Biotech Daily

Wednesday September 11, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 15%; ELLEX DOWN 6.45%**

*** STARPHARMA: DENDRIMER-OXALIPLATIN SUPERIOR, LESS TOXIC IN MICE**

*** REGENEUS IPO RAISES $10.5m, ASX LISTING NEXT WEEK**

*** MAYNE LICENCES SUBA-ITRACONAZOLE TO HEDGEPATH FOR CANCER**

*** UK APPROVES VIRALYTICS PHASE I/II CAVATAK CANCER TRIAL**

*** QRX LICENCES MOXDUO TO ASPEN FOR AUSTRALASIA**

*** CORRECTION: UNILIFE**

*** CALZADA PLEADS SCHULTZ TO ASX 10.5% FALL QUERY**

*** CHAIRMAN ANDREW KROGER TAKES 25% OF CRYOSITE**

MARKET REPORT

The Australian stock market was up 0.64 percent on Wednesday September 11, 2013 with the S&P ASX 200 up 33.2 points to 5,234.4 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and five were untraded.

Atcor was the best, up two cents or 15.4 percent to 15 cents with 2.3 million shares traded, followed by Benitec up 10.2 percent to 32.5 cents with 305,465 shares traded.

Circadian climbed 7.7 percent; Bionomics was up 6.25 percent; Patrys and Starpharma were up more than five percent; Avita, Prana and Reva were up more than four percent; both Allied Health and Mesoblast were up 3.2 percent; Acrux, GI Dynamics and Resmed rose more than two percent; Cochlear, Neuren, Prima and Sirtex were up more than one percent; with Nanosonics up 0.6 percent.

Ellex led the falls, down two cents or 6.45 percent to 29 cents with 55,000 shares traded.

Antisense lost 5.9 percent; Optiscan and Tissue Therapies fell more than four percent; Pharmaxis and Psivida were down more than three percent; Alchemia and Impedimed shed more than two percent; Anteo, Genetic Technologies, Universal Biosensors and Viralytics were down more than one percent; with CSL down by 0.1 percent.

STARPHARMA HOLDINGS

Starpharma says that two dendrimer-enhanced versions of cancer drug oxaliplatin improve tumor-inhibiting efficacy and reduce overall toxicity in mice.

Starpharma said the study examined dendrimer-enhanced nanoparticle versions of oxaliplatin compared with oxaliplatin in a colon cancer xenograft model.

The company said that oxaliplatin was sold by Sanofi as Eloxatin, primarily for colon and colorectal cancer and had sales of about $US2 billion in 2012.

Starpharma said that bone marrow toxicities including the serious white blood cell disorder neutropenia were reported in more than 70 percent of patients receiving Oxaliplatin.

The company said that the observation that its dendrimer-enhanced oxaliplatin nanoparticles substantially reduced the life threatening and dose-limiting neutropenia toxicity was “an important finding, both for this drug candidate … and potentially also for Starpharma’s platform more broadly”.

Starpharma chief executive officer Dr Jackie Fairley said the results were impressive and demonstrated the dendrimer technology could be used “to both enhance the efficacy and improve the safety profile of oxaliplatin”.

The company said that dendrimer-enhanced oxaliplatin was being developed as part of its internal drug delivery program and the most advanced candidate, dendrimer-docetaxel, was expected to begin a phase I clinical trial later this year.

Starpharma said the pre-clinical study results, with two different dendrimer-enhanced oxaliplatin nanoparticles, were the subject of a patent filing and the company intended to advance dendrimer-enhanced oxaliplatin formulations into development.

The company said that additional studies were ongoing to further explore the positive impact on bone marrow toxicity and the potential for the dendrimer-enhanced nanoparticles to reduce other clinically important toxicities.

“These results and other studies indicate that Starpharma’s dendrimer-enhanced oxaliplatin delivers better efficacy compared to oxaliplatin, as well as reduced neutropenia and myelosuppression more broadly,” Dr Fairley said.

“Currently patient outcomes with oxaliplatin in colon cancer are negatively impacted by these toxicities so the clinical and commercial potential of an improved oxaliplatin product which offers both enhanced efficacy and reduced bone marrow toxicity is very significant,” Dr Fairley said.

