Biotech Daily

Wednesday October 17, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 25%; BENITEC DOWN 9%**

*** ACRUX NEW GENERIC TESTOSTERONE FDA APPLICATION**

*** AIRXPANDERS: 'RADIATION OK WITH AEROFORM BREAST EXPANDER'**

*** CPS UNDERWRITES $4.7m EXPIRING BIOTRON OPTIONS**

*** PROTEOMICS RECEIVES $834k FEDERAL R&D TAX INCENTIVE**

*** TELIX, RADBOUD TLX250 RENAL CANCER MANUFACTURING DEAL**

*** PRESCIENT, UNNAMED US COMPANY NEW FORMULATIONS WORK**

*** NUHEARA WELCOMES US FDA DE NOVO DEVICE PATH**

*** IMPEDIMED 44% REMUNERATION 1st STRIKE**

*** ALCHEMIA PLEADS SCHULTZ TO ASX 187.5% QUERY**

*** SUDA PLEADS SCHULTZ, 'TWEETS' TO ASX 100% QUERY**

*** RESAPP PLEADS SCHULTZ TO ASX 24% QUERY, MEDIA AFTER**

*** MGC PLEADS SCHULTZ, CANADA MARIJUANA LAW TO ASX 25% QUERY**

*** KAZIA TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**

*** CLINICAL GENOMICS MARY PADBURY, KATHERINE KALIN TO BOARD**

MARKET REPORT

The Australian Stock Market was up 1.18 percent on Wednesday October 17, 2018 with the ASX200 up 69.2 points to 5,939.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and five were untraded. All Big Caps rose.

Prescient was the best, up 1.8 cents or 25 percent to nine cents with 1.4 million shares traded. Dimerix climbed 14.1 percent; Polynovo and Pro Medicus were up seven percent or more; Actinogen was up 6.5 percent; Volpara rose 5.3 percent; Factor, Impedimed and Imugene were up more than four percent; Clinuvel, Cochlear, Mesoblast, Resmed, Starpharma and Telix were up three percent or more; Bionomics, CSL, Nanosonics and Paradigm rose more than two percent; with Medical Developments up 1.2 percent.

Benitec led the falls, down 1.5 cents or 8.6 percent to 16 cents, with 42,243 shares traded. Optiscan lost 8.3 percent; Genetic Signatures fell 7.3 percent; Ellex shed 6.8 percent; Osprey was down 5.7 percent; Avita fell 4.55 percent; Airxpanders, Immutep, Oncosil and Reva shed more than two percent; Pharmaxis fell 1.7 percent; with Cynata and Opthea down by less than one percent.

ACRUX

Acrux says the US Food and Drug Administration has accepted its application for a generic based on Perrigo's testosterone topical solution.

Acrux said the abbreviated new drug application was for a 30mg/1.5mL testosterone topical solution, applied to the armpit, for conditions associated with a deficiency or absence of endogenous testosterone.

Last year, Acrux and Eli Lilly and Co had agreed to terminate their licence for its armpit-applied Axiron testosterone replacement product, ending US sales (BD: Sep 6, 2017).

Biotech Daily calculated at that time that over the course of the agreement Eli Lilly received revenue of more than $US810.8 million ($A975.5 million) from Axiron sales.

Acrux chief executive officer Michael Kotsanis told Biotech Daily last year that following US concerns over testosterone replacement drugs, the FDA-required a trial that would have cost "hundreds of millions of dollars" and sales had fallen since July 5, 2017, when generic versions of Axiron appeared on the market.

In November, Acrux said the US Court of Appeals for the Federal Circuit affirmed a previous judgement in a case involving Perrigo Israel Pharmaceuticals that invalidated its Axiron patent (BD: Aug 23, 2016; Nov 23, 2017).

Today, Acrux chief executive officer Michael Kotsanis told Biotech Daily that because Axiron had been taken off the market, the Perrigo product had become the reference standard for subsequent generic testosterone solution products.

