

**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

7<sup>th</sup> June 2017

### NOVOGEN NEWSLETTER

Sydney, 7<sup>th</sup> June 2017, Novogen Ltd (ASX: NRT; NASDAQ: NVGN) an Australian oncology-focused biotechnology company is pleased to present its June 2017 Newsletter which follows on the next page of this announcement.

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Media and Investor Relations	Investor Relations (US)
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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 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](http://www.novogen.com)

Welcome to the latest edition of our newsletter. The first few months of the year have been highly productive, and have continued to reflect Novogen's transformation into a clinical-stage drug development organisation, working on potential new therapies for a number of types of cancer.

In April, we shared our planned phase II clinical trial of GDC-0084 in glioblastoma, the most common and most aggressive form of primary brain cancer. The design has benefited from extensive consultation with clinicians and expert advisors, and we are confident it represents the most effective path forward.

We plan to focus the study on the almost two-thirds of patients who will not respond significantly to temozolomide, currently the most commonly used drug for this disease. Approximately 200 patients will be recruited, and we aim to start the study in the second half of calendar 2017.

The study will be a randomised controlled trial and, if it is successful, it may offer an opportunity to approach FDA, the US regulatory agency, to discuss accelerated approval without waiting for a full phase III study. For example, Avastin, which is used to treat some patients whose glioblastoma has recurred after treatment, was approved in this way using data from two studies with 141 patients in total.

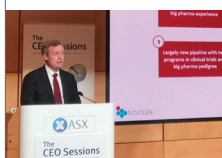
Meanwhile, our phase I study of Cantrixil in ovarian cancer is progressing well. Five of the six participating hospitals are now open to recruitment. The timing of initial data is difficult to predict, because the design entails increasing doses until patients start to experience side effects, and this cannot be accurately predicted in advance. However, we hope to be able to share the maximum tolerated dose towards the end of 2017 or early 2018, and then plan to recruit additional patients at this dose to look for efficacy signals.

Our decision in April to terminate the development of Anisina, the lead program from our anti-tropomyosin

research, was a difficult one. We are mindful though that successful biotech companies take tough decisions to focus their resources where they will have the most impact for patients. Despite the great work that has been done with Anisina, the emerging data did not, in our view, make it a promising candidate to take forward into human trials.

Although the Anisina program did not progress, we believe that targeting anti-tropomyosin for the treatment of cancer remains a sound approach. We were enormously excited to learn in February that we had successfully been awarded a CRC-P grant from the Federal Government, which provides up to \$3 million in funding over three years. We believe that we are the first drug development program in Australia to be so recognised. The funds will be applied to a 'next-generation ATM' program, which we hope will better fulfil the promise of this very exciting science.

In closing, the Novogen team remains tightly focused on delivering its programs, and we are pleased at the progress that has been made since the start of 2017. We are one of a relatively small pool of Australian companies with two drug candidates in human trials, and we hope that this exciting pipeline will translate into meaningful benefit for patients with some of the most challenging diseases in modern medicine.



Best wishes,  
DR JAMES GARNER

## Glioblastoma in focus: phase II trial design for GDC-0084

### Recent developments

In April 2017, Novogen released details of its phase II trial protocol for GDC-0084. It is expected that the trial will commence in the second half of 2017, and will see around 200 patients treated in a two arm, randomised, controlled study where GDC-0084 will be tested against the standard of care.

### GLIOBLASTOMA - DID YOU KNOW?

The five-year survival rate for GBM patients (around 12,500 new cases per year in the USA) is around 3%, compared with approximately 89% for patients with breast cancer.

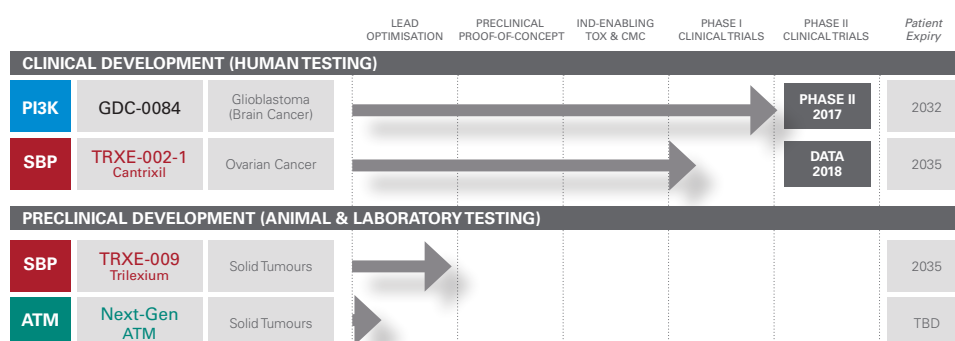
Newly-diagnosed patients typically undergo surgery to remove as much of the tumour as possible, and are then treated with radiotherapy and a drug named temozolomide in order to delay recurrence.