“The fact that we also observed good anti-cancer activity in a colon cancer model that is refractory to oxaliplatin is also an impressive result for the dendrimer-enhanced oxaliplatin formulations,” Dr Fairley said

Starpharma said Eloxatin was compared with two dendrimer-enhanced oxaliplatin formulations in mice implanted with human colon cancer cells and dosed three times over 15 days.

The company said that the response of the colon cancer xenografts to Eloxatin alone was “very limited … unresponsive or refractory” but both of the two dendrimer-enhanced oxaliplatin formulations showed good efficacy as measured by inhibition of tumor growth.

Starpharma said that mice treated with dendrimer-enhanced oxaliplatin exhibited less bone marrow toxicity than those treated with Eloxatin and Eloxartin-treated mice suffered a rapid and severe drop in neutrophil count, while the dendrimer-enhanced oxaliplatin group showed normal white cell counts and a lack of neutropenia.

The company said the observations were consistent with separate studies which showed that dendrimer-enhanced oxaliplatin caused less bone marrow toxicity than Eloxatin alone.

Starpharma said it intends to advance dendrimer-enhanced oxaliplatin derivatives into development.

Starpharma was up five cents or five percent to $1.05.

REGENEUS

Regeneus says it has raised $10.5 million in its initial public offer at 25 cents a share and expects to start trading on the ASX under the code RGS on September 17, 2013.
Regeneus said that the offer was jointly managed by BBY and Peloton Capital.
Regeneus executive chairman John Martin said the company was “very pleased that existing and new investors have expressed their confidence in Regeneus by supporting the offer”.
“We are now well-positioned to pursue our business milestones for the next two years and build the next phase of value for the company in this rapidly emerging regenerative medicine space,” Mr Martin said.
The Sydney-based Regeneus said it was founded in 2007 to develop and commercialize proprietary cell-based technologies that enable the regenerative capacities of adipose or fat-derived cells, including mesenchymal stem cells to be used for the treatment of musculoskeletal and other inflammatory conditions in humans and animals.
Regeneus said it would have a total of 183,865,077 shares on issue and a market capitalization of $45,966,267.

MAYNE PHARMA GROUP

Mayne says it has licenced Suba-itraconazole to Hedgepath Pharmaceuticals to develop the patented formulation of itraconazole for a variety of cancers in the US.
Mayne says the licence is for the clinical development, registration and commercialization of Suba-itraconazole for cancers in the US and is independent of Mayne’s commitment to commercialize Suba-itraconazole as Subacap for fungal infections.
The company said it expected to appoint a representative to the board of the Tampa, Florida-based Hedgepath and the agreement was effective immediately, but subject to conditions detailed in a Hedgepath report to the US Securities and Exchange Commission, Mayne expected to acquire an equity stake of between 30 and 45 percent.
Mayne said it would supply Suba-itraconazole and with Hedgepath collaborate on a joint oncology development program, with initial indications prostate, lung and skin cancer.
The company said that the US had more than two million new cases of the three cancers reported each year and the market size to treat the diseases was more than $US5 billion.
Mayne chief executive officer Scott Richards said that Hedgepath was “the best commercial vehicle for the development and exploitation of Suba-itraconazole as a potential treatment for certain cancers”.
“Over the last 18 months, the team behind [Hedgepath] has explored the clinical potential of itraconazole as a treatment for cancer which culminated in a restructure … into a public company,” Mr Richards said.
Mayne said that although itraconazole was used extensively for fungal infections, it appeared to have anti-cancer effects through two key mechanisms, the control of cell division via the Hedgehog pathway and anti-angiogenesis effects.
“Since itraconazole is already an FDA-approved drug, we believe that the potential exists for an expedited development program due to the drug’s well established safety profile,” Mr Richards said. “We are further encouraged by the recently reported third party phase II data demonstrating itraconazole’s anti-cancer effects in humans.”
“The superior pharmacokinetic profile of the Suba-itraconazole capsule formulation is expected to be advantageous in the cancer setting, as research in patients with prostate cancer has shown a significant correlation between the anti-cancer effects and levels of itraconazole in the blood,” Mr Richards said.
Mayne was up two cents or 3.3 percent to 62 cents with 1.5 million shares traded.

