Biotech Daily

Wednesday November 2, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ADMEDUS UP 4%, IMPEDIMED DOWN 10%**

*** IDT SHIPS 1st NEW DRUG TEMOZOLOMIDE TO US DISTRIBUTOR MAYNE**

*** OSPREY LAUNCHES DYEVERT PLUS, AVAILABLE IN 2017**

*** REDHILL $13m ADS CAPITAL RAISING**

*** ACRUX FILES ACR-065 FOR ONYCHOMYCOSIS PATENT**

*** SUDA APPLIES FOR ORAL MUCOSAL DRUG DELIVERY PATENT**

*** BIOXYNE LAUNCHES PROGASTRIM FOR GUT, PROTRACT FOR ECZEMA**

*** MEDIBIO DEPRESSION STUDY CLAIMS 86% ACCURACY**

*** RECCE: 'RECCE 327 SAFE IN MICE, DOES NOT INHIBIT CANCER'**

*** NOVOGEN'S GDC-0084 TRIGGERS 16m DR KELLY, TRIAXIAL SHARES**

*** NUHEARA APPOINTS WYNIT FOR US, CANADA IQBUDS DISTRIBUTION**

*** PRESCIENT RECEIVES $645k FEDERAL R&D TAX INCENTIVE**

*** IMUGENE REMUNERATION 1ST STRIKE WITH 37% AGAINST**

*** BANK OF AMERICA BELOW 5% IN SUDA, AGAIN**

MARKET REPORT

The Australian stock market lost 1.16 percent on Wednesday November 2, 2016 with the ASX200 down 61.5 points to 5,229.0 points. Five of the Biotech Daily Top 40 stocks were up, 28 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Admedus was the best of the few, up 1.5 cents or 4.3 percent to 36.5 cents with 2.9 million shares traded. Prima rose 2.9 percent; Cyclopharm and Polynovo were up more than one percent; with Airxpanders up 0.85 percent.

Impedimed led the falls, down 16.5 cents or 10.3 percent to $1.435 with 1.7 million shares traded. Dimerix lost 10 percent; Oncosil fell 9.1 percent; Anteo and Psivida fell more than seven percent; Bionomics was down 6.4 percent; Actinogen, Nanosonics, Osprey and Prana fell five percent or more; Compumedics lost 4.9 percent; Avita, Cellmid, Medical Developments, Resmed, Universal Biosensors and Viralytics were down more than three percent; CSL, Mesoblast, Neuren, Orthocell, Pro Medicus and Starpharma shed two percent or more; with Acrux, Cochlear, Factor Therapeutics, Genetic Signatures, Reva and Sirtex down more than one percent.

IDT AUSTRALIA

IDT says it has shipped the first of its new proprietary generic pharmaceutical products, the brain cancer drug temozolomide, to US distributor Mayne Pharma Group.

IDT said that temozolomide was one of 25 generic products in its generic product portfolio and the shipment was “the realization of the company’s push to extend its share of the value chain via the ownership of generic finished pharmaceutical products”.

The company said it would receive payment from Mayne on shipment, on usual commercial terms for the cost of goods, with the companies also sharing the gross profit on sale of the goods, on a quarterly basis.

IDT chief executive officer Dr Paul MacLeman said the shipment was “a real milestone moment … as we continue to pursue the manufacture of sophisticated generic pharmaceuticals that allow us to earn more appropriate margins compared to contract manufacturing”.

“The sale of our CMax clinical trial facility in Adelaide will allow us to further populate our generics pipeline which already features 25 drugs,” Dr MacLeman said.

“We are actively searching for new opportunities with significant addressable markets that play to our manufacturing strengths and we will announce these to the market as they are finalized,” Dr MacLeman said.

IDT was unchanged at 22.5 cents.

OSPREY MEDICAL

Osprey says has launched its Dyevert Plus cardiac-imaging dye modulation and monitoring system, which it expects to make available by April 2017.

Osprey said that Dyevert Plus integrated the existing Dyevert technology “with substantial patient management and monitoring capabilities”.

The company said the system had received Conformité Européenne (CE) mark approval and US Food and Drug Administration clearance was pending.

