Biotech Daily

Wednesday November 13, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 41%, PATRYS DOWN 22%**

*** QRX RAISES $7.5m; 34% OPPOSE REMUNERATION**

*** NSW $250k TO CARDIOVASCULAR RESEARCH NETWORK**

*** VIRAX RELEASED FROM ADMINISTRATION**

*** SUDA RAISES $5.6m**

*** CANADA APPROVES IMMURON OTC TRAVELAN**

*** PATRYS RIGHTS ISSUE TO RAISE $12.5m**

*** IMPEDIMED: AMA RAISES BIS LYMPHOEDEMA TEST TO CPT CODE I**

*** ACRUX, ELI LILLY SUE ACTAVIS OVER AXIRON PATENTS**

*** REVA REZOLVE2 SALES DELAY, FINANCE, NEW PRODUCTS PIPELINE**

*** ISONEA TO LOSE CEO MICHAEL THOMAS IN 2014**

*** THAI QUOC TANG GAOL FOR TISSUE THERAPIES SHARE TRADING**

*** CONSEGNA AGM VOTES TO BECOME RHINOMED**

MARKET REPORT

The Australian stock market fell 1.37 percent on Wednesday November 13, 2013 with the S&P ASX 200 down 73.9 points to 5,319.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and two were untraded. All Big Caps fell.

Impedimed was best, up 6.5 cents or 40.6 percent to 22.5 cents with 2.7 million shares traded. Optiscan climbed 8.9 percent; Atcor was up 5.6 percent; Alchemia, Cellmid and Viralytics rose more than two percent; with Anteo, Living Cell, Nanosonics and Prana up more than one percent.

Patrys led the falls, down 1.8 cents or 22.2 percent to 6.3 cents with 42.9 million shares traded. Clinuvel fell 12.15 percent; Phosphagenics and QRX lost more than 11 percent; Neuren was down 8.7 percent; Benitec fell 7.5 percent; Allied Health and Genetic Technologies lost more than six percent; Prima fell 5.3 percent; Avita fell 4.55 percent; Acrux, GI Dynamics and Mesoblast were down three percent or more; IDT shed 2.2 percent; Ellex lost 1.5 percent; with Cochlear, CSL, Resmed and Universal Biosensors down by less than one percent.

QRX PHARMA

QRX says it is has raised $7.5 million through the issue of shares at 60 cents a share, but 33.9 percent of annual general meeting votes opposed the remuneration report.
On Monday, QRX said it hoped to raise about $5.0 million through the issue of shares at 60 cents a share with a share plan to raise a further $3 million (BD: November 11, 2013).
The company said that the funds were to take the company through the anticipated US Food and Drug Administration Prescription Drug User Fee Act (PDUFA) date for Moxduo immediate release and provide working capital required for commercialization if approved.
QRX said it would refile its Moxduo immediate release new drug application by the end of November 2013.
The company said that its remuneration report was opposed by 14,310,456 votes or 33.9 percent, providing the first trigger for a potential board spill at the next annual general meeting, with 27,931,568 votes (66.1%) supporting the remuneration report.
The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
The company's most recent Appendix 3B new issue announcement said that QRX had 144,785,606 shares on issue, meaning that the votes against the remuneration report amounted to 9.9 percent of the company, sufficient to requisition extraordinary general meetings.
Directors Dr Gary Pace and Michael Quinn were re-elected overwhelmingly with a constitutional amendment also passed overwhelmingly.
QRX fell eight cents or 11.3 percent to 63 cents.

NEW SOUTH WALES GOVERNMENT

New South Wales Minister for Health and Medical Research Jillian Skinner has committed $250,000 to the New South Wales Cardiovascular Research Network.
Ms Skinner said the $250,000 brought the amount the Government had committed to the Cardiovascular Research Network over the last two years to $2 million.
"Cardiovascular disease is Australia's biggest killer, claiming a life every 12 minutes," Ms Skinner said.
Ms Skinner said that in New South Wales 32 percent of all deaths were from cardiovascular disease.
"It is vital that we build our research into cardiovascular disease, understanding that research unlocks the new techniques and models of clinical care which directly impact on the lives of individuals," Ms Skinner said.
A media release from the Minister said the Cardiovascular Research Network was "a unique network of research institutes, researchers, clinicians and organizations within NSW which specialize in areas such as congenital heart disease, acute coronary syndrome, heart failure and the link between depression and heart disease, as well as related conditions such as stroke, kidney disease and diabetes".
The media release said that plans included a focus on Aboriginal health to address inequalities in the treatment and prevention of heart disease.

VIRAX HOLDINGS

Grant Thornton administrators says the deed of company arrangement with Virax was fully effectuated and the company is no longer subject to external administration.
Virax is suspended and last traded at 0.9 cents.

SUDA

Suda says it has raised $5.6 million through a placement of about 170 million shares at 3.3 cents a share.

