Biotech Daily

Tuesday September 17, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: REVA UP 8%; ATCOR DOWN 9%**

*** OSPREY FOCUS ON HEART DYE REDUCTION OVER CAPTURE**

*** GENETIC TECHNOLOGIES SETTLES GENELEX NON-CODING DNA CASE**

*** MEDIVAC SELLS METAMIZER**

*** ECO QUEST PLEADS SCHULTZ, CYNATA TO ASX 28% QUERY**

*** ENDER 1, SNP, APERCEN, POLANSKY TAKE 6% OF CLINUVEL**

*** ELLEX REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Tuesday September 17, 2013 with the S&P ASX 200 up 3.2 points to 5,251.2 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and three were untraded.

Reva was the best, up five cents or 8.3 percent to 65 cents with 35,200 shares traded.

Circadian climbed 7.7 percent; Alchemia was up 5.3 percent; Optiscan rose 4.8 percent; Genetic Technologies and Neuren were up more than three percent; Bionomics, Patrys and Phosphagenics rose more than two percent; Anteo, Benitec, Clinuvel, Nanosonics, Osprey, Starpharma and Viralytics were up more than one percent; with Cochlear and Resmed up by less than one percent.

Atcor led the falls, down 1.5 cents or 8.8 percent to 15.5 cents with two million shares traded.

Prana lost 7.5 percent; Cellmid, GI Dynamics and Pharmaxis were down more than three percent; Acrux, Medical Developments, Sirtex and Tissue Therapies shed one percent or more; with CSL, Mesoblast and QRX down by less than one percent.

OSPREY MEDICAL

Osprey says the US Food and Drug Administration has approved a trial of its Avert system to expand claims to include “reduction of contrast induced nephropathy” in stenting.

In a separate ‘Investor Newsletter’ Osprey said the Avert trial would enroll about 700 patients at up to 45 sites in the US, Western Europe and Australia.

The company said it planned to begin the Avert trial by the end of 2013 with the aim of completing enrolment by April 2015, with FDA clearance to expand its marketing claims for reduction of contrast-induced nephropathy by mid-2015.

Osprey said it intended “to focus its clinical trial program on the Avert trial and will likely direct its financial and personnel resources to this project in preference to the Preserv trial”.

“An update on the Preserv trial will be made at the appropriate time,” Osprey said.

Osprey is developing the Cincor system to reduce kidney damage from cardiac angiography dye contrast used to visualize the stenting procedures and has also developed the FDA-approved Avert dye reduction system to reduce dye by up to 40 percent without compromising image quality (BD: Oct 31, 2012; May 21, Aug 23, 2013).

According to www.clinicaltrials.gov the Preserv trial’s primary endpoint was to reduce kidney damage through the removal of the dye using a catheter to capture the contrast material.

Today’s announcement implied that the new 700-patient Avert trial would supercede the 600-patient Preserv trial, but no one from the company was available to comment at the time of publication.

In its media release, the company said that since including the Avert system in its 600-patient phase III pivotal trial, entitled ‘Prospective Randomized Evaluation to Study the Effects of Reduced Contrast Media on the Vitality of the Kidney’ (Preserv) it had received “strong and consistent positive feedback from key opinion leading physicians about the performance of the system and the potential benefits for their patients”.

Osprey said the simplicity of use made the Avert system “the most attractive product for reducing [contrast-induced nephropathy] in a significant proportion of the target market”.

The company said that doctors had identified other patient groups that could benefit from the system, including those with pre-existing diabetes and those suffering from ST segment elevation myocardial infarction (Stemi).

Osprey said that following discussions with the FDA and the submission of a new clinical trial protocol, it had approval to begin a multi-site clinical trial to support application for an expanded marketing claim to include contrast-induced nephropathy (CIN) reduction.

Osprey chief executive officer Mike McCormick said the “FDA’s quick approval to commence the Avert clinical trial is reflective of the scientifically sound study protocol and simplicity of the system”.

