Biotech Daily

Thursday September 19, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AVITA, OSPREY UP 4%; PRIMA DOWN 51%**

*** PRIMA SUSPENDS PHASE II/III CVAC CANCER STUDY FOR ENDPOINT**

*** MESOBLAST: 'STEM CELLS EQUAL GRAFT FOR LUMBAR SPINAL FUSION'**

*** ELLEX PLACEMENT RAISES $3.3m**

*** PHOSPHAGENICS BEGINS PHASE I TPM-OXYMORPHONE DOSING**

*** REGENEUS OPENS UP 14%**

*** BIONICHE RAISES RAISING TO $9m**

*** VIRAX PLACEMENTS TO RAISE UP TO $2.5m**

*** CONSEGNA NAME CHANGE TO RHINOMED, SELLS IMUGENE SHARES**

*** BIOTA REVENUE UP 65% to $35m, LOSS DOWN 55% TO $9m**

*** SUNSHINE HEART CAPITAL RAISING**

*** PHARMAXIS LOSES DR JOHN VILLIGER, RICHARD VAN DEN BROEK**

MARKET REPORT

The Australian stock market climbed 1.1 percent on Thursday September 19, 2013 with the S&P ASX 200 up 57.4 points to 5,295.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and five were untraded.

Avita and Osprey were the best, up 4.2 percent to 12.5 cents and 75 cents, respectively, with 346,990 shares and 394,360 shares traded, respectively. Atcor and Bionomics climbed more than three percent; Alchemia and Viralytics rose more than two percent; Medical Developments, Neuren, Sirtex and Tissue Therapies were up more than one percent; with Acrux, CSL and Mesoblast up by less than one percent.

Prima fell as much as 54.2 percent to 3.8 cents, closing down 4.1 cents or 50.6 percent to four cents with 97.4 million shares traded. Allied Health lost 10.1 percent; Optiscan fell 9.1 percent; Prana was down 8.7 percent; Psivida fell 5.6 percent; Ellex was down 3.3 percent; Benitec and Nanosonics shed more than two percent; Anteo, Clinuvel, Genetic Technologies, QRX, Resmed and Universal Biosensors were down more than one percent; with Cochlear and GI Dynamics down by less than one percent.

PRIMA BIOMED

Prima fell as much as 54.2 percent to 3.8 cents on news that it had suspended temporarily its phase II/III CAN-004 Australian, European and US trial of CVac for ovarian cancer.

Prima said that top-line analysis of its 63-patient CAN-003 phase II trial had failed to show significant progression-free survival.

The company said it had suspended enrollment in the CAN-004 'Canvas' trial, which had been designed with progression-free survival as the primary endpoint, but currently enrolled patients could continue on the existing protocol.

In July activated "a substantial number" of additional European trial sites for the phase II/III trial doubling the number of actively recruiting clinical trial sites (BD: Jul 4, 2013).

The European arm of the 'Canvas' trial began in February 2013, following the US start in February 2012 (BD: Feb 3, 2012; Feb 5, 28, 2013).

Today, the company said that other immuno-therapies had been approved on the basis of overall survival, rather than progression-free survival, and it would "engage with regulators to make appropriate amendments to the clinical development plan for CVac in ovarian cancer and identify the most appropriate endpoints for evaluation of clinical benefit".

Prima said that while variable, immune monitoring data indicated that CVac induced a T-cell response which could be beneficial for patients with ovarian cancer "no evidence was seen of a humoral, or antibody, response after CVac administration which is also considered a positive signal".

The company said that the study was not adequately powered to detect statistical significance, but the estimate of median progression-free survival for all randomized patients resulted in no observed difference between the CVac and control groups.

Prima said that the median progression-free survival was also estimated separately for patients in first and second remission and in first remission, the median progression-free survival favored the control arm, when compared to the CVac treated patients.

The company said that in second remission, the median progression-free survival favored CVac as compared to patients on the control group, but "neither of these trends was statistically significant".

Prima said it was "too early to make conclusions based on overall survival data" and the company would continue to monitor patient outcomes until overall survival data matured.

Prima said it would discuss the results in detail following a presentation of the data by Dr Jeffrey Goh at the European Cancer Congress in Amsterdam on October 1, 2013.

The company said that inconclusive progression-free survival data was consistent with the trial results of a number of cancer immunotherapy products.

Prima said that trials of sipuleucel-T and ipilimumab and the recently reported trial of MAGE-A3 immuno-therapy, indicated that progression-free survival, and similar endpoints like disease-free survival, might not be useful markers of clinical benefit for cancer immuno-therapeutics.

The company said that several immuno-therapies demonstrated the ability to extend overall survival and overall survival was the basis for marketing approvals for sipuleucel-T and ipilimumab.

Prima chief executive officer Matthew Lehman said that CVac continued to demonstrate a favorable side effect profile and positive immune activity.

