to be completed. It is a powerful testament to the efforts of the Novogen team that this milestone was met.

Cantrixil commenced an international phase 1 study in ovarian cancer on schedule in December. It remains early days, but the study's expert clinicians are carefully following the patients who have been enrolled so far.

In October, we announced the in-licensing of GDC-0084 from Genentech, one of the world's most successful and admired drug development companies. We and our advisors believe that GDC-0084 has enormous potential to benefit patients with glioblastoma, the most common and aggressive form of brain cancer.

GDC-0084 had been deprioritised by Genentech because of their resource commitments to other, later-stage programs, but their enduring belief in GDC-0084 led them to seek an external partner. Novogen is proud to have

been entrusted with moving GDC-0084 forward, and we are already working closely with expert neuro-oncologists in the US to design the phase 2 study.

Consequently, we now have half of our pipeline in the clinic undergoing human trials, each under a US Investigational New Drug application (IND). This places us among perhaps a dozen or fewer companies on the ASX with open INDs, and establishes us as a significant player in both glioblastoma and ovarian cancer.

We have also been delighted to welcome new colleagues to the team. Their international experience in larger companies will be invaluable as Novogen progresses its pipeline. In addition, we are tremendously excited to be working with our newly established Scientific Advisory Board. Their wealth of expertise in drug development is a remarkable asset for Novogen.

So although we continue to apply ourselves to the development of new cancer therapies, as we have always done, Novogen is, substantively speaking, a largely new organisation. We are focused on the active clinical development of tangible new therapies with the potential to bring real benefit to defined groups of cancer patients. We expect 2017 to be a year of considerable achievement in our company, and we look forward to sharing our progress.

Best wishes,  
DR JAMES GARNER

## Novogen licenses phase 2 - ready molecule GDC-0084

In late 2016, Novogen announced that it had in-licensed a drug from Genentech, a subsidiary of Roche. The drug, a small molecule phosphoinositide-3-kinase (PI3K) inhibitor, called GDC-0084, targets Glioblastoma Multiforme (GBM), the most common form of primary brain cancer, two thirds of whom are largely unresponsive to existing pharmaceutical treatments.

### GDC-0084 IN 30 SECONDS

- GDC-0084 was licensed from Genentech in late 2016
- GDC-0084 is being developed to treat Glioblastoma Multiforme (GBM)
- GBM is the most common form of primary brain cancer
- Current GBM standard of care is ineffective in ~65% of patients
- Five year survival rate is around 3%, compared to 89% for patients with breast cancer
- GDC-0084 has successfully completed a phase 1 clinical trial - commencement of a phase 2 clinical trial is planned in 2017

### Novogen's pipeline of four assets under development.

		DISCOVERY	PRECLINICAL DEVELOPMENT		CLINICAL DEVELOPMENT		
			PROOF OF CONCEPT	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3
<b>GDC-0084</b> PI3K	GLIOBLASTOMA	→				PHASE 2 2017	
<b>CANTRIXIL™</b> SUPERBENZOPYRAN	OVARIAN CANCER	→					
<b>ANISINA™</b> ANTI-TROPOMYOSIN	SOLID TUMOURS	→				IND* 2017	
<b>TRILEXIUM™</b> SUPERBENZOPYRAN	SOLID TUMOURS	→					

\* United States Food and Drug Administration (FDA), Investigational New Drug (IND) application



GDC-0084 CONTINUED FROM PAGE 1

For GBM patients (around 12,500 new cases per year in the USA), the five-year survival rate is around 3%, compared with approximately 89% for patients with breast cancer. Despite all efforts, there have been few significant advances in treatment over the last decade, and the prognosis remains poor.

Newly-diagnosed patients typically undergo surgery to remove as much of the tumour as possible, and are then treated with radiotherapy and a drug named temozolomide in order to delay recurrence. However, the vast majority of patients soon experience disease progression and survival, even in optimally-treated patients, averages approximately fifteen months.

