Biotech Daily

Monday August 10, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ORTHOCELL UP 6%, ANALYTICA DOWN 11%**

*** ANTISENSE: CORTENDO US IPO DETAILS ATL1103, COR-004 PROGRAM**

*** BENITEC $95m NASDAQ LISTING DELAYED, CONTINUING**

*** BIONOMICS REVENUE DOWN 40% TO $17m, PROFIT TO $17m LOSS**

*** NUSEP BEGINS SPERMSEP IVF TRIAL, SHARE PLAN**

*** REGENEUS BEGINS PROGENZA STEM CELL KNEE TRIAL**

*** MEDIVAC $200k LOAN TO RELIST, BOARD CHANGES, REVIEW**

*** MAYNE LAUNCHES 50mg DORYX FOR ACNE AS US SCHOOLS RETURN**

*** PRATT'S THORNEY (TIGA) DILUTED BELOW 5% OF MAYNE**

*** ANALYTICA APPOINTS EMA, CBIO DR THOMAS LÖNNGREN DIRECTOR**

*** BIO-MELBOURNE JP MORGAN CONFERENCE BRIEFING**

MARKET REPORT

The Australian stock market climbed 0.63 percent on Monday August 10, 2015 with the ASX200 up 34.4 points to 5,509.2 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and one was untraded.

Orthocell was the best, up five cents or 6.3 percent to 84.5 cents with 219,774 shares traded. Circadian and Living Cell climbed more than four percent; Biotron, Compumedics and Viralytics were up more than three percent; Impedimed and Universal Biosensors rose more than two percent; IDT was up 1.85 percent; with Cochlear, CSL and Mesoblast up by less than one percent.

Analytica led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 8.2 million shares traded, followed by Genetic Technologies down 10.3 percent to 2.6 cents with 1.1 million shares traded. Benitec lost 5.4 percent; Anteo, Bionomics and Neuren fell more than four percent; Antisense and Prana were down more than three percent; Acrux, Admedus, Atcor, Avita, Cellmid, Medical Developments, Nanosonics and Osprey shed more than two percent; Clinuvel and Psivida were down more than one percent; with Resmed, Sirtex and Starpharma down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says that Cortendo, which has licenced ATL1103 endocrinology applications, including acromegaly has filed a prospectus to list in the US.

In May, Antisense said that the Trevose, Pennsylvania-based Cortendo AB would pay an upfront fee of $6.2 million and up to $131 million for the rights to ATL1103 for endocrinology applications, including acromegaly and pay for all further development of ATL1103 for endocrine applications, while Antisense would retain the rights for all other indications as well as the commercialization rights of ATL1103 for endocrine applications in Australia and New Zealand (BD: May 15, 2015).

Today, Antisense said that the prospectus contained details on the background, rationale and additional plans with respect to ATL1103, also described as COR-004, as well as “broader detail” of the licencing agreement.

The company said that Cortendo planned to complete the initial public offering in September 2015.

Antisense said that Cortendo intended to seek orphan drug designation for COR-004 from the US Food and Drug Administration and the European Medicines Agency, conduct phase III-enabling chronic toxicology studies in two animal species and in parallel seek a pre-investigational new drug application (IND) meeting with the FDA by the end of 2015 to discuss requirements for entry into phase III clinical development.

The company said that Cortendo intended to file an IND for COR-004 in the US and begin a multinational development program to support regulatory approval in the US and the European Union.

Antisense said that Cortendo expected at least one pivotal registration clinical trial with at least six months of controlled treatment needed to evaluate efficacy, along with at least six additional months of treatment observation to evaluate safety.

The company said that depending on advice from the regulatory authorities, Cortendo might be required to complete an additional clinical trial prior to initiating the pivotal program.

Antisense fell 0.3 cents or 3.3 percent to 8.7 cents.

BENITEC BIOPHARMA

Benitec has fallen behind its timeline to raise up to $US70 million ($A94.7 million) and list on the Nasdaq, but is continuing with the US initial public offer.

In June, Benitec said it would raise the funds through the offer of 5,750,000 American depositary shares, each equivalent to 20 Australian shares, or a total of 115,000,000 shares to advance its therapeutic programs (BD: Jun 23, 2015).

The company said at that time that the final number of US shares and the issue price would be determined in conjunction with the underwriters at the conclusion of an investor road-show in the US in late July 2015.

Benitec chief business officer Carl Stubbings told Biotech Daily: “We are continue to progress our activities to a US IPO and listing”.

An article posted on the Nasdaq website by Renaissance Capital said that Benitec had “postponed its [initial public offer], likely reflecting its early stage and a lack of in-human efficacy data”.

Benitec previously said the offer and Nasdaq listing was “to access the US public equity market” and the offer was subject to market conditions.

Benitec has two US over-the-counter listings that can be viewed through the Nasdaq website: the pink sheet BNIKF and the level 1 American depositary receipts BTEBY.

Benitec fell five cents or 5.4 percent to 87 cents.

