Biotech Daily

Monday August 7, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 24%, REVA DOWN 7%**

*** STARPHARMA: 'VIVAGEL BEATS PLACEBO FOR BV RECURRENCE'**

*** CORRECTION: AIRXPANDERS**

*** AIRXPANDERS UP TO $25m OXFORD FINANCE LOAN, $567k OPTIONS**

*** ADALTA RECEIVES $1.8m FEDERAL R&D TAX INCENTIVE**

*** UNIVERSAL BIO H1 REVENUE UP 37% TO $14m, LOSS TO $2.5m PROFIT**

*** AUSTRALIAN PATENT FOR BARD1 LUNG, COLORECTAL TESTS**

*** CRESO, VIRBAC MARIJUANA DEAL FOR CATS, DOGS**

*** AUSCANN REQUESTS 'UPDATE' TRADING HALT**

*** UNIVERSAL BIOSENSORS CEO RICK LEGLEITER STARTS ON $450k**
- FOUNDING DIRECTORS ANDREW DENVER, DENIS HANLEY GO

MARKET REPORT

The Australian stock market was up 0.93 percent on Monday August 7, 2017 with the ASX200 up 53.0 points to 5,773.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and one was untraded.

Prima was the best for the second trading day in a row, up 0.5 cents or 23.8 percent to 2.6 cents with 11.7 million shares traded. Airxpanders and Starpharma climbed more than nine percent; Mesoblast was up 5.3 percent; Living Cell climbed 4.35 percent; Benitec, Impedimed, Sirtex and Universal Biosensors were up more than three percent; Nanosonics and Polynovo rose more than two percent; Cyclopharm and Oncosil were up more than one percent; with Cochlear, Opthea, Psivida and Resmed up by less than one percent.

Reva led the falls, down five cents or 6.8 percent to 68.5 cents with 15,132 shares traded. Ellex fell 4.8 percent; Genetic Signatures and Orthocell lost more than three percent; Admedus, Compumedics and Pro Medicus shed two percent or more; Acrux, Clinuvel, Factor Therapeutics, LBT, Osprey and Pharmaxis were down more than one percent; with CSL down 0.2 percent.

STARPHARMA

Starpharma says that two phase III trials show that Vivagel (SPL7013) statistically significantly reduces bacterial vaginosis recurrence compared to placebo.

Starpharma said that in the 585-patient SPL7013-017 Americas trial Vivagel reduced bacterial vaginosis recurrence at week-16 to 44.2 percent compared with placebo 54.3 percent ($p = 0.015$); and in the 636-patient SPL7013-018 Europe and Thailand trial Vivagel reduced bacterial vaginosis recurrence to 15.7 percent at week-16 compared to placebo reducing bacterial vaginosis by 22.6 percent ($p = 0.027$).

The company said that vaginally-delivered placebos could affect bacterial vaginosis, as seen in both trials, with expected rates of bacterial vaginosis recurrence over 16 weeks without any intervention between 65-85 percent.

Starpharma said that the 16-week historical recurrence rate using trial participants' data immediately prior to the trial was estimated.

The company said that the 16-week historical recurrence rate for the trial participants in the US trial was about 65 percent and in the European trial was about 50 percent.

Starpharma said that given the rates of recurrence in the European trial were lower than expected, and low compared with the US trial, an investigation was conducted prior to data unblinding and efficacy analyses were conducted on a modified subset population, excluding a number of sites in countries including the Ukraine and Romania, where recurrence rates were lower than anticipated.

The company said that the same pattern of benefit of reduced recurrence was also demonstrated for Vivagel compared with placebo as for the full analysis, although due to the reduced sample size of 327 patients, the difference was not statistically significant with Vivagel reducing recurrence to 28.2 percent versus placebo at 33.9 percent ($p = 0.266$).

Starpharma said that combining the data from all patients in both trials showed that Vivagel was statistically significantly superior to placebo ($p = 0.002$), as well as using the modified European results with the US trial results ($p = 0.014$).

The company said it intended to submit a marketing application to the US Food and Drug Administration for Vivagel for prevention of recurrence of bacterial vaginosis.

Starpharma said that there were no approved products for the prevention of recurrence of bacterial vaginosis, which was a significant unmet medical need.

