

Biotech Daily

Monday October 12, 2009

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: VIRALYTICS UP 10%; PHYLOGICA DOWN 15%
- * ANTISENSE ATL1103 READY FOR ACROMEGALY, RETINOPATHY TRIALS
- * BIOTA TAKES OFF: 33.5¢ TO \$3.15 IN NINE MONTHS
- * PATHEON MANUFACTURES QRX'S MOXDUO CR FOR TRIALS
- * HELICON SHARE PLAN TO RAISE \$1m
- * TYRIAN VOTES ON 5.5m CEO PERFORMANCE RIGHTS
- * STARPHARMA VOTES ON 1.9m CEO 'APPRECIATION SHARES'
- * MEDICAL THERAPIES SNARES ARANA'S ROBIN BEAUMONT

MARKET REPORT

The Australian stock market fell 0.28 percent on Monday October 12, 2009 with the S&P ASX 200 down 13.1 points to 4739.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, nine fell, 12 traded unchanged and four were untraded.

Viralytics was best, up 0.3 cents or 10 percent to 3.3 cents with 2.9 million shares traded, followed by Biota up 17 cents or 5.8 percent to \$3.12 with 1.3 million shares traded.

Compumedics climbed 5.7 percent; Circadian and Tyrian were up four percent or more; Alchemia, Clinuvel, Nanosonics and Resmed were up more than three percent; Living Cell and Sunshine Heart both rose 2.1 percent; with Benitec, Cathrx and Mesoblast up more than one percent.

Phylogica led the falls, down two cents or 15.4 percent to 11 cents with 50,000 shares traded, followed by Prana down 1.5 cents or 6.8 percent to 20.5 cents.

Novogen lost 5.5 percent; Genetic Technologies and Tissue Therapies fell four percent or more; Progen shed 3.3 percent; with Cochlear down one percent.

ANTISENSE THERAPEUTICS

Antisense says repeat dose toxicology studies for ATL1103 in mice and monkeys support plans for the continued development of ATL1103 for acromegaly and retinopathy.

Antisense said ATL1103 was a second-generation antisense drug that targeted the growth hormone receptor.

The company said that by blocking the action of the receptor, ATL1103 inhibited production of insulin-like growth factor -1 (IGF-I) from the liver thereby reducing its levels in the blood.

Antisense said that the growth hormone receptor (GHR) was "a clinically validated therapeutic target" in the growth disorder acromegaly, which was an excessive growth of parts of the body and organs including the liver, kidney and heart.

The company said the goal of treatment was to normalize IGF-1 levels in the blood. Antisense said there was "a clear need for better treatments for this niche and difficult to treat disease" with a market potential of \$US1 billion a year in drug sales.

Antisense said that treatments that reduce IGF-I levels in the blood, such as irradiation of the pituitary gland, had shown clinical benefit in the treatment of the disease diabetic retinopathy, a complication associated with diabetes where new blood vessels were formed in the eye with the potential to cause blindness.

The company said there was no pharmaceutical therapeutic approved for the treatment of vision impairment in the advanced stage of diabetic retinopathy and an effective treatment "could secure a major position in this potentially multi-billion dollar market".

Antisense said a previously reported animal study showed that ATL1103 significantly reducing IGF-I levels in the blood.

The company said ATL1103 has also demonstrated its intended therapeutic action in an animal model of retinopathy by significantly reducing retinal neo-vascularization or the formation of new blood vessels.

Antisense said the repeat toxicology dosing studies in two species over several months were the major component of the ATL1103 toxicology program.

The company said it expected the two remaining short term or acute studies, referred to as safety pharmacology and genotoxicity, would be completed by end of this year, after which it intended to submit an application for a human clinical trial in Australia by July 2010.

Antisense said its major shareholder and technology partner, Isis Pharmaceuticals, would complete the characterization and release of the drug compound for formulation of the supplies to be used in the planned clinical trial.

Antisense said Isis would prepare the drug substance chemistry, manufacturing and controls documentation for inclusion in the clinical trial application.

The company said Isis was doing this additional work in return for 18,475,000 new Antisense shares, which would be placed in escrow for 12 months.

Antisense said shareholder approval was not required for the issue of shares to Isis. The head of research at Isis Dr C Frank Bennett said his company was "very pleased to see another one of our satellite company partners progress another antisense drug towards the clinic".

"This follows their lead compound ATL1102 which demonstrated successful phase II results in patients with relapsing remitting [multiple sclerosis]," Dr Bennett said.

"Similarly we are excited about the potential of ATL1103 to treat and improve the quality of life in patients suffering from difficult to treat diseases," he said.

Antisense was unchanged at five cents.

BIOTA

Biota broke through the \$3 barrier today on strong volumes having started the year at 33.5 cents.

Relenza royalties pushed Biota's revenue for the year to June 30, 2009 to \$83.3 million leading to a profit for the year of \$38.2 million, the largest biotechnology company profit following the Big Caps of CSL, Cochlear and Resmed.

Biota closed at 33.5 cents on December 31, 2008 following a year of poor share performance, a less than impressive settlement of its litigation with Glaxosmithkline, attributed to poor judgment by the board, as well as fluctuating Relenza royalties.

This year began with the appointment of a new chairman, Dr Jim Fox, and the company's fortunes were boosted significantly with the outbreak of the H1N1 'swine flu' and fears of a global pandemic.

