Biotech Daily

Thursday November 13, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIOTRON UP 7%, PRANA DOWN 11%**

*** BENITEC DOSES 2nd TT-034 HEP C PATIENT; 4D, TOUCHLIGHT DEALS**

*** IMPEDIMED $33m UNDERWRITTEN 3-FOR-13 RIGHTS ISSUE**

*** UK NICE SENDS AVITA RECELL BACK TO LARGE AREA WOUND XP FUTURE**

*** OSPREY AVERT SALES UNDERWAY, TRIALS ON TRACK**

*** BELGIUM APPROVES PSIVIDA'S ILUVIEN FOR DME**

*** MESOBLAST PHASE II BACK PAIN DATA PRESENTED**

*** CHINA ALLOWS STARPHARMA DENDRIMER AGRO-CHEMICAL PATENT**

*** IMUGENE PLACES $2.25m, SHARE PLAN FOR MORE**

*** 37% OF BIOTA OPPOSE DIRECTORS RUSSELL PLUM, DR JIM FOX, PAY**

*** ANALYTICA PERICOACH LAUNCH DELAY**

*** CALZADA APPOINTS PAUL BRENNAN CEO**

*** LANG WALKER TAKES 16% OF MEDICAL AUSTRALIA, NZ WINDFALL 14%**

*** CORRECTION: AGENIX**

MARKET REPORT

The Australian stock market fell 0.37 percent on Thursday November 13, 2014 with the S&P ASX 200 down 20.4 points to 5,442.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and six were untraded. All Big Caps rose.

Biotron was the best, up 0.7 cents or 7.1 percent to 10.5 cents, with 2.2 million shares traded. Universal Biosensors climbed 6.25 percent; Anteo rose 4.8 percent; Antisense, Bionomics, Prima and Psivida were up more than two percent; with Alchemia and Nanosonics up more than one percent.

Prana led the falls, down 2.5 cents or 11.4 percent to 19.5 cents with 292,466 shares traded. Benitec eased 8.3 percent; Avita and Patrys lost five percent or more; Admedus and Medical Developments fell more than four percent; Analytica, Ellex, GI Dynamics, Pharmaxis and Starpharma were down more than three percent; Impedimed shed 2.2 percent; Atcor fell one percent; with Clinuvel down 0.2 percent.

BENITEC BIOPHARMA

Benitec says it has dosed the second patient in its first-in-man phase I/IIa trial of TT-034 for hepatitis C.

Benitec said that the patient was treated with a single infusion of the DNA-directed RNA interference (ddRNAi) drug TT-034 at the Durham, North Carolina-based Duke Clinical Research Unit.

The company said that approval to dose the second patient followed the data safety monitoring board assessment of data from the first patient and recommended that the study could continue without modification.

Benitec said that the same review process would occur after each patient group.

The company said that a third patient had been identified as suitable for inclusion in the trial and would be dosed provided the prospective third patient's clinical data remained within the enrollment criteria and the data safety monitoring board determined it was safe to do so after reviewing the second patient over the next six weeks.

Benitec said that the trial was an open label, dose-escalation study of 14 hepatitis C genotype 1 patients.

Benitec chief executive officer Dr Peter French told a webcast of the annual general meeting, that the first two patients were in the first cohort, with subsequent cohorts dosing one patient, assessing and then dosing two patients.

Dr French said that he expected 12 patients to be dosed in 12 to 18 months with "efficacy dosing in the third and fourth cohort" and that in the first patient, TT-034 had "reached the liver with no safety effects".

Dr French said that the company had signed an agreement with the San Francisco, California based 4D Molecular Therapeutics to develop adeno-associated virus (AAV) vectors for use in a treatment for age-related macular degeneration.

In his presentation, Dr French said that AAV vectors had been shown to "produce years of expression following a single administration ... [and would] deliver exciting advancement and significant competitive advantages for Benitec's [age-related macular degeneration] program".

Dr French said that the 4D collaboration could also be used ot develop other vectors targeting tissues other than liver and neuronal.

Dr French said that Benitec had an option agreement to licence the Surrey, UK-based Touchlight Genetics closed linear 'doggy bone' DNA (dbDNA) platform for non-small cell carcinoma and hepatitis B, with the potential to encompass ddRNAi in general.

He said the two companies were working to develop and test doggybone ddRNAi constructs for lung cancer and hepatitis B.

