Biotech Daily

Monday November 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TISSUE THERAPIES UP 24%, AVITA DOWN 13%**

*** IDT FILES FIRST FDA ANDA FOR GENERIC TEMOZOLOMIDE FOR CANCER**

*** PRANA SAYS MOST ALZHEIMER'S TRIAL PATIENTS IN EXTENSION STUDY**

*** FDA APPROVES MEDICAL DEVELOPMENTS' SPACE CHAMBERS**

*** US PATENT FOR PATRYS PAT-SM6**

*** ASX REINSTATES VIRAX FROM TOMORROW**

*** ECO QUEST, CONSEGNA BECOME CYNATA, RHINOMED**

*** CELLMID TO PAY BRYNNE EDELSTEN UP TO 1.4m SHARES FOR HAIR**

*** COGSTATE REQUESTS CAPITAL RAISING, GUIDANCE TRADING HALT**

*** OSPREY APPOINTS AVERT CARDIAC DYE STUDY INVESTIGATORS**

MARKET REPORT

The Australian stock market fell 0.31 percent on Monday November 18, 2013 with the S&P ASX 200 down 17.0 points to 5,384.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and two were untraded. All Big Caps fell.

Tissue Therapies was the best, up 5.5 cents or 24.4 percent to 28 cents with 1.0 million shares traded, followed by Compumedics up 20.9 percent to 11 cents with 73,411 shares traded, Prana up 19.35 percent to 55.5 cents with 2.7 million shares traded and Medical Developments up 11.3 percent to $1.425 with 176,919 shares traded.

Ellex climbed 7.7 percent; IDT and Patrys were up more than four percent; Antisense was up 3.1 percent; Prima rose 2.5 percent; Genetic Technologies and Viralytics were up more than one percent; with Bionomics, GI Dynamics and Mesoblast up by less than one percent.

Avita led the falls, down 1.5 cents or 13.0 percent to 10 cents with 1.1 million shares traded. Atcor lost 9.5 percent; Universal Biosensors fell 7.4 percent; Reva was down six percent; Anteo and Neuren fell four percent or more; Allied Health, Cellmid and Impedimed shed two percent or more; Acrux, Alchemia, Clinuvel, Cochlear, Living Cell, Nanosonics, QRX and Starpharma were down one percent or more; with CSL, Resmed and Sirtex down by less than one percent.

IDT AUSTRALIA

IDT Australia says it has filed an abbreviated new drug application with the US Food and Drug Administration for six different strengths of temozolomide capsules.

IDT managing director Dr Paul MacLeman told Biotech Daily that the cytotoxic temozolomide was marketed by the US-based Merck Inc as Temodar and was indicated for the treatment of melanoma and glioblastoma multiforme.

Dr MacLeman said temozolomide was already off-patent in the Europe Union and would come off-patent in the US in 2014.

IDT said that for the year to March 31, 2013, the global market for temozolomide was about $US996 million.

Dr MacLeman said that IDT had previously manufactured a large batch of the temozolomide and FDA submission "[leveraged] the specialist manufacturing plant, formulation expertise, handling and know-how that have been built up at IDT to handle difficult to manufacture drugs".

IDT said it had a wide body of manufacturing expertise and know-how relating to a number of drug classes and many of the products had become available for generic registration as their patents expired.

The company said it had "a suite of potential generic products with substantial markets and short timelines to market".

IDT said that the abbreviated new drug application for temozolomide was achieved by the manufacture of three finished dose stability batches and demonstration of bioequivalence.

The company said that intravenous drugs were automatically deemed to be equivalent, while oral drugs could require in-vitro studies, or in some cases a small human or animal equivalence study.

"IDT's strategy is to maximize the value of our substantial infrastructure, experience and intellectual property to selectively grow our own generic drug portfolio," Dr MacLeman said.

"IDT is now in the process of moving up to a greater share of the industry value chain as the owner of a range of registered and marketed drugs rather than solely as a contract manufacturer of pharmaceutical ingredients," Dr MacLeman said.

