

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 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

ASX RELEASE

29 AUGUST 2017

### NOVOGEN ANNUAL REPORT AND FULL-YEAR FINANCIAL RESULTS

Sydney, 29 August 2017 – Novogen Ltd (ASX: NRT; NASDAQ: NVGN), an Australian oncology drug development company, has released its audited Annual Report, including full-year financial results, for the year ending 30 June 2017.

#### Operational Highlights

- Successful in-licensing of GDC-0084 from Genentech in October 2016 provided Novogen with a high-potential clinical-stage asset as part of new strategy
- Phase I clinical trial of Cantrixil commenced on schedule in December 2016, and is progressing well at five hospitals in United States and Australia
- Award of \$3 million competitive Federal Government Grant provided support to Novogen's 'next-generation ATM' drug discovery program
- Ongoing portfolio optimisation resulted in discontinuation of Anisina (ATM-3507) due to unpromising preclinical data; funds reallocated to higher-value projects
- Novogen reported a loss of \$10.7 million (down 11.5% from \$12.1 million in prior corresponding year)
- Key upcoming milestones in FY18 include commencement of phase II study in glioblastoma (on schedule for 1HFY18) and receipt of Phase I study data for Cantrixil (on schedule for 2HFY18)

Novogen CEO, Dr James Garner, commented, “2017 saw Novogen transform from an early-stage, preclinical, drug discovery company into a clinical-stage drug development organization. Our enviable pipeline of two clinical-stage assets are progressing well through human trials and we have met or exceeded all milestones that we set for the period. We are well-positioned to commence our phase II clinical trial of GDC-0084, and look forward to reporting clinical data from Cantrixil in FY2018. In the meantime, the company will continue to explore both in-licensing and out-licensing opportunities in order to grow the business.”

#### GDC-0084 to Enter Phase II Clinical Trials in 4Q 2017

GDC-0084 was in-licensed from Genentech in October 2016. The drug has completed, under Genentech's stewardship, a phase I clinical trial in patients with advanced glioma, which showed it to be safe and well-tolerated, and which provided promising signals of clinical efficacy.

Since taking over the asset, Novogen has assumed responsibility for the open Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA), and has

successfully secured patents in several territories, including the United States. The company intends to develop the drug as a potential therapy for glioblastoma, the most common and most aggressive form of primary brain cancer, with an estimated market size in excess of US\$ 1 billion per annum.

Novogen has worked closely with expert neuro-oncologists in the United States, and with its Scientific Advisory Board, to design an optimal phase II clinical trial, It is expected that this trial will commence by the end of calendar 2017. The Company has signed a Master Services Agreement (MSA) with Chiltern Oncology, a leading international Contract Research Organisation (CRO) with a specialist focus on oncology trials. Novogen has also manufactured an initial batch of capsules for oral administration in the clinical trial.

#### Cantrixil Phase I Study Progressing According to Plan

The phase I clinical trial of Cantrixil (TRX-E-002-1) commenced in December 2016, in line with the Company's prior guidance to the market. The trial seeks to establish the safety and tolerability of Cantrixil in human subjects, and will explore signals of clinical efficacy.

Five hospitals in the United States and Australia are currently participating in the phase I study, and recruitment of patients continues according to plan. A second batch of clinical trial material is planned to be produced under Good Manufacturing Practice (GMP) conditions in the second half of calendar 2017.

Subsequent to the 2017 financial year, Novogen was notified that the patent covering Cantrixil had proceeded to grant in the United States and Europe, providing additional protection for the Company's intellectual property.

#### Preclinical Programs Rationalised and Supported by \$3M Federal Government Grant

In April 2017, the Company announced termination of the Anisina (ATM-3507) program due to unfavourable preclinical data. Funds that had been allocated to a planned phase I clinical trial have been reallocated to programs with greater commercial potential.

In February 2017, Novogen was awarded a CRC-P grant to the value of \$3 million over three years from the Federal Government. This grant will be used to develop a 'next-generation ATM' program, which it is hoped will yield one or more promising drug development candidates in the future.

#### Full Year FY17 Financial Results

Novogen reported a loss of \$10.7 million (down 11.5% from \$12.1 million in prior corresponding period). Investment in R&D was \$11.1 million, an increase of 12.6% over the prior corresponding period. This expenditure was principally associated with preparation and implementation of clinical trials for GDC-0084 and Cantrixil.

An Operational Review identified \$1.8 million of annualized cost savings in FY18 and subsequent years. This rationalization program puts Novogen on a strong basis for success moving forward, with a more efficient cost base and a proportionally greater investment in R&D.

The Company reported a Cash position at year-end of \$14.5 million. With the ongoing support of its shareholders, Novogen will continue to pursue all opportunities to sustain its business for the long-term, and these may include access to further grant funding, licensing and partnering transactions, or recruitment of additional investment in the company.

## **Outlook**

The key milestone for FY 2018 will be commencement of the phase II clinical study of GDC-0084, which is expected to begin in the fourth quarter of calendar 2017. Given the high mortality associated with glioblastoma, and dependent on the performance of GDC-0084 relative to current standard-of-care, FDA may consider the drug for ‘accelerated approval’, a mechanism whereby the FDA may sometimes approve drugs for high-need diseases prior to completion of a formal phase III clinical study.

Novogen also expects to report initial data from the phase I clinical study of Cantrixil in the first quarter of calendar 2018. It is anticipated that exploratory efficacy data from additional patients will be available later in calendar 2018.

In parallel, the Company continues to actively explore licensing and partnering opportunities with other companies, which have the potential to effect further stepwise transformations in the scope of Novogen’s business.

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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, TRX-E-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)