"The FDA concerns over safety related to the class of testosterone replacement products and the post-market study commitment required the sponsors of branded products to undertake a long-term study to assess the safety of testosterone replacement products" Mr Kotsanis said.

"The Acrux generic has the same active pharmaceutical ingredient in the same applicator as Axiron but the regulatory dossier submitted to the FDA is different, the product will have different packaging and on approval the product will be substitutable for Perrigo's topical testosterone solution product," Mr Kotsanis said.

Acrux said the FDA had accepted the abbreviated new drug application for review and the addressable market was worth $US139 million ($A194.6 million) a year.

The company said it was the second product under review by the FDA from its portfolio of 13 generic topical products.

In August, Acrux said the US regulator had accepted an application for Jublia, or efinaconazole, 10 percent topical solution for fungal nail infections (BD: Aug 2, 2018).

Mr Kotsanis said the company was "excited to announce that a second product in our generic topical pipeline is now being reviewed by the FDA for approval".

"This submission is another example of the exceptional work conducted by our [research and development] and product development teams in developing generic products that significantly lower the cost of healthcare for consumers," Mr Kotsanis said.

The company said that the testosterone solution was indicated for topical replacement therapy in males who have low or no endogenous testosterone and is applied via an axilla, or armpit, applicator.

Acrux said that testosterone deficiency was a clinical condition in which the testicles, hypothalamus or pituitary gland was affected by disease or damage that results in decreased testosterone production.

The company said that there were no branded products on the market, with four generic products occupying the market.

Acrux said that during the FDA review process it would focus on the optimal licencing and distribution agreements to begin marketing and sales of the testosterone solution.

Acrux was up 3.5 cents or 16.3 percent to 25 cents with 1.1 million shares traded.

AIRXPANDERS

Airxpanders says a study concludes that post-mastectomy radiation therapy can be undertaken in patients with its implanted Aeroform breast tissue expanders.

Study lead investigator Dr Yvonne Zissiadis said the primary aim of the eight-patients study was “to examine the effects of radiation treatment on Aeroform tissue expanders and to describe the planning protocol for these patients”.

“Our findings revealed that it is feasible to plan with a conventional [three-dimensional] planning technique that is reproducible and the early outcomes of Aeroform patients treated with external beam radiation therapy are similar to patients without Aeroform tissue expanders,” Dr Zissiadis said.

Airxpanders chief executive officer Frank Grillo said the study results showed Aeroform was compatible with radiation therapy and provided information to aid radiation oncologists who were unfamiliar with how to develop treatment plans for patients with the device in place.

“It is very encouraging to see such positive results which demonstrate that radiation therapy can be used with Aeroform patients,” Mr Grillo said.

Airxpanders said that the study reviewed eight patients with Aeroform who underwent external beam radiation therapy, with side effects assessed at two, four and six weeks during radiation therapy and at six weeks after the final treatment.

The company said that the treatment planning method in the study used a three-dimensional conventional planning technique with density overrides that were applied to account for factors such as the presence of air and position of the metallic reservoir within the expander.

The article, titled ‘Development of a treatment technique for the Aeroform tissue expander breast implant system–A single department experience’ was published in the Journal of International Radiology and Radiation Therapy and is available at: https://medcraveonline.com/IJRRT/IJRRT-05-00182.php.

Airxpanders fell 0.2 cents or 6.5 percent to 4.9 cents with 2.7 million shares traded.

BIOTRON

Biotron said it has a $4.7 million option underwriting agreement with the Perth-based CPS Capital Group, for options due to lapse on November 30, 2018.

Biotron said that CPS would underwrite any shortfall from the issue of 78,429,130 listed options exercisable at six cents each by November 30, 2018.

The company said there would be an underwriting fee of five percent with a “principal commercial termination event being a seven percent fall in the ASX All Ordinaries Index at any time after the date of the agreement”.

Biotron said the underwriting would place it “in a sound financial position as it focuses on achieving a commercial outcome following the recent successful results from the phase II clinical trial of … BIT225 for the treatment of HIV-1’ (BD: Sep 28, 2018).

