



Biotech Daily

Wednesday April 3, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: VIRALYTICS UP 12%, ANTISENSE DOWN 10%**
- * **STARPHARMA VAGINOSIS TRIAL 'NOT SIGNIFICANT'; ADVERSE EVENTS**
- * **RESONANCE WINS \$200k EU TRIAL CONTRACT**
- * **IDT APPOINTS DR PAUL MACLEMAN CEO ON \$300k**
- * **NOVOGEN: 'CS-6 KILLS OVARIAN CANCER STEM CELLS IN-VITRO'**
- * **ADVANCED SURGICAL RAISES \$252k OF HOPED-FOR \$1.5m**
- * **CONSEGNA SHARES, OPTIONS CONSOLIDATION CODE CHANGE**
- * **DATA BOARDS BACK PRANA HUNTINGTON'S, ALZHEIMER'S TRIALS**
- * **JASON PETERSON, ASSOCIATES TAKE 9% OF CONSEGNA**
- * **NEURODISCOVERY APPOINTS MARTIN ROGERS DIRECTOR ON \$80k**
- * **VICTORIA PRESENTS VOUCHER WINNERS AT STC NETWORKING EVENT**

MARKET REPORT

The Australian stock market fell 0.56 percent on Wednesday April 3, 2013 with the S&P ASX 200 down 27.8 points to 4,957.7 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and five were untraded.

Viralytics was the best, up 3.5 cents or 12.1 percent to 32.5 cents with 179,566 shares traded.

Benitec climbed 8.3 percent; Anteo, Neuren, Patrys, Sirtex and Tissue Therapies were up more than three percent; Living Cell rose 2.2 percent; with Heartware and Resmed up by less than one percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents with 3.1 million shares traded.

Osprey lost eight percent; Medical Developments fell 7.8 percent; Genetic Technologies was down 5.4 percent; Phylogica, Prana and Prima fell more than four percent; Cellmid was down three percent; with Acrux, Atcor, Bionomics, Circadian, Cochlear, GI Dynamics, Nanosonics and Pharmaxis were down more than one percent.

STARPHARMA

Starpharma says that its phase II trial of Vivagel for recurrence of bacterial vaginosis was clinically, but not statistically, significant with a greater rate of adverse events.

After the market closed, Starpharma said that the one percent dose of Vivagel was close to statistically significant in reducing the risk of bacterial vaginosis at week-16 compared to placebo ($p = 0.0588$).

The company published data showing that discontinuing Vivagel treatment provided little if any longer term protection from the recurrence of bacterial vaginosis.

Starpharma said that reducing the risk of recurrence through the use of one percent Vivagel was "considered to be clinically significant".

Starpharma said that 179 patients were recorded in the trial with 65 receiving one percent Vivagel (SPL7013), 53 receiving three percent Vivagel and 61 patients on placebo.

The company said that across all measures there was little difference between the three percent Vivagel and placebo groups.

Starpharma said that a total of 205 patients were enrolled in the randomized, double-blind, multi-centre, placebo-controlled, dose-ranging study of women with active bacterial vaginosis and a history of recurrent bacterial vaginosis.

The company said that recurrent bacterial vaginosis was defined as a history of at least three episodes in the past 12 months, including the current episode.

Starpharma said that after screening for bacterial vaginosis, and receiving successful treatment with metronidazole for seven days, eligible subjects were randomized at baseline to receive one percent SPL7013 gel, three percent SPL7013 gel, or placebo gel every second day for 16 weeks, followed by an eight-week follow-up period without drug. In results published by Starpharma there was no difference in the percentage of women with symptoms at 20 weeks what appeared to be a slight advantage for Vivagel at 24 weeks.

The company said there were no deaths or serious adverse events during the study and in general, the safety profile of SPL7013 gels and placebo was comparable.

Starpharma said that 19 percent of women in the one percent SPL7013 gel, compared with 18 percent in the three percent SPL7013 gel group and 13 percent in the placebo group experienced any treatment-related adverse events.

The company said that treatment-related genitourinary adverse events were reported in 19 percent of women in the one percent SPL7013 gel group, compared with 17 percent in the three percent SPL7013 gel group and 13 percent in the placebo group.

Starpharma said that candidiasis was reported in 19 percent of women in the one percent SPL7013 gel group, compared with 26 percent in the three percent SPL7013 gel group and 15 percent in the placebo group.

The company said that during treatment, 15 percent of women reported candidiasis in the one percent SPL7013 gel group compared with nine percent in placebo.

Starpharma said the results showed a reduced overall risk of the recurrence of bacterial vaginosis in patients using one percent Vivagel and time to first recurrence was delayed compared with placebo and demonstrated the ability of Vivagel to inhibit recurrence, providing "strong support for the advancement to phase III clinical trials".

Starpharma chief executive officer Dr Jackie Fairley said the company was "very pleased with these phase II results".

"We have seen consistently lower recurrence rates with Vivagel by every measure and these clinically relevant findings, if replicated in an appropriately designed larger phase III study, would yield a positive pivotal result," Dr Fairley said

Starpharma last traded at \$1.085.