Suda said the new capital would be used to accelerate the business development of Artimist and other development products, including SUD-001 for migraine, SUD-002 for chemotherapy-induced nausea and SUD-003 for erectile dysfunction; establish an in-house formulation laboratory to expand the pipeline of drug candidates based on the oro-mucosal drug delivery platform; expand the existing management team, including a head of regulatory affairs; and to strengthen the balance sheet.

The company said the placement was made to institutional investors and was managed by Ord Minnett.

Suda was up 0.4 cents or 10.8 percent to 4.1 cents with 18.8 million shares traded.

IMMURON

Immuron says that Health Canada has authorized the over-the-counter sale of its bovine colostrum-derived Travelan for travellers' diarrhoea.

Immuron said the authorization allowed its Canadian partner Paladin Labs to market tablets comprising 200mg of Immuron's anti-entero-toxigenic Escherichia coli hyperimmune bovine colostrum.

The company said that in Canada, Travelan was classified as a natural health product and would be available over-the-counter, without the need for a prescription.

Immuron said the authorization entitled Paladin Labs to claim on the product package that Travelan was "clinically proven to help reduce the risk of travellers' diarrhoea".

Immuron chief executive officer Amos Meltzer said the company was "delighted that Paladin Labs has secured approval to commercialize Travelan in Canada".

"We know that the Travelan team at Paladin has worked tirelessly to obtain the authorization and we have confidence that Paladin's expertise will underlie the successful commercialization of Travelan in Canada, which similarly to Australia, is a nation of many international travellers," Mr Melzer said.

Mr Melzer said that Canadian approval was "a significant milestone".

Immuron fell 0.2 cents or 14.3 percent to 1.2 cents with 107.0 million shares traded.

PATRYS

Patrys hopes to raise about $12.5 million through a one-for-two non-renounceable rights issue and top-up facility at five cents a share.

Patrys said the record date would be November 25, the offer would open on November 27 and close on December 11, 2013.

The company said that Azure Capital and BBY would be joint lead managers for the issue.

Patrys said that Amgen subsidiary Onyx Pharmaceuticals had agreed to fund an investigator-sponsored trial evaluating PAT-SM6 in combination with carfilzomib in patients with relapsed and refractory multiple myeloma (BD: Nov 11, 2013).

"Given the interest of Onyx in supporting this trial Patrys will not be actively seeking a licencing partner for PAT-SM6 at this time," Patrys said.

The company said that it needed funds for the manufacturing of the product to be used in the trial as well as other activities associated with advancing the pipeline.

Patrys said that the proceeds would be used to support, in part, lead product clinical development, operations, business development and corporate development.

Patrys fell 1.8 cents or 22.2 percent to 6.3 cents with 42.9 million shares traded.

IMPEDIMED

Impedimed says the American Medical Association has provided a category I code for bio-impedance spectroscopy lymphoedema assessment for extra-cellular fluid

Impedimed said that the AMA posted its current procedural terminology (CPT) editorial summary from its October 10-12, 2013 meeting recommending the addition of category I CPT code 937XX2 and deletion of category III code 0239T for bio-impedance spectroscopy lymphoedema assessment for extra-cellular fluid.

Impedimed said that category I CPT codes were reserved for those procedures that have demonstrated clinical efficacy, widespread use and have U.S. Food and Drug Administration clearance.

The company said the purpose of the CPT codes was to provide a uniform language that described medical, surgical and diagnostic services and was widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs.

Impedimed said that future CPT panel actions might affect the decision, and new and revised code descriptions might be further refined prior to publication each year.

The company said that code numbers were not assigned, nor exact wording finalized, until just prior to publication of the annual CPT code set, effective from January 1, 2015.

Impedimed was up 6.5 cents or 40.6 percent to 22.5 cents with 2.7 million shares traded.

ACRUX

Acrux says that with Eli Lilly it is suing the Dublin, Ireland-based Actavis Inc for infringement of six issued US patents that cover Axiron.

Acrux sayid that Eli Lilly and Co, Eli Lilly Export SA and Acrux DDS filed a lawsuit in the US District Court for the Southern District of Indiana against Watson Laboratories Inc, Actavis Pharma and parent company, Actavis Inc for infringement of the six patents, owned by Acrux DDS, a wholly-owned subsidiary of Acrux and exclusively licenced to Lilly.

The company said that the legal action was in response to a notice letter sent by Watson regarding its filing with the US Food and Drug Administration of an abbreviated new drug application for a testosterone metered dose transdermal solution.

Acrux said that the letter stated that the application contained paragraph IV certifications with respect to US Patent Numbers 6,299,900, 6,818,226, 6,923,983, 8,071,075, 8,419,307 and 8,435,944, which were expected to expire between 2017 and 2027.

The company said that the patents included claims relating to the penetration enhancer, the quick drying formulation, the application of testosterone formulations to the underarm and to the applicator used to apply Axiron.

Acrux said that a paragraph IV certification alleged invalidity, unenforceability and/or non-infringement of a patent.

Acrux said that with Lilly it was committed to asserting their intellectual property rights for Axiron.

Acrux said that it expected that, in much the same way as the Israel-based Perrigo litigation, the conduct of the lawsuit would not have a material impact on its operating expenditure (BD: May 27, 2103).

