

# Biotech Daily

## Marc Sinatra's Bioguide

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### NOVOGEN – CATCHING A FALLING KNIFE

**Overview:** The first thing you notice about Novogen is that their share price has been falling for most of the last four years, from a high of \$8.49 on December 5, 2003 to yesterday's close of \$1.325. Looking deeper into the company, you see an initial foundation built on alternative medicines, a range of subsidiary companies and a technology that is producing potential drugs with widely varied applications. This plus the falling share price, could lead one to think that Novogen is a blue-sky company that is now well and truly post-blue-sky.

Over this same period of time, the company, through its majority-owned subsidiary Marshall Edwards Inc, has moved its lead anti-cancer drug, Phenoxodiol, steadily through development to the point where it has gained US Food and Drug Administration fast track status for resistant ovarian cancer and hormone refractory prostate cancer and is in a phase III trial for resistant ovarian cancer as a combination therapy with carboplatin, under an FDA special protocol assessment. This type of progress hardly seems to justify Novogen's sustained, long term, share price slide.

Is Novogen the falling knife its share price suggests or is its handle big enough to be caught safely?

**Financials:** Market cap: \$129 million; group cash: \$50.7 million; 2007 gross profit on sales: \$3.6 million; 2007 group loss: \$24.3 million.

**Directors & Management:** Independent chairman, Philip Johnston; managing director, Christopher Naughton; non-executive directors, Peter Simpson, Prof Paul Nestel; Geoffrey Leppinus; executive director, Prof Alan Husband.

Novogen has a solid board with skills covering the required areas. Two professors is probably one too many. Academics do their best work on advisory boards.

**Group Divisions & Activities:** Novogen has four divisions.

1) Pharmaceutical - Isoflavone-based internal drug development division:

- a. Anti-restenosis compounds - a phase I trial of an early compound successfully completed. A phase I trial of a more active compound is scheduled for 2008.
- b. NV-52 - an anti-inflammatory compound being developed for inflammatory bowel disease (IBD). Phase IIa trial to commence in Q1, 2008.

2) Marshall Edwards Inc - 72% Novogen owned. Licensees of putative anti-cancer compounds from Novogen. Currently developing:

- c. Phenoxodiol - an anti-cancer drug that evidence suggests may be able to re-sensitize resistant cancers to some anti-cancer drugs, while also having an anti-cancer effect in its own right. In addition to the trial above, Phenoxodiol is in an investigator sponsored phase II trial as a monotherapy for prostate cancer and is completing a phase I trial as monotherapy for cervical cancer.
- d. Triphenidiol 196 - Similar to phenoxodiol. It is being developed as a treatment for pancreatic cancer and cholangiocarcinoma (bile duct cancer). Currently, in a phase I trial.

3) Glycotex Inc - 81% Novogen owned. Licensees of putative wound management compounds from Novogen. They are developing a topical treatment for chronic venous ulcers, which has completed a phase II trial.

4) Consumer Products - Isoflavone-based over the counter products Promensil (menopausal and post-menopausal formulations) for women and Trinovin for men. They also produce a menopause test. The US rights to Promensil and Trinovin have been licenced to Natrol Inc. Sales are likely to remain stable.

**Significant Product Markets:** The most relevant markets are those for Phenoxodiol. Those for IBD and wound management are also significant.

Worldwide 190,000 patients are diagnosed with ovarian cancer, 680,000 with prostate cancer and 473,000 with cervical cancer. The ovarian cancer therapeutic market is estimated at \$US600 million and the prostate cancer market at \$US2.1 billion. The cervical cancer market is in a state of flux with the recent introduction of cervical cancer vaccines. There are a reasonable number of drugs in development for resistant ovarian cancer and hormone refractory prostate cancer. The most anticipated of the ovarian cancer drugs is Avastin. There are few therapeutics in development for cervical cancer.

Up to 3.6 million people in Europe and the US suffer IBD. There are a number of treatments and most have significant side effects. The IBD market is about \$US1.5 billion.

The wound management market is worth billions of dollars, with many single indications worth more than \$US1 billion.

**Verdict:** One issue I have with Novogen's isoflavone technology is that the mode(s) of action is not overly clear. For this reason, Novogen's future is highly dependent on Phenoxodiol, not just because of the cash it could generate, but because of the credence it will give to the other earlier stage compounds they have in development.

Phenoxodiol's chance of success can be gauged by looking at flavopiridol. It is chemically similar to Phenoxodiol and has been studied in a range of cancers. As a monotherapy, flavopiridol's results have been disappointing and explain Novogen's share price slide. Recent results from the Mayo Clinic, however, show that flavopiridol combined with cisplatin produces a response rate twice that usually seen in resistant ovarian cancer, an almost identical to the response obtained when phenoxodiol is used with cisplatin.

I doubt Phenoxodiol will be a blockbuster, but I do think there is a reasonable chance it will find its way to market and create solid cash flows. In doing so, it will also increase interest and belief in Novogen's other compounds.

Catching this knife may be hard, but the handle is visible. I value the stock at \$1.74 a share.

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