

ASX:NRT  
NASDAQ:NVGN

Novogen Ltd  
(Company)

ABN 37 063 259 754

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### Capital Structure

Ordinary Shares on  
issue:

423 M

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### Board of Directors

**Ian Phillips**  
Interim Chairman

**Steve Coffey**  
Non-Executive Director

**John O'Connor**  
Non-Executive Director

**Prof Peter Gunning**  
Non-Executive Director

**Bryce Carmine**  
Non-Executive Director

**Dr Graham Kelly**  
Chief Executive Officer

### ASX RELEASE

14 July 2015

## Pre-clinical studies suggest Anisina may improve chemotherapy effectiveness in childhood cancer.

- Potential to improve effectiveness of chemotherapy
- May reduce the risk of life-long side-effects associated with childhood chemotherapy.

**New York, USA 13 July 2015:** US- Australian drug discovery company, Novogen Limited (NRT: ASX; NVGN: NASDAQ), today announced details of an in vivo proof of concept study that demonstrates their lead anti-tropomyosin drug candidate, Anisina, has the potential to improve the effectiveness of chemotherapy in children and reduce life-long side-effects.

The study results were presented by Dr Timothy Cripe from the Nationwide Children's Hospital Research Institute, at the Eighth Annual Cancer Molecular Therapeutics Research Association (CMTRA) meeting in Boston, USA. The results demonstrated that Anisina significantly improved the efficacy of standard of care microtubule targeting compound, vincristine, in an animal model of neuroblastoma.

Neuroblastoma is a cancer that is most frequently observed in the young with more than 90% of diagnoses occurring in children under 5 years of age. It is considered to be the most common solid tumour in children outside the brain. Although childhood cancers such as neuroblastoma are relatively rare compared to adult cancers, the potential years of life lost are substantial making it imperative that new clinical strategies are developed to treat this disease.

The importance of this study, from a clinical perspective, is that it shows we can dose animals with a proprietary formulation of Anisina in combination with the standard of care and recapitulate in an animal model of neuroblastoma the same effect as observed in the test tube.

According to Dr Justine Stehn, Novogen Anti-Tropomyosin Program Director, this represents an important milestone in the development of Anisina as a combination therapy for the treatment of neuroblastoma.

The study was done as part of the Children's Oncology Drug Alliance (CODA) involving Australian charity, The Kids' Cancer Project (Sydney), The University of New South Wales (Sydney), The Nationwide Children's Hospital (Columbus, Ohio), and Novogen. The objective of this study was to evaluate the effectiveness of Anisina either alone or in combination with vincristine, in a mouse model of human neuroblastoma (CHLA20).

Animals with tumors were treated with i) no drug (control), ii) Anisina alone (150mg/kg), iii) vincristine alone (0.5mg/kg) or iv) Anisina (150mg/kg) + vincristine (0.5mg/kg). Consistent with existing data, Novogen was able to show that Anisina on its own was effective in reducing tumor growth by about 35%.

Dr Timothy Cripe, principal investigator, Nationwide Children's Hospital said more importantly, when used in combination, the Anisina/vincristine treatment not only reduced tumor growth but also made tumors "regress".

"Of the five animals in the combinatorial Anisina/vincristine treatment group three (60%) reached a complete response- meaning that their tumors were deemed to be too small to be measured, with one animal showing a 'maintained complete response' meaning that the tumor had disappeared for more than 60 days after treatment had stopped," Dr Cripe said.

"What is exciting about this novel drug technology is that Anisina has the potential to improve the effectiveness of the current standard of care chemotherapeutic, vincristine. What this means from a clinical perspective is that chemotherapy may be more effective in treating patients. In some cases doses of vincristine used in the clinic could be lowered thereby minimizing the risk of leaving children with side-effects that have life-long consequences."

Dr Stehn said the outcome of this study was encouraging.

"Studies are now underway to validate the combinatorial effect of Anisina with a microtubule targeting compound in an animal model of adult cancer with the objective still being to have first-in-man studies commencing by mid-2016 once we have completed the standard battery of toxicology studies that are requisite for any experimental drug prior to entering the clinic", Dr Stehn said.

