# Biotech Daily

Monday May 26, 2014

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: ANTISENSE UP 11%, BIOTRON DOWN 6%**

*** FDA REQUIRES QRX MOXDUO 'SUPERIORITY'**

*** CLINICAL GENOMICS READY FOR COLOVANTAGE PLASMA ROLL-OUT**

*** US PATENT FOR PRIMA'S CVAC FOR OVARIAN, PANCREATIC CANCER**

*** PHOSPHAGENICS: 7% OPPOSE REMUNERATION, DIRECTORS OPTIONS**

*** VERITAS TAKES 6% OF COCHLEAR**

*** MEDICINES AUSTRALIA TO LOSE CHIEF EXECUTIVE DR BRENDAN SHAW**

*** ACUVAX APPOINTS ALEX BAJADA DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.36 percent on Monday May 26, 2014 with the S&P ASX 200 up 20.0 points to 5,512.8 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Antisense was the best, up 1.5 cents or 11.1 percent to 15 cents with 223,306 shares traded.

Oncosil climbed 9.5 percent; Genetic Technologies was up 8.1 percent; Prima was up 6.4 percent; Cellmid, Compumedics and Pharmaxis were up more than four percent; Ellex was up 3.2 percent; Optiscan rose 2.5 percent; Clinuvel was up 1.4 percent; with Cochlear, CSL and Resmed up by less than one percent.

Biotron led the falls, down 0.6 cents or 6.3 percent to 8.9 cents with 320,594 shares traded.

Universal Biosensors lost 5.3 percent; Admedus and Atcor fell more than four percent; Tissue Therapies was down three percent; Analytica, Anteo, Benitec, GI Dynamics, Phosphagenics and Prana shed more than two percent; Bionomics, Nanosonics, Neuren and Starpharma were down more than one percent; with Alchemia, Acrux and Sirtex down by less than one percent.

## QRX PHARMA

QRX says the US Food and Drug Administration requires a demonstrated clear benefit for Moxduo over oxycodone and morphine alone.

QRX said that it had received the FDA complete response letter following the third rejection of the Moxduo new drug application in April for the treatment of moderate to severe acute pain (BD: Apr 23, 2014).

QRX originally said that under the FDA combination rule it only needed to show that Moxduo's combination 12mg morphine and 8mg oxycodone was no worse than 12mg morphine alone and 8mg oxycodone alone (BD: Aug 5, Dec 16, 2008).

Following the first rejection in 2012, the FDA said it required evidence comparing Moxduo to equi-analgesic doses of its component parts, either 24mg morphine alone or 16mg oxycodone alone (BD: Jun 27, 2012).

Today, QRX said that the FDA has said there was not sufficient evidence to support approval of Moxduo at this time.

The company said that the FDA "indicated clinical information demonstrating a clear benefit over oxycodone and morphine alone, either by efficacy, or safety, in an appropriate patient population, [was] needed".

QRX said it was reviewing the Agency's feedback and would request a meeting with the FDA to clarify the steps required for approval.

QRX chief executive officer Dr Ed Rudnic said the company would "work with FDA to develop a clinical program that addresses the Agency's feedback and ensure that the completed program will clearly demonstrate Moxduo's benefit".

QRX fell 0.2 cents or 2.4 percent to 8.1 cents.

## CLINICAL GENOMICS

Clinical Genomics says it is ready to roll-out its Colovantage Plasma, the first commercially-available blood-based test for bowel cancer in Australia.

Clinical Genomics said the test would be subject to a series of regional pilot projects later in 2014 and was the result of a decade of research with the Commonwealth Scientific and Industrial Research Organisation and Flinders Centre for Innovation in Cancer in Adelaide.

The company said that the molecular test was based on two genes that leaked into the blood and could detect 65 percent of bowel cancer cases, increasing to 73 percent for more advanced cancers.

Clinical Genomics chief executive officer Dr Larry LaPointe said the company was working with stakeholders in bowel cancer testing to confirm the appropriate place for the test in the context of existing protocols.

"The test is primarily intended for patients who cannot, or will not, carry out recommended screening with a faecal immunochemical test for occult bleeding," Dr LaPointe said.

Speaking at the General Practitioner Conference and Exhibition in Sydney on May 24, 2014, Dr LaPointe said that general practitioners would "clearly play a key role as the blood test evolves".