Osprey said that Dyevert Plus was launched at the Transcatheter Cardiovascular Therapeutics conference in Washington DC, October 29 to November 2, 2016 at the ‘Contrast-induced acute kidney injury forum’ by the Lubeck, Germany-based Prof Steffen Desch who said the platform connected the Dyevert contrast reduction capability “with the means to actively manage a patient during intervention”.

Osprey said the Dyevert Plus system allowed the technology to interface through wireless communications with a disposable ‘smart syringe’ and reusable monitor to monitor and display imaging dye dose levels based on a patient’s kidney function, providing real-time tracking of contrast injected during a procedure, allowing physicians to proactively manage a patient and provide a more accurate method of recording contrast doses.

Osprey said that the industry-guiding US Society for Cardiovascular Angiography and Interventions published a best practice update which “heightened focus on contrast management of kidney-impaired patients” which Dyevert Plus addressed, including minimization of contrast dose, contrast monitoring in real-time, and physicians being informed when limits were reached.

Osprey chief executive officer Mike McCormick said the company’s “commercialization strategy encompasses continued technology advancement, to augment our expanding sales force with the tools to ensure sustained growth”.

“Given increased scrutiny of patient outcomes, the Dyevert Plus is well situated to address new industry guidelines,” Mr McCormick said. “We expect this system will have a strong uptake as soon as it becomes available in the US.”

Osprey fell 2.5 cents or 5.9 percent to 40 cents.

REDHILL BIOPHARMA

Redhill says it hopes to raise at least $US10 million ($A13.1 million) in an underwritten offer of American depository shares, each representing 10 ordinary shares.
Redhill chief executive officer Dror Ben Asher told Biotech Daily that the company intended to raise a minimum of $US10 million at $US11 a share.
Redhill said it expected to grant the underwriters a 30-day option to purchase an additional 15 percent of the American depository shares (ADSs) offered to the public.
The company said it could not disclose “whether or when the offering may be completed, or as to the actual size or terms of the offering”.
Redhill said the funds would be used to fund clinical development programs, potential acquisitions, commercial operations and for general corporate purposes.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
The company said that Roth Capital Partners and the Arlington, Virginia-based FBR (Friedman, Billings and Ramsey) & Co were acting as joint book-running managers, with Echelon Wealth Partners as Canadian manager for the offer.
Redhill said that a preliminary prospectus supplement related to the offering had been filed with the US Securities and Exchange Commission.
On the Nasdaq, Redhill fell 22 US cents or 1.85 percent to $US11.70 ($A15.30) with 64,171 shares traded.

ACRUX

Acrux says it has filed a provisional patent application covering ACR-065 for fungal infection of the nail bed in toes and fingers, or onychomycosis.
Acrux said that the patent, entitled ‘Topical Antifungal composition and Method for treatment of Fungal Infections’ would provide coverage until November 2036, when granted and had been filed to IP Australia (formerly the Australian Patent Office) as part of an international Patent Co-operation Treaty application.
The company said that the patent application was “an important step in progressing [its] product development pipeline”.
The company said that ACR-065 was an improved formulation of Jublia, containing the anti-fungal agent efinaconazole, which was “the most effective and leading topically applied treatment on the market for onychomycosis”.
Acrux said it expected to begin clinical trials by the end of 2017.
Acrux fell half a cent or 1.5 percent to 33.5 cents.

SUDA

Suda says it has filed a provisional patent application with IP Australia (Australian Patent Office) for a novel mucosal penetration drug delivery technology.
Suda said that the patent application, entitled ‘A method for modifying the penetration of active agents through mucosal membranes using hydrotopes’ was filed under the international Patent Cooperation Treaty.
The company said that the patent was based on positive results from pre-clinical studies evaluating SUD-003 sildenafil (Viagra) oral spray for erectile dysfunction, together with in-vitro data investigating the technology with a broad range of other molecular drug classes.
Suda said its in-vivo SUD-003 study showed a significant improvement in the bioavailability, or quantity of drug absorbed, compared to the original formulation.
Suda fell 0.1 cents or 4.55 percent to 2.1 cents with 1.1 million shares traded.