Biotron was up 6.5 cents or 26.5 percent to 31 cents with 85.2 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $834,403 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Proteomics said the rebate related to research and development expenditure for the year to June 30, 2018.

Proteomics was up 3.5 cents or 15.6 percent to 26 cents.

TELIX PHARMACEUTICALS

Telix says it has a manufacturing agreement with the Nijmegen, Netherlands-based Radboud Translational Medicine BV for TLX250 for renal, or kidney, caner.
Telix said it had been working with Radboud under a technology transfer and research agreement for the past six months, in which time the companies had completed process development and production optimization, and validation runs were being completed to provide patient doses for European trial sites expected by the end of October 2018.
Telix said that Radboud would be a backup production site to its partner production sites of Isologic in North America and Cyclotek in Australia (BD: Oct 15, 2018).
Telix European Union president Odile Jaume said Radboud had been “a core part of taking the 89Zr-girentuximab [TLX250] process development out of Radboud University Medical Centre and industrializing the radiochemistry for Telix’s phase III study”.
Telix was up 2.5 cents or 3.2 percent to 81 cents.

PRESCIENT THERAPEUTICS

Prescient says it has a collaboration with an unnamed private US drug development company for new formulations of Pleckstrin homology domain and Akt inhibitors.
In 2015, Prescient said the protein kinase B or Akt inhibitor compound PTX-200, formerly known as GGTI-2418 or triciribine phosphate monohydrate, was in development for chemotherapy-resistant ovarian cancer (BD: Feb 23, 2015).
Today, the company said the collaboration would build on “knowledge gained during its development of PTX-200”.
Prescient said the collaboration’s objective was “to develop novel proprietary formulations to expand the potential therapeutic applications of PTX-200 as a targeted cancer therapy”.
Prescient chief executive officer Steven Yatomi-Clarke said the collaboration was “an important strategic initiative for Prescient”.
Prescient said that PTX-200 was in a phase II trial in women with HER2-negative locally advanced breast cancer where it “demonstrated encouraging efficacy signals”, as well as a phase Ib/II trial for relapsed and refractory acute myeloid leukaemia and a phase Ib/II trial for platinum-resistant ovarian cancer.
Prescient was up 1.8 cents or 25 percent to nine cents with 1.4 million shares traded.

NUHEARA

Nuheara says it welcomes the US Food and Drug Administration approval of de novo status for a self-fitting hearing device.
Nuheara said the de novo process provided an alternative pathway for medical device manufacturers to classify new devices that could be shown to be safe and effective for consumer use and did not fit the current FDA class I or class II medical device categories.
The company said that as a result of the de novo approval secured by Bose Corp of the Bose hearing aid, Nuheara would assess the alternative regulatory pathway to potentially market a self-fitting hearing aid.
Nuheara said it would proceed when the FDA released both the special controls document, which governed the requirements applicable to subsequent companies, as well as the details of the Bose clinical study, expected within the next month.
The company said that the approved Bose hearing aid had not been launched, but the action by a major electronics manufacturer, “brought valuable focus for the growing hearing healthcare channel”.
Nuheara was up 0.1 cents or 1.2 percent to 8.3 cents with 3.85 million shares traded.