"We are committed to progressing our CVac clinical trials – in ovarian cancer as well as other cancer types – in an expeditious manner," Mr Lehman said.

Prima said the top-line analysis of the phase II study showed the drug is well-tolerated with no serious adverse events considered related to protocol therapy and the majority of non-serious adverse events were considered mild and transient in nature.

Prima closed down 4.1 cents or 50.6 percent to four cents with 97.4 million shares traded.

MESOBLAST

Mesoblast says its phase II trial of mesenchymal precursor cells for lumbar spinal fusion showed the cells were as good as hip autograft for reducing pain and improving function.
Mesoblast said hip autograft was the gold standard for the procedure but required for a second surgical procedure to remove bone for the graft which could cause blood loss and chronic pain at the bone harvest site.
The company said there were no cell-related serious adverse events such as excessive bone formation or nerve compression, reported with other biologic therapies in lumbar spinal fusion.
Mesoblast said that data would be presented by the principal investigator, the Central Texas Spine Institute's Dr Randall Dryeat, the North American Spine Society meeting in New Orleans from October 9 to 12, 2013.
The company said it intended to begin a phase III trial in interbody lumbar fusion this year.
Mesoblast said that there were about 380,000 lumbar spinal fusion procedures in the US in 2012 and the overall worldwide market for bone graft substitutes was nearly $1.6 billion dollars in 2012 with about 70 percent of revenue from spinal fusion procedures.
Mesoblast was up four cents or 0.7 percent to $5.72 with 564,040 shares traded.

ELLEX MEDICAL LASERS

Ellex says it has raised $3.3 million through a placement to institutional and sophisticated investors at 26 cents a share.
Ellex chief executive officer Tom Spurling said the funds would "support a range of initiatives related to our proprietary 2RT laser in the treatment of early age-related macular degeneration … [and] enable Ellex to accelerate recruitment for the 300-patient early [age-related macular degeneration] clinical trials via new sites in the US, Europe and Australia".
Ellex said that Taylor Collison was the lead manager for the oversubscribed placement.
Ellex fell one cent or 3.3 percent to 29 cents.

PHOSPHAGENICS

Phosphagenics says it has begun dosing subjects in its phase I multi-dose trial of tocopheryl phosphate mixture or TPM technology oxymorphone pain relief patch.
Phosphagenics said that the trial on 12 healthy volunteers was being conducted at the Perth, Western Australia-based Linear Clinical Research Facility.
The company said that the volunteers would undergo patch rotation every three days to mimic a normal pain medication administration regime and the primary end point of the trial was safety.
Phosphagenics said that the trial was expected to take about five weeks to complete with results due by the end of 2013.
The company said that the results would provide data and information to assist with the design of a phase II trial due to begin by July 2014.
Phosphagenics said the data generated in the two trials would be used to seek partnering opportunities to collaboratively manage a later stage trial, approvals, sales and distribution, targeting the $6 billion a year chronic pain market based on extended release opioids.
The company said it would begin phase II studies with its oxycodone patch for peripheral pain indications by July 2014.
Phosphagenics was unchanged at 9.2 cents.

REGENEUS

Regeneus opened on the ASX today at 28.5 cents, 14 percent above its initial public offer price of 25 cents.
The company, which is trading under the ASX code of RGS, raised $10.5 million to develop its fat-based stem cell technology for musculo-skeletal and other inflammatory conditions (BD: Aug 8, Sep 11, 2013).
Regeneus climbed as much as four cents or 16 percent to 29 cents before closing up two cents or eight percent to 27 cents with 1.4 million shares traded.

BIONICHE LIFE SCIENCES

Bioniche says it has raised its public offer of shares at 29 Canadian cents each from $C7,500,000 ($A7,735,850) to $C9,000,000 ($A9,282,670).
In August, Bioniche said it hoped to raise funds to develop its phase III bladder cancer product Urocidin and for general corporate purposes (BD: Aug 7, 8, 2013).
Bioniche was untraded at 38 cents.

VIRAX HOLDINGS

Virax has announced a series of placements to raise up $2,501,250.
Virax said it would raise $250 through the placement of 25,000,000 shares at 0.001 cents a share and $1,000 through the placement of 100,000,000 options at 0.001 each.
The company said it would offer a minimum of 360,000,000 second placement shares and up to 500,000,000 shares at 0.5 cents a share to raise from $1,800,000 to $2,500,000.
Virax said the funds would be used to settle obligations to creditors under the deed of company arrangement and were intended to permit the deed to be effected and the company to be recapitalized and trade as a going concern.
The company said the opening date for the placement was September 26 and the closing date was October 4, 2013.
In July, administrators Grant Thornton said that Virax's proposed new directors would be Dr Wayne Millen, Dr Roland Toder and Dr Brendan de Kauwe and funds would also be used to review the business and cover expenditure on new projects (BD Jul 31, 2013).
Virax last traded at nine cents.