BIOXYNE

Bioxyne says it has launched its first two own-brand probiotic products Progastrim for gut and immune health and Protract for atopic dermatitis, or eczema, in Australian.
Bioxyne acquired the proprietary probiotic Lactobacillus fermentum VRI-003, or PCC, assets in 2012, through the merger of Probiomics, which then had the ASX code of PCC, and Hunter Immunology (BD: Oct 11, 2011; Apr 4, 2012).
Today, the company said Progastrim and Protract Both contained the probiotic PCC, which had been "shown in several Australian scientific and clinical studies to promote gastrointestinal health and to reduce severity and duration of cold symptoms".
Bioxyne said that initially both products would be available on-line at www.progastrim.com and www.protract.com.au but it planned to make them available in Australian pharmacies.
The company said that Progastrim was listed on the Australian Register of Therapeutic Goods with the claims that it "may assist in the maintenance or improvement of general well-being, the maintenance of a normal healthy gastrointestinal system, the maintenance of a normal healthy immune system".
Bioxyne said that Protract was a formulation of PCC in sachets for infants from six to18 months suffering from eczema and was "demonstrated in an Australian clinical study to significantly improve the symptoms of moderate to severe atopic dermatitis".
Bioxyne chairman Tony Ho said it was "pleasing to have our own probiotic products in our home market to bring the benefits of PCC directly to Australians [and we will also use the products to advance our marketing efforts into other markets including China".
Bioxyne said that Progastrim was the subject of a current 60-patient clinical trial for gastrointestinal health (BD: Oct 17, 2016).
Bioxyne was unchanged at two cents.

MEDIBIO

Medibio says a University of Ottawa assessment of 259 patients for major depressive disorder using its cardiac rhythm technology was 86 percent accurate.
Medibio said that diagnostic concordance among experienced psychiatrists was 70 percent and for US general practitioners accuracy was 33 to 50 percent.
The company said its algorithm "leverages objective biomarkers computed from overnight heart rate recordings and sleep annotations to distinguish between the clinical groups".
Medibio said that the clinical assessment was performed by two University of Ottawa psychiatrists and the algorithm was trained on 630 patients, of which 315 had major depressive disorder and 315 were controls, and was then tested on 259 individuals of which 125 had major depressive disorder and 134 were controls.
The company said its cardiac rhythm algorithm had a sensitivity rate (true positives) of 82 percent and a specificity rate (true negatives) of 88 percent.
Medibio said its initial 83 percent diagnostic accuracy announced in August was based on training the algorithm with 228 patients and tested on a blinded data set of 98 patients.
The company said that the retrospective data was compiled with the University of Ottawa and included overnight heart rate recordings, sleep annotations and clinical assessments of psychiatric status.
Medibio said that a further and final 300 patients from the University of Ottawa would be used to generate an independent validation paper which would be peer-reviewed and published by the University of Ottawa.
The company said that it would expand and validate its diagnostic algorithm to identify the different presentations of depression, increasing its clinical utility.
Medibio was unchanged at 48 cents.

RECCE

Recce says that preliminary results from a mouse study of its lead synthetic anti-infective Recce 327 shows the compound is safe but did not inhibit cancer.

Recce said it was compiling pre-clinical efficacy and toxicology data across several anti-bacterial, anti-cancer and anti-viral models as part of its planned investigational new drug application to the US Food and Drug Administration by July 2017 with the pre-clinical studies expected to be completed by April 2017.

The company said that a recent dose escalation study of Recce 327 in a cancer mouse model showed the "treatment with Recce 327 was tolerated without animal deaths at both doses tested".

Recce said that "growth of the human HCT-116 colon carcinoma xenografts was not significantly inhibited by treatment with Recce 327 at either dose".

Recce executive chairman Dr Graham Melrose said that the data was "encouraging and supports the continuation of the current test protocols".

"While there was no significant inhibition of growth in the cancer cells, the good toxicology data give us confidence to the dosing of our in-vivo protocol for testing of Recce 327 activity in mice," Dr Melrose said.

Recce fell half a cent or 2.8 percent to 17.5 cents.

NOVOGEN

Novogen says it has reached a milestone which triggered the conversion 16,000,000 shares of its convertible notes.

