Biotech Daily

Monday September 14, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ATCOR UP 8%; ANALYTICA DOWN 14%**

*** HATCHTECH, DR REDDY'S UP TO $279m XEGLYZE (DEOVO) DEAL**

*** MEDICAL DEVELOPMENTS, MUNDIPHARMA UP TO $77m EURO DEAL**

*** CYCLOPHARM DRAXIMAGE $6m US TECHNEGAS TRIAL DEAL**

*** COMPUMEDICS $2m SOUTH KOREA NEUROSCAN DISTRIBUTION DEAL**

*** ELLEX CITES 2 CASE STUDIES OF 2RT FOR AMD**

*** SUN ENROLS 1st DMX-200 KIDNEY DISEASE PATIENT**

*** BIOTECH TAKES 3 OF 24 FEDERAL GRANTS WORTH $2.4m OF $14.6m**

*** PROTEOMICS 'LOYALTY OPTIONS' TO RAISE $126k**

*** RHINOMED, SLEEPGP PARTNER FOR SNORING, SLEEP, MUTE PLUGS**

MARKET REPORT

The Australian stock market climbed 0.5 percent on Monday September 14, 2015 with the ASX200 up 25.4 points to 5,096.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and three were untraded.

Atcor was the best, up two cents or 8.2 percent to 26.5 cents with 565,591 shares traded.

Antisense climbed 7.9 percent; Medical Developments was up 5.3 percent; Admedus, Avita and Optiscan improved more than four percent; IDT was up 3.7 percent; Anteo, Orthocell, Pharmaxis and Starpharma rose more than two percent; Compumedics, CSL and Ellex were up more than one percent; with Mesoblast and Resmed up by less than one percent.

Analytica led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 1.5 million shares traded, followed by Living Cell down 12.5 percent to 3.5 cents with 158,843 shares traded.

Genetic Technologies lost 8.7 percent; Neuren was down 5.4 percent; Nanosonics fell 4.5 percent; Tissue Therapies was down 3.7 percent; Benitec, Bionomics, Impedimed, Reva and Universal Biosensors shed more than two percent; Biotron, Osprey and Prima were down by more than one percent; with Cochlear, Psivida and Sirtex down by less than one percent.

HATCHTECH

Hatchtech says it has a commercialization agreement with India's Dr Reddy's Laboratories for its Xeglyze head lice treatment (formerly Deovo) for up to $279 million.

Hatchtech chief executive officer Hugh Alsop told Biotech Daily the deal included $85 million in pre-commercialization milestone payments for the one-shot ovacide treatment for head lice, but no up-front fee was specified.

Mr Alsop said that Hatchtech would file its new drug application to the US Food and Drug Administration for Xeglyze, today, its first regulatory filing for the ovacide.

In a media release, Hatchtech said Dr Reddy's would have the Xeglyze rights for the US, Canada, India, Russia and the Commonwealth of Independent States, Australia, New Zealand and Venezuela.

Mr Alsop said that Hatchtech retained the rights to Xeglyze in Europe, Asia, Africa and South America, except Venezuela, but including Brazil.

Mr Alsop said that chairman and Oneventures partner and managing director Dr Paul Kelly had been integral to the deal.

"Paul Kelly has great experience in doing deals," Mr Alsop told Biotech Daily.

"He's a doctor with a long history in the US in working with life sciences companies and has exited several successfully," Mr Alsop said.

"Dr Kelly was very involved in the sale process and the support from Oneventures has been very important," Mr Alsop said.

Mr Alsop said that Hatchtech retained the rights to non-human applications of Xeglyze and its active ingredient abametapir as well as the right to commercialise the product for human uses against other ectoparasite infections.

Hatchtech said Xeglyze was identified for pre-clinical development in 2005, with a phase I trial in 2006, a phase II trial in 2008 and in 2014 the company reported 81.5 percent of 704 participants in US phase III trials remained headlice-free 14 days after a 10 minute application (BD: May 15, 2006; May 21, 2007; Jan 21, 2008; Mar 25, 2010; Sep 2, 2014).

The company said that, if approved, Xeglyze would be marketed in the US by Dr Reddy's Promius Pharma.

Hatchtech said the deal "signifies the successful exit of … venture capital investors, including Oneventures, QIC, GBS Ventures, Uniseed and Blue Sky Ventures, along with a number of private sophisticated investors", with $33 million invested since the formation of the company, and Oneventures the largest shareholder at 37 percent.

"Hatchtech will seek additional commercialisation partners in other territories for further human and non-human applications of Xeglyze," he said.

"Additionally, the submission of our new drug application to the FDA today is a significant achievement and represents the culmination of many years of development work," Mr Alsop said.

Dr Kelly said "the success of Hatchtech has not only maximized the value for shareholders, it has enhanced the experience in later-stage drug development of the researchers and the executive team involved, who will continue to reinvest their rich skills to advance other novel therapies".

Hatchtech said it had benefited from the Federal Government's R&D Tax Incentive, the Export Market Development Grant and the Innovation Investment Fund, amounting to $6 million in Government funding since inception.