The vast majority of patients undergoing existing treatment soon experience disease progression and survival, even in optimally-treated patients, averages approximately fifteen months.

### Following the fastest path to registration

The phase II trial follows on from Genentech's phase I study of GDC-0084 which was conducted with 47 patients, where encouraging safety and efficacy signals were observed.

## Portfolio / Diversified Pipeline – Two Assets in Human Trials



Designed in collaboration with leading global oncologists, the phase II study is intended to provide robust evidence of clinical efficacy, using 'progression free survival' (PFS) as the primary endpoint.

### Pursuing accelerated approval

In the lead up to the GDC-0084 phase II trial, together with our regulatory consultants, Novogen will be communicating closely with the US Food and Drug Administration (FDA) to ensure that the study is optimally designed. These consultations may help to increase the chance of obtaining "accelerated approval" at conclusion of the study, a mechanism whereby FDA sometimes allows drugs to be made commercially available to high-need patients without waiting for completion of a phase III trial. As a comparator, Avastin was approved under the FDA's 'accelerated approval' mechanism through which diseases with a high unmet need can be approved prior to the completion of a definitive phase III study.

### MORE ON GDC-0084

To read the April announcement on the phase II trial for GDC-0084, view "Novogen update on Phase II Development Plans for GDC 0084" (10 April 2017), available via the ASX Announcements section of our website at [Novogen.com](http://Novogen.com). Additional information can be found in our recent investor presentation, available under the Corporate Presentations section of our website.

Further information can be learned about GDC-0084 from an interview with Dr James Garner. To listen to the recording of 16 March, visit Novogen's website under the Media Centre. [click here](#)

Care, Brisbane. I provide medical oversight for the conduct of early phase cancer clinical trials, one of which is the ongoing study of Cantrixil for chemoresistant ovarian cancer.

I took an interest in cancer research during my training as a medical oncologist at both Westmead Hospital, Sydney & The Royal Marsden Hospital, London and I undertook a PhD at the Barts Cancer Institute, Queen Mary University of London. This entailed a combination of basic and clinical research into the efficacy of immunotherapy in advanced ovarian cancer.

On completing specialist training, I returned to Australia and was appointed as a Research Group Leader at Mater Research, Translation Research Institute (TRI). In April 2016, I was appointed Associate Professor at the University of Queensland School of Medicine, and I remain heavily involved in both basic laboratory and clinical research.

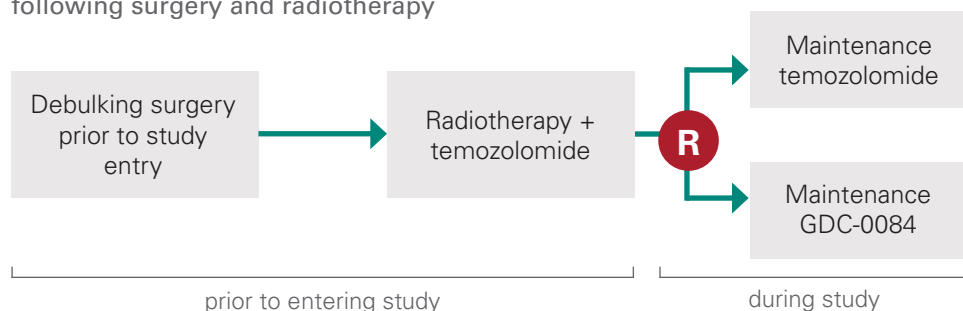
### 2. What are the main challenges in the treatment of ovarian cancer? How effective are existing therapies?

There are many challenges. There is no proper screening test, which means that in many cases ovarian cancer goes unnoticed and is frequently diagnosed at an advanced stage. Despite most patients initially responding to chemotherapy, many will relapse within two years of completing first line therapy. Cancer stem cells are believed to be integral to this recurrence.

