



Biotech Daily

Wednesday November 15, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ACTINOGEN UP 8%; COMPUMEDICS DOWN 10%**
- * **TELIX \$50m IPO UP 25% FOR MOLECULAR TARGETED CANCER RADIATION**
- * **G MEDICAL RAISES \$13.5m**
- * **CYNATA HALF WAY IN PHASE I CYP-001 GVHD TRIAL**
- * **BIOTRON 'PRE-CLINICAL COMPOUNDS ACTIVE AGAINST HEPATITIS B'**
- * **EPAT PAINCHEK CHILDREN'S APP 'ON-TRACK'**
- * **UNIVERSAL BIOSENSORS HITS J&J \$45m FEE BUY-OUT TRIGGER**
- * **MEDICAL AUSTRALIA VOTES FOR ICU ACQUISITION**
- * **MMJ GELPELL-CBD MARIJUANA CAPSULES AVAILABLE IN AUSTRALIA**
- * **HYDROPONICS DISTRIBUTES ENDOCA MEDICAL MARIJUANA IN AUSTRALIA**
- * **ACTINOGEN RECEIVES \$1.2m FEDERAL R&D TAX INCENTIVE**
- * **35% OF IMPEDIMED OPPOSE 1.6m CEO OPTIONS, 1.3m CEO RIGHTS OKAY**
- * **LIVING CELL WITHDRAWS 6 DIRECTOR FEES, 3m OPTIONS AGM RESOLUTIONS**
- * **UP TO 23% OPPOSE NOVOGEN AGM RESOLUTIONS, NAME CHANGE APPROVED**
- * **CHALLENGER TAKES 8.6% OF AIRXPANDERS**
- * **PARADIGM M-D PAUL RENNIE, KZEE, EAR, AT 19%**
- * **OCEANIA CAPITAL TAKES 9% OF MACH7**
- * **ATCOR APPOINTS CRAIG COOPER DIRECTOR**

MARKET REPORT

The ASX200 fell 34.5 points or 0.58 percent to 5,934.2 points on Wednesday November 15, 2017, the day a \$122 million, non-binding, voluntary, postal ballot confirmed the polls that more than 60 percent of Australia supported equal marriage. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and four were untraded.

Actinogen was the best, up 0.4 cents or eight percent to 5.4 cents with 138,709 shares traded. Living Cell was up 6.45 percent; Medical Developments, Orthocell and Universal Biosensors climbed more than five percent; Starpharma improved 4.7 percent; Impedimed and Pharmaxis were up more than three percent; Admedus rose 2.2 percent; with Airxpanders, Clinuvel, ITL and LBT up more than one percent.

Compumedics led the falls, down four cents or 10.4 percent to 34.5 cents with 12,381 shares traded. Dimerix lost 10.0 percent; Mesoblast and Uscom fell more than eight percent; Oncosil was down 6.9 percent; Neuren and Prime fell four percent or more; Bionomics, Sirtex and Viralytics were down more than three percent; Avita, Benitec, Osprey and Volpara shed more than two percent; with Factor Therapeutics and Polynovo down more than one percent.

TELIX PHARMACEUTICALS

Telix opened up 24.6 percent at 81 cents following a \$50 million initial public offer to develop its 'molecularly-targeted radiation' radio-pharmaceutical programs for cancer. Telix said it was "focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or molecularly-targeted radiation ... [and] developing an advanced portfolio of oncology products that address significant unmet medical need in renal, prostate and brain, or glioblastoma, cancer".

The company's website said that it was established in January 2017 and the lead program was a zirconium-TX250 positron emission tomography agent for imaging clear cell renal cell carcinoma and in a phase III trial.

Telix said that lutetium-TX250 was also in a phase IIa trial as a therapy for renal cancer. The company said that the TX250 antibody, licenced from the Munich, Germany-based Wilex AG, bound to carbonic anhydrase 9 which was highly expressed by clear cell renal cell carcinoma tumors, including metastases and could act as a vehicle for zirconium for imaging and lutetium for therapy.

Telix said that the TX591 antibody was in a phase IIa trial for imaging and therapy of metastatic prostate cancer, and was developed at New York's Cornell University and licenced from the Cambridge, UK-based Abzena, with the TX101 small molecule, licenced from the Dresden, Germany-based Therapiea GMBH and in a phase IIa glioblastoma imaging trial and phase I glioblastoma therapy trial.

