SYDNEY (24th October, 2014) - Novogen Ltd. (ASX: NRT, NASDAQ: NVGN)

Dr Graham Kelly, Novogen CEO speaks with ShareCafe reporter James Dunn about the Novogen pipeline and the current Capital Raise

With an exciting program of clinical trials ahead of it, drug developer Novogen (ASX code: NRT) is tapping the Australian Securities Exchange for up to $10 million to help take at least the first of a pipeline of four drug candidates through to patient use.

Capitalised at $20 million, Novogen is using the ASX OnMarket BookBuild facility to raise the funds through the issue of ordinary shares plus options.

Novogen has two ground-breaking drug technology platforms. The first one is called super-benzopyrans (SBPs): these have shown the ability to kill cancer stem cells. The second is called anti-tropomyosins (ATMs): these can destroy the "skeleton" of a cancer cell.

There are three SBP drugs in the pipeline: Cantrixil, aimed at abdominal cancers; Trilexium, aimed at brain cancers; and Trx-7, aimed at prostate cancer. There is one ARM drug, with melanoma and prostate cancer the targets.

All of the Novogen drugs are in the pre-clinical phase. The company is raising the funds to bring the first candidate, Cantrixil, into the clinic in the US, UK and Australia.

Cantrixil is being developed jointly with Yale University in the USA. Yale and Novogen have formed a US-based joint venture company, CanTx Inc. (Novogen owns 85%), for the program. For its part, Yale has identified and isolated the ovarian cancer stem cells that are responsible for tumour formation and chemo-resistance.

"Yale Medical School became involved because they are the only researchers in the world who have managed to isolate ovarian cancer stem cells. These are the cells responsible for starting ovarian cancer, its spread and its eventual recurrence after treatment," says Novogen CEO, Dr Graham Kelly. "If we are to make any real progress in fighting ovarian cancer, then we must be able to kill these cancer stem cells.

"Yale has created a library of ovarian cancer stem cells they've collected from patients who have died of the condition, and made that library available as a resource to companies. We went there with our product, and Yale said to us, 'if you think you're going to do anything meaningful, you've got to be able to knock out the cancer stem cells, otherwise the cancer just comes straight back again.' They'd looked at more than 300 compounds over the last four or five years and nothing had worked – until Cantrixil."

Not only did Cantrixil work against ovarian cancer stem cells, says Kelly, it worked against cancer cells of all types. “Once Yale saw just how powerful this drug was against cancer stem cells, they asked for an equity participation in its future, and so CanTx was born.”

Kelly says Cantrixil started life as a treatment for late-stage ovarian cancer that had failed to respond to standard forms of therapy. “We were going to give it to patients intravenously, the way all other drugs given for ovarian cancer are given,” he says. “But then we realised that it made better sense to put it directly into the abdominal cavity, where the cancer is growing and where the cancer stem cells are found. This way the cancer cells are exposed to much more effective levels of drug.”

Yale Cancer Center (sic) in New Haven, Connecticut will be the primary site for a Phase 1 clinical trial of Cantrixil in patients with late-stage ovarian cancer. These will be patients with end-stage disease but who are still relatively well. Kelly hopes to start this study in mid-2015.

Cantrixil will then be tested in a second trial in patients with more advanced cancer. Kelly says Novogen’s oncology advisors pointed out that there was an even greater clinical need, and that was in patients with cancer of the ovary, stomach, large bowel, pancreas and breast, as well as lymphomas, where the cancer was disseminated throughout the abdomen, resulting in a build-up of fluid. (This condition is known as malignant ascites and affects upwards of 40% of people with any form of cancer: malignant ascites has no standard of care, and patients generally receive palliative therapy and have an expected lifespan of three to six months.)

“Our advisers said, stop thinking only ovarian cancer, and think more broadly. Malignant ascites is a major community problem that is crying out for an effective treatment.”

“We hope to make a meaningful difference to the life of these people by hopefully putting the cancer into long-term remission so that we can extend their lives,” says Kelly.

Kelly is equally upbeat about the ATM drug technology. ATMs were discovered in 2007 by a team led by Professor Peter Gunning and Doctor Justine Stehn of the University of New South Wales. Novogen acquired this technology in 2013, with Dr Stehn joining the company as the manager of the ATM program and Professor Gunning joining the Novogen board as a non-executive director.

Kelly says the ATMs target the skeleton of the cancer cell. “Knock out the skeleton, and the cancer cell cannot function. Some of the most widely prescribed drugs in oncology (taxanes) are drugs that target the cancer cell’s skeleton, so it is a highly validated target. The problem with those drugs is that they only knock out half of the cancer cell’s skeleton. The other half remains, which means that those drugs are very limited in their

effectiveness. But despite that, they are still the most widely used drugs in chemotherapy."

The cleverness of the Gunning-Stehn discovery, he says, lies in them showing that if the entire skeleton could be knocked out, the anti-cancer effect was extraordinarily high. "They did this by making drugs that knocked out one part of the cancer cell's skeleton, and combining them with the taxanes that knocked out the other part. This comprehensive destruction of the cancer cell's cytoskeleton yielded a very potent anti-cancer effect," says Kelly. "We see the ATM drugs becoming just as widely used in chemotherapy as the taxanes are now."

Novogen anticipates having its three SBP drugs and one ATM drug in clinical trials by the end of 2015.

But for now, as the Book Build approaches, it is stock brokers and fund managers that Kelly has to spend his time talking to, not hospital ethics committees, stumping up capital instead of clinical trial participation. He says he is pleasantly surprised by how a raising works under the ASX BookBuild facility.

"For us it opens the market up enormously, we can reach all the brokers that we're not going to get around to seeing," says Kelly. "We've probably spoken to eight or ten brokers, and the idea is that they will contact their sophisticated investors clients and then direct their investment via the bookbuild. And with the one lead manager, CMC Markets, co-ordinating it all – it's a great idea," he says.

About Novogen Limited

Novogen is a public, Australian drug-development company whose shares trade on both the Australian Securities Exchange ('NRT') and NASDAQ ('NVGN'). The Novogen Group includes a New Haven, Connecticut-based joint venture company, CanTx Inc., with Yale University.

Novogen has two main drug technology platforms: super-benzopyrans (SBPs) and anti-tropomyosins (ATMs). SBP compounds have been created to kill the full range of cells within a tumor, but particularly the cancer stem cells. The ATM compounds target the microfilament component of the cancer cell and when used in conjunction with standard anti-microtubular drugs, result in comprehensive and fatal destruction of the cancer cell's cytoskeleton. Ovarian cancer, colorectal cancer, malignant ascites, prostate cancer, neural cancers (glioblastoma, neuroblastoma in children) and melanoma are the key clinical indications being pursued, with the ultimate objective of employing both technologies as a unified approach to first-line therapy.

Further information is available on our website www.novogen.com

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