Biota's pipeline includes the influenza antiviral drug Laninamivir in phase III trials in Japan, a human rhinovirus drug in phase IIa trials as well as preclinical compounds being developed for respiratory syncytial virus and hepatitis C virus.

At a market capitalization of \$545.8 million at today's closing price, Biota has jumped Pharmaxis (\$496.8 million) for the title of fourth highest market capitalization after the three Big Caps.

While some analysts, including Biotech Daily's Marc Sinatra, have said that Biota is overpriced at this level, Biotech Daily congratulates the company on its transformation and strong share price.

Biota climbed as high as \$3.15 during trading, closing up 17 cents or 5.8 percent at \$3.12, with 1.3 million shares traded.

Biotech Daily editor David Langsam has held shares in Biota.

QRX PHARMA

QRX has contracted the Canada-based Patheon to manufacture clinical supplies of its controlled release dual-opioid, Moxduo CR.

QRX said Moxduo CR was designed to provide 12 hours of pain relief in patients suffering from moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic.

QRX chief executive officer Dr John Holaday said the Patheon relationship was "a major step forward" for QRx that completed its platform of Moxduo products.

"Patheon is a well-known manufacturing organization with proven ability to develop novel formulations of drugs that address global markets," Dr Holaday said.

"Our goal is to provide physicians and patients with a variety of complementary dual opioids for managing moderate to severe pain," Dr Holaday said.

He said that Moxduo CR was expected to deliver clinical benefits similar to those with Moxduo IR (immediate release), fewer side effects and superior pain relief.

"We are targeting a twice daily dosage with Moxduo CR and we anticipate our initial phase I studies will begin this year to evaluate the pharmacokinetic profile of this patented formulation," Dr Holaday said.

He said QRX's most advanced product for acute pain, Moxduo IR, was in phase III trials and scheduled for new drug application filing with the US Food and Drug Administration in 2010.

He said Moxduo CR should complete clinical trials in 2012.

QRX was up 13 cents or 13.7 percent to \$1.08.

HELICON

Helicon is offering eligible shareholders parcels of shares up to \$15,000 each at 10 cents a share to raise \$1.0 million.

Helicon said the record date would be October 20, 2009 and the share plan closes on November 6, 2009.

The company said it was "in the process of documenting an underwriting agreement for the full amount of the plan", expected to be completed this week.

Earlier this month Helicon said it would add gold and copper mining to its activities to underpin its original activity of the sale and distribution of Australian medical devices to China (BD: Oct 2, 2009).

Helicon fell 0.4 cents or four percent to 9.6 cents.

TYRIAN DIAGNOSTICS

Tyrian shareholders will vote on the issue of up to 5,500,000 performance rights to chief executive officer Dr Jenny Harry.

At the time of writing Tyrian was trading at 2.5 cents, valuing the total parcel at \$137,500. The Tyrian annual general meeting will also consider the election of director Dr Merilyn

Sleigh.

The company said the performance rights would be subject to performance conditions and would vest over three years.

Tyrian said each performance right provided the right to acquire one share at no cost.

Dr Harry held 2,232,807 shares in Tyrian at June 30, 2008 of which 596,781 shares were from the exercise of performance rights in the previous 12 months.

The meeting will be held at Unit 1, 35-41 Waterloo Road, North Ryde, New South Wales on November 11, 2009 at 3pm.

Tyrian was up 0.1 cents or four percent to 2.6 cents.

STARPHARMA

Starpharma shareholders will vote on the issue of 1,900,000 "appreciation shares" to chief executive officer Dr Jacinth (Jackie) Fairley.

At the time of writing Starpharma was trading at 56.5 cents, valuing the total parcel at \$1,073,500.

In the explanatory notes for the meeting, Starpharma said the shares were conditional on meeting performance conditions and the board said that Dr Fairley had met the short and long term goals of advancing the development of Vivagel, signing licencing and collaboration agreements, expanding the product pipeline, securing adequate working capital and protecting the company's intellectual property.

Starpharma's board said "the company has achieved superior performance under the stewardship of Dr Fairley ... [and] Dr Fairley's performance has been outstanding during the period".

The Starpharma annual general meeting will also consider the re-election of directors Dr John Raff and Dr Peter Jenkins as well as the ratification of prior share issues and the company's share appreciations rights plan.

The meeting will be held at Deacons, Level 15, RACV Tower, 485 Bourke Street, Melbourne on November 12, 2009 at 4pm.

Starpharma was up 0.1 cents or 2.1 percent to 4.9 cents.

MEDICAL THERAPIES

Medical Therapies has appointed former Arana chairman Robin Beaumont as a non-executive director.

The company said Mr Beaumont had "two decades of outstanding track record as nonexecutive director having served on a number of public and private company boards in the healthcare and life sciences sectors as well as in other industries".

Mr Beaumont was chairman of Arana until the takeover by Cephalon and was a director of Evogenix until its merger with Peptech to form Arana Therapeutics in 2007.

He was chairman of Select Vaccines and the Cooperative Research Centre for Diagnostics and a non-executive director of Gropep.

Mr Beaumont was managing director of the Advent venture capital group until 1998. Medical Therapies was up half a cent or 17.2 percent to 3.4 cents.