In a phase 1 clinical trial conducted by Genentech, GDC-0084 was shown to have acceptable tolerability in a group of patients with advanced brain tumours, including a majority of patients with GBM. It also showed an ability to reduce tumour size in some patients, and demonstrated a reduction in the activity of some tumours using an experimental imaging technology known as FDG-PET. These **data were presented** at the ASCO Annual Meeting in June 2016.

GDC-0084 may represent a new treatment for GBM patients and for that reason, its development is being watched by clinicians around the world. Novogen is currently completing the work necessary to prepare to commence a Phase 2 clinical trial.



Novogen CEO, Dr James Garner appearing on Sky News discussing the licensing of GDC-0084

More on GDC-0084 – an excellent range of resources is available for review on the GDC-0084 program:

- The **GDC-0084 licensing announcement** and **investor presentation** which provide an overview of the deal and strategic rationale
- A **Sky News** interview with Dr James Garner, which occurred directly following the announcement of licensing of GDC-0084 in October 2016
- A **video interview** with Finance News Network, which discusses the strategic rationale behind the program
- **Edison Investment Research Limited's** updated analyst report on Novogen, covering the licensing of GDC-0084.

## Cantrixil enters phase 1 clinical trials

Novogen was pleased to announce a milestone in December with the enrolment of the first patient in the Phase I trial for Cantrixil (TRX-E-002-1). The trial, which will be run at hospitals in the US and Australia, will primarily determine safety and tolerability in the treatment of ovarian cancer patients.

Leading clinicians in the US and Australia will be involved, with 60 patients expected to be recruited into the trial across six hospitals and research centres. The trial is likely to run for approximately 18 months.

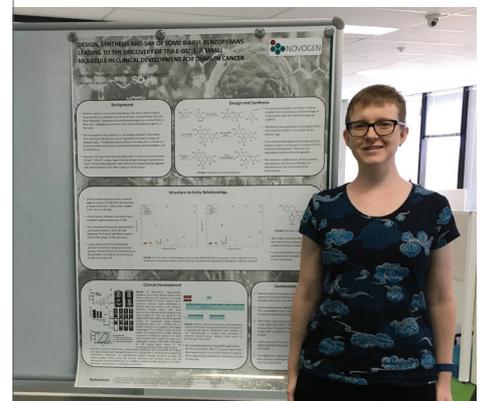
Brisbane based Associate Professor Jim Coward is the principal investigator overseeing the phase 1 clinical program across a number of hospitals in Australia and commented "with 50% of diagnosed ovarian cancer patients relapsing within 2 years under the current chemotherapy treatment regime, Cantrixil has the potential to target and kill cancerous stem cells remaining in the body after chemotherapy which could lead to a significantly more effective treatment for ovarian cancer. I'm excited to be working on the program with Novogen."

## Scientific papers and representation at scientific conferences

Novogen presented a number of peer reviewed research papers from its portfolio of assets to the research community at conferences over the course of the second half of calendar 2016.

Novogen's Program Directors for Cantrixil and Anisina were in attendance:

- **Journal of Cancer Chemotherapy and Pharmacology (Cantrixil), December 2016**
- **World Pre-clinical Congress in Lisbon, Portugal (Cantrixil), November 2016**
- **28th EORTC Conference 2016 in Munich, Germany (Anisina), December 2016**
- **RACI Medicinal Chemistry and Chemical Biology Conference 2016 in Coojee (Anisina), New South Wales, November 2016**



Dr Eleanor Eiffe presented a poster on Cantrixil at the World Pre-clinical Congress in Lisbon, Portugal

Novogen was also an active contributor to cancer research, publishing a number of peer reviewed scientific research papers in recent months.

Further conference posters and scientific research paper abstracts can be found on **Novogen's website**.

## Presence at investor conferences

Novogen actively engages with the investment community to ensure its evolving story remains well understood. In recent months a number of investment conferences globally in the biotechnology sector were attended in Australia and overseas by CEO, Dr James Garner and Chief Scientific Officer, Dr David Brown.