VIRALYTICS

Viralytics says the UK Medicines and Healthcare products Regulatory Agency has approved a phase I/II clinical trial of Cavatak in cancer patients.

Viralytics said the study would assess the multiple intravenous systemic delivery of Cavatak in patients with late stage melanoma, prostate, lung or metastatic bladder cancers and was expected to begin “soon”.

The company said the systemic treatment of resistant malignancies (Storm) study would be undertaken at three UK cancer centres with lead investigators the University of Surrey’s Prof Hardev Pandha, the Institute of Cancer Research and the Royal Marsden’s Kevin Harrington and St James's University Hospital, Leeds’ Prof Alan Melcher.

Viralytics said that in the first stage of the study, Cavatak would be administered as a monotherapy in late stage cancer patients and in the the second stage, Cavatak would be administered in conjunction with docetaxel or carboplatin/paclitaxel targeting only one cancer type.

The company said that the cancer type would be identified as the most promising target from the first stage of the study.

Viralytics chief executive officer Dr Malcolm McColl said the MHRA approval and the beginning of the Storm study “are key steps forward for our company”.

“Clinical success in these important cancer types would significantly advance the commercial application of Cavatak and benefit many more cancer patients,” Dr McColl said.

Viralytics fell half a cent or 1.4 percent to 34.5 cents.

QRX PHARMA

QRX says it has licenced the commercialization rights to immediate release Moxduo in Australia, New Zealand and Oceania to Aspen Pharma Pty Ltd.

QRX said that Aspen Pharma was a subsidiary of South Africa’s Aspen Pharmacare and the agreement also provided an option to licence the commercialization rights to immediate release Moxduo in South Africa.

In 2011, Actavis Inc paid QRX a $US6 million upfront fee for a US licence for Moxduo Immediate Release (IR) with a potential 50 percent royalty on $US150 million in sales (BD: Jan 22, Mar 19, 2102).

US approval for Moxduo has been delayed following earlier rejections by the US Food and Drug Administration and requests for more data (BD: Aug 28, 2013)

QRX chief executive officer Dr John Holaday said that Aspen had a “strong marketing presence in Australia, [and] combined with its extensive experience in the pain sector, will be a credit to the launch of Moxduo in Australia”.

The company said that Aspen would assume responsibility for the regulatory filings in each country, all product launch costs as well as ongoing marketing and sales efforts.

QRX said it would receive $1,250,000 in regulatory approval milestones, together with double digit royalties on the sales of immediate release Moxduo in all markets and would retain all rights to the intravenous and controlled release formulations of Moxduo.

Dr Holaday said that QRX would “work closely with Aspen with the aim of submitting a marketing authorization application to Australia’s Therapeutic Goods Administration in the coming months”.

“The Australian filing will also benefit from extensive Study 022 data analyses that were undertaken following discussion with the US Food and Drug Administration,” Dr Holadya said.

QRX was unchanged at 75.5 cents.

UNILIFE CORP

Last night's edition reported that Unilife had a long-term supply contract worth up to $15 million with the Paris, France-based Sanofi for retractable pre-filled syringes.
The sentence should have specified that the $15 million was for milestone payments alone and the contract involved payment and royalties for syringe sales.
Unilife fell 2.5 cents or 4.3 percent to 56 cents with 1.9 million shares traded.

CALZADA

Calzada 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 fell from 7.6 cents on September 9, to 6.8 cents on September 10, 2013 a 10.5 percent fall and noted an increase in trading volume.
Calzada was unchanged at 7.3 cents.

CRYOSITE

Cryosite chairman Andrew Kroger increased his substantial shareholding in his company from 10,706,943 shares (22.96%) to 11,706,943 shares (25.10%).
The substantial shareholder notice said the 1,000,000 shares were acquired at 53 cents a share by Process Wastewater Technologies, of which Mr Kroger was the managing director, along with Colfax Bay Pty Ltd as trustee for the Andrew Kroger Family Superannuation Fund.
Cryosite was up seven cents or 13.2 percent to 60 cents.