BIONOMICS

Bionomics says that total revenue for the year to June 30, 2015 fell 39.7 percent to $16,616,405, with the previous year's net profit after tax turning to a loss of $16,949,405.
Bionomics said that its revenue consisted of payments under the 2014 agreement with Merck & Co (BD: Jun 24, 2014), contract service revenue of its European subsidiaries Neurofit SAS and Prestwick, rental and interest income and the Federal Government's R&D Tax Incentive similar incentives for the French subsidiaries.
The company said the loss reflected its "investment in research and development activities" and the previous maiden profit was due to the Merck licence.
Bionomics said that research and development spending increased 30.3 percent to $23,181,790.
The company said diluted earnings per share fell from one cent at June 30, 2014 to a loss of four cents per share at June 30, 2015,
Bionomics said it had cash and equivalents of $26,512,533 at June 30, 2015 compared to $9,567,307 at June 30, 2014.
Bionomics fell two cents or 4.3 percent to 45 cents.

NUSEP

Nusep says it has begun an in-vitro clinical trial of its Spermsep sperm separation device at the ASX-listed Monash IVF in Melbourne.
Nusep said that the Monash IVF [in-vitro fertilization] team would be led by Prof Rob McLachlan and would test the Spermsep device to determine how well it could isolate sperm from three challenging sources where viable sperm recovery is difficult: a biopsy from the testes and epididymis; from cryo-stored or frozen ejaculates; and from seriously compromised samples with very low sperm count.
The company said that Monash IVF would compare sperm number and motility against conventional sperm preparation methods.
Nusep said that collaborators at the University of Newcastle led by Prof John Aitken had oversight of the program and would perform DNA damage analysis on snap frozen material.
The company said that Spermsep used electrical forces and a porous polymer membrane that enabled contaminants to be separated and the best sperm, which was negatively charged, to be harvested.
Nusep said that University of Newcastle researchers had shown that the Spermsep device imparted less oxidative damage to the sperm than current processing methods and it efficiently selected viable sperm.
The company said that Spermsep's ability to handle multiple samples in a busy in-vitro fertilization clinical setting would be assessed against present methods.
Nusep said that other in-vitro fertilization centres would join the trial shortly and the trial was expected to take about six months to complete.
Nusep executive chairman Alison Coutts said the trial was "the culmination of six months of hard work repositioning the company in line with its strategy to focus on its Spermsep product".
Separately, Nusep said it would offer a share purchase plan at 2.7 cents a share to shareholders at the record date of August 7, 2015 to fund the development of the Spermsep business, for new membrane developments and general operations.
The company said that the offer would open on August 13, and close on August 28, 2015.
Nusep fell 0.1 cents or three percent to 3.2 cents.

REGENEUS

Regeneus says the first patient of 20 has been enrolled and treated in its phase I safety, tolerability and efficacy of Progenza trial for knee osteoarthritis.
Regeneus said that a review of the patient's safety data by the study safety oversight committee identified no safety concerns and enrolment was open to the remainder of the first cohort of 10 patients, with a second cohort of 10 patients receiving a higher dose.
Regeneus said that dosing of the first patient was "another milestone in the clinical development of the company's allogeneic stem cell therapy".
The company said that the trial was entitled 'A phase I randomized, double-blind, placebo-controlled single ascending dose study to evaluate the safety, tolerability and preliminary efficacy of intra-articular Progenza in adults with symptomatic knee osteoarthritis' with Sydney Sportsmed Specialists partner Dr Donald Kuah as principal Investigator.
The company said that patients would receive ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint.
Regeneus said that the primary objective was to evaluate the safety and tolerability of Progenza, with secondary objectives to investigate the effect of Progenza on knee pain and function, quality of life, knee joint structures and osteoarthritis biomarkers.
The company said that Progenza was an off-the-shelf allogeneic stem cell product derived from adipose or fat tissue from a healthy donor and included secretions from donor cells that improved viability and functionality of the cells after freezing.
Regeneus was up two cents or 15.4 percent to 15 cents.