IMPEDIMED

Impedimed has a remuneration report first strike with the annual general meeting voting 82,807,214 votes (44.33%) against the report and 103,993,820 votes (55.67%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill, and if passed, the directors must stand for re-election within 90 days.
Impedimed's most recent Appendix 3B new issue announcement said it had 378,993,655 shares, meaning the votes against the report were 21.85 percent of the company.
Impedimed said that the issue of 2,473,000 options and 2,988,000 performance rights to chief executive officer Richard Carreon was opposed by 27.62 percent and 22.17 percent of votes cast, respectively, with the election of directors Dr Robert Graham, Scott Ward and Gary Goetzke opposed by 23.34 percent, 29.78 percent and 23.33 percent, respectively, while the placement capacity was passed with 92.71 percent of votes cast.
Last year, Impedimed said 34.9 percent of votes opposed the issue of options to Mr Carreon but the issue of performance rights passed overwhelmingly (BD: Nov 15, 2017).
In 2016, Impedimed avoided a remuneration report second strike and potential board spill with 84.8 percent of votes in favor and in 2015, the company earned a remuneration report first strike with 25.1 percent against the report and 25.9 percent opposing the grant of 512,500 options to Mr Carreon (BD: Oct 29, 2015; Nov 14, 2016).
Impedimed was up two cents or 4.4 percent to 47.5 cents.

ALCHEMIA

Alchemia 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 rose 187.5 percent from 0.8 cents on October 15 to 2.3 cents today October 17, 2018, and noted an increase in the trading volume.
Alchemia closed up 0.5 cents or 45.45 percent to 1.6 cents with 130.4 million shares traded.

SUDA PHARMACEUTICALS

Suda 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 rose 100 percent from 40 cents on October 15 to 80 cents today, October 17, 2018 and noted a "significant increase" in trading volume.
Suda said that two users of the social media platform Twitter had 'tweeted' a comparison of Suda and Biotron, but it did not know the identity of the users and was not involved.
Suda was up 0.3 cents or 60 percent to 0.8 cents with 275.8 million shares traded.

RESAPP HEALTH

Resapp 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 24.3 percent from 20.5 cents to 25.5 cents yesterday October 16, 2018, but did not note an increase in trading volumes.
Resapp said its Smartcough-C-2 trial results were expected this month it had "positive results" from its sleep apnoea trial and was featured in a news program after the market closed yesterday (BD: Oct 11, 2018).
Resapp fell half a cent or 18.9 percent to 21.5 cents with 11.9 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC 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 rose 24.6 percent from 6.5 cents to 8.1 cents on October 16, 2018, and noted a "significant increase" in the trading volume.
MGC said it had "recently released a number of material announcements" and that from October 17, 2018 Canada would legalize marijuana use for recreational purposes.
MGC fell 0.7 cents or 8.9 percent to 7.2 cents with 25.1 million shares traded.

KAZIA THERAPEUTICS

Kazia has requested a voluntary suspension to follow the trading halt requested on October 15 "pending the release of an announcement with regard to a proposed capital raising" expected by October 22, 2018 (BD: Oct 15, 2018).
Kazia last traded at 43 cents.

CLINICAL GENOMICS

Clinical Genomics says it has appointed Mary Padbury as the company's chair and Katherine Bach Kalin as a director.
Clinical Genomics said that chair Max Mawhinney would continue as a director.
The company said that Ms Padbury was a lawyer who had worked in intellectual property for Australian and multinational companies in a variety of technology areas and had international, legal, and governance experience.
Clinical Genomics said that Ms Padbury was formerly a partner and vice-chair of law firm Ashurst and chair of Ashurst Australia for eight years and previously was employed by UK law firm Bristows.
The company said that Ms Padbury was a director of the Macfarlane Burnet Institute for Medical Research, the Commonwealth Bank of Australia, and Victorian Legal Admissions Committee.
Clinical Genomics said that Ms Padbury held a Bachelor of Laws from the University of Melbourne Law School.
The company said that Ms Kalin had more than 25 years of experience as an executive in the healthcare and professional services industries, with expertise in diagnostics, medical devices, and pharmaceuticals, in Asia, Europe and North America.
Clinical Genomics said that Ms Kalin led corporate strategy at Celgene for five years and previously held leadership roles at Johnson & Johnson in marketing, sales, strategy and new business development.
The company said the Ms Kalin had been a partner at McKinsey and a corporate finance manager at Nomura International in the UK and Japan.
Clinical Genomics said that Ms Kalin held a Bachelor of Arts from England's Durham University and a Master of Business Administration from Harvard Business School.
Clinical Genomics is a private company.