### **About Anisina**

Anisina is a small molecule which belongs to a family of compounds termed the anti-tropomyosins or ATMs. Anisina has been designed to inhibit a protein known as Tpm3.1. Tpm3.1 is a structural protein and is a core component of the skeleton, or cytoskeleton of a cancer cell. By binding to Tpm3.1, Anisina impacts the function of this structural protein causing the collapse of the cytoskeleton which results in the death of the cancer cell. Anisina has been shown to be effective against a broad range of cancer types. At Novogen we are focused on the clinical development of Anisina for the treatment of both adult (melanoma and prostate) and pediatric (neuroblastoma) cancers.

### **About CODA**

CODA's mission is to accelerate development of innovative new therapeutic approaches to the treatment of childhood cancers and to take account of the fact that childhood cancers are different to adult cancers and that the lifelong consequences of cancer drug side-effects can be far more devastating in a child than in an adult.

CODA unites the research and resources of five organizations in Australia and the US.

The Australian members are:

- The charity, **The Kids' Cancer Project**
- The originator of the anti-tropomyosin technology, the **University of New South Wales** and its commercial arm, **New South Innovations**
- Biotechnology company, **Novogen Limited**

The US member is:

- **Nationwide Children's Hospital**, Columbus, Ohio

Novogen is providing access to both its anti-tropomyosin and super-benzopyran drug technologies. Anisina is being evaluated for its ability to complement the action of standard chemotherapies in childhood cancers. TRXE-009 is being evaluated for its ability to treat brain cancers in children.

Further information on CODA is available at [www.childrenoncologydrugalliance.org](http://www.childrenoncologydrugalliance.org)

### **About Novogen**

Novogen is a public, Australian-US drug development company whose shares trade on both The Australian Securities Exchange (NRT) and NASDAQ (NVGN). The Novogen group includes US-based, CanTx Inc, a joint venture company with Yale University. Novogen has two drug technology platforms (the super-benzopyrans (SBPs) and anti-tropomyosins (ATMs)) yielding drug candidates that are first-in-class with potential application across a range of degenerative diseases. Given the encouraging data from in vitro and in vivo pre-clinical Proof-of-Concept studies in the field of Oncology, our immediate focus is to bring our lead Oncology drug candidates Cantrixil, Anisina and Trilexium into the clinic in 2016 pending successful completion of their respective toxicology programs. Ovarian cancer, colorectal cancer, malignant ascites, prostate cancer, neural cancers (glioblastoma, neuroblastoma in children) and melanoma are the potential clinical indications being pursued, with the ultimate objective of employing both technologies as a unified approach to therapy.

### **About The Kids' Cancer Project**

The Kids' Cancer Project is an Australian charity dedicated to funding medical research to find a cure for childhood cancer. Thanks to community support the charity has invested more than \$24 million into research and is currently supporting 13 research projects. The independent charity is the largest not-for-profit funder of childhood cancer in Australia. The Kids' Cancer Project was inspired by one man who promised to find the cure for childhood cancer and make a difference. The Kids' Cancer Project supports research that will increase a child's chance of survival and that will eradicate or minimise the toxicity of current treatments children endure. The Kids' Cancer project supports collaborative research that has the greatest chance of clinical success and is excited about the potential that Anisina presents as a potential improvement in chemotherapy treatment. Visit [www.thekidscancerproject.org.au](http://www.thekidscancerproject.org.au) for further information or to donate.

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

### **Media Enquiries**

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### **Forward Looking Statement**

*This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "appear," "intends," "hopes," "anticipates," "believes," "could," "should," "would," "may," "target," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to any statements relating to the Company's drug development program,*

*including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, Anisina, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to Anisina, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, Anisina, that could slow or prevent products coming to market, the uncertainty of patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to Anisina, and other risks detailed from time to time in the filings the Company makes with Securities and Exchange Commission including its annual reports on Form 20-F and its reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factors including those risks and uncertainties mentioned or referred to in this press release. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.*

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