

ASX:NRT  
NASDAQ:NVGN

Novogen Ltd  
(Company)

ABN 37 063 259 754

### Capital Structure

Ordinary Shares on  
issue:

420 M

### Board of Directors

**Dr Graham Kelly**  
Chairman &  
Executive Director

**Steve Coffey**  
Non-Executive Director

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

**Prof Peter Gunning**  
Non-Executive Director

**Ian Phillips**  
Non-Executive Director

**Bryce Carmine**  
Non-Executive Director

### ASX RELEASE

5 June 2015

### STUDIES CONFIRM TRXE-009 CROSSES THE BLOOD-BRAIN BARRIER

- **Crosses the BBB in a proprietary lipid construct**
- **Potential to treat both primary and secondary brain cancers**

**June 4, 2015, New York, USA:** US-Australian drug discovery company, Novogen Limited (ASX:NRT; NASDAQ:NVGN) confirms that a lipid formulation of TRXE-009 dosed intravenously to animals was able to deliver therapeutic concentrations of TRXE-009 to brain tissue. This confirms that the drug is able to cross the blood brain barrier.

The blood-brain barrier is a defence mechanism intended to protect the brain from the unwanted toxic effects of drugs and food chemicals. It serves to prevent some 98% of all drugs used in humans from reaching the brain. This, plus the inherent resistance of primary brain cancers to chemotherapies, is the reason behind the poor survival prospects of adults and children with brain cancer.

Eleanor Ager PhD, Novogen GBM Program Manager, said, "TRXE-009 shows remarkably potent killing in the test tube against a wide range of cancer types, but it has been its particularly potent activity against brain cancers including glioblastoma and DIPG that has marked it as a potential treatment of primary brain cancers in both adults in children. These are tumors that show high levels of resistance to standard of care drugs, so even if it was possible to get those drugs into the brain, they may not offer clinical benefit."

"We know TRXE-009 kills these highly resistant cancer cells *in vitro*, with toxic effects on normal brain cells only occurring at very high doses of the drug. So a vital step forward for us was to see whether we could get the drug to cross the blood-brain barrier. Today's data shows that it does. The next key step is to confirm that the drug is effective against brain cancer cells growing in the brain."

Graham Kelly, Novogen Group CEO, said, "TRXE-009 is already on its way into the clinic early next year in the form of Trilexium, a proprietary dosage form of TRXE-009 utilising the compound's potent general anti-cancer activity. What marks this agent as particularly exciting is its particular ability to kill the full range of cells within a tumor, including the tumor-initiating or cancer stem cells. Cancers such as malignant melanoma and metastatic castrate-resistant prostate cancer are in our sights."

"Today's data is important in showing that the compound now will also be able to proceed into the clinic for testing as a therapeutic for brain cancer, and where others in this field are focusing on the development of treatments just for cancers that arise in the brain, the much larger problem is cancers that arise elsewhere in the body and spread

to the brain, so-called secondary brain cancers. About 25% of all malignant cancers that spread within the body, metastasize to the brain. This includes cancers such as cancers of the lung, breast, kidney and bladder, and melanoma, leukaemia, lymphoma and sarcomas. This is a significant problem that is not currently addressed with currently used therapeutics.”

“When you consider the broad anti-cancer activity of TRXE-009, combined its ability to kill cancer stem cells, and now combined with its confirmed ability to get it across the blood-brain barrier, TRXE-009 in our view represents an exciting drug prospect and a breakthrough in the search for an avenue of treatment for the large unmet clinical need of both primary and secondary brain cancer,” Kelly added.

#### **About TRXE-009**

TRXE-009 is a super-benzopyran compound that demonstrates cytotoxicity against cancer cells, but particularly activity against cancer cells with stem-cell like activity. TRXE-009 demonstrates potent killing against a range of neural cancers (glioblastoma multiforme and diffuse intrinsic pontine glioma), neuro-endocrine cancer (neuroblastoma) and other forms of cancer (melanoma, prostate cancer, lung cancer, ovarian cancer). TRXE-009 is highly cytotoxic to glioblastoma stem cells. The putative molecular target is an NADH oxidase involved in regulation of the trans-membrane electron transfer mechanism and up-regulated in cancer cells. Inhibition of this pump mechanism induces a range of pro-death signals leading to caspase-induced apoptosis.

#### **About Trilexium**

Trilexium is the name given to a proprietary parenteral formulation of TRXE-009 developed for its ability to maximize systemic drug delivery and effectiveness in pre-clinical rodent models of human non-neural cancers.

#### **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 yielding drug candidates that are first-in-class with potential application across a broad range of degenerative diseases. In the oncology field, the ultimate objective is to see both drug technologies used in combination as first-line therapy across most forms of cancer, with the objective of preventing tumor recurrence. This objective is based on a strategy of achieving comprehensive destruction of the full hierarchy of cells within a tumor with the super-benzopyran technology platform killing the tumor-initiating cells and the anti-tropomyosin technology, combined with vinca alkaloids, to deliver a potent chemical debulking effect on their daughter cells.

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

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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, TRXE-009, 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 TRXE-009, 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, TRXE-009, 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 TRXE-009, 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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