RESONANCE HEALTH

Resonance says it has a two-year \$200,000 agreement to provide image analysis services for a European Union-funded clinical trial of an iron chelation therapy. Resonance said the project, entitled Deferiprone Evaluation in Paediatrics would require Ferriscan liver iron concentration measurements and cardiac iron overload measurements to about 15 magnetic resonance imaging centres in Europe and North Africa. The company said that the patients in the study had inherited blood disorders that required regular blood transfusions from a very young age, which could result in iron overload.

Resonance said that the European organisation commissioned to run the study, Consorzio per Valutazioni Biologiche e Farmacologiche, evaluated technologies for the measurement of iron overload and concluded that Ferriscan "showed a better accuracy compared to other MRI technique and can be used routinely in the liver iron measurement".

Resonance said it was contracted to provide Ferriscan services in trials of three different iron chelation drugs and funding by the European Union "further consolidates Ferriscan's reputation as the gold standard test for the measurement of liver iron overload".

Resonance was up 0.2 cents or 13.3 percent to 1.7 cents.

IDT AUSTRALIA

IDT has appointed Dr Paul MacLeman as chief executive officer, effective from April 15, 2013 on a base salary of \$300,000 a year.

IDT said that Dr MacLeman had led a number of companies through turnaround and expansion programs, successfully transitioning geographically or sector restricted business to new markets and, like IDT, those businesses had sound business and asset foundations but required a re-focusing of strategy to generate maximum value.

IDT said that most recently Dr MacLeman was the chief executive officer of Genetic Technologies "where he led a significant turnaround of the business, building on the non-proprietary genomics capability through acquisition and US launch of new assets to create a growing global cancer diagnostics business".

In 2011, Biotech Daily awarded Dr MacLeman the chief executive officer of the year title for his efforts at Genetic Technologies (BD: Dec 15, 2011), but in 2012, founder and major shareholder Dr Mervyn Jacobson moved against then chairman Dr Mel Bridges, precipitating Dr MacLeman's resignation (BD: Nov 27, 28, 2012).

Previously, Dr MacLeman was the chief executive officer of Hatchtech and before that the general manager of veterinary pharmaceutical company RWR Nature Vet Pty Ltd.

Dr MacLeman holds a Bachelor of Veterinary Science from the University of Sydney, a Post Graduate Certificate of Engineering, from Wollongong University, a Graduate Diploma in Technology Management from Melbourne's Swinburne University and a Masters of Business Administration from Macquarie Graduate School of Management.

IDT said that Dr MacLeman's annual base salary would be \$300,000, excluding statutory superannuation, with an annual performance bonus of up to 30 percent of base salary, the immediate issue of 250,000 executive options exercisable within four years, at a 20 percent premium to the five-day volume weighted average price to April 3, 2013 and the immediate issue of a further 250,000 executive options at a 50 percent premium to the five-day volume weighted average price to April 3, 2013.

The appointment of Dr MacLeman follows the appointments of director Dr Roger Aston and business development manager Dr Ashley Bates (BD: Mar 20, Jul 19, 2012).

IDT was up two cents or 8.3 percent to 26 cents.

NOVOGEN

Novogen says that further in-vitro research has shown that CS-6 is highly cytotoxic against ovarian cancer stem cells.

In February, Novogen said an in-vitro study by Yale University spin-off Mazor Oncology, designed to test the ability of CS-6 to kill ovarian cancer stem cells showed anti-cancer activity against cancer cells representative of malignancies, including ovarian cancer and glioma (BD: Nov 19, 2013).

Today, Novogen said a follow-up study examined the effect of CS-6 against a range of other ovarian cancer stem cell lines, including cell lines virtually indestructible by both standard-of-care and experimental anti-cancer drugs.

The company said the study also looked at the effect of CS-6 on the differentiated daughter cells of the cancer stem cells, mirroring the situation in patients with ovarian cancer where the cancer responds to chemotherapy initially, but then recurs, with the chemo-resistant cancer stem cells in the tumor surviving the chemotherapy to produce a new population of daughter cells with increased resistance to chemotherapy.

Novogen chief scientific officer Dr Andrew Heaton said that the cancer stem cell lines used in the follow-up study were "extraordinarily difficult to kill".

"They are impervious to virtually all drugs," Dr Heaton said.

"Drug levels required to kill these cells typically have been so high as to be impractical or would be so toxic as to destroy the rest of the body," Dr Heaton said. "The behavior of these cells is why late-stage ovarian cancer carries such a poor prognosis."

"CS-6 proved to be highly cytotoxic against all cancer stem cell lines tested," Dr Heaton said. "But even more impressive was the sensitivity of the cancer stem cells to CS-6, with both the cancer stem cells and their daughter cells being wiped out at drug levels down to picomolar levels [and] just as remarkably, the cytotoxic effects of CS-6 were evident as early as 4 hours."

Novogen chief executive officer Dr Graham Kelly said that for many common cancers, cancer stem cells were thought to be the reason why cancers recur after responding initially to treatment and "having the ability to knock out these progenitor cells holds the potential at most of being able to block the growth and establishment of cancers, and at least of being able to prevent or slow down cancer recurrence following anti-cancer therapy".