Telix said former Macquarie Group chairman Kevin McCann was its chairman with Dr Christian Behrenbruch as chief executive officer with non-executive directors including Caledonia Investments chairman Dr Mark Nelson, Dr Andreas Kluge and Oliver Buck.

Telix said that with a market capitalization of \$128 million, it was the largest for the Australian ASX biotechnology drug development sector, by capital raised, since 1994.

In 2011, the GI Dynamics initial public offer raised about \$80 million of the hoped for \$95 million at \$1.10 a share for its Endobarrier duodenum insert (BD: Aug 30, 2011).

In 2010, the San Diego-based Reva Medical raised \$85 million in its initial public offer at \$1.10 a share to develop cardiac stents (BD: Dec 16, 2010, Jan 16, 2011).

Telix said that the raising was fully underwritten by lead managers Taylor Collison and Wilsons Corporate Finance and strongly supported by existing shareholders, including Acorn Capital, CVC, Monash Investors, Viburnum Funds, Alium Capital Management and Allan Moss, with Fidelity International as a 10 percent cornerstone investor.

Dr Behrenbruch said the company was "delighted with the strong support from our partners, institutional and retail investors".

The company said that the proceeds from the initial public offer would fund the development and completion of clinical trials in renal, prostate and brain cancer and enable it to complete multiple clinical and product development milestones over the next 24 months.

Telix closed up 12 cents or 18.5 percent at 77 cents with 3.6 million shares traded.

G MEDICAL INNOVATIONS

G Medical says it has raised \$13,500,000 in a "substantially oversubscribed" placement to institutional and sophisticated investors at 43 cents a share.

G Medical chief executive officer Dr Yacov Geva said the company was "moving to commercialization of our medical devices and ancillary support service offerings at a rapid pace and this expansion capital allows us the flexibility to capitalise on our opportunities at hand".

G Medical fell 1.5 cents or 2.9 percent to 51 cents with 9.4 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has treated eight of up to 16 patients in its phase I trial of CYP-001 mesenchymal stem cells for steroid-resistant acute graft versus host disease.

Cynata said that recruitment of its first cohort had been completed and the patients received two CYP-001 infusions one week apart at the lower dose level of one million cells/kg up to a maximum of 100 million cells per infusion.

The company said a review by the independent data safety monitoring board would begin 28 days after the eighth participant's first infusion, prior to recruitment of a second cohort.

Cynata said the second cohort will receive two CYP-001 infusions one week apart at a higher dose level of two million cells/kg up to a maximum of 200 million cells per infusion.

Cynata head of product development Dr Kilian Kelly said "the completion of enrolment of the first cohort of participants in this ground breaking trial is a significant milestone".

Cynata was unchanged at 64.5 cents.

BIOTRON

Biotron says that in-vitro pre-clinical studies on several of its compounds show "significant anti-viral activity against hepatitis B".

Biotron said the US studies were in cell culture models considered industry standard and were recognized by potential pharmaceutical and biotechnology company partners.

The company said that 257 million people had hepatitis B, up to 900,000 people died every year, there was no cure and the market was expected to be \$US3.5 billion by 2021.

Biotron said that leading pharmaceutical and biotechnology companies were developing drugs to treat hepatitis B.

Biotron managing-director Dr Michelle Miller said that although her company's work was pre-clinical "the interest level in the development of [hepatitis B] treatments is ... at an all-time high".

Biotron was unchanged at 3.9 cents with 4.2 million shares traded.

EPAT TECHNOLOGIES

Epat says the first of its Painchek programs for infants, toddlers and children are on-track to be ready for approval by July 2018 and on the market by the end of 2018.

Epat chief executive officer Philip Daffas told Biotech Daily that the company had completed the video library collections for the three age groups of infants (up to 12 months), toddlers (1 to 3 years) and children (3 to 12 years), with about 70 videos compiled in each group with each video including a large number of images.

Mr Daffas said that the Painchek mobile telephone application would be able to "rule in or rule out physical pain and discomfort as compared to distress or other issues".

Epat said that the Painchek Infant video facial assessment features had been coded and these were being used for modelling and prototype development.

The company said that the Painchek Infant would be the first of the three children's applications to be commercialized.

"We believe the Painchek Infant App is the ideal market entry point," Mr Daffas said.

"There are 130 million births worldwide each year and new parents often struggle to learn how to discriminate between pain and other causes of anguish for their child," Mr Daffas said. "The Painchek Infant App will help address this need."