Benitec fell seven cents or 8.3 percent to 77 cents with 1.1 million shares traded.

IMPEDIMED

Impedimed says it expects to raise about $33 million through a fully underwritten, non-renounceable, three-for-13 entitlement offer of up to 55 million shares at 60 cents a share.

Impedimed said that the record date was November 19, the offer would open on November 24 and close on December 5, 2014.

The company said the funds were to "accelerates its interactions with major customers and partners" and part of the proceeds would go to sales, marketing and training; the expansion of reimbursement; continued product development and enhancement; post-approval clinical trial support; inventory growth; and general working capital purposes.

Impedimed said the offer was fully underwritten by Canaccord Genuity Australia.

Impedimed fell 1.5 cents or 2.2 percent to 67.5 cents with four million shares traded.

AVITA MEDICAL

Avita says a UK agency wants more evidence before it can recommend Recell for acute burns and has recommended it return to its original large area use.

In 2008, Clinical Cell Cultures merged with Visiomed to form Avita and then chief executive officer Dr Bill Dolphin said that Cellspray and Cellspray XP, developed by Prof Fiona Woods for large acute burns, were “on the shelf” and the company would proceed with Recell for dermatology and cosmetic uses (BD: Jun 4, 2008).

Today, Avita said that the UK National Institute for Health and Care Excellence (Nice) said that Recell “demonstrates potential to improve healing of acute burns, [but] more evidence is required before a formal recommendation can be granted” for the use of Recell Spray-on Skin for the treatment of skin loss, scarring and depigmentation after a burn injury.

The company said that the Institute provided guidance and advice to improve the quality of health and social services in the UK and was an advisory agency to the National Health Service but was not statutory like the pharmaceutical guidance given by the European Medicines Agency, nor was it a reimbursement agency.

Avita said that technologies, such as Recell, could apply for a Nice guidance recommendation which could be positive, negative or require more evidence.

Avita said that a positive guidance recommendation often streamlined the purchase and procurement process in NHS hospitals but was not a prerequisite for procurement as demonstrated by the various NHS hospitals already using Recell.

The company quoted the Institute’s media release saying “It’s essential to note that these recommendations for further research don’t mean that these promising technologies should not be used, as it’s important that more data can be generated to help inform further considerations on their clinical utility”.

Avita said the Nice Recell application was initially reviewed by the Agency’s Medical Technologies Advisory Committee in November of 2013 and the Committee requested further evidence of Recell’s efficacy in the treatment of acute large full-thickness or deep partial-thickness burn injuries, which was in part produced by the External Assessment Centre and subsequently the company provided new data in May 2014.

Avita said that the Medical Technologies Advisory Committee reviewed the additional evidence in September and said that Recell was a “promising technology with potential to improve healing in acute burns, especially for patients with burns that need skin grafting”, but cited insufficient evidence when they attempted to determine the most appropriate patient population for the Recell Spray-on Skin system.

The Committee said its expert clinical advice was that Recell might be most beneficial for treating large area full-thickness or deep partial-thickness burns requiring skin grafting.

The Committee said that medical professionals who had used Recell when treating skin graft patients, saw the benefit to the healing process and found the immediate availability of the cells produced was an advantage over cultured cells which required a two week waiting period and had limited availability and noted the potential for Recell to reduce graft donor sites healing time, allowing further grafts to be taken earlier from the same site.

Avita said it had planned the introduction of a higher capacity device for treatment of larger burn injuries and re-positioning of the product for complementary use in patients requiring grafting.

Avita chief executive officer Tim Rooney said that further evidence would be provided to aid the Committee determine which patient population was best served by Recell.

“The treatment of more patients with large-area full-thickness or deep partial-thickness burns requiring skin grafting in our US clinical burns trial will give rise to key evidence for MTAC’s evaluation,” Mr Rooney said.

Avita fell half a cent or five percent to 9.5 cents.

OSPREY MEDICAL

Osprey says that sales of its Avert system are underway in the US with three hospitals acquiring the cardiac dye reduction system and eight more evaluating it.

In Australia for investor meetings, Osprey chief executive officer Mike McCormick told Biotech Daily that the company would report its first sales in the three months ending December 31, 2014.

Mr McCormick said that the company provided the Avert system to hospitals for free, but the disposables cost $US450 per procedure.

