Biotech Daily

Monday April 28, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: ALCHEMIA, IDT UP 8%, ACRUX DOWN 33%**

*** ACRUX FALLS 37% ON AXIRON Q1 SALES DOWN 27% ON Q4**

*** US PATENT FOR PROGEN 500 SERIES ANTI-CANCER COMPOUNDS**

*** PRIMA RE-STARTS EURO CAN-004 CVAC OVARIAN CANCER TRIAL**

*** OBJ, PROCTOR & GAMBLE DEAL ON UNNAMED 'PRODUCTS'**

*** NUSEP LOSES DIRECTOR DR STEPHEN VAN DER MYE**

*** CLAIRE NEWSTEAD-SINCLAIR RETURNS AS COGSTATE CO SEC**

MARKET REPORT

The Australian stock market edged up 0.09 percent on Monday April 28, 2014 with the S&P ASX 200 up 5.1 points to 5,536.1 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and five were untraded.

Both Alchemia and IDT were up eight percent to 54 cents and 27 cents, respectively, with 8.3 million shares and 12,000 shares traded, respectively.

Anteo climbed 7.1 percent; Circadian and Prima were up more than five percent; Cellmid was up 4.2 percent; Reva was up 3.2 percent; Patrys rose 2.9 percent; Universal Biosensors was up 1.3 percent; with Clinuvel and CSL up by less than one percent.

Acrux led the falls, down as much as 60.5 cents or 36.6 percent to $1.05, closing down 55 cents or 33.2 percent to $1.105 with 10.2 million shares traded, followed by Benitec down 13.8 percent to $1.065 with 930,339 shares traded.

Tissue Therapies lost five percent; Avita, Mesoblast, Neuren, Phosphagenics, Prana and QRX fell four percent or more; Admedus, Bionomics and Starpharma were down more than three percent; Genetic Technologies, GI Dynamics, Impedimed, Medical Developments, Oncosil and Osprey shed two percent or more; Sirtex was down 1.3 percent; with Cochlear and Resmed down by less than one percent.

ACRUX

Acrux says Axiron net sales for the three months to March 31, 2014 fell 26.7 percent to $US39.5 million ($A42.5 million) compared to the three months to December 31, 2013.
The sales reported by US-based partner Eli Lilly was 6.5 percent higher than the $US37.1 million for the three months to March 31, 2013, but Axiron sales had been increasing significantly over most quarters.
Eli Lilly reported Axiron sales of $US47.1 million for the three months to June 30, 2013; $US40.6 million for the three months to September 30, 2013; and $US53.9 million for the three months to December 31, 2013.
Earlier this year, Axiron earned a $US25 million royalty for reaching $US100 million in sales in a calendar year (BD: Jan 31, 2014).
Today, Acrux said that the next $US50 million royalty milestone might not meet the calendar year global sales hurdle.
Acrux said that on January 31, 2014, the US Food and Drug Administration issued a drug safety communication (DSC) which said the FDA was investigating the risk of stroke, myocardial infarction, or heart attack, and death in men taking approved testosterone products (BD: Feb 4, 2014).
The company said that the FDA had not concluded that approved testosterone treatments increased the risk of stroke, heart attack, or death, and said that patients should not stop taking prescribed testosterone products without discussing any questions or concerns with their healthcare professionals.
Acrux said that the FDA assessment process did not have a defined time period.
The company said that the two observational studies that triggered the safety communication had been criticized for misrepresenting the study results.
Acrux said that three professional medical societies and an international group of more than 160 scientists and physicians had petitioned the Journal of the American Medical Association to retract one of the study articles, stating that it was “no longer credible”.
Acrux said that Axiron had been launched in Canada, Australia, Germany and Brazil and was approved in South Korea with a launch planned for the end of June 2014.
Acrux chief financial officer Tony Dipietro told Biotech Daily that the company was entitled to an 11 percent royalty on sales, equating to about $4,675,000 for the three month sales period.
Mr Dipietro said that the Acrux cash burn was about $5 million a year excluding a 3.5 percent royalty payable to Monash University for all product sales until 2017.
Acrux fell as much as 60.5 cents or 36.6 percent to $1.05 (after the market closed Commsec Iress reported an unexplained $1.025) before closing down 55 cents or 33.2 percent to $1.105 with 10.2 million shares traded.