According to Novogen's 2016 annual report it signed an agreement with the convertible note holder, former shareholders of Triaxial Pharmaceuticals Pty Ltd on November 4, 2013, allowing $400,000 of the convertible note to be exercised for 16,000,000 shares on completion of a phase Ia clinical trial.

The 2016 annual report said "the previous annual report incorrectly stated that 'the milestones listed above refer to any drug developed based on the super-benzopyran technology' but any drug developed by Novogen can trigger the milestones listed above".

"Moreover, the previous report referred to trials in relation to the milestone listed above, when in fact a single study can serve as a trigger for the relevant milestone," it said.

On Monday, Novogen licenced Genentech's phase II-ready GDC-0084 for glioblastoma multiforme for $US5 million up-front (BD: Oct 31, 2016).

The report said the other milestones included an investigational new drug application approval from the US Food and Drug Administration allowing the conversion of $500,000 into 20,000,000 shares and completion of a phase II clinical trial or breakthrough designation allowing for the conversion of $600,000 into 24,000,000 shares, with an early conversion if a third party acquired more than 50 percent of the consolidated entity.

In 2012, Novogen said it had an agreement to acquire Triaxial Pharmaceuticals for $1.88 million in scrip and debt, based on clinical milestones (BD: Nov 12, 2012).

Shortly after, Novogen appointed Dr Graham Kell chief executive officer and said it had acquired 100 percent of Triaxial for $1,885,000 consisting of 15.4 million Novogen shares and a $1.5 million loan payable to the Triaxial shareholders.

According to Dr Kelly's Noxopharm website, in 2011, Dr Kelly "joined private biotechnology company Triaxial Pharmaceuticals Pty Ltd as executive chairman".

"Concerned at the direction being taken by the Novogen board in having stripped all assets from the company and leaving it without a business, [Dr Kelly] engineered a reverse takeover of Novogen by Triaxial in December 2012," Noxopharm said.

Novogen fell 0.2 cents or 2.3 percent to 8.4 cents.

NUHEARA

Nuheara says it has appointed Wynit Distribution LLC to distribute its Iqbuds sound filtering and device ear buds for the US and Canada.
Nuheara was up 0.2 cents or 3.3 percent to 6.3 cents with 14.5 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has received $644,827 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prescient said the rebate was for expenses for the year to June 30, 2016.
Prescient fell half a cent or 4.55 percent to 10.5 cents.

IMUGENE

Imugene's remuneration report was defeated with 115,922,498 votes (37.04%) against, providing the first trigger for a board spill at the next annual general meeting.
Imugene said that 193,528,069 votes were cast for the resolution, with 3,474,722 at the proxy's discretion, voted for the resolution.
The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
The company's most recent Appendix 3B new issue announcement said that Imugene had 1,991,954,950 shares on issue, meaning that the votes against the remuneration report amounted to 5.8 percent of the company, sufficient to requisition extraordinary general meetings.
Imugene said that chairman Paul Hopper was re-elected with 115,529,791 votes (22.2%) against with a combined proxy discretion and approval of 404,526,441 votes (77.8%).
The company said that the approval of the employee share options plan and additional placement capacity were passed overwhelmingly.
Imugene was unchanged at 0.9 cents or 20.2 million shares traded.

SUDA

The Bank of America and related bodies say they have reduced their holding in Suda from 70,702,534 shares (6.20%) to below five percent.
Last year, the Charlotte, North Carolina-based Bank of America said it had reduced its holding in Suda from 77,387,842 shares (6.81%) to below five percent and 12 days later said it had "returned" 26,312,000 shares and "borrowed" 26,287,000, all at no cost (BD: Nov 12, 2015).
Bank of America previously said it had "borrowed" and "returned" shares under a prime brokerage agreement and the Sydney-based Merrill Lynch (Australia) Futures and London-based Merrill Lynch International were the holders of the shares as beneficial owner and as the borrower of securities in a prime brokerage agreement, respectively (BD: Jul 22, Dec 5, 2014).
Today, Bank of America said that between December 7, 2015 and October 28, 2016 through Merrill Lynch it sold more than 15 million shares with the single largest sale 4,500,000 shares for $90,405 or two cents a share.