

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on
issue:

424 M

Board of Directors

Ian Phillips MNZM
Interim Chairman

Mr Iain Ross
Director
Acting CEO

Steve Coffey
Non-Executive Director

John O'Connor
Non-Executive Director

Prof Peter Gunning
Non-Executive Director

Bryce Carmine
Non-Executive Director

ASX RELEASE
30 July 2015

NEWLY APPOINTED ACTING CEO OUTLINES IMMEDIATE PLANS FOR NOVOGEN

COMPANY CONFIRMS ITS COMMITMENT TO BRINGING TECHNOLOGY PLATFORMS TO THE CLINIC

Sydney, July 30, 2015 - US-Australian drug discovery company, Novogen Limited (ASX: NRT; NASDAQ: NVGN) today confirmed it is committed to progressing its ground-breaking technology platforms to Phase 1 clinical trials as soon as practicable and to ensure the Company delivers the best value for shareholders.

Acting Chief Executive Officer, Iain Ross, said the Company currently had an extensive program of activities underway including the lead pre-clinical programs, discovery programs and academic partnerships and initiatives, and he was working with the newly evolved Board and incumbent Scientific Management Team to review the Company's immediate priorities with the intent of providing a shareholder update by 1 September 2015.

"We remain committed to exploiting and creating value from all our technology platforms in order to build a sustainable, international, biotech company. Whilst we do not rule out securing third party collaborations and partnerships to further validate and fund our programs, I can confirm there are no M&A plans," Mr Ross said.

"Notwithstanding, it is clear that we cannot realistically undertake and fully resource all our research and development programs in parallel all the way through to market approval and launch. These are new ground-breaking and first in class technologies and it is critical that we understand which indications, stage of disease and combinations with other oncology agents will deliver the best outcome for patients and value for shareholders."

"Accordingly I have initiated a Company-wide review and I am working closely with the Board, Management and Company's scientific advisers to review immediately the pre-clinical programs in detail, including the targeted indications, route of patient administration, product formulations, manufacturing scale-up and regulatory requirements," Mr Ross continued.

“Whilst not wanting to pre-empt the outcome of the review I anticipate we may have to re-prioritize some of the programs as outlined in the PRODUCT UPDATE section below.”

“One outcome from this process will be to focus our valuable resources; set clear, realistic, scientific and commercial priorities in order that we can execute and manage the business effectively and report our on-going progress to our shareholders against the priorities we have established. We know already we are under-resourced in some areas and therefore I have commenced the search for a world class CEO and authorized the immediate recruitment of additional staff including a full time CMO, project, and manufacturing management support.

“We operate in a highly competitive market place and we will ensure as an organization we are fit for purpose.”

“In summary Novogen is in an excellent situation. The Company is in a solid financial position with a suite of promising drug candidates. Novogen has world-class science, a scientific team of the highest quality, and some strong academic partnerships. I am delighted to be able to lead the Company through this period of transition and intend to keep shareholders updated,” Mr Ross concluded.

PRODUCT UPDATE

Novogen has two drug technology platforms - the Superbenzopyran (SBP) and anti-tropomyosin (ATM) - around which the Company has established very strong patent positions. Our medicinal chemistry programs have identified two promising drug candidates (Cantrixil and Anisina), which the Company is progressing down the translational development path in concert.

Cantrixil

Cantrixil is being developed by the Company's subsidiary company CanTx (a joint venture between Yale University and Novogen). Cantrixil has been designed to be injected into the peritoneal cavity with the aim of treating both differentiated cancer cells and cancer initiating cells, the cells thought to be primarily responsible for cancer recurrence post chemotherapy.

Our Yale collaborators have demonstrated that Cantrixil modulates both the JNK and PKC pathways resulting in caspase-mediated cell death. Yale researchers also demonstrated that Cantrixil was active in a stringent, clinically relevant rodent model of human ovarian cancer. Pending successful completion of our toxicology program, an initial first-in-human clinical study assessing the safety and tolerability of Cantrixil in late-stage cancer patients is planned to commence in 2016.