Acrux fell eight cents or three percent to $2.59 with 995,567 shares traded.

REVA MEDICAL

Reva executive chairman Bob Stockman says the company is “exploring attractive options” for finance in the run-up to sales in early 2015.

Reva previously said it hoped to have European approval and sales by the end of 2014, but in a teleconference, Mr Stockman said that had been delayed slightly to the “first quarter of 2015” (BD: Nov 14, 2012).

Mr Stockman told a teleconference that with 87 of 125 patients implanted with the Rezolve2 bioresorbable cardiac stent, he expected full enrolment by the end of November 2013 and the Conformité Européenne (CE) mark application to be filed by the end of this year, with approval expected by April 2015.

Reva chief financial officer Katrina Thompson told the teleconference the company had a net loss for the nine months to September 30, 2013 of $US20.2 million ($A21.7 million) and had $US27 million in cash and investments.

Mr Stockman said that “additional funding will be necessary and we are exploring attractive options”.

“We have potential offers and good options and Reva will be in a good shape financially beyond 2014,” Mr Stockman said.

Mr Stockman said that the company’s pipeline of new products included stents that would be “stronger thinner and more flexible that the Rezolve2” to be used in a range of interventions including tight vessel turns and bifurcations.

Mr Stockman told Biotech Daily that the Reva range of bioresorbable scaffolds were unique because using covalently-bonded iodine the stents could be seen by imaging equipment while the stenting was being done and remained visible at a decreasing rate for up to 18 months.

Mr Stockman told the teleconference that the Abbott Absorb bioresorbable scaffold had been demonstrated as superior to the Abbott Xience V everolimus-eluting coronary stent and the Absorb began sales at the end of 2012 with full roll-out by May 2013.

Mr Stockman said that the Abbott Absorb had sales revenue of $US23 million in the three months to September 30, 2013 with $US90 million expected for the full year of 2013.

Reva was unchanged at 54 cents.

ISONEA

Isonea says that chief executive officer Michael Thomas would resign in May 2014.

Isonea said that in the interim, director and medical device entrepreneur Jerry Korten would assume an executive director position and oversee the transition of Mr Thomas’ duties, including international market development and preparation for US launch of the company’s Airsonea digital health technology.

Mr Thomas was appointed chief executive officer in 2011 (BD: Jun 14, 2011).

Isonea chairman Dr Stewart Washer said the company was seeking to appoint an international sales and marketing executive to the chief executive officer position, to further drive the company’s transition from a development company to a sales and marketing organization.

“With the significance of the global opportunity, we are seeking to appoint a CEO with international sales and market growth background and the expertise to implement a worldwide campaign,” Dr Washer said.

Isonea fell three cents or 5.2 percent to 55 cents.

TISSUE THERAPIES

The Australian Securities and Investments Commission says Thai Quoc Tang has been gaoled for four months for market manipulation of Tissue Therapies shares.
ASIC said that in the Brisbane District Court, Judge Michael Shanahan convicted and sentenced Mr Tang for two years imprisonment for each of two market manipulation charges, relating to trades through 11 separate online accounts, to be served concurrently.
ASIC said that Justice Shanahan directed that Mr Tang be released after four months with a $5,000 three-year good behavior bond.
ASIC said that Mr Tang, 58, of Durack, admitted to creating a false or misleading appearance in the market when trading in Tissue Therapies shares between December 23, 2010 and January 24, 2012.
ASIC said that during the 13 months Mr Tang was the sixth largest shareholder of Tissue Therapies shares and traded heavily through the 11 separate online accounts
ASIC alleged that Mr Tang conducted 100 separate 'price support' trades which had the effect of creating a false or misleading appearance in the share price because the trades were undertaken for the primary purpose of increasing the share price on the ASX.
ASIC said that between April 27, 2011 and September 5, 2011 Mr Tang conducted 41 additional 'wash trades', in which one person executes both sides of the trade, effectively selling and buying the shares themselves and creating an appearance of trading activity in the market without there being any change in beneficial ownership of the shares.
ASIC said the matter was prosecuted by the Commonwealth Director of Public Prosecutions.
Tissue Therapies 2010-2011 Annual Report published on October 26, 2011, listed Mr Tang twice among the top 20 holders owning one parcel of 3,330,000 shares (1.97%) and another parcel of 1,684,000 shares (1.00%).
Tissue Therapies was unchanged at 21.5 cents.

CONSEGNA GROUP, RHINOMED

Consegna says shareholders have voted to change the company name to Rhinomed and the new ASX codes will be RNO for shares, RNOO for listed 12.5 cent options and RNOOA for listed six cent options.
The company said it was awaiting confirmation from the ASX on the date that the ASX codes would change.
All other resolutions were passed easily with about 3.9 percent of votes opposing the remuneration report and with 666,096 votes opposing both the election of director Simon Reading (Simon Isaacs) and the issue of 3,809,524 shares to Golden Five, with more than 19.5 million votes in favor.
Consegna fell 1.6 cents or 20 percent to 6.4 cents with six million shares traded.