The company was founded in 2001 by the University of Melbourne's Dr Vern Bowles with seed funding from Uniseed.

The company said that the New York based Molecular Securities acted as its financial advisor for the transaction and Skadden, Arps, Slate, Meagher & Flom LLP provided legal counsel, with Deloitte providing tax advice.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Mundipharma will pay up to $US54.5 million ($A76.9 million) for the exclusive rights to Penthrox in 39 European countries.

Medical Developments said the Cambridge, UK-based Mundipharma deal included a $US7 million ($A9.8 million) payment on signing and $US10 million ($A14.1 million) for marketing approvals and first re-imbursed sales of the Penthrox methoxyflurane inhaled analgesic for the emergency treatment of pain.

The company said that Mundipharma would have exclusive product rights in 39 European markets including France, Germany, Italy and Spain, but excluding Hungary, the Republic of Ireland and the UK.

Medical Developments said that first country launches might begin in 2016 following registration and local pricing and reimbursement approvals.

The company said that Mundipharma would pay up to $US37.5 million on sales-based milestones, as well as a gross margin on product sold to Mundipharma and royalties based on net sales.

Medical Developments said that Mundipharma had extensive experience in pain management and strong commercial capabilities.

Medical Developments chief executive officer John Sharman said that Mundipharma had "the reach and financial capacity to drive sales much harder and faster than we could do with our own resources".

"Their role extends beyond simply marketing the product, as Mundipharma will play an active role in the further development of Penthrox for existing and new clinical applications," Mr Sharman said.

Medical Developments was up 12 cents or 5.3 percent to $2.40.

CYCLOPHARM

Cyclopharm says it has a term sheet with Jubilant Draximage, to provide up to $6.3 million for US trials and take an exclusive licence to market and distribute Technegas in the US.

Cyclopharm managing director James McBrayer told Biotech Daily that in 2014, 600,000 US citizens had nuclear imaging for pulmonary embolisms worth $US90 million and it would be reasonable to expect that, when approved, Technegas could be used in 80 percent of that market, and earn a 17.5 percent royalty from Draximage, in addition to an agreed margin above the cost of goods sold.

Cyclopharm said that the Kirkland, Quebec-based Draximage was a subsidiary of the Uttar Pradesh, India-based Jubilant Life Sciences and would assist it in the development and financing of phase III Technegas trials and other steps required to file and obtain US Food and Drug Administration approval.

The company said that the agreement was expected to be completed within 60 to 90 days, subject to due diligence and approvals.

Cyclopharm said that Draximage would provide a non-refundable up to $US4.5 million ($A6.3 million) for the FDA clinical trial currently under development with any additional costs to be funded by both parties equally.

The company said that on successful completion of the US trial, Draximage would be able to convert the trial costs into shares up to 15 percent of Cyclopharm.

"Draximage is the market leader for nuclear medicine lung imaging in the US," Mr McBrayer said.

"We are confident that the synergies that exist between the two organisations will ensure faster acceptance of our proprietary technology," Mr McBrayer said.

Cyclopharm was up five cents or 10 percent to 55 cents.

COMPUMEDICS

Compumedics says it has a $2 million three-year contract with partner Kwangwon to distribute its Neuroscan brain research and neurology systems in South Korea.
Compumedics said the contract built on its relationship with Kwangwon and provided scope to expand and introduce its Ehealthmedics cloud-based sleep diagnostic services model in Korea.
Compumedics executive chairman Dr David Burton said his company had “spent more than a decade, with many of our Asian distributors, building a foundation for future growth in one of the world’s most challenging but highest growth regions”.
“Compumedics is now the number one premium supplier of sleep diagnostic and neurological research systems in China and has been the pre-eminent supplier of brain research equipment into [South] Korea over the same time period,” Dr Burton said.
“As a result, Compumedics is well positioned to capture growth not only in brain research across Asia, but also in sleep diagnostics and in neurological monitoring, a relatively new and untapped market for the company in Asia,” Dr Burton said.
“Compumedics has built a very strong installed base for it brain research systems in China with some 650 sites and more to come,” Dr Burton said.
Compumedics was up half a cent or 1.9 percent to 26.5 cents.

ELLEX MEDICAL LASERS

Ellex says its first commercial user case studies of its laser retinal rejuvenation therapy (2RT) have shown positive results for age-related macular degeneration.
Ellex said that in the first case an 84-year old female patient had large confluent soft drusen with few hyperpigmented areas, with some drusen, or fatty protein deposits, calcified and advanced age-related macular degeneration in the fellow eye.
The company said that following treatment with 2RT, the patients had increased best-corrected visual acuity and contrast sensitivity and marked reduction in drusen.
Ellex said that the second patient was an 81-year old female patient with bilateral confluent soft drusen and pigmentary change, a past history of bilateral cataract surgery with significant functional defects at the majority of sensitivity points. The company said that treatment with 2RT resulted in drusen resolution and concurrent improvement in best-corrected visual acuity and contrast sensitivity.
The company said the two case studies were presented by Vienna’s Prof Christopher Kiss and New Zealand’s Dr David Worsley, respectively, at the 2RT commercial release at the European Society of Cataract and Refractive Surgeons meeting in Barcelona, Spain, September 5 to 9, 2015
“2RT nano second laser has demonstrated an effective intervention for degeneration and improvement in macular function,” Dr Worsley said.
“For me this case represents 2RT providing a benefit in macular function and appearance in patients with drusen and functional defects,” Prof Kiss said.
Ellex said that at mid-August 2015, commercial 2RT procedures had been carried out on about 1,000 patients.
Ellex chief executive officer Tom Spurling said the long term laser intervention in early age-related macular degeneration (Lead) trial of 2RT being conducted in Australia was expected to provide quantative data on the efficacy of 2RT (BD: Nov 23, 2012).
“In the meantime our early adopters are providing important information about 2RT’s clinical usage and potential,” Mr Spurling said.
Ellex was up half a cent or 1.3 percent to 38 cents.