Epat said that the Painchek Infant application would be the first taken to market by the end of 2018 with the Toddler and Children versions to follow.

Epat fell 0.3 cents or 5.9 percent to 4.8 cents with 1.9 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received more than \$US45 million in aggregate quarterly service fees from Johnson & Johnson, triggering a possible fees buy-out.

Universal Biosensors said that the agreement with Johnson & Johnson subsidiary Lifescan included a clause that should the trigger be passed, Lifescan had the option to give notice to buy-out its obligation to pay quarterly service fees.

The company said that if Lifescan exercised the option it would continue to pay quarterly services fees for the balance of the applicable year in which the notice was given and then must additionally pay a one-time lump sum amount of double the total for the 12 months following the threshold limit request.

Universal Biosensors said that if Lifescan did not exercise the option, the fees would continue until bought out or otherwise terminated under the agreement.

Universal Biosensors chief financial officer Salesh Balak told Biotech Daily that the trigger was for the quarter in which the trigger was reached, meaning the earliest Lifescan could make the option request was January 1, 2018.

Mr Balesh said that the pay-out would be double the total amount received in service fees in the year of the request.

For the nine months to September 30, 2017, Universal Biosensors said it had received \$15.7 million in service fees from Lifescan, implying a minimum buy-out fee of about \$41.9 million, based on the sales to date, not including continued service fees growth.

In 2014, Universal Biosensors fell 39.4 percent when some investors became aware of the \$US45 million trigger (BD: May 12, 2014).

At that time Biotech Daily was contacted by a specialist finance group asking whether it was publicly known that Johnson & Johnson had a lump sum service fee option to acquire all the rights to the Universal Biosensors produced blood glucose test strips after Lifescan reached a threshold of \$US45 million in cumulative quarterly service fees.

Universal Biosensors was up two cents or 5.9 percent to 36 cents.

MEDICAL AUSTRALIA

Medical Australia says its shareholders have voted in favor of the scheme of arrangement for ICU Medical to acquire the company.

Medical Australia said it would apply to the Federal Court of Australia for orders to approve the scheme, scheduled for November 17, it proposed to lodge Court orders with the Australian Securities and Investments Commission on November 20, with the scheme becoming effective on that date and if the timetable was met the last day its shares would trade on the ASX would be November 20, 2017, with implementation expected on November 29 and shareholders receiving 8.6 cents for each share.

Medical Australia was untraded at nine cents.

MMJ PHYTOTECH

MMJ says its Melbourne distributor HL Pharma has begun distribution of Satipharm's marijuana Gelpell-CBD capsules to approved patients in Australia.

MMJ said that its 59 percent subsidiary Harvest One Cannabis, through its wholly-owned Swiss subsidiary Satipharm AG had begun distribution through HL Pharma of the Gelpell-CBD capsules which contain the marijuana extract cannabidiol (CBD) but no detectable levels of tetrahydrocannabinol (THC) and was available in 10mg and 50mg packs.

MMJ was up six cents or 14.8 percent to 46.5 cents with 9.9 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it will distribute the Hoofddorp, Netherlands-based Endoca BV medical cannabis products in Australia.

Hydroponics said that its wholly-owned subsidiary Canndeo signed the agreement with Endoca, which had sales of certified medicinal cannabis products of more than EUR50 million (\$A77.7 million) a year.

The company said that initial imports would will include cannabidiol oil, capsules and a combination oil.

Hydroponics chief executive officer David Radford said the agreement was “an important milestone” for its program to deliver medicinal cannabis in Australia.

Hydroponics rose 39.5 cents or 75.2 percent to 92 cents with eight million shares traded.

ACTINOGEN

Actinogen says it has received \$1,215,997 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Actinogen said the rebate related to research and development expenditure for the year to June 30, 2017.

Actinogen was up 0.4 cents or eight percent to 5.4 cents.

IMPEDIMED

Impedimed says that 34.88 percent of annual general meeting votes opposed the issue of 1,553,000 options to chief executive officer Richard Carreon (BD: Oct 16, 2017).

Impedimed said that the issue of 1,262,000 performance rights to Mr Carreon was passed overwhelmingly.

The company said that 80,150,432 votes (34.88%) opposed the options vote, with 149,629,447 votes (65.12%) in favor.

Impedimed said there was a 17.15 percent vote against employee incentive plan and 12.81 percent vote against the remuneration report.