CONSEGNA GROUP

Consegna says that, pending shareholder approval, it will change its name to Rhinomed to reflect its focus on nasal technology and has sold 75 million Imugene shares.
Consegna said that it held a 29 percent stake of 100,000,000 shares in Imugene as a result of the sale of the Linguet asset in August last year, which were in escrow until July this year (BD: Aug 1, 2012).
The company said that following yesterday's announcement by Imugene to discontinue its Ibuprofen program, it sold 75,000,000 shares and retained 25,000,000 shares "in the event that [Imugene] is able to secure a positive future".
"The proceeds of the share sale will be applied to bolster the working capital of the company as we progress the launch of the Turbine," Consegna said.
Consegna said it had appointed Chinamed as its manufacturing partner and the company had begun manufacturing the Breatheassist Turbine nasal plugs, with a launch planned for November 2013.
Consegna was up 0.6 cents or 18.75 percent to 3.8 cents with 8.4 million shares traded.

BIOTA PHARMACEUTICALS

Biota says revenue for the year to June 30, 2013, was up 64.7 percent to $US33.6 million ($A35.4 million) reducing net loss after tax 54.7 percent to $US8.7 million ($A9.2 million).
Biota said that royalty revenue from sales of Relenza and Inavir were up 13.6 percent to $US9.6 million ($A10.1 million).
Biota said that the full-year revenue increase was a result of increased service revenue of $US12.8 million in 2013 due to the advancement of laninamivir octanoate into a phase II trial under the US Biomedical Advanced Research and Development Authority (BARDA) contract, as well as a net increase of $US800,000 in royalty revenue and sales milestones for Relenza and Inavir, offset in part by a $US400,000 decrease in grant revenue.
The company said that for the 12 months to June 30, 2013 the $US10.5 million decrease in net loss was the result of a $US13.2 million increase in revenue, a $US7.8 million gain recorded in November 2012 from the merger with Nabi, an increase of $US4.4 million in research and development tax credits received in 2013, offset in part by a $US12.4 million increase in operating expenses that included a $US1.8 million reduction from a foreign exchange gain, a $US1.9 million decrease in interest and other income, and a $US600,000 decrease in income tax benefit.
Biota said that “due to a recent increase in the amount of returns of Relenza from distributors to Glaxosmithkline, the company recorded no royalty revenue in the quarter ended June 30, 2013 and anticipates earning an equal or lesser amount of royalty revenue from net sales of Relenza in 2014 than in 2013”.
The company said that diluted loss per share fell 63.5 percent to 31 US cents at June 30, 2013.
Biota said it had cash and cash equivalents of $US66.8 million at June 30, 2013, compared to $US53.8 million at June 30, 2012.
Last night on the Nasdaq, Biota fell 13 US cents or 2.97 percent to $US4.25 ($A4.48, equivalent to 56 cents pre-merger) with 75,056 shares traded.

SUNSHINE HEART

Sunshine Heart says it will raise funds through an underwritten public offering of its US common stock, but did not say how much it intended to raise.
In April, Sunshine Heart filed a US ‘shelf registration’ with the US Securities and Exchange Commission allowing it to raise up to $US75 million and later that month said it had raised $13.5 million (BD: Apr 11,17, 2013).
Last year, the company raised $17 million of a hoped for $27 million in a US offer to fund trials of its C-Pulse aorta cuff heart assist device (BD: Aug 16, 2012).
Sunshine Heart said that Piper Jaffray & Co and Cowen and Co were joint book-running managers and Lazard Capital Markets was co-lead manager for the offer.
The company said that Craig-Hallum Capital Group and Northland Securities were acting as co-managers for the offer.
Sunshine Heart said it expected to grant the underwriters a 30-day option to purchase up to an additional 15 percent of the shares of common stock offered, solely to cover over-allotments, if any.
Sunshine Heart said that it intended to use the net proceeds from the offer for general corporate purposes, including its ongoing US pivotal trial and post-market European study, initial commercialization of the C-Pulse heart assist system in the European Union and product development.
Last night on the Nasdaq, Sunshine Heart fell 49 US cents or 4.1 percent to $US11.35 ($A11.95, equivalent to 5.975 cents before it left the ASX) with 416,323 shares traded.

PHARMAXIS

Pharmaxis says non-executive directors Dr John Villiger and Richard van den Broek have resigned.

Pharmaxis said that Dr Villiger joined the board in November 2006 and Mr van den Broek was appointed a director in April 2009.

The company said the board would comprise chairman Malcolm McComas, Dr Simon Buckingham, Will Delaat and chief executive officer Gary Phillips.

Pharmaxis said the vacated board positions would not be filled to reduce costs.

Pharmaxis was unchanged at 13 cents with 2.8 million shares traded.