

## **OZEQUITIES NEWSLETTER**

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### ***SPECIAL***

#### **Week's Special**

**NRT: TECHNOLOGY THAT FOR THE FIRST TIME ATTACKS CANCER + CANCER STEM CELLS - EXPECTED TO BE IN CLINICAL TRIALS FOR BRAIN AND OVARIAN CANCER EARLY NEXT YEAR/AIMING FOR FDA'S ACCELERATED "BREAKTHROUGH" CATEGORY. PRESTIGIOUS AND WELL RESPECTED MANAGEMENT. TIGHTLY HELD  
By Jenny Prabhu and Gerald Stanley**

Novogen Limited (NRT) founder, Prof Graham Kelly, who formed the company in 1994, returned last year after Novogen's \$1.9M takeover of Triaxial Pharmaceuticals Pty Ltd, the company that he and two other ex-Novogen employees formed after leaving Novogen in 2006.

The old Novogen had developed a family of anti-cancer drugs known as *benzopyrans* that in 2010 were sold into their listed US subsidiary, Marshall Edwards Inc (MEI). MEI is now known as MEIPharma. Novogen and MEIPharma are now fully independent companies (Novogen divested its remaining 65% stake in MEI as an in specie distribution to shareholders last year).

Triaxial took the original technology platform with the objective of creating more powerful anti-cancer drugs with greater capacity to seek out cancer cells. This led them to develop a new family of drugs known as *super-benzopyrans* which can be thousands of times more potent than the original *benzopyran* drugs.

These new drugs display very high killing activity against all forms of cancer cells, but in a ground-breaking discovery, also kill the undifferentiated (or stem) cancer cells in tumors. These cells are believed to be the originators of cancer and also are responsible for a tumor developing resistance to anti-cancer drugs. No standard anti-cancer drugs on the market today kill these cancer stem cells.

The Company's first super-benzopyran drug, CS-6, has been shown to kill both regular cancer cells as well as cancer stem cells. The Company believes that this is the first drug to do so at drug levels that can be achieved in patients and without causing serious side-effects.

***Targeting cancer stem cells is a new direction in oncology drug development as a means of preventing cancer recurrence and NRT leads the field.***

#### **CS-6**

The Company is targeting CS-6 at brain cancer and ovarian cancer. There are a few reasons for this. First, both are cancers where there is a substantial unmet clinical need - there are no available therapies. This means that bodies such as the FDA in the US lower the bar to bringing any successful therapies to market. A second reason is that CS-6 has been deliberately designed to cross the blood-brain barrier. This is a physical barrier that prevents drugs from leaving the bloodstream to enter brain tissue. Only one anti-cancer drug is able to do this, known as temozolomide. Unfortunately, this drug only works in about 20% of cases of the main form of brain cancer and even then, only delivers short-term benefit of several months. Having the ability to cross this barrier gives CS-6 an enormous advantage in the race to find an effective treatment for brain cancer.

Novogen expects to be in the clinic in patients with glioblastoma (the main form of brain cancer) in 2Q14. This will be in an Australian hospital.

The ovarian cancer indication is being pursued in collaboration with Yale University Medical School and a Phase 1b trial in late-stage ovarian cancer is scheduled to start in 2Q14 in the US.

#### **FDA Breakthrough Status**

The FDA recently announced a new policy on drug approval. In areas of significant unmet clinical need (eg. multiple sclerosis, motor neurone disease, brain cancer etc) where no effective therapies are available, the FDA in Feb 2013 said that it will greatly accelerate its approval process for drugs that show early clinical benefit in any of these areas.

Novogen has said that it proposes to conduct its Phase 1b studies with a view to achieving Breakthrough status for CS-6.

Phase 1b studies normally are focused on determining the safety of the experimental drug. The drug is given in increasing dosages in an effort to identify the highest dose that is safe to use. Phase 1b patients normally have advanced cancers with no remaining treatment options. They usually have cancers across the full spectrum of cancer type and given the late stage of those cancers, it is highly unusual to see any anti-cancer effect. That is, Phase 1b studies at the moment are all about safety and not about clinical benefit.