The company said that the 1,223-patient double-blind, randomized, placebo-controlled trials were identical in design and enrolled women who had at least three episodes of bacterial vaginosis in the preceding 12 months, with participants using either Vivagel (1% SPL7013 gel) or placebo gel on alternate days for 16 weeks.

The company said the US trial was conducted in the US, Puerto Rico, Canada and Mexico and the European trial was mainly in Europe as well as Thailand and the US.

Starpharma said that Vivagel was superior to placebo for time to recurrence; reduced recurrence of patient reported symptoms of vaginal odor and/or discharge; and reduced recurrence by Nugent score and by clinical findings, including the whiff test.

The company said that Vivagel resulted in sustained benefits beyond cessation of treatment, with discharge, odor and clinical findings) were observed not only during the 16-week treatment, but sustained during the 12-week follow-up period off-treatment.

Starpharma chief executive officer Dr Jackie Fairley said the company was "delighted to report these successful phase III trial results, in which Vivagel BV has demonstrated compelling efficacy in all six primary and secondary efficacy measures".

"Our [new drug application] for Vivagel BV for both treatment and [recurrence of bacterial vaginosis] is well-advanced, and we'll be using these data to complete the clinical package for submission to the FDA and other regulatory authorities," Dr Fairley said.

Starpharma climbed seven cents or 9.2 percent to 83 cents with 3.7 million shares traded.

AIRXPANDERS

In last Friday's Dr Boreham's Crucible on Airxpanders, Biotech Daily asserted that "clinical practice has shifted to breast conservation surgery" from mastectomy and that "classic mastectomy is becoming less common, partly because of earlier diagnosis. A technique called acellular dermal matrix is a direct-to-implant option that does not require an expander".

In fact, the evidence is that - in the US, at least - double mastectomy rates have increased significantly for a variety of reasons.

There is also evidence that the direct-to-implant option has its own set of issues.

Airxpanders chief executive officer Scott Dodson told Biotech Daily that "as tissue expander based reconstruction remains far and away the leading procedure for women seeking reconstructive surgery the number of procedures and devices are increasing".

Biotech Daily apologizes unreservedly.

Airxpanders was up 6.5 cents or 9.3 percent to 76.5 cents.

AIRXPANDERS

Airxpanders says it has a $US15 million ($A18.9 million) loan facility with the Alexandria, Virginia-based Oxford Finance LLC.

Airxpanders said that it had an option for a further $US5 million line of credit with a third-party lender, subject to a right-of-first-refusal by Oxford and certain other conditions, of up to US$5.0 million up to December 31, 2018.

In its most recent Appendix 4C quarterly report Airxpanders said it had receipts from customers for the three months to June 30, 2017 of $US391,000, a cash burn $US8,360,000, with cash and short-term investments $US27,115,000 and an estimated expenditure for the three months to September 30, 2017 of $US8,800,000.

Airxpanders chief executive officer Scott Dodson said that the "minimally dilutive debt financing positions us strongly with the working capital we need for our full US sales and marketing efforts and to drive our business expansion throughout the foreseeable future".

The company said that the facility was a secured note, with interest-only instalments to be paid monthly over the first 24 months, with a 12-month extension of the interest-only period if it complied with certain financial milestones, primarily revenue based.

Airxpanders said that loan was for 59 months, with a variable rate equal to the greater of the 30-day London interbank offered rate, which was 1.22 percent in July and was currently 1.23 percent; or 0.99 percent plus 7.26 percent, so based on the current Libor rate, the note had an interest rate of 8.48 percent.

The company said that as well as the loan funding, it had issued about $US450,000 ($A566,869) of warrants to Oxford Finance to buy shares at a price equal to the lower of either the average closing price of its Chess depositary interests (CDIs) for the previous 10 trading days or the closing price on the trading day prior to funding.

ADALTA

Adalta says it has received $1,777,030 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Adalta said the rebate related to research and development expenditure on AD-114 for fibrosis for the year to June 30, 2017.