There is no doubt that targeted therapies such as Avastin, and PARP inhibitors such as olaparib, have changed the therapeutic landscape in this disease when used alongside or following chemotherapy. Moreover, intraperitoneal chemotherapy, which is reserved for patients who have had all visible disease resected, substantially prolongs survival when compared to traditional intravenous chemotherapy. Despite this, survival rates for this disease are still poor. I believe there is a need to improve the effect of both intraperitoneal chemotherapy and maintenance treatments by developing agents such as Cantrixil which target cancer stem cells.

### GDC-0084 PHASE II STUDY DESIGN

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



### TRXE-002-1 (Cantrixil) phase I clinical trial update

The phase I clinical trial in humans for Cantrixil (TRXE-002-1), under development for ovarian cancer, is ongoing. Dosing of patients is underway and Novogen expects to provide an update once a maximally-tolerated dose is reached.

Once fully recruited, the trial will involve up to 60 patients across six hospitals and research centres in the US and Australia. The trial is likely to report phase I data in 1H calendar 2018.

### Cantrixil trial investigator interview – with Professor Jim Coward



Brisbane-based Associate Professor Jim Coward is the Principal Investigator overseeing the phase I clinical trial in Australia. We asked Prof Coward to comment on his role in

treating ovarian cancer, and how he sees Cantrixil fitting in as a potential treatment option for patients.

#### 1. Please tell us something about your background and role in cancer research?

I run a newly developed Phase I unit co-located at the Wesley Medical Research Institute and ICON Cancer

### 3. What are we hoping to learn from the Cantrixil phase I study?

Safety and tolerability are the main focus in this Phase I study. We are seeking to understand what maximum tolerated dose is feasible in humans. If we get an indication of efficacy too, that would be a great insight to tell us we are on the right track.

### 4. What is the opportunity for Cantrixil? If the trials are successful, what may it offer to patients with ovarian cancer?

I am hopeful that Cantrixil will have a bright future as a possible maintenance therapy following standard treatment of debulking surgery and chemotherapy. Targeting cancer stem cells, which could potentially prevent ovarian cancer recurrence, may be a novel approach to significantly prolonging survival in this disease.

## ATM platform preclinical development program update

The anti-tropomyosin (ATM) platform is a novel approach to the potential treatment of cancer. It aims to target the structure of the cancer cell.

### Termination of ATM-3507 preclinical development program

Anisina (ATM-3507) was among the first generation of ATM drug development candidates. In April 2017, Novogen announced that it would terminate the pre-clinical program, due to an unfavourable balance of efficacy and safety in the preclinical data.

For further information please read the ASX announcement on our web site under the Investor Centre / ASX Announcements.

### Next-Gen ATM program

The decision to terminate the ATM program for Anisina does not affect the 'next-generation ATM' program which is under development, and is the subject of a A\$3 million Cooperative Research Centre Project (CRC-P) scheme grant from the Federal Government, announced in February 2017.

The next generation ATM program is based on an entirely novel approach to targeting tropomyosin, with distinct intellectual property, and it offers the opportunity to produce a therapy with a superior profile.

We are grateful of the support of the CRC-P scheme, which was started in 2015 to support industry-led collaborations between industry and academia and currently has 17 funded projects. To read about the grant, read our announcement (9 Feb 2017) entitled "Novogen awarded grant of up to \$3m by Australian Federal Government for Novel Drug Discovery Program". For further information please read the ASX announcement on our web site under the Investor Centre / ASX Announcements.

The Hon Paul Fletcher MP, Minister for Bradfield recently visited Novogen's offices in Hornsby and was briefed on the new Next-Gen ATM program. For further information, please view a video on our website under the Media Centre. [click here](#)

## Edison research report update

Edison Investment Research has updated their report on Novogen. For further information, please view the announcement on our website under the Investor Centre / Analyst Reports.