Colorectal surgeon and Bowel Cancer Australia spokesperson, Prof Graham Newstead said the test was "an important development in bowel cancer screening."

"A continuing focus on [faecal immunochemical test] first with the option of a blood test for those who would not otherwise screen has the potential to see more Australians participate in screening and more lives being saved," Prof Newstead said.

Clinical Genomics is a private company.

## PRIMA BIOMED

Prima says the US Patent and Trademark Office has allowed a patent protecting CVac for ovarian and pancreatic cancer.
Prima said that the patent was entitled 'Compositions for immunotherapy and uses thereof' with protection to at least September 2018, pending the formal grant of the patent.
The company said that the patent application protected the method of composition and method of use of its CVac for the generation of a cytotoxic T-cell response against the mucin 1 antigen.
Prima said that CVac was a personalized immunotherapy composed of patients' own dendritic cells pulsed with the cancer antigen mucin 1, conjugated to oxidised mannan fusion protein.
The company said that the pulsed dendritic cells were then re-injected into the patient to stimulate an immune response to the mucin 1 cancer antigen.
Prima chief executive officer Matthew Lehman said that "the allowance of this key US patent is a significant milestone".
"The grant of the US patent would complete the granting of all pending applications relating to the company's intellectual property portfolio," Mr Lehman said.
Prima was up 0.3 cents or 6.4 percent to five cents with 16.8 million shares traded.

## PHOSPHAGENICS

All resolutions at the Phosphagenics annual general meeting were passed, but with up to 7.3 percent opposition to the remuneration report, directors' options and fees pool.
The strongest opposition was to the remuneration report with a poll resulting in 25,003,361 votes against (7.3%) and 315,860,535 votes (92.7%) in favor.
The issue of 1,000,000 options to chairman Lawrence Gozlan was opposed by 27,355,530 proxy votes (7.2%) and supported by 354,942,558 proxy votes (92.8%), with similar opposition to the issue of 1,000,000 options each to directors Nathan Drona and Dr Geert Cauwenbergh (BD: Apr 17, 2014).
A proposal to increase the directors' fees pool by $100,000 to $400,000 was passed by a slightly larger margin, with the election of chief executive officer Harry Rosen, Mr Gozlan, Mr Drona and Dr Cauwenbergh passed overwhelmingly.
The company's most recent Appendix 3B said that Phosphagenics had 1,020,465,957 shares on issue meaning that the largest opposition vote, to Mr Gozlan's options, amounted to 2.7 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.
Phosphagenics was up 0.2 cents or 2.2 percent to nine cents with 1.4 million shares traded.

## COCHLEAR

The London-based Veritas Asset Management says it has increased its substantial shareholding in Cochlear from 2,864,715 shares (5.02%) to 3,479,785 shares (6.10%).
Veritas said it held the shares on behalf of clients including State Street UK, Bank of New York Mellon, JP Morgan, National Australia Bank, Northern Trust UK, Kasbank Netherlands, Citibank Ireland, Deutsch Bank, HSBC Ireland and BNP Paribas UK.
The company said it acquired the shares between May 6 and 20, 2014 with the single largest acquisition 307,406 shares for $18,146,708 or $59.03 a share.
Cochlear was up 57 cents or 0.96 percent to $59.77 with 140,625 shares traded.

## MEDICINES AUSTRALIA

Medicines Australia says chief executive Dr Brendan Shaw has resigned effective from September 12, 2014.

Medicines Australia chairman Dr Martin Cross said that Dr Shaw had been appointed to “a senior position within the global pharmaceutical industry”.

The industry organization did not specify whether the position was with a pharmaceutical company or industry body.

“While obviously challenging for Medicines Australia, the board recognizes this is a great opportunity for Brendan, fully supports his appointment and wishes him well for the future,” Dr Cross said.

Dr Cross said that Medicines Australia had begun a search to find a new chief executive.

## ACUVAX

Acuvax says it has appointed Alex Bajada as a non-executive director.

Acuvax said that Mr Bajada had long-term experience as chairman and a director of several ASX listed companies, including as chairman of WA Super and deputy chair of Advance Healthcare.

The company said that Mr Bajada was a non-executive director of private equity fund Hawkesbridge and Wesmaem.

Acuvax was untraded at 0.1 cents.