“Avert has attracted strong feedback from our network of key opinion leading physicians, due to its simplicity, immediate dye reduction and potential to protect at-risk patients from CIN,” Mr McCormick said.

“The move toward focusing on Avert is a very natural progression for Osprey Medical,” Mr McCormick said.

“Positive physician response to the potential benefits of Avert has been overwhelming and has created a clear path for maximizing value for the company and its shareholders,” Mr McCormick said.

Mr McCormick said the company could undertake a focused launch of Avert in Texas by the end of 2013 to establish its use under its current claim.

Osprey was up one cent or 1.6 percent to 65 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a settlement and release agreement with the Seattle, Washington-based Genelex Corp relating to its non-coding DNA patents.
Genetic Technologies said that in late 2012, it filed suit against Genelex in the US District Court for the Western District of Washington at Seattle (BD: Dec 21, 2012).
The company said that following the final settlement the legal action would be dismissed.
Genetic Technologies said the precise commercial terms of the agreement were covered by formal confidentiality provisions and could not be disclosed.
Earlier this month Genetic Technologies said it had a settlement and release agreement with the Detroit, Michigan-based Genesis Genetics Institute relating to its non-coding DNA patents (BD: Sep 3, 2013).
Genetic Technologies was up 0.3 cents or 3.75 percent to 8.3 cents.

MEDIVAC

Medivac says it has sold its Metamizer assets, including intellectual property, to RR Taylor Pty Ltd for an upfront fee of $250,000 and a royalty per machine.
Medivac said that in the event that a proposed Sri Lankan deal for Metamizer did not proceed, an alternate and ongoing royalty would apply.
The company said that the transaction was expected to generate $1 million in cash receipts over the life of the project.
Medivac said that RR Taylor was a medical equipment manufacturer, based on the Central Coast of New South Wales, and was the party that negotiated the Sri Lankan project and it was “understood” that RR Taylor intended to manufacture the Metamizer in Australia and add it to its existing export activities.
Last year, Medivac began the acquisition of Republica Capital and the change the company’s nature and scale of activities (BD: Sep 28, Oct 29, 2012).
Medivac had been attempting to commercialize its Metamizer hospital waste crushing system and Sunnywipes cleaners and Republica’s website said it made “strategic investments in businesses with the aim of restructuring, recapitalizing and/or amalgamating to add value for all parties”.
In August, Medivac said it had received an offer to acquire the rights to manufacture and distribute the Metamizer and the associated intellectual property, subject to a royalty payable over at least the next three years, based on whether a previously foreshadowed sale to Sri Lanka was finalized (BD: Aug 16, 2013).
Medivac fell 0.1 cents or 50 percent to 0.1 cents.

ECO QUEST

Eco Quest has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price climbed from 2.5 cents on September 13 to 3.2 cents, a 28.0 percent increase, on September 16, 2013, and noted an increase in trading volumes.
Eco Quest said that other than announcements in July, August and September, regarding the acquisition of Cynata, the appointment of directors Dr Stewart Washer and Dr Ross Macdonald, a $300,000 placement, lodging financial statements and completion of the share plan, it was “not aware of any other explanation for the recent trading in its securities” (BD: Jul 12, Aug 1, 27, 2013).
Eco Quest was unchanged at 2.9 cents with 19.3 million shares traded.

CLINUVEL

Ender I, SNP Ventures, Apercen and Michael Polansky have become substantial shareholders in Clinuvel with 2,340,824 shares or 6.13 percent of the company.
The Palo Alto, California-based Michael Polansky as managing director for Ender I and SNP Ventures said the 2,340,824 shares were acquired for $5,000,000 or $2.14 cents a share.
Clinuvel was up 2.5 cents or 1.5 percent to $1.65.

ELLEX MEDICAL LASERS

Ellex has requested a trading halt “pending an announcement … in relation to a capital raising”.
Trading will resume on September 19, 2013 or on an earlier announcement.
Ellex was untraded at 30 cents.