MEDIVAC

Medivac says it has a six-month $200,000 converting loan to re-list on the ASX, has changed its board and is conducting a review of its business.
Medivac was originally commercializing its Metamizer medical waste system and Sunnywipes hand hygiene products (BD: May 13, 2011; May 7, 2012).
In 2012, the company merged with Republica Capital and in 2014 sought funds to rebadge itself as Woolwich Capital (BD: Oct 29, 2012; Jan 31, 2014).
Executive director Craig Hitchings told Biotech Daily that the company had sold Sunnywipes and licenced Metamizer, from which it was receiving some revenue.
Mr Hitchings said the company's primary aim was to comply with ASX listing requirements and the new board would review the company's business and all options were open.
In a media release Medivac said the $200,000 loan from sophisticated investors was at 15 percent a year, converting to shares at 0.2 cents a share, subject to shareholder approval.
The company said it would complete all outstanding financial reports required by the ASX to be re-quoted and in the coming three months it intended recommence trading on the ASX, present a detailed business plan and strategy to the annual general meeting, raise a further $300,000, and "pursue a number of growth opportunities and continue to seek liquidity solutions for a number of existing investments".
Medivac said that Phillip Pryor had been appointed chairman, Mr Hitchings would be an executive director and company secretary, managing-director Rodger Johnston had stepped down to a non-executive director and Peter Elliott has resigned as a director.
The company said that Mr Pryor was previously the Australian Institute of Refrigeration, Air Conditioning and Heating chief executive officer and prior to that had worked for Amcor, Watyl Paints, BTR Nylex and Brick and Pipe Industries, and was a director of the Essendon Football Club.
Medivac said that Mr Pryor held a Bachelor of Economics degree.
Medivac last traded at 0.3 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has launched a 50mg strength of Doryx doxycycline hyclate delayed-release tablets for severe acne and has recorded its first sales.
Mayne said it received approval for the tetracycline-class antimicrobial Doryx in December 2014 and this was the second dermatology product promoted by the US specialty brands division established earlier this year.
The company said that the delayed-release tablet incorporated its drug delivery technology to minimise exposure of doxycycline to the upper gastro-intestinal tract.
Mayne chief executive officer Scott Richards said that the Doryx 50mg tablet was “the lowest delayed-release, enteric-coated dose for the adjunctive treatment of severe acne available in the United States [and] launch timing coincides with the US back-to-school period when use of acne medications traditionally increases”.
Mayne was up 1.5 cents or 1.3 percent to $1.17 with 1.9 million shares traded.

MAYNE PHARMA GROUP

Thorney International says the issue of 13,553,133 management shares has diluted its holding below the five percent substantial shareholding level.
In March, Thorney increased its holding to 40,300,000 shares but was diluted to 5.14 percent by the one-for-3.45 rights issue on February 19, 2015 (BD: Mar 13, 2015).
In 2010, the then Tiga Trading became a substantial shareholder in Mayne Pharma, then known as Halcygen, with the acquisition of 9,488,557 shares or 6.31 percent of the company (BD: Nov 15, 2010).
Today, the Pratt Industries-related company Thorney International said that it sold 300,000 shares between April 2 and May 28, 2015 at “market prices”.

ANALYTICA

Analytica says it has appointed former European Medicines Agency head and CBio director Dr Thomas Lönngren as a non-executive director, effective from today.
CBio (now Invion) appointed the Dr Lönngren as a director in January 2011 but he resigned in December 2011 (BD: Jan 27, 2011; Jan 22, 2012)
Analytica chairman Dr Michael Monsour was previously a founder, chairman and major shareholder of CBio, also resigning in 2011 (BD: Nov 29, 2011).
In August 2011, CBio’s 155-patient phase IIa safety and efficacy trial of chaperonin 10, Cpn10 or XToll, failed to meet its primary endpoint (BD: Aug 1, 2011).
Today, Analytica said that Dr Lönngren brought “a wealth of knowledge to the board having had a distinguished career serving as top international regulator for over 25 years”.
Analytica said Dr Lönngren was the head of the European Medicines Agency for 10 years and was previously Sweden’s Medical Products Agency deputy director general.
The company said that Dr Lönngren was currently the founder of London’s Pharma Executive Consulting and a director of Global Kinetics Corp.
Dr Monsour said that Dr Lönngren had “a profound knowledge and experience in drug and medical device regulation and health economics across the world's major markets”.
“His extensive network of contacts in multinational pharmaceutical and medical device companies and capital markets will be a great asset for our company as we expand our operations into the United States and Europe,” Dr Monsour said.
Analytica said that Dr Lönngren held a Degree in Pharmacy and a Master of Science Degree from Sweden’s University of Uppsala.
Analytica fell 0.1 cents or 11.1 percent to 0.8 cents with 8.2 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its August 18, 2015 Bio-Briefing will explore investor relations, approaches to partnering and licencing deals, with a focus on JP Morgan.

The Network said that the briefing, entitled 'Investor Relations: The JP Morgan Annual Healthcare Conference Experience' will be an interactive session and provide a "field guide" to the event itself, how to get the most out of the JP Morgan week, including tips and advice for those thinking of attending in future.

The Network said that investors and bio-pharmaceutical executives gather in San Francisco each year for the JP Morgan Annual Healthcare Conference, known as the largest and most frenzied healthcare conference of the year and there was a growing number of associated side events held in the same week, such as the Biotech Showcase, an investor and partnering conference.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "all this activity makes San Francisco the place to be each January for those looking for investments and drug licencing or development deals".

"But how does it work?" Dr Evans asked. "Is it worth going?"

The Network said that the Bio-Briefing panel included IDT Australia's managing director Dr Paul MacLeman, Buchan Communications head of investor communication Kyahn Williamson, Nucleus Network chief executive officer Dr Bev Thomas and Nexvet Biopharma's chief financial officer Damian Lismore.

The August 18, 2015 Bio-Briefing will be held at the Nexia Australia, Level 18, 530 Collins Street, Melbourne with registration from 3.45pm and the panel discussion from 4pm to 5.15pm followed by a networking session.

To register go to: http://www.biomelbourne.org/events/view/375