Biotech Daily

Thursday July 16, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 10%; ANALYTICA DOWN 20%**

*** OSPREY COMPLETES AVERT EXPANDED CLAIMS TRIAL ENROLMENT**

*** STUDY BACKS ORTHOCELL 'CELL FACTORY' FOR CARTILAGE REPAIR**

*** US ORPHAN DRUG DESIGNATION FOR NOVOGEN'S ANISINA**

*** PHARMAUST TREATS 2 DOGS WITH PPL-1, CARBOPLATIN**

*** DORSAVI SALES REVENUE UP 157% TO $1.4m**

*** BARCLAYS 'RETURNS' 1% OF GENETIC TECHNOLOGIES TO 5%**

*** GORDAGEN APPOINTS DR ROCCO IANNELLO, PROF DAVID PRIOR**

MARKET REPORT

The Australian stock market climbed 0.59 percent on Thursday July 16, 2015 with the ASX200 up 33.4 points to 5,669.6 points. Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 13 traded unchanged and three were untraded.

Prima was the best on no news, up 0.6 cents or 10.2 percent to 6.5 cents with 19.3 million shares traded.

Cellmid and Impedimed climbed more than five percent; Oncosil was up 4.8 percent; Medical Developments rose 2.6 percent; Resmed was up 1.2 percent; with Cochlear, Mesoblast, Nanosonics, Osprey and Viralytics up by less than one percent.

Analytica led the falls, down 0.2 cents or 20 percent to 0.8 cents, with 4.8 million shares traded, followed by Compumedics down 10.3 percent to 26 cents with 167,000 shares traded.

Tissue Therapies lost 6.9 percent; Universal Biosensors fell 5.9 percent; Actinogen, Biotron, Living Cell and Neuren fell more than four percent; Bionomics, Psivida and Reva shed more than two percent; Avita and Sirtex were down more than one percent; with Acrux, CSL and Starpharma down by less than one percent.

OSPREY MEDICAL

Osprey says it has completed enrolment for its trial of the Avert cardiac dye reduction system, with 578 patients at 40 sites across the US, Europe and Australia.

Osprey said that the randomized, controlled US Food and Drug Administration investigational device exemption study was aimed at strengthening the claims of the Avert system which was already FDA approved (BD: Jan 19, Nov 13, 2014).

The company said it was seeking five additional claims of dye savings, reflux reduction, image quality, contrast-induced nephropathy (CIN) reduction and hospital cost savings.

Osprey said that a 30-day follow-up period was required for all patients which was expected to be completed by mid-August, with the monitoring of sites, complete data cleaning and adverse event adjudication occurring prior to the database being locked.

The company said that following data collection and analysis it expected the trial results would be announced in November 2015, with FDA submission for claims to follow.

Osprey clinical studies vice-president Michele Shepherd said that enrolment was completed “on time and on budget, which is an encouraging endorsement by the physicians involved”.

Osprey chief executive officer Mike McCormick said that final patient enrolment was “an important corporate milestone”.

“With enrolment for the trial now complete, combined with new dye monitoring standards in the US and continued support from the physician community, it is an exciting time for Osprey,” Mr McCormick said.

Osprey was up half a cent or 0.7 percent to 70 cents.

ORTHOCELL

Orthocell says its ‘cell factory’ derived proteins pipeline product has been further validated with data from a collaborative research project.

Orthocell said that the research involved centres in Sweden, Australia and India and concluded that “intra-articular injection with bioactive molecules alone may be used for the repair of subchondral cartilage defects and bioactive molecules along with chondrocyte-seeded scaffolds further enhance the repair”.

The article, co-authored by Orthocell chief scientific officer Prof Ming Hao Zheng and entitled ‘Cell factory-derived bioactive molecules with polymeric cryogel scaffold enhance the repair of subchondral cartilage defect in rabbits’, was published in the Journal of Tissue Engineering and Regenerative Medicine.

An abstract is at: http://onlinelibrary.wiley.com/doi/10.1002/term.2063/abstract.

Orthocell said the research supported a new approach to regeneration of damaged cartilage within joints which was “highly complementary to Orthocell’s current OrthoACI cartilage repair product”.

Orthocell is developing autologous tenocyte implants (Ortho-ATI) and autologous chondocyte implants (Ortho-ACI), as well as the Celgro pig-based collagen scaffold for soft tissue reconstruction indications (BD: Apr 16, 2014).

Today, the company said that the paper demonstrated that growth factors and extra cellular matrix proteins derived from cells cultivated in a quality controlled cell factory, when concentrated and used as an intra-articular injection alone or combined with scaffolds, regenerated deep articular cartilage defects in rabbits.

Orthocell chief executive officer Paul Anderson said that the “bioreactor-produced native proteins have the potential to be a clinically important and cost effective procedure for the regeneration of articular cartilage of the knee and also other joints”.

Orthocell climbed 11.5 cents or 24.7 percent to 58 cents with 1.7 million shares traded.