For its Phase 1b studies, Novogen will be recruiting patients with the same type of cancer (glioblastoma or ovarian cancer) to give it the best opportunity to see early clinical responses.

#### **NOVOGEN LTD - A SNAPSHOT**

Novogen Ltd was founded as Norvet Ltd in 1994 by Dr Graham Kelly. It originally focused on developing both human and veterinary therapeutics including glucans and a group of naturally occurring plant compounds known as isoflavones. The company soon dropped its veterinary interests, focusing on its human therapeutic business, and changing its name to Novogen Ltd in 1997.

Novogen then set about building a business based around naturally-occurring compounds known as isoflavones. It had identified these relatively common dietary compounds as having highly interesting biological properties and had an extensive R&D program looking at developing these as pharmaceuticals in cancer, cardiovascular and inflammatory diseases. In the meantime, it used its knowledge of these compounds to bring to market two products, Promensil and Trinovin, as dietary supplements. Novogen set up a global marketing network for these two products, eventually selling the consumer product business for \$10.1m in 2011. These two products continue to be sold world-wide today.

Meanwhile, Novogen continued with its primary focus of drug development, with an increasing focus on anti-cancer drugs. The anti-cancer drug technology was licensed into subsidiary MEI in 2001 and the company floated on NASDAQ. Eventually four anti-cancer drugs were developed and put into MEI.

Dr Kelly left Novogen in 2006, reportedly dissatisfied with the research and commercial directions being taken by the Board.

By 2011, it looks like Novogen either was being wound-up or prepared for a back-door listing opportunity. Novogen proceeded to sell off the consumer product business, another subsidiary, Glycotex Inc was sold off, and all of the Company's isoflavone drug technology was sold into MEIPharma, with Novogen's remaining 65% of MEIPharma distributed in specie to shareholders.

By the end of 2012, the only assets in the Company were about \$1m in cash and its ASX and NASDAQ dual listings.

Triaxial Pharmaceuticals, the company that Dr Kelly and two other ex-Novogen employees had put together, then did a reverse takeover of Novogen, funded by a Convertible Note issued by Triaxial from funds provided by Hudson Bay Capital, which is to be repaid in the form of shares that will be granted on three key milestones being met – successful completion of a Phase 1a study, grant of IND or Breakthrough status by the FDA, and successful completion of a Phase 2 study.

Novogen currently employs 5 people. It is being run on a 'virtual' basis with a small management group coordinating an extensive R&D drug program outsourced to universities and other biotech companies around the world. This is a vast difference to the older Novogen which at one stage employed 100 staff and ran all its own laboratories. Novogen now works with a large Swiss chemical manufacturer that is producing CS-6 and other new drugs. This virtual model gives the company tighter control over its finances and allows it to switch on and out of projects with greater flexibility.

Novogen has stated publicly that it believes it is better placed than any other company in the world to deliver a drug(s) that will offer cancer patients the chance to achieve long-term remission by killing both regular cancer cells (which current standard therapies target) and the cancer stem cells (currently untreatable).

As experienced investors in the biotech sector know, the path to success cannot be guaranteed, even for the most promising of drug candidates being developed by the world's largest biotech companies.

But the rewards when success is achieved for even the largest biotech firms are huge and for small biotechs, when a new drug achieves clinical Phase II or III success, the gains are spectacular.

Under highly regarded management, and with some of the world's most prestigious funds as major shareholders (becoming shareholders within the last few months) alongside management, Novogen is an opportunity well worth considering.

While some brokers are believed to be working on reports, none are yet public.