Adalta was untraded at 24.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2017 was up 36.5 percent to $14,327,351 turning last year's loss to a $2,499,369 net profit after tax.
Universal Biosensors said that revenue from products was up $2.1 million to $2.3 million, revenue from services was $600,000 and quarterly service fees for sale of test strips was up $1.2 million and was "driven by both of [its] lead products Onetouch Verio blood glucose strips and Xprecia Stride coagulation analyzer test strips" for Johnson & Johnson and Siemens, respectively.
The company said it spent $4,429,064 for the six months to June 30, 2017, down 27.2 percent compared to the previous corresponding period.
The company said that net tangible asset backing per share was up 50 percent to nine cents a share, with diluted net earnings per share of one cent compared to the previous period's one cent diluted net loss per share.
Universal Biosensors said that it held cash and cash equivalents of $19,957,765 at June 30, 2017, compared to $20,402,322 at December 31, 2016.
Universal Biosensors was up 1.5 cents or 3.75 percent to 41.5 cents.

BARD1 LIFE SCIENCES

Bard1 says that IP (Intellectual Property) Australia has issued a patent entitled 'Bard1 isoforms in lung and colorectal cancer and use thereof'.
Bard1 said that the patent family protected the sequence of various Bard1 isoforms specific to lung and colorectal cancer, a method for detecting the presence of the specific Bard1 isoforms, and a method for treating and/or preventing lung cancer and colorectal cancer until August 17, 2031.
The company said that the patent was filed in the name of Université De Genève and Hôpitaux Universitaires de Genève on August 17, 2011, from where it licenced the commercial rights to the technology.
Bard1 chief executive officer Dr Leearne Hinch said the core patent family had four granted patents in the US, Japan, China and Australia, with other jurisdictions pending and the portfolio included "five patent families covering various Bard1 DNA and protein sequences, methods of diagnosis and treatment and use in multiple cancers".
Bard1 said its lung cancer test was in development for the early detection of lung cancer.
Bard1 was up 0.1 cents or 11.1 percent to one cent.

CRESO PHARMA

Creso says it has a three-year commercialization deal with Virbac Switzerland to distribute marijuana-based food additives for cats and dogs in Switzerland and Lichtenstein.
Creso said that from September 1, 2017 Virbac would be the exclusive distributor of its products with the rights to sell and distribute the products under Creso's trademark.
The company said that it had developed, and would manufacture the products, and Virbac would launch, market and promote the products to veterinarians and pet owners.
Creso said that Switzerland was "a regulatory and marketing reference country for many countries in Europe, Latin America and Asia Pacific … [and a successful launch would] enable expansion into additional international markets in 2018".
The company said that anibidiol1.25 and anibidiol 2.5 were designed for companion animals such as dogs and cats and came in proprietary granule formulations for stress and behavioral problems, chronic pain, primarily arthritis, and age-related ailments.
Creso climbed 3.5 cents or 7.2 percent to 52 cents.

AUSCANN GROUP

Auscann has requested a trading halt “pending [the] release of an announcement regarding an update to the Australian operations”.
Trading will resume on August 9, 2017 or on an earlier announcement.
Auscann last traded down half a cent or 1.1 percent to 46 cents with one million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says Rick Legleiter has been appointed chief executive officer, starting on $450,000 a year, with directors Andrew Denver and Denis Hanley retiring.
Universal Biosensors said that Mr Denver and Mr Hanley retired from the board, effective from today, with Mr Denver continuing as interim chief executive officer until September 30 with Mr Legleiter appointed, effective from October 1, 2017.
The company thanked the two founding directors for their contribution to the company including Mr Denver’s term as executive chairman and said that Mr Denver would remain as an advisor for a minimum of 12 months.
Universal Biosensors said that Mr Legleiter had 16 years’ experience in healthcare and medical technology in Europe, Australia, Asia and the US and most recently held senior roles at Siemens Healthcare in America and Germany.
The company said that Mr Legleiter held Bachelor of Science in nuclear engineering and a Bachelor of Science in applied mathematics from Kansas State University and a Master of Business Administration from Harvard Business School.
Universal Biosensors said that Mr Legleiter’s salary would be $450,000 a year including superannuation, with a short term incentive of up to 50 percent the base rate excluding superannuation, along with a long term incentive of up to 7,600,000 options in three tranches vesting over three years with 1,600,000 options exercisable at 50 cents each 2,700,000 options exercisable at 50 cents each and 3,300,000 options exercisable at 50 cents each to
Mr Denver said he remained “a significant … shareholder … [and] led the board renewal process”.
The company said that Craig Coleman had been appointed chairman with David Hoey, Judith Smith and Marshall Heinberg continuing as non-executive directors.