NOVOGEN

Novogen says that the US Food and Drug Administration has granted orphan drug designation for Anisina for neuroblastoma.
Novogen said that orphan drug designation encouraged the development of experimental drugs for clinical indications that did not have a high incidence and provided eligibility for US government grants to defray clinical trial costs; tax incentives for clinical research conducted in the US; the waiver of US prescription drug filing fees; and enhanced marketing rights on authorization.
Novogen was up 5.5 cents or 22.9 percent to 29.5 cents with 6.4 million shares traded.

PHARMAUST

Pharmaust says it has completed the treatment with PPL-1 in combination with carboplatin of two dogs with cancer.
Pharmaust said that neither dog suffered any adverse events despite the fact they both had progressive, advanced cancers and few treatment options.
The company said that one of the dogs, treated with 5mg/kg PPL-1 in addition to carboplatin, had stable disease for a short period.
Pharmaust executive chairman Dr Roger Aston said that combining chemotherapy with PPL-1 in a target species with a natural cancer was “an important step”.
“Previous studies in rodents … showed highly significant synergy between chemotherapy and PPL-1 without enhancement of the associated side-effects commonly seen with anticancer drugs,” Dr Aston said.
“As such, the lack of any adverse events in canines is an exciting outcome,” Dr Aston said.
“Furthermore, this gives us much confidence in moving forward with phase II combination therapies in man,” Dr Aston said.
Pharmaust said that with the Sydney-based Veterinary Oncology Consultants it would continue the recruitment and treatment of canine patients with combination therapy for the possibility that the preliminary effects observed on stabilising progressive cancer in one of the two dogs could be further evaluated.
Pharmaust fell 0.1 cents or 11.1 percent to 0.8 cents with 21.8 million shares traded.

DORSAVI

Dorsavi says that sales revenue for the 12 months to June 30, 2015 was up 156.7 percent to $1,358,000 compared to the previous corresponding period.
Dorsavi said that it had recorded its strongest quarter in revenue with record new contracts resulting in revenue for the three months to June 30, 2015 of $492,000, up 97 percent on the previous quarter and 29 percent above the previous best quarter.
The company said it had more than 200 active customers and “entered the first quarter of the 2016 financial year with 42 open [occupational health and safety] projects as compared to 24 OHS projects at the start of the previous quarter”.
Dorsavi said the number of active customers increased substantially over the last few months.
Dorsavi was up one cent or 3.6 percent to 29 cents.

GENETIC TECHNOLOGIES

Barclays Bank says it has reduced its substantial holding in Genetic Technologies from 105,649,121 shares (6.16%) to 87,949,121 shares (5.13%).

In April, the London-based Barclays Bank said it had become a substantial holder in Genetic Technologies with 122,877,121 shares, held for various custodians and in June "returned" 131,691 American depository receipts (ADRs) to an unnamed third party, increased its borrowing from an unnamed third party by 17,491 ADRs and returned "collateral securities" including 8,000 Australian shares and 600 ADRs to an unnamed third party (BD: Apr 14, Jun 12, 2015).

Today, Barclays said it had returned 118,000 ADRs "borrowed" from an unnamed third party or third parties.

Each Genetic Technologies ADR is equivalent to 150 Australian shares

Genetic Technologies was unchanged at 2.7 cents.

GORDAGEN PHARMACEUTICALS

Gordagen says it has appointed Dr Rocco Iannello as business development director, responsible for licencing and partnering its prescription and over-the-counter products.

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily that the company's first food additive or "nutraceutical" product was a "tocotrienol-melt" which would act as an "anti-oxidant and potentially maintain heart health by maintaining cholesterol at healthy levels" (BD: May 29, 2015).

Dr Tong said the second product was intended "to improve exercise endurance and post-exercise muscle recovery, subject to phase II clinical studies next year, for a launch in 2017".

Gordagen said that Dr Iannello had overseen significant transactions in the pharmaceuticals industry and had "a proven ability to build research alliances and out-licencing opportunities between industry and academia".

The company said that Dr Iannello was most recently Monash Institute of Pharmaceutical Sciences' business development director, where he was involved in "numerous high value commercial transactions involving partners such as Glaxosmithkline, Servier, Takeda, and Capsugel" and was involved in the formation of a number of spin-out biotechnology companies.

Gordagen said that previously Dr Iannello was a non-executive director of several companies, including a founding director of Paranta Biosciences and CRC Biomedical Imaging Development.

The company said that it had appointed Melbourne's St Vincent's Hospital deputy director of cardiology Prof David Prior to its scientific advisory board as a specialist advisor to assist with its heart health, exercise endurance and hyper-lipidaemia clinical and product development programs, providing guidance to clinical unmet needs and current approaches.

Gordagen said that one of Prof Prior's focus areas was the effects of endurance exercise on cardiac function and mechanisms of cardiac dysfunction following extreme exercise.

Gordagen is a private company.