"This change could potentially take our share of the value chain for such products from single digit percentages to tens of percentages of the wholesale price," Dr MacLeman said.

IDT said it was "in regular discussions with several large generic pharmaceutical distributors in the US and elsewhere who … expressed interest in partnering for the sales and marketing of IDT generic products".

The company said that its supply of "turnkey" products with marketing approvals, materially de-risked deals for the companies, delivering more value to IDT.

IDT said it was beginning with this first oncology drug filing but planned to file for selected additional generic drugs over the next 12 to 18 months.

The company said that prioritization would be focused on those drugs where IDT had a clear competitive advantage, encompassing existing tight active pharmaceutical ingredient supply, a difficult to manufacture or difficult to handle drug, which was off or coming off patent and where there was strong market demand.

IDT said that many of these drugs were likely to be oncology drugs, which in addition to being high value, often required specialized manufacturing facilities and skills.

The company said that the global generics market was estimated at about $US225 billion in 2011 and was expected to rise to $US358 billion by 2016.

IDT was up two cents or 4.6 percent to 45.5 cents.

PRANA BIOTECHNOLOGY

Prana says that 29 of the 42 patients in its phase II Alzheimer's disease imaging trial have completed treatment.
Prana said the 'Imagine' trial was a 12-month double-blind phase II trial of PBT2 in Alzheimer's patients, with an open-label extension available to patients completing the 12-month term of the trial, with results expected in March 2014.
The company said that participants in the extension study would receive a 250mg once daily oral dose of PBT2 for an additional 12 months.
Prana said that 24 of the 29 patients had continued to the extension trial, with a further patient currently being screened.
The company said that the data safety monitoring board had met for the fifth and final time and made no recommendations to review or alter the original trial protocol.
Prana was up nine cents or 19.35 percent to 55.5 cents with 2.7 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the US Food and Drug Administration has granted 510(k) approval to sell its range of Space Chamber Plus medical devices.
Medical Developments said the approval gave access to "the largest respiratory devices market in the world" with more than 20 million space chambers sold each year in the US.
The company said it hoped to win significant market share.
Medical Developments chief executive officer John Sharman said the FDA approval was "a great achievement for our company".
"We are in discussion with a number of business partners in the US at the date of this release and we are hopeful we can agree formal arrangements in due course which will deliver significant sales," Mr Sharman said.
Mr Sharman said that the Space Chamber and Space Chamber Plus delivered "category leading performance" for asthma and chronic obstructive pulmonary disease sufferers and both had the patented cross-valve technology which allowed patients "to manage their disease more effectively and deliver medication more efficiently".
The company said it completed several independent clinical trials proving the Space Chambers' performance as best practice for the FDA approval.
Medical Developments was up 14.5 cents or 11.3 percent to $1.425.

PATRYS

Patrys says it has been granted a second Australian patent for its anti-cancer product PAT-SM6, entitled 'Novel glycosylated peptide target in neoplastic cells', valid until 2027.
Patrys said the patent was one of a series of applications to cover the PAT-SM6 product, target and mechanism of action and the claims covered the PAT-SM6 antibody and binding fragments and methods of use of the antibody and binding fragments for treatment of various cancers including multiple myeloma.
Patrys said that in February 2012, it was granted a US patent that contained claims that covered the PAT-SM6 antibody which bound to apolipoprotein B containing low-density lipoprotein and apolipoprotein B containing oxidised low-density lipoprotein, which were part of the complex, multi-step mechanism of action for the product and that seven patents in the PAT-SM6 family had been granted in Europe, Japan, the US and Australia.
Patrys chief executive officer Dr Marie Roskrow said that the new patent "goes a step further in protection for our lead clinical candidate PAT-SM6 until 2027".
Patrys was up 0.3 cents or 4.9 percent to 6.4 cents with 29.25 million shares traded.