#### NOVOGEN LTD FINANCIALS

Code: NRT  
Last Traded price 17c.  
Shares Issued 139.1m.  
Market Cap 23.65m.  
Year ended June 30, Values in \$m's

<b>INCOME</b>	<b>2013 Int</b>	<b>2012</b>	<b>2011</b>
Op Revenue	0.61	1.51	2.03
Op Profit (loss)	0.02	(1.35)	(9.48)
Net profit (loss)	0.02	1.31	(9.48)
(Loss)PS (Cents)	0.01	1.3	(6.4)

<b>BALANCE SHEET</b>	<b>2013 Int</b>	<b>2012</b>	<b>2011</b>
Current Assets	1.33	8.96	12.66
Non Current Assets..	2.91	0.03	0.06
Current Liabilities	0.40	3.87	8.20
Non Current Liabilities	0.93	0.01	0.10
Net Assets & Shareholders' Funds	2.91	5.11	4.42
Less Outside Interests	-	1.64	0.19
Shareholders Net Equity	2.91	3.47	4.23
Gearing (Net of Cash) %	.nil	.nil	.nil
NTA per share (cents)	0.06	5	4
Shares Issued (m's)	103.8	103.8	102.1

<b>Cash Flows:</b>	<b>2013 Int</b>	<b>2012</b>	<b>2011</b>
Cash on hand (at open)	8.10	5.77	14.13
Operating Activities	(7.54)	0.64	(8.70)
Investing	0.18	-	0.29
Financing Activities	-	1.75	0.76
Exchange Rate Impacts	-	(0.06)	(0.71)
<b>Cash on hand at Year end</b>	<b>0.74</b>	<b>8.10</b>	<b>5.77</b>

Novogen has raised capital on 3 occasions this year. The first was in March with a private placement organized by Patersons raising \$2.4M. Then \$800K was raised in April through an SPP. On July 4 Novogen announced it has put a funding arrangement in place with a US-based institutional investor, Hudson Bay Capital Management LP, via a Convertible Note to raise \$A5 million. Hudson Bay will be able to convert a portion of the note into equity at either a 10% discount to the stock's three day VWAP or a 30% premium to NRT's current 5 year VWAP. The funding is seen as sufficient to bring CS-6 through into the clinic, as well as the secondary goal of identifying a panel of phenotype specific anti cancer drugs for the purpose of personalised chemotherapy, and minimising dilution to existing shareholders.

**Directors:**

**Prof. Graham Kelly**, B.Sc (Hons), B.VSc (Hons), Ph.D. Executive Chairman and CEO.

Was founder and previous CEO and Chairman of Novogen and Marshall Edwards Inc. Has spent 25 years in cancer research at the Department of Surgery, University of Sydney and German Central Cancer Research Institute, Heidelberg. Prof Kelly has personally overseen the design and implementation of thirty three Phase I and II clinical trials, and a multi national Phase III trial in conjunction with the US FDA.

**Robert Birch** Non-Executive Director and Deputy Chairman.

A Royal Australian Navy officer for 23 years, later established a successful business he has managed for 20 years. A long-term Novogen shareholder and founding investor in Triaxial Pharmaceuticals.

**Dr Andrew Heaton** BSc (Hons), PhD, President and CEO, Novogen North America.

Has an extensive drug discovery background.

Dr Heaton completed his Ph.D in a study of the complex interactions of signaling molecules associated with the mass spawning phenomena on the Great Barrier Reef. He first joined Novogen in 1998 as GM of the drug discovery program, progressing 4 compounds to clinical trials. He is the principal inventor on a series of global patents for Novogen's lead compounds, ME-128, ME-196, ME-143 and ME-344 . He was instrumental in setting up Triaxial Pharmaceuticals and developing their novel technology platform.

**John P O'Connor** B.Ec, MAICD, Non Exec Director.

A funds management and stockbroking veteran, having worked across Australia, the UK and US.

**Steven Coffey** CA. Non-Executive Director

A chartered accountant with an extensive public practice over the past 30 years including as partner at Watkins Coffey Martin since 1993.

Company Secretary : **Andrew Bursill**

**Major shareholders:**

El Coronado Holdings 16/17%

Southern Company System Master Retirement Trust 7.921%.

Massachusetts Mutual Life Insurance 7.7546%.

Dr Andrew Heaton has 6.47%

Prof Kelly about 6%