SUN BIOMEDICAL

Sun says the first patient has been enrolled in a phase II study of DMX-200, a combination of irbesartan and propagermanium for chronic kidney disease.

Sun said that irbesartan was used to treat hypertension and nephropathy in type II diabetic patients and propagermanium was used for hepatitis B in Japan and as a dietary supplement in the US.

The company said it had previously published pre-clinical data showing that combining the drugs blocked an inflammatory response which prevented the kidneys from functioning properly and releasing protein into the urine, or proteinuria.

Sun said the primary goal of the single-arm, open-label study was to demonstrate the safety of DMX-200 in patients with chronic kidney disease, with secondary endpoints including reduction of levels of protein in the urine in patients with the disease.

Sun said the two part trial would enrol up to 30 patients in the first part, with an interim look at 15 patients by mid-2016, with the second part also enrolling up to 30 patients.

Sun executive chairman Dr James Williams said that DMX-200 had a number of potential advantages over current therapeutic approaches and “to expedite our path to market we intend pursuing registration initially for an orphan indication”.

“Analysis of the interim data of up to the first 15 patients in the study will be used to inform and support regulatory paths required to achieve this outcome,” Dr Williams said.

Sun was up 0.1 cents or 12.5 percent to 0.9 cents.

FEDERAL GOVERNMENT

The Federal Government says that of 24 companies winning grants worth $14.6 million under the Entrepreneurs’ Program, three medical research projects won $2,379,466.

In a media release the Federal Industry and Science Minister Ian Macfarlane announced the $14.6 million in commercialisation investments under the program.

The media release referred to a Government website business.gov.au which said that the Parkville, Melbourne-based Avipep Pty Ltd had been awarded $410,816 for the development of high-value cancer targeted therapies.

Avipep’s website said that its executive chair was Dr Clement Leong with Dr Peter Hudson as chief scientific officer.

The media release said that the East Brisbane-based Ellume Pty Ltd was awarded $1,000,000 for the validation of the Respirio ’Flu Test, and the Sydney-based Kico Knee Innovation Company Pty Ltd was awarded $968,650 for abstraction image guided surgery.

PROTEOMICS INTERNATIONAL

Proteomics says it expects to raise $126,454 in an underwritten, rights issue of one option for every four shares held at the record date of September 18, 2015.

Proteomics managing-director Dr Richard Lipscombe told Biotech Daily that the options offer was foreshadowed in initial public offer prospectus (BD: Nov 14, 2014, Apr 17, 2015).

“These are loyalty options for the original investors in the IPO,” Dr Lipscombe said.

The company said that the options in the non-renounceable offer, fully underwritten by the Sydney-based KS Capital Pty Ltd, would be issued at one cent each and would be exercisable at 20 cents each by March 31, 2018, with offer opening on September 21 and closing on October 9, 2015.

Proteomics said that $40,000 of the funds raised would be used for expenses of the offer, including underwriter, ASX and ASIC fees, and $86,454 for working capital.

Proteomics fell one cent or 3.2 percent to 30 cents.

RHINOMED

Rhinomed says it has formed a partnership with general practitioner practice network SleepGP to raise awareness of sleep disordered breathing issues in family medicine.
Rhinomed said that breathing and sleep played a crucial role in ensuring good health and medical research linked sleep, snoring and breathing issues at night to a range of physical and mental health conditions including depression, dementia and Alzheimer's disease.
Rhinomed chief executive officer Michael Johnson said that general practitioners played "a vital role in educating Australians about the role sleep plays in maintaining good health".
"Sleep disordered breathing is a hugely under-diagnosed and untreated condition," Mr Johnson said.
"With over 80 percent of obstructive sleep apnoea patients remaining undiagnosed, this is a significant health issue," Mr Johnson said.
Mr Johnson said that medical professionals were recognizing the role the company's Mute anti-snoring nasal plugs had to play in relieving nasal pressure and reducing snoring.
SleepGP founding clinician Dr John Malouf said his group was "pleased to be partnering with Rhinomed to drive awareness of this issue".
"Relieving airway resistance at the nasal valve is one of the important components of the SleepGP algorithm and Rhinomed's Mute performs this task admirably," Dr Malouf said.
Rhinomed was untraded at 3.5 cents.