Biotech Daily's CEO interview

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NOVOGEN'S CHRIS NAUGHTON:
'THE LONG WAIT FOR PHASE III RESULTS'

A thoroughly Sydney boy, Novogen's Chris Naughton has impeccable political qualifications, but has taken a completely different professional course.

Educated at Prime Minister Gough Whitlam and Nationals leader Ian Sinclair's alma mater, Knox Grammar, Mr Naughton is quite proud of his primary school association with Midnight Oil and Labor environment spokesman Peter Garrett and his senior school contemporary Finance Minister Senator Nick Minchin.

His qualifications would suit a budding politician as much as a biotech chief executive officer, with a Bachelor of Economics from the Australian National University and an Bachelor of Laws from the University of New South Wales.

Chris Naughton's working life began in real estate before ascending to licencee of the Rag and Famish "the oldest pub in North Sydney". He joined the merchant bank AMP Morgan Grenfell as a dealer and became an AMP in-house corporate lawyer.

Moving to Wellcome Australia as in-house counsel and director led to London and the Wellcome Foundation and "that's where I fell in with biotech," Chris Naughton says.

Returning to Australia he joined Novogen in 1996 and took the reins as CEO in 1997.

At yesterday's Melbourne presentation to investors and shareholders, Mr Naughton and the heads of the company's cardiovascular and oncology division Dr Cath Walker and Dr David Brown mapped out Novogen's evolution from wound care and research into isoflavonoids derived from legumes to a technology platform led by phase III candidate phenoxodiol for drug-resistant ovarian cancer. And phenoxodiol appears to be a more general cancer treatment, with potential as a monotherapy.

The phase III phenoxodiol 'Overture' trial will enroll 470 women in 60 centres in Europe the US and Australia and cost Novogen $25 million of its $55 million cash reserves.

An analysis of interim results will be possible after 95 patients have progressed with their disease and with full enrolment completed the route to registration should be relatively quick under the US Food and Drug Administration special protocol assessment (SPA). If the data is significant, it can be used to support a request for grant of marketing approval.

Chris Naughton said the phase II results were very encouraging and Novogen's share price was attributable to the lack of news as the major trial proceeded.

"We're in better shape than we've ever been and a better prospect than ever and the share price has languished.

"US investors and Australian shareholders have a fairly good understanding of our current program and opportunity. Shareholders like the company, like the science and think it can be a great benefit to patients.

"Some drugs have been registered because they offer weeks of benefit for end-stage patients. We're planning for a statistical benefit. We saw that in our phase II trial – we had survival of 20 weeks over published data – and if we see that in the phase III trial under the SPA, we have every expectation of FDA approval," Mr Naughton said.

Phenoxodiol is also under investigation for prostate cancer and is only the first of a pipeline of drug candidates. Novogen has "31 patent families, 75 patents granted world wide and 230 applications in the system".

NV-196 is being researched for bile duct and pancreatic cancer with an investigational new drug application planned for early in 2008. Dr David Brown said NV-196 killed pancreatic cancer cells in mice by inducing apoptosis while leaving healthy cells unharmed. NV-143 is being tested for melanoma.

Dr Cath Walker said NV-52 was in phase I trials for inflammatory bowel disease and a flavonoid anti-inflammatory molecule (FAIM) was hoped to replace non-steroidal anti-inflammatory drugs and COX inhibitors for a range of inflammatory diseases including arthritis.

NV-27 and NV-147 are at the preclinical stage as adjunctive therapies for problems associated with cardiac stents.

Glyc-101 has completed phase II trials for wound repair, in particular for venous ulcers.

“We are a technology company not an anti-cancer or cardiovascular company,” Chris Naughton said.

“Opposite to other drug companies who start with a problem and try to fit a molecule to a receptor, we’ve started with a safe compound and made it more active,” Mr Naughton said.