Novogen was up 12.5 cents or 73.5 percent to 29.5 cents with 7.9 million shares traded.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical says its one-for-three rights issue has raised \$252,440 of a hoped-for \$1.5 million for sales development and working capital (BD: Feb 25, 2013).

Advanced Surgical said it received applications for 2,294,903 shares at 11 cents a share and the rights issue was undersubscribed by 11,274,047 shares which the company would attempt to place.

Advanced Surgical was unchanged at 10.5 cents.

CONSEGNA GROUP

Consegna says its shares will trade under the ASX code CGPDA and listed options under CGPDB during the five-to-one consolidation process until April 16, 2013.

The company said shares would resume trading under the code CGP and options under the code CGPO on April 17, 2013.

Consegna was up 0.5 cents or 14.3 percent to four cents (post-consolidation).

PRANA BIOTECHNOLOGY

Prana says two independent data safety monitoring boards have recommended that its phase II trials of PBT2 for Huntington's and Alzheimer's disease continue as planned.

Prana said that both boards met at the end of March.

The company said that across the two trials about 37 percent of patients had been dosed to six months or longer, twice the duration of the previous phase II Alzheimer's trial.

Prana said that PBT2 was well tolerated and both trials were on schedule "with very pleasing retention rates and compliance".

The company said that the Alzheimer's disease imaging trial (Imagine), with 12 months of treatment aimed to establish PBT2 as a safe and effective treatment for Alzheimer's disease, with the last patient recruited in November 2012 and expected to have the last dose in November 2013.

The company said that seven percent of patients had completed 12 months of dosing and 50 percent had reached 26 weeks of dosing.

Prana said that the Huntington's disease trial was a six month trial in 109 patients with early to mid-stage Huntington disease, with the last patient recruited in December 2012 and expected to be dosed in June, 2013 with results in October, 2013.

The company said that 97 percent of patients had completed 12 weeks of dosing, equal to previous longest exposure of PBT2 and 32 percent had completed six months of dosing.

Prana fell one cent or 4.55 percent to 21 cents.

CONSEGNA GROUP

Jason Peterson and associated companies have become substantial shareholders in Consegna with 126,744,999 shares or 8.86 percent.

The initial substantial shareholder notice said that the Perth-based Mr Peterson was associated with Celtic Capital Pty Ltd, Professional Payment Services Pty Ltd and Cunningham Peterson Sharbanee Securities.

In February, Consegna raised \$632,500 through a share purchase plan and placement at 0.4 cents a share (BD: Feb 15, 2013).

NEURODISCOVERY

Neurodiscovery says it has appointed Martin Rogers as deputy chairman effective immediately.

Neurodiscovery said that Mr Rogers was the former chief executive officer of Prima and continued as a non-executive director of Prima.

The company said that Mr Rogers held degrees in chemical engineering and science, had experience in incubating companies and helped raise more than \$100 million.

Neurodiscovery said that Mr Rogers was chairman of Consegna and a director of Cellmid.

The company said that Mr Rogers's remuneration package included a salary of \$80,000 a year plus statutory superannuation contributions as well as 19,000,000 options subject to shareholder approval.

Neurodiscovery said that along with the appointment of Dr Roger Aston as a director and the Enigma Therapeutics acquisition, the appointment of Mr Rogers "created a stronger management team to advance the company's business".

The company said that subject to shareholder approval it would place 10,000,000 shares to Mr Rogers at 2.5 cents a share to raise \$250,000 for working capital.

Neurodiscovery was up half a cent or 13.9 percent to 4.1 cents with 2.5 million shares traded.

VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

Victoria Minister for Technology Gordon Rich-Phillips will award technical implementation vouchers at a Small Technologies Cluster networking event on April 11, 2013.

A media release from the Small Technologies Cluster (STC) said the event would continue the event series discussing Victoria's impact in small technologies, industrial biotechnology and information and communications technology, highlighting the progress of the State Government's technology voucher program (TVP).

The Small Technologies Cluster said the afternoon would feature presentations from past small technology industry uptake program (STIUP) and TVP applicants and suppliers discussing how the program helped them to absorb technologies into their products, processes and services, followed by an expert panel session, chaired by Minifab chief executive officer Erol Harvey.

The Cluster said that presentations would include will include Anatomics Andrew Batty and the Commonwealth Scientific and Industrial Research Organisation's Jim Grigoriou on their craniofacial implant; as well as Universal Biosensors' Fred Davis and Planet Innovation's Ian McFarlane on a microfluidic biosensor diagnostic device.

The Cluster said the expert panel would comprise STC chairman Andrew Kings, Australian Industry Research Group president Leonie Walsh, Australian Academy of Technological Sciences and Engineering chief executive officer Margaret Hartley, Mr Harvey and a representative from Victoria's Department of Business and Industry

The networking event will be held at 1 Dalmore Drive, Caribbean Business Park, Scoresby on Thursday April 11, 2013 with presentations from 3pm.

The Cluster said that although a free event, registration was necessary to Nicole Goding, by email to nicole@stc-melbourne.com by April 5, 2103.