CEO, Dr James Garner, presenting at Biotech Showcase in San Francisco in January 2017



Chief Scientific Officer, Dr David Brown, presenting at Sachs Associates 16th Annual Biotech Forum in Basel in September 2016

## Annual General Meeting

Following formal proceedings at the AGM with the successful adoption of all resolutions, CEO Dr James Garner gave a presentation to shareholders on Novogen's portfolio of assets – from preclinical to mid-stage clinical. In order to make the presentation available to all shareholders, a video version was recorded on the day. To view the presentation, please [click here](#).



Chairman, John P O'Connor and CEO, Dr James Garner, presenting to shareholders at Novogen's AGM

## Relaunched website

The revamped website which went live in October 2016 brings stakeholders closer to Novogen. If you haven't been there recently, [browse the new website](#). It's filled with a host of information.

## Introduction of a Scientific Advisory Board and key management personnel appointed

A newly formed scientific advisory board and key management personnel will support Novogen transition from a scientific, discovery-focused organisation, to a development-focused organisation.

Novogen has built out a strong management team with international experience in big pharma. Recent additions include Dr Gordon Hirsch, Chief Medical Officer and Dr Peng Leong, Chief Business Officer along with Mr David Cain as Director of Chemistry, Manufacturing and Controls.

### Interview with Dr Gordon Hirsch.

#### Where are you based and what is your role?

I'm based in Sydney Australia. As Chief Medical Officer, my role is to primarily develop and lead Novogen's activities in relation to successful early clinical development of our portfolio of medicines, to increase treatment options available for patients suffering from cancer. Our aim is to try to facilitate this as efficiently and effectively as possible and to the highest standards and quality of research.

#### What is your background?

I am a scientist, specialist physician and business administrator by qualification and training. I practised medicine for a number of years before joining the biopharmaceutical industry about 20 years ago. In industry, I have been fortunate to have been able to continue my learning from my varied experiences across a number of roles at different levels and in different countries, regions and continents, and I look forward to applying these skills and experiences at Novogen.

#### What led you to join the Novogen business?

I was keen to join Novogen since it is quite different to other companies I have worked for in that Novogen is a small company, focused on discovery and early development and focused on oncology medicines. It is exciting to have



the opportunity to join a company like this at a time when Novogen is working to establish and develop its early drug development capability and programs, in a way that will bring benefit to patients with cancer in a clinical practice setting.

**Which are your primary areas of focus for 2017?**

Foremost, successful conduct of clinical programs (phase 1) with Cantrixil on patients with recurrent ovarian cancer, and initiation and conduct of the GDC-0084 phase 2 study in patients newly diagnosed with Glioblastoma Multiforme (GBM). I would also like to evolve potential clinical development opportunities for Novogen’s current pre-clinical phase molecules (Anisina and Trilexium) and in addition, develop Novogen’s early clinical development capabilities, ensuring our processes deliver patient benefits.

**Novogen also appointed a Scientific Advisory Board (SAB)**, bringing global expertise and experience to our organisation.

This development saw Professor Peter Gunning transition across as a director of Novogen’s board to the newly created position on the SAB. Joining Professor Gunning are Professor Sir Murray Brennan, Dr Karen Ferrante and Professor Alex Matter.

The group is highly experienced across thought leadership, global drug development expertise, clinical research, industry executive roles and scientific academia.

**Milestones**

Significant milestones were achieved in 2016 across granting of patents to reshaping the portfolio of development assets.

Following the granting of a number of patents in the first half of calendar 2016 and the conclusion of CanTX joint venture with Yale University, Novogen undertook a number of important activities in the second half of the year:

- Submitted an IND for Cantrixil
- Bolstered management team and appointed a Scientific Advisory Board
- Licensed GDC-0084 from Genentech
- Initiated Cantrixil phase 1 study

**A rich series of value-driving events is expected in 2017 (see table).**

**KEY MILESTONES FOR 2017**

- IND submission and approval for Anisina
- Initiation of Anisina phase 1 study
- Initiation of GDC-0084 phase 2 study
- Full recruitment of Cantrixil phase 1 study
- Initiation of IND-enabling activities for Trilexium