### GDC-0084 TRIAL DESIGN IN 60 SECONDS

- Planned to enrol patients recently diagnosed with glioblastoma multiforme (GBM), common and aggressive form of brain cancer
- Patients to have already undergone surgical resection and radiotherapy (under the standard existing treatment practice)
- Patients are largely resistant to most common existing treatment option, temozolomide
- Randomised, two arm design of approximately 200 patients
- Orally-administered therapy
- Trial to measure efficacy of GDC-0084 in patients
- Commencement in second half of calendar 2017
- 18 months to reach full recruitment with progression-free survival data available 12 months thereafter

## Shareholder information sessions

Thanks all those shareholders who attended our info sessions in Sydney and Melbourne during April 2017. To reach as many shareholders as possible, the Sydney session was also live webcast and a recording was lodged with the ASX post the event. To view a recording of the webcast, including Q&A, visit the Media Centre on our web site.

[click here](#)



## Presence at investor conferences

**Roth Conference:** Novogen continued to actively engage with the investment community to ensure its evolving story remains well understood.

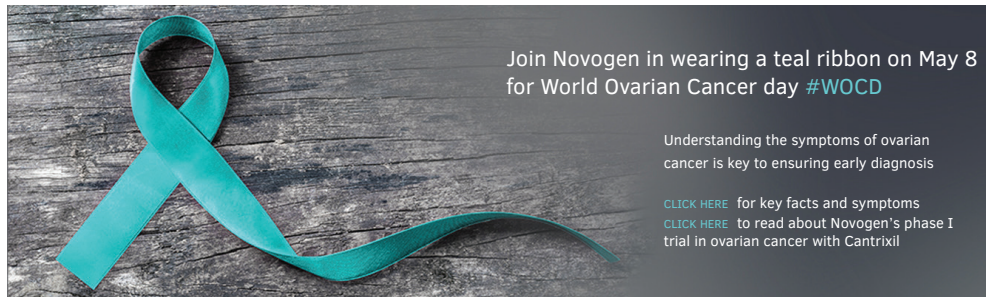
Dr James Garner presented at the Roth Conference in California in March and to a number of retail investor focused events across Australian capital cities including at Wholesale Investor, Canary Networks and The ASX CEO Sessions.

To view the Roth Conference presentation, please view the announcement on our website under the Investor Centre / ASX Announcements. [click here](#)

To view a recording of the Canary Networks presentation, please view the video on our website under the Media Centre. [click here](#)

**ASX CEO Sessions:** Dr James Garner presented at the ASX CEO Sessions in mid May. A recording of the presentation and an interview with Finance News Network at the event can be found on Novogen's website under the Media Centre. [click here](#)





Join Novogen in wearing a teal ribbon on May 8 for World Ovarian Cancer day #WOCD

Understanding the symptoms of ovarian cancer is key to ensuring early diagnosis

[CLICK HERE](#) for key facts and symptoms  
[CLICK HERE](#) to read about Novogen's phase I trial in ovarian cancer with Cantrixil

## World Ovarian Cancer Day

May 8 - World Ovarian Cancer day, has special significance to the Novogen team whose purpose is to discover and develop significant new therapies cancer where there is a high unmet need. We are proud to be developing Cantrixil for the underserved area of ovarian cancer and believe our phase I trial to be the only phase I trial for ovarian cancer in Australia.

Ovarian cancer is diagnosed annually in nearly a quarter of a million women globally, and is responsible for 140,000 deaths each year. Statistics show that just 45% of women with ovarian cancer are likely to survive for five years compared with up to 89% of women with breast cancer.

Source: <http://ovariancancerday.org>

Any women hoping to participate in the Cantrixil trial should speak with their clinical oncologist.

## Ovarian Cancer Symptoms

Read up on symptoms of ovarian cancer, which can often be confused with other less serious conditions such as gastrointestinal disorders at <http://ovariancancerday.org>



## OVARIAN CANCER - 5 KEY FACTS

1. Women are at risk of ovarian cancer
2. Awareness of the early warning signs of the disease could save lives
3. Diagnosis at an early stage vastly improves a woman's chance of survival
4. Ovarian cancer is often diagnosed at a late stage
5. Many women mistakenly believe the cervical smear test (Pap test) will detect ovarian cancer

Source: <http://ovariancancerday.org>

## MILESTONES

Upcoming milestones by development candidate

### 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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## Keep up to date at Novogen.com

Please view our website to stay up to date with our progress. From upcoming events to ASX announcements and detailed information on each of our development candidates, visit [www.novogen.com](http://www.novogen.com) for all the latest info.