Mr McCormick said that the sales representative explained the system to the doctors who were using cardiac dye, principally for stent procedures, and "the doctor doesn't do anything different" to their normal dye injection except they can see how much dye has not been wasted.

He said physician concerns were primarily that reduced dye would mean a less clear image, but the Avert system was removing reflux dye that wasn't used in showing the blood vessels being imaged and was not only wasted, but potentially toxic to kidneys.

Mr McCormick said that the Avert system with its controlled injector saved up to 40 percent of cardiac dye.

Mr McCormick said that 55 patients had been enrolled in the 700-patient European and US trial to win approval for the claim that the system was effective for reducing contrast-induced nephropathy (CIN).

He said that enrollment in the trial was ahead of target and it was expected to finish by July 2015 with US Food and Drug Administration approval expected in "late 2015".

Mr McCormick said that once the claim had been approved, the company would hire 40 sales representatives in the US to begin sales.

Mr McCormick said that at the same time the company expected FDA approval for the Avert Plus in December and once approved, all Avert systems would become Avert Plus systems with its sophisticated dye dosage measurement monitor display.

The Avert Plus combination of the Avert dye reduction system, with a 'smart' syringe and comprehensive monitor was launched at the Transcatheter Cardiovascular Therapeutics meeting in Washington DC in September (BD: Sep 18, 2014).

Mr McCormick said that Osprey's programs were on-track and on-budget.

In a presentation, Osprey said that 15 patients had been enrolled in its 20-patient trial of its diabetic limb recovery system, which was expected to complete enrollment this year.

Osprey's technology was originally developed at Melbourne's Baker IDI and Alfred Hospital, with the company listed on the ASX and headquartered in Minnetonka Minnesota, 15kms from Minneapolis and close to major cardiac device companies.

Osprey was untraded at 59.5 cents.

IMUGENE

Imugene says it has issued 210,000,000 shares at one cent a share raising $2.10 million with shareholder approval sought to issue 15,000,000 shares to director Otto Buttula.

Last week, Imugene announced the placement to clients of Forrest Capital and to be followed by a share plan for investors at the record date of November 3, 2014, with the offer opening on November 7 and closing on November 28, 2014 (BD: Nov 5, 2014).

Today, Imugene said that Forrest Capital was entitled to a management fee of two percent and a selling fee of four percent of the gross proceeds.

Imugene chief executive Charles Walker said the funds would support the development of HER-Vaxx and a "promising new therapy for gastric and other HER-2 positive cancers".

Imugene was unchanged at 1.2 cents.

PSIVIDA

Psivida says that the Belgium is the 12th country to grant marketing authorization for Iluvien for chronic diabetic macular oedema.
Psivida said that the Belgium's Federal Agency for Medicines and Health Products granted authorization for Iluvien for vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies.
Psivida said Iluvien was marketed in the UK and Germany, was scheduled to launch in Portugal this year, had approval in 11 EU countries with approval pending in six others.
The company said that Iluvien was recently approved in the US for treatment of diabetic macular oedema (DME) for patients previously treated with a course of corticosteroids who did not have a clinically significant rise in intraocular pressure and was expected to be marketed in the US in early 2015 (BD: Sep 29, 2014).
Psivida chief executive officer Dr Paul Ashton said the company was pleased with the Iluvien's progress gaining approvals in Europe and the US.
"We believe Iluvien's efficacy and three-year duration will make it an attractive treatment option for many DME patients, particularly in the US where it has broader labeling," Dr Ashton said.
Psivida said it was entitled to 20 percent of the net profits from sales of Iluvien by its licencee Alimera Sciences on a country-by-country, quarter-by-quarter basis.
Psivida was up nine cents or 2.1 percent to $4.36.