PROGEN PHARMACEUTICALS

Progen says the US Patent and Trademark Office has granted a patent, entitled ‘Novel Sulfated Oligosaccharide Derivatives’ which includes the phase I cancer drug PG545.
Progen said the patent protected the composition and use of, and methods of treatment for, the compound PG545 and related PG500 series compounds until 2028 and could be extended under certain circumstances.
The company said that the methods of treatment encompassed a variety of therapeutic areas and included oncology, namely to control angiogenesis and metastasis.
Progen acting managing director Heng Tang said “the allowance of this key US patent is a significant milestone and valuable addition to the company’s intellectual property portfolio”.
Progen was up eight cents or 9.1 percent to 96 cents.

PRIMA BIOMED

Prima says it has begun enrolment for its 210-patient, amended phase II European trial of CVac for ovarian cancer.

In February, Prima said that regulators in Latvia, Lithuania, Bulgaria, Ukraine and Belarus approved its amended protocol for the CAN-004 trial (BD: Feb 6, 2014)).

Last year, Prima suspended its phase II/III CAN-004 Australian, European and US trial of CVac for ovarian cancer saying that that top-line analysis of its 63-patient CAN-003 phase II trial failed to show significant progression-free survival. (BD: Sep 19, Nov 7, 2013).

Today, Prima said that the amended phase II trial would enrol 210 epithelial ovarian cancer patients in remission after second-line platinum-based chemotherapy, with the primary endpoint of overall survival, with secondary endpoints including progression-free survival, adverse events and immune monitoring.

The company said that the CAN-003 trial demonstrated that CVac increased progression-free survival in patients who were in remission after second-line therapy.

Prima said it would manufacture CVac for all of the European clinical trial sites from its facility in Leipzig, Germany in collaboration with the Leipzig-based Fraunhofer Institute for Cell Therapy and Immunology.

Prima chief executive officer Matt Lehman said the start of recruitment was “a major milestone in our clinical trial program for CVac”.

“We now have a clear, data-driven clinical development plan for CVac in second-remission ovarian cancer, which is a significant unmet medical need,” Mr Lehman said.

Prima was up 0.2 cents or 5.7 percent to 3.7 cents with five million shares traded.

OBJ

OBJ says it has agreements including a multi-product development agreement and a licencing agreement with Procter and Gamble for its magnetic micro-array technology.

OBJ said that it had granted Procter and Gamble world-wide, exclusive access to its non-powered micro-array technology in specific consumer product categories, but did not specify the products.

OBJ has previously been developing magnetic transdermal technology, but at the time of publication no-one from the company was able to elaborate on the products in the agreements.

Proctor and Gamble’s website said its brands included soap products, cosmetics, nappies, shaving equipment and batteries.

The company said the agreements included a product development agreement and work plans for the first three products to use the technology, including an initial licence for the first product and the terms included minimum funding levels required to maintain exclusivity rights in certain product categories; three funded work plans for products; and royalty payments to OBJ on further licenced products.

OBJ quoted Proctor and Gamble saying the two companies had been working together since 2011.

The company said that Proctor and Gamble had a worldwide exclusive right to commercialize its non-powered magnetic micro-array technology within specifically defined product categories, but OBJ retained all rights in other product categories and in its other technologies.

OBJ said that in addition to the three product development work plans in the agreement package, four additional product development programs had been proposed by Proctor and Gamble and were being evaluated.

OBJ was up 3.7 cents or 92.5 percent to 7.7 cents with 138.1 million shares traded.

NUSEP HOLDINGS

Nusep says that director Dr Stephen van der Mye has resigned as a director for health reasons, effective from today.
Nusep said Dr van der Mye had offered to stay in touch with the company.
Nusep said it wished Dr van der Mye all the best for the future.
Nusep was untraded at seven cents.

COGSTATE

Cogstate says Claire Newstead-Sinclair has returned from maternity leave to resume the role of company secretary.
Cogstate said that Mark Edwards was appointed joint company secretary in May 2013 and his appointment had ended (BD: May 24, 2013).
Cogstate was untraded at 31.5 cents.