The company's most recent Appendix 3B new issue announcement said that Impedimed had 375,676,036 shares on issue meaning the votes against Mr Carreon's options amounted to 21.3 percent of the company sufficient to call extraordinary general meetings. The election of directors Judith Downes, Amit Patel and Don Williams were passed overwhelmingly.

Last year, Impedimed avoided a remuneration report second strike and potential board spill with 84.8 percent of votes in favor, but 22.8 percent opposed an amendment to the terms of options for Mr Carreon (BD: Nov 14, 2016).

Impedimed was up three cents or 3.7 percent to 84.5 cents with 1.2 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it withdrew six annual general meeting resolutions to increase directors' fees by 33 percent and issue 600,000 options to each of five directors.

Last week, Living Cell announced non-significant results for its 18-patient trial of its NTCeLL treatment for Parkinson's disease (BD: Nov 10, 2017).

Today, the company said that it faced about 6.5 percent opposition to the remuneration report, the re-election of directors Roy Austin and Bernard Tuch and 4.8 opposition to the 10 percent placement facility (BD: Oct 16, 2017).

Living Cell was up 0.2 cents or 6.45 percent to 3.3 cents with 13.5 million shares traded.

NOVOGEN

Novogen annual general meeting faced strong dissent against the remuneration report, employee option plan and the increased placement capacity (BD: Oct 16, 2017).

Novogen said the strongest opposing vote saw 32,123,823 votes (23.3%) against the employee share option plan with 105,544,305 votes (76.7%) in favor.

The company said that similar numbers opposed the increased placement capacity with the remuneration report opposed by 24,946,066 (20.9%) and the re-election of director Bryce Carmine, the change of name to Kazia Therapeutics and the 10-to-one consolidation of shares passed by wider margins.

The company's most recent Appendix 3B new issue announcement said that Novogen had 483,287,914 shares on issue, meaning that the votes against the share options scheme amounted to 6.65 percent of the company, sufficient to requisition extraordinary general meetings.

Novogen fell 0.2 cents or 5.1 percent to 3.7 cents with 2.1 million shares traded.

AIRXPANDERS

Challenger and its entities say they have become substantial shareholders in Airxpanders with 24,740,731 shares or 8.60 percent of the company.

The Sydney-based Challenger said it held 9,336,046 shares at July 9 and between July 26 and November 10, 2017 acquired a further 15,404,685 shares, with most shares bought on November 10 at 68 cents a share.

A similar announcement was made by Greencape Capital yesterday and today a Challenger executive told Biotech Daily that Challenger owned 50 percent of Greencape, hence the similar filings (BD: Nov 14, 2017).

Airxpanders was up one cent or 1.4 percent to 74 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm managing-director Paul Rennie says he has increased his holding but has been diluted from 22,389,543 shares (22.06%) to 22,599,543 shares (18.73%).

The Adelaide-based Mr Rennie said that the investment was with Kzee Pty Ltd and Ear Investments and he acquired 210,000 shares for \$132,090 or 62.9 cents a share, the price approved by the board earlier this year and approved at the annual general meeting.

Paradigm fell one cent or 3.3 percent to 29.5 cents.

MACH7 TECHNOLOGIES

Oceania Capital and related parties have become substantial shareholders in Mach7 with 11,428,541 shares or 8.79 percent.

The Sydney-based Oceania Capital said it held the shares with HCI Australian Operations and HCI Investments Australia and acquired the shares in a placement at 17.5 cents a share (BD: Nov, 13, 2017).

Mach7 was up 0.25 percent to 1.4 percent to 18 cents.

ATCOR MEDICAL

Atcor says it has appointed Craig Cooper as a non-executive director effective from December 1, 2017.

Atcor said that Mr Cooper would consult with the company on a range of strategic business opportunities with a focus on digital health and artificial intelligence-based technologies.

The company said that Mr Cooper had founded health, digital media, technology and health businesses and was the co-founder of the telecommunications company Boost Mobile US and had experience in mobile and wireless technology.

Atcor said that Mr Cooper's venture capital funds had raised more than \$1 billion and have funded digital media, health and technology companies.

The company said that Mr Cooper was a director of IQ Medical and held a Bachelor of Law and Bachelor of Economics from the University of Sydney and divided his time between Sydney and Los Angeles, California.

Atcor was unchanged at 2.3 cents.