MESOBLAST

Mesoblast says a presentation on its phase II degenerative disc disease trial shows that a single injection of its stem cells resulted in improved pain and function at 12 months.
Mesoblast first published the results in January and said that the Los Angeles-based Cedars-Sinai Medical Center trial investigator Dr Hyun Bae presented the results on behalf of the trial investigators at the North American Spine Society (BD: Jan 30, 2014).
Dr Bae said that there was "a critical need for a non-surgical biologic approach to improve pain and function in the millions of patients suffering from chronic low back pain associated with disc degeneration".
"The results to date seem promising and I believe Mesoblast's stem cell therapy product could have the potential to transform the treatment of back pain," Dr Bae said.
Mesoblast said the trial enrolled 100 patients with moderate to severe low back pain caused by early disc degeneration, who were randomized to receive direct intra-disc injection of saline (n= 20), hyaluronic acid (HA, n=20), 6 million allogeneic mesenchymal precursor cells in hyaluronic acid carrier (6M, n=30) or 18 million allogeneic mesenchymal precursor cells in hyaluronic acid carrier (18M, n=30) and were being assessed for safety and efficacy over 36 months to evaluate long-term treatment effects.
Mesoblast said that the key findings presented to the meeting were that the cells were well tolerated and both active doses showed improvement relative to controls for pain and functional improvement and reduced interventions.
The company said that radiographic evidence showed decreased abnormal vertebral movement, suggesting improvement in disc structure and stability.
Mesoblast said that mesenchymal precursor cell-treated patients were three times more likely to achieve treatment success defined as clinically significant pain and function improvement without further intervention at both six and 12 months, compared to controls
Mesoblast said that in line with discussions with the US Food and Drug Administration, it expects to begin a phase III regulatory directed program by the end of this year.
Mesoblast was unchanged at $4.04 with 388,118 shares traded.

STARPHARMA HOLDINGS

Starpharma says that China's State Intellectual Property Office will grant a formulation patent for Priostar dendrimers with agro-chemicals, including with glyphosate.
Starpharma said the patent, with a term projected to be until 2030, would further strengthen and expand its patent portfolio for the use of its proprietary dendrimers in agro-chemical products.
The company said that glyphosate was the world's leading herbicide with global sales of more than $US5 billion in 2012 and China was the largest producer of glyphosate, with production capacity exceeding 600,000 tonnes s at the end of 2012.
Starpharma chief executive officer Dr Jackie Fairley said that the Priostar dendrimers "enhanced ... glyphosate formulations, especially when used with hard-to-kill weeds".
Dr Fairley said the patent would support commercialization of Starpharma's dendrimer technology in China and, because of China's glyphosate manufacturing, globally.
Starpharma said that patent applications covering this subject matter had been filed in the other major agro-chemical markets, with the Chinese patent the first to be allowed.
Starpharma fell two cents or 3.4 percent to 56.5 cents with one million shares traded.

BIOTA PHARMACEUTICALS

Biota says its annual general meeting voted strong dissent against the re-election of directors Russell Plumb and Dr Jim Fox, as well as executive pay.
In September, Biota said that Dr Fox would resign as chairman and be replaced by Mr Plumb as executive chairman, with Dr Joseph Patti appointed as chief executive officer, effective from October 1, 2014 (BD: Sep 29, 2014).
Biota said that 5,043,239 shareholder votes (36.5%) were "withheld" from the election of Mr Plum, with 8,786,589 votes (63.5%) in favor and 9,775,423 "broker non-votes", indicating shares in which the proxy vote was not specified or not valid.
Dr Fox faced a slightly lower level of opposition with 4,970,021 votes withheld and 8.859,807 votes in favor, with five other directors, Mr Patti, Dr Geoffrey Cox, Michael Dougherty, John Richard and Anne VanLent opposed by more than 1.3 million votes with more than 12.1 million votes in favor.
All directors had 9,775,423 broker non-votes.
Depending on companies' constitutions "withheld" votes are not able to remove directors, even when they are a majority.
A non-binding vote on compensation for named executives faced 4,886,342 votes (36.5%) against and 8,507,127 votes (63.5%) for, with 9,775,423 broker non-votes.
The ratification of Pricewaterhousecoopers as its accountant was passes overwhelmingly.
Biota said it had 35,100,961 shares on issue, meaning that the votes against Mr Plum amounted to 14.4 percent of the company.
In August, Biota said that top-line data from its phase II 'Igloo' trial comparing 40mg and 80mg laninamivir octanoate to placebo showed no significant benefit (BD: Aug 4, 2014).
In June, following the termination of its $US231 million 2011 BARDA contract, Biota said it would close its Australian operations and sack more staff (BD: Jun 3, 2014).
Biota was developing its long-acting neuraminidase inhibitor laninamivir octanoate, when it merged with Nabi Pharmaceuticals to access its $US54 million in cash, eventually settling for $US27 million in cash (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).
Last night on the Nasdaq, Biota was up three US cents or 1.3 percent to $US2.29 ($A2.63 - equivalent to 32.875 cents prior to the Nabi merger, when it was trading around $A1.00), with 11,455 shares traded.