At the Company's pre-IND meeting with the US Food and Drug Administration (FDA), the agency agreed with our strategy on manufacturing and toxicology evaluation. Subsequent to this meeting, the Company has been able to produce both the active drug substance and drug product that both meet Good Laboratory Practice (GLP) standards. Critically the drug has shown an excellent stability profile, all manufacturing

processes have proven robust and scalable. Novogen has commenced manufacture to Good Manufacturing Practice (GMP) standards enabling the Company to meet product demand for clinical trials.

The Company has commenced its Cantrixil toxicology evaluation with the aim of gaining Investigational New Drug (IND) status with the FDA. This evaluation will characterize the toxicology signals associated with the experimental drug, and correlate any toxicities with drug concentrations achieved in mammalian models. This information will enable regulators, such as the FDA and clinical investigators to assess the drug's safety, ascribe a starting dose in humans and to establish monitoring of potential toxicities encountered in humans.

Results to date indicate that the drug is associated with gastrointestinal toxicity manifest as diarrhoea and some haematological toxicity manifest as anaemia. Also, while not uncommon for oncology drugs, preliminary studies suggest that Cantrixil is associated with cardiovascular toxicity though this observation is being assessed further. The Company anticipates completing the Cantrixil toxicology evaluation by the end of 2015.

Novogen has assembled a Medical Study Committee for Cantrixil and commenced writing the Phase I clinical trial protocol where the Company will assess the safety and tolerability of Cantrixil in late stage cancer patients. Novogen is also planning to conduct a second trial in women with late-stage ovarian cancer who have become unresponsive to standard of care therapy once the Company has received IND status for Cantrixil from the FDA. The FDA recently granted Cantrixil Orphan drug status for ovarian cancer.

Progress and timing of these clinical studies will depend upon the outcome of the toxicology program and therefore it is not possible at this stage to be precise as to when clinical studies will commence however the Company continues to aim to start the trials in 2016.

Anisina

Anisina is an anti-tropomyosin (ATM) small molecule targeting a protein component of the actin microfilaments, tropomyosin Tpm3.1 which is essential for tumor cell survival. In vitro studies confirm that inhibition of Tpm3.1 function impacts the structural integrity of the cancer cells cytoskeleton causing the cancer cell to die. In addition to being an effective anti-cancer agent, these ATM compounds are also novel in that when administered to animals and used in combination they can enhance the killing effect of one of the most widely used classes of chemotherapy drugs in cancer- the anti-microtubules.

Preclinical studies are underway to validate the effectiveness of Anisina in animal models of adult (prostate and melanoma) and pediatric (neuroblastoma) cancers both on its own, and in combination with standard of care microtubule inhibitors. Importantly, a proof of concept study done in an animal cancer model as part of the Children's Oncology Drug Alliance (CODA) has confirmed that Anisina is not only effective on its own in reducing neuroblastoma tumor growth but also enhances the sensitivity of cancer cells to microtubule targeting compounds.

The Company has successfully optimized the manufacturing process of the Anisina Active Pharmaceutical Ingredient (“API”) using a process that is scalable and meets GLP standards. The process has proven robust and as a consequence manufacturing programs were completed 6 weeks ahead of schedule. The GMP manufacture of material for clinical trials has been accelerated to commence in August.

Novogen has identified the drug product that the Company intends to use in the clinic. This has enabled the Company to initiate its Anisina toxicology program with a view to filing an IND with the FDA. The Company has assembled a Medical Advisory Board for Anisina and, based on our pharmacology package, anticipates initially taking Anisina through to the clinic as an IV delivered drug in combination with taxanes or vinca alkaloids targeting prostate, melanoma or neuroblastoma. Further studies are ongoing to identify the Anisina adult cancer indication. The FDA recently granted Anisina Orphan drug status for neuroblastoma.

Pending the outcome of our Anisina toxicology program and discussions with the FDA, the first-in-human studies are predicted to start in 2016.

TRXE-009 (Trilexium)

TRXE-009 is the Company’s second lead SBP drug candidate. Researchers have shown in animal models that Trilexium affects the viability of cancer cells by increasing rates of cell death (via caspase-mediated apoptosis) and reducing proliferation. This was observed in cancer cells representative of Glioblastoma, melanoma and prostate cancer. The Company has also demonstrated tumor growth inhibition in several other animal models (flank models of melanoma, prostate and GBM).

These findings combined with recently announced pre-clinical in-vitro studies demonstrate that TRXE-009 is highly cytotoxic to chemo-resistant pediatric brain cancers including Diffuse Intrinsic Pontine Glioma (DIPG). Using a proprietary formulation, animal studies have confirmed that TRXE-009 inhibits the proliferation of prostate, melanoma, and GBM tumors grown subcutaneously (under the skin).

A major hindrance to the use of chemotherapeutic agents for brain tumors is the presence of the blood brain barrier, which blocks drug access to the brain tumor. To counter this, the Company has identified a micelle formulation that was able to deliver potentially therapeutic concentrations of TRXE-009 to the brain tissue of rodents. This finding represents a step forward in the development of the drug with the next key step being to demonstrate that this micelle drug product inhibits the growth of human brain cancer cells growing in the brain of rodents (orthotopic model of human brain cancer). Another key goal will be to demonstrate anti-tumor efficacy of the micelle drug product in rodent models of prostate cancer and melanoma.

Once Novogen has optimized the TRXE-009 formulation and confirmed activity in the above key studies, the Company will commence the requisite toxicology program required prior to the conduct of a first-in-human trial in 2016/2017.

Jacob's Hope

Jacob's Hope is the name the Company has given to the degenerative disease and regenerative medicine program that is highly experimental and investigational. It is named after a very brave young man called Jacob who has a disease known as Duchenne muscular dystrophy (DMD). Jacob and thousands of children like him around the world, is the reason we are running this program.

Jacob Hope consists of three exploratory programs:

- Regenerative Medicine Program,
- **Facioscapulohumeral muscular dystrophy (FSHD) program** and
- Lysosomal Storage Disorder (LSD) Program.

Regenerative Medicine

Studies in the test tube have demonstrated that SBP analogues are able to promote the differentiation of neural progenitors into functional neural cells. The Company has commenced a medicinal chemistry program aimed at refining the SBP chemical scaffolds with the intention of identifying lead compounds that can be appraised in an appropriate model of brain injury such as stroke and traumatic brain injury.

FSHD

The Company's initial evaluation of a panel of SBP analogues in an in vitro model of FSHD using diseased embryonic stem cells have demonstrated that discrete analogues may have a positive effect on the phenotypic appearance of myotubes when compared with the formation of myotubes with no treatment. This is an intriguing finding as the screen may provide a tool by which a medicinal chemistry program could identify potential lead analogues to progress into in-vivo translational models of FSHD.

LSD

Contracts are in place with a world expert in LSD, where a panel of SBP analogues will be assessed in human fibroblasts isolated from patients with LSD. These fibroblasts are unable to prevent the accumulation of intracellular heparan sulfate, which leads to the death of the cell. The aim of this screening program is to identify a subset of analogues that inhibit this accumulation and thus rescue cell function.

Given the data achieved to date in the Regenerative Medicine and FSHD programs, the Company intends to pursue patent protection around the discrete SBP pharmacophores that are attributable to either potentiating neurogenesis in the Regenerative Medicine Program, or normalizing the myotube phenotype in the FSHD program. The Company will also endeavor to protect any SBP pharmacophore that is active in the LSD setting.

This patent protection strategy will increase the intrinsic value of each program and establish a priority date from an intellectual property perspective thereby enabling the Company to re-visit each program that has promise when funds and time permits.

About the Children's Oncology Drug Alliance (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 from adult cancers and the lifelong consequences of side-effects from cytotoxic treatment 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 the: [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.childrensoncologydrugalliance.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 superbenzopyrans (SBPs) and anti-tropomyosins (ATMs)] yielding drug candidates that are first-in-class with potential application across a range of oncology and 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 advance our lead Oncology drug candidates 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.

For more information, please visit 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, Cantrixil, Anisina, Trilexium, 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, Cantrixil, Anisina, Trilexium, 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, Cantrixil, Anisina, Trilexium, 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 Cantrixil, Anisina, Trilexium, 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.