VIRAX HOLDINGS

The ASX says that Virax Holdings will be reinstated to official quotation at the beginning of trading on November 19, 2013.
The ASX said that Virax had effected its deed of company arrangement and completed a capital raising.
In October Virax said it expected to raise $2.5 million to return to biotechnology development (BD: Oct 25, 2013)
In July, Virax, then in voluntary administration, announced a series of capital raisings to effect a deed of company arrangement with Otsana Capital “which embodied a proposal by Otsana for the reconstruction and recapitalization of the company” (BD: Jul 31, 2013).
The proposal included a 10-for-one consolidation; the issue of shares and proposed new directors Dr Millen, Dr Roland Toder and Dr Brendan de Kauwe.
Virax last traded at 0.9 cents and is expected to resume trading around nine cents.

ECO QUEST, RHINOMED

The companies formerly known as Eco Quest and Consegna have formally become Cynata and Rhinomed trading under the ASX codes of CYN and RNO, respectively.
Cynata is hoping to commercialize mesenchymal-angioblast stem cells to provide stem cells for a range of indications (BD: Sep 24, 2013).
Rhinomed is involved with the Breatheassist range of nasal dilators (BD: Sep 19, 2013).
Cynata chief executive officer Dr Ross Macdonald told Biotech Daily the company hoped to resume trading “towards the end of this month”.
Rhinomed was up 0.3 cents or 4.8 percent to 6.6 cents with one million shares traded.

CELLMID

Cellmid says it will issue up to 1,400,000 shares under the company’s employee incentive plan to Brynne Pty Ltd, a company associated with Brynne Edelsten.
Ms Edelsten is the wife of controversial de-registered doctor and entrepreneur Geoffrey Edelsten.
Cellmid said that the shares would be issued “under a brand endorsement agreement” with 1,200,000 shares to be issued for a 12 month agreement and an additional 200,000 shares to be issued as a bonus depending on performance criteria.
The company said that Ms Edelsten would provide endorsement services for the company’s FGF-5 inhibitor hair growth products.
Cellmid said shareholder approval was not required.
Cellmid fell 0.1 cents or 2.4 percent to 4.1 cents with 4.55 million shares traded.

COGSTATE

Cogstate has requested a trading halt pending an announcement “in relation to a proposed capital raising and the release of financial results guidance”.
Trading will resume on November 20, 2013 or on an earlier announcement.
Cogstate last traded at 45 cents.

OSPREY MEDICAL

Osprey says New York's Mount Sinai Hospital Prof Roxana Mehran will be the principal investigator of the trial evaluating its Avert system for reducing cardiac imaging dye.

Osprey said the trial would be used for approval for a marketing claim expansion to include "reduction of contrast-induced nephropathy" for patients undergoing angiogram or stenting procedures (BD: Sep 18, 2013).

The company said that the randomized, multi-center, investigational device exemption trial would enroll about 700 patients at up to 45 sites in the U.S., Canada, Europe, Australia, and New Zealand.

Osprey said the trial was expected to begin by the end of this year, and obtain US Food and Drug Administration clearance for the expanded claim by July 2015.

Osprey said that Prof Mehran was an interventional cardiologist and interventional cardiovascular research director at Mount Sinai.

Prof Mehran said the cardiology community had been looking for potential solutions to prevent contrast-induced nephropathy [CIN] in those patients at risk for acute kidney injury.

Osprey said that New York-Presbyterian Hospital and Columbia University Medical Center Prof Gregg Stone would be chairman of the trial's steering committee, providing strategic direction and oversight of publications.

The company said that Prof Stone was also the co-director of Transcatheter Cardiovascular Therapeutics, the world's largest symposium on interventional cardiology and vascular medicine.

Osprey said that in addition to evaluating the effectiveness of the Avert system for contrast induced nephropathy reduction, the trial would include a health economics sub-study to evaluate potential benefits for patients, hospitals and payers.

The company said that the primary investigator for the health economic sub-study would be University of Tennessee in Chattanooga Prof James Tumlin,

Osprey chief executive officer Mike McCormick said the company was "pleased to have a world-recognized medical team leading our Avert clinical trial efforts".

"The Avert system's ability to reduce the amount of dye used in commonly performed heart procedures may provide a significant benefit in patients with at-risk kidneys," Mr McCormick said.

Osprey was untraded at 73 cents.