ANALYTICA

Analytica says its launch of the Pericoach system has been delayed several weeks following the identification of a fault in a “widely-used third-party driver software”.
Analytica said that the updated, dual-operating system product version had its first batch in the final stages of production and was awaiting final Iphone operating system application approvals from Apple Inc.
Pericoach is an intra-vaginal diagnostic to improve pelvic floor strength and reduce stress incontinence.
The company said its engineers were delayed several weeks identifying the fault and had worked with external developers to rectify the issue for users of the Bluetooth electronics.
Analytica said that the Apple application shop approval had been delayed with additional requests for hardware samples for testing at Apple headquarters in Cupertino, California.
The company said that the hardware samples had been sent and the approvals process would resume shortly.
Analytica chief executive officer Geoff Daly stated the “challenges were frustrating to be sure, but just a natural part of the product development process”.
Analytica fell 0.1 cents or 3.3 percent to 2.9 cents with 1.6 million shares traded.

CALZADA

Calzada says it has appointed Paul Brennan as chief executive officer.
Calzada said that Mr Brennan had been Smith and Nephew Australia and New Zealand Marketing Director since 2008 and had extensive knowledge of the health systems of Australia, New Zealand and the Asia-Pacific Region.
The company, which was developing the Polynovo Novosorb wound treatment, said that Smith and Nephew was a wound-care, orthopaedic implant, endoscopy and biologic manufacturer and the market leader in wound-care in Australia and New Zealand.
Calzada said that Mr Brennan had coordinated the marketing, manufacturing, strategy development, new product development and regulatory processes for the Asia-Pacific region for medical products and devices.
The company said that from 2003 to 2008 Mr Brennan was Ansell Healthcare’sAsia-Pacific marketing director and Australia and Zealand sales director.
Calzada said that Mr Brennan held Bachelor of Science from the University of New England in New South Wales and a Masters of Business Administration from Melbourne’s Swinburne University.
Calzada was untraded at 9.5 cents.

MEDICAL AUSTRALIA

Lang Walker and associated companies have increased their substantial holding in Medical Australia from 11,087,170 shares (10.86%) to 22,174,340 shares (16.21%).
The substantial shareholder notice said that Auckland Trust Co as trustee for the Second Pacific Master Superannuation, Walker Group Holdings and Langley Alexander Walker acquired the shares in the recent rights issue at six cents a share (BD: Nov 10, 2014).
In a separate notice, the Nelson, New Zealand-based Windfall (NZ) Trust said it had increased its holding in Medical Australia from 10,000,000 shares (9.78%) to 20,000,000 shares (14.62%).
The substantial shareholder notice said that Lance Ogilvie and Andrew Talijancich as trustees for the Windfall (NZ) Trust acquired the shares in the rights issue.
Medical Australia was up 0.5 cents or 7.7 percent to seven cents.

AGENIX

Last night's edition reported that Agenix director Anthony Lee, who was appointed in 2007, had left the company but no other information was given.

Agenix has told Biotech Daily that Mr Lee's departure was announced in the notice of annual general meeting on October 2, 2014, albeit on page six of a nine page document.

Agenix said in its notice of meeting that Mr Lee was granted the title of 'datuk' in Malaysia for services rendered and congratulated the "significant achievement".

Agenix said that Mr Lee had determined that following the exit from its China operations he would not offer himself for reelection as a director.

The company said that Mr Lee was instrumental in the involvement with its China operations, providing guidance and insight to the complexity of the Chinese legal systems and knowledge of local laws.

Agenix said that Mr Lee would remain a director of the subsidiary until it had all regulatory approvals required in China to cease operations.

The company said it would reimburse Mr Lee on a time spent basis during this time, but not exceeding the amount that he would have been otherwise entitled to as a non-executive director.

Agenix said it thanked Mr Lee for his services as a director.

Biotech Daily apologizes for the oversight and the Wednesday sub-editor has been appointed to the AFL Umpires Association, sponsored by OPSM.

Agenix fell 0.2 cents or 12.5 percent to 1.4 cents.