



Biotech Daily

Tuesday October 18, 2016

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: IDT UP 7%; ADMEDUS DOWN 16%
- * PHOSPHAGENICS – BACK FROM THE BRINK
- * PARADIGM PLACEMENT RAISES \$6m, SHARE PLAN FOR \$1m MORE
- * ALLEGRA \$755k ROBINWOOD RELATED-PARTY PLACEMENT
- * MAYO, ATLANTIC HEALTH STUDY IMPEDIMED SOZO FEASIBILITY
- * GENETIC SIGNATURES: 'EASYSscreen STI VALIDATED'
- * ORTHOCELL BEGINS CELGRO SCAFFOLD NERVE REPAIR STUDY
- * CLINUVEL: UK NICE RECOMMENDS STA REVIEW
- * COCHLEAR DIRECTOR DONAL O'DWYER FACES 22% AGM DISSENT
- * UP TO 17% DISSENT AT IDT AGM, GEOFF LORD GOES
- * LIVING CELL 2nd STRIKE BOARD SPILL AGM
- * BLACKROCK TAKES 5% IN CSL, AGAIN
- * LBT'S LUSIA GUTHRIE TAKES PROFIT ON 1.75m SHARES TO BELOW 5%
- * CHRIS RETZOS, ASSOCIATES TAKE 5% OF IMMURON
- * BENITEC GAINS, LOSES CO SEC SAKURA HOLLOWAY

MARKET REPORT

The Australian stock market climbed 0.41 percent on Tuesday October 18, 2016 with the ASX200 up 22.1 points to 5,410.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

IDT was the best, up 1.5 cents or 7.1 percent to 22.5 cents with 582,568 shares traded. Opthea climbed 5.3 percent; Bionomics and Cyclopharm rose more than four percent; Benitec and Impedimed were up more than three percent; Cellmid and Compumedics improved more than two percent; Clinuvel, CSL, Factor Therapeutics and Universal Biosensors were up one percent or more; with Cochlear, Resmed, Sirtex and Starpharma up by less than one percent.

Yesterday's 60 percent best, Admedus, led the falls, down 8.5 cents or 16.35 percent to 43.5 cents with 18.9 million shares traded. Airxpanders lost 7.1 percent; Psivida fell 5.8 percent; Acrux, Actinogen and Polynovo fell four percent or more; Neuren, Orthocell, Prana, Prima and Pro Medicus shed more than two percent; with Genetic Signatures and Viralytics down by more than one percent.

PHOSPHAGENICS

Phosphagenics chief executive officer Dr Ross Murdoch has begun a road-show to re-establish the company significantly damaged by his predecessor.

Two years ago, former Phosphagenics chief executive officer Dr Esra Orgu, Dr Robert Gianello and Dr Woei-Jia Jiang were gaoled for stealing \$6,146,732.70 from the company, with Dr Ogru sentenced to six years in gaol, with a two year minimum (BD: Nov 7, 2014). Phosphagenics co-founder Harry Rosen assumed the role of chief executive officer, and in 2015 former Shire executive and Prana president and chief operating officer Dr Murdoch was appointed as its chief executive officer (BD: Jan 18, 2015).

Dr Murdoch immediately moved to turnaround the troubled company, including board changes, the disposal of the Elixia range of cosmetics and finding new uses for the company's tocopheryl phosphate mixture (TPM), a blend of phosphorylated vitamin E. Dr Murdoch said that the damage done to the company by Dr Ogru in terms of stalled development of its assets was worse than the theft of the \$6 million.

Earlier this year, Phosphagenics announced that a then unnamed Japanese company, later disclosed as Terumo, had a licence option for its TPM-oxymorphone patch and had formed an alliance for three more products (BD: April 29, 2016).

Today, Dr Murdoch told Biotech Daily that the Terumo options on the TPM-oxymorphone and TPM-oxycodone patches were due this month, along with three other milestones due by the end of 2016, and if progressed would see payments to the company.

Dr Murdoch said he expected litigation involving US joint venture partner Prophase Laboratories to be settled this year, resulting in the disentangling of the Elixia assets.

"When the case closes, we hope that Bio-Elixia will be clear and we can find a buyer for it," Dr Murdoch said.

Dr Murdoch said that Terumo had the rights for the opioid patches in Japan only and Phosphagenics held them for all other jurisdictions.

Dr Murdoch said that, once developed with Terumo, the opioid patches would be more attractive to a pharmaceutical company partner, than previously when the company tried to develop them alone.

The opioid patch program began under Dr Ogru in 2009 and faced several hurdles including changing the manufacturer from the St Paul, Minnesota-based 3M to Germany's Tesa Labtec GMBH (BD: Jun 29, 2009; Nov 16, 2010; May 23, 2012).

Dr Murdoch said that Phosphagenics also had deals with Terumo covering injectable TPM-propofol, which he said was normally a milky-appearance pre-anaesthetic which the TPM turned into a clear liquid, removing potential contamination issues, along with a gel and a spray version of unnamed existing products.

He said that Terumo had the rights to these for Japan, Phosphagenics held them for Australia and New Zealand with a 50-50 share for the rest of the world.

Dr Murdoch said that the animal health business expected results from a TPM chicken-feed study by the end of 2016, along with the lead injectables candidates entering development.

Dr Murdoch said that Phosphagenics was currently earning revenue from its Vital ET product sales by the Covington, Kentucky-based Ashland and primarily used for cosmetics.

Phosphagenics chief financial officer Anna Legg, who uncovered the Dr Ogru theft, said the company had \$9.9 million at June 30, 2016, with a six month cash burn of \$2.6 million. The company had a market capitalization of \$213 million in August 2006 falling to a low of \$43 million in October 2008, a high of \$244 million in March 2012 and fell from Dr Ogru's gaoling to a low of \$9 million, again recovering to \$40 million at September 30, 2016.

Phosphagenics was up 0.1 cents or 3.6 percent to 2.9 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised \$6,210,000 in an oversubscribed placement at 48 cents a share and will offer a share plan to raise a further \$1 million.

Paradigm said that the placement was well-supported by sophisticated and institutional investors with Baker Young Stockbrokers and DJ Carmichael joint lead managers.

The company said that managing-director Paul Rennie intended to subscribe for \$200,000