

# ASX:NRT NASDAQ:NVGN

Novogen Ltd (Company)

ABN 37 063 259 754

#### **Capital Structure**

Ordinary Shares on issue:

483 M

#### **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**

2 November 2016

# NOVOGEN'S DR JAMES GARNER DISCUSSES IN-LICENSING OF GDC-0084 WITH FINANCE NEWS NETWORK

Sydney, 2<sup>nd</sup> November 2016 – Australian oncology-focused biotechnology company Novogen Limited (ASX: NRT; NASDAQ: NVGN) is pleased to invite investors to view a video interview with CEO, Dr James Garner, where he discusses key elements of their in-licensing of a phase II ready molecule (GDC-0084) from Genentech for treatment of brain cancer (Glioblastoma).

To view the video interview, please copy and paste the URL below into your web browser:

http://www.finnewsnetwork.com.au/MediaCenter/MediaCenterMobile.aspx?Site=FNN813

## Interview transcript

#### -Begins-

**Carolyn Herbert:** Hello I'm Carolyn Herbert from the Finance News Network (FNN) and joining me from Novogen Limited (ASX: NRT; NASDAQ; NVGN) to discuss its licensing deal with Genentech is CEO Dr James Garner. James, welcome to FNN.

**James Garner:** Thank you Carolyn, it's great to be here.

Carolyn Herbert: Can you start by giving us a brief introduction to Novogen?

James Garner: Novogen is an oncology focused biotechnology company; we're targeting new therapies for a range of different types of cancer. We are listed on the ASX, and we are also actually listed on Nasdaq; we have the advantage of being present in both countries and we have about 40 per cent of our shareholders in the United States through Nasdaq. We are a lean team with about 16 people, from a variety of backgrounds including a number of people from a background in international pharma. We are a well capitalised company, we have about a little north of A\$30 million on the balance sheet and we have now after today's news a pipeline of four molecules of which two are in clinical development and two of which are still in animal studies.

Carolyn Herbert: Now to your deal with Genentech, can you tell us a little bit more about that?

James Garner: We have successfully in-licensed a new molecule from Genentech and Genentech by way of background is one of the world's most successful oncology drug development companies. It's the company behind drugs like Avastin and Herceptin which have been very, very successful in their fields; it is part of the Roche Group which is the world's third largest pharmaceutical company. The molecule we have inlicensed is part of a class of drugs called PI3K inhibitors and these drugs target a particular process in cancer cells and it has been an area of interest to pharmaceutical companies in a range of different cancer types. We are developing the drug in an area called glioblastoma primary brain cancer which is one of the most challenging indications in drug development.

Carolyn Herbert: So how common is glioblastoma and what are the current treatment options?

James Garner: Glioblastoma is one of the most common forms of brain cancer and there are about 12,500 new cases each year in the United States and perhaps about ten times that many worldwide. It is a very challenging disease to treat. Life expectancy at the time of diagnosis even with the best available treatment is something like 12 to 15 months. After five years only about 3 per cent of glioblastoma patients are still alive compared to somewhere like 89 to 90 per cent of breast cancer patients, so it remains a very challenging disease to treat. The most commonly used pharmaceutical treatment at the moment is a drug called Temozolomide, otherwise known as Temodar, and this drug has been shown to be effective, but it's only really effective in under half of the patients with glioblastoma, so there is still a very real need for new therapies in this disease area.

**Carolyn Herbert:** James as you say other companies have been looking at this disease area, so what makes your drug different?

James Garner: We are excited for a number of reasons; the first is we know the PI3K pathway is very relevant to glioblastoma as a disease area. Somewhere around 80 to 90 per cent of glioblastoma patients have a disordered PI3K pathway as part of their tumour. So this represents a really good target for drug development. The second advantage of this molecule is that it is able to cross the so-called blood brain barrier, which separates the brain from the circulation, and is often a challenge for new drugs that target diseases of the central nervous system, so this is something that really differentiates it from most drugs in the PI3K class and indeed most other drugs that have been tried to approach glioblastoma.

**Carolyn Herbert:** So what does this mean for Novogen, and does the company still plan to develop its existing pipeline?

James Garner: Yes we do. We have a pipeline of three other molecules, apart from the molecule we just inlicensed and the most advanced of these is about to enter human trials for the fourth quarter of this year with ovarian cancer as a lead indication. So we continue to work on the rest of the pipeline and we're looking forward to seeing those molecules progress in parallel.

**Carolyn Herbert:** So James, can you tell us some more about the deal terms and how do you know it's good value?

James Garner: We have paid US\$5 million for the molecule as an upfront payment and we also have some limited commercial and regulatory millstones as the project moves forward and then a royalty payable on sales. So we have benchmarked the transaction quite carefully against other comparable deals in the life-

sciences space and we feel the transaction we've done is a good one for Novogen and it represents good value for the company. We have also had an independent fairness opinion prepared by an independent corporate advisory firm in London and they have confirmed our view that this represents good value for shareholders.

**Carolyn Herbert:** So what happens next, what are your plans for the drug and do you need to raise further capital?

James Garner: Our immediate plans are logistical, we have to transfer all of the data and all of the regularity matters from Genentech to Novogen and that's work that will probably take the next couple of months. One of the key things is to transfer the open IND, with the United States Food and Drug Administration from Genentech to Novogen. We also get as part of the deal a large quantity of premanufactured drug substance which will be a great help for us when we are starting the clinical trials. So the logistics of transferring that to our ownership will take us a little bit of time over the next month or so. In parallel to that we are going to be investing plenty of time in planning the optimal phase II clinical study. We will be sitting down with key option leaders, as well as scientists and clinicians to work out the best way to take the drug forward and that's work that we also anticipate will take place over the next few months. In terms of our capital requirements we remain a well funded company and we will obviously be continuing to evaluate our portfolio in light of the work we are doing and keeping a close tab on that.

**Carolyn Herbert:** James Garner congratulations on the news and thanks for the update.

James Garner: Thanks very much Carolyn.

-Ends-

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#### About the GDC-0084 development candidate

GDC-0084 is a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is distinguished from other molecules in the class by its ability to penetrate the blood-brain barrier. The molecule was developed by Genentech, who completed a phase I study in recurrent glioblastoma patients, and was licensed to Novogen in October 2016. A phase II clinical trial is slated to begin in 2017.

#### **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 four development candidates, diversified across three distinct technologies, with the potential to yield first-in-class and best-in-class agents across 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. Three further molecules have been developed in-house from two proprietary drug discovery platforms (superbenzopyrans and anti-tropomyosins) to treat ovarian cancer and a range of solid tumours. Cantrixil, the most advanced of these, is slated to enter clinical trials in late 2016, while Anisina and Trilexium are in preclinical development.

For more information, please visit: <a href="https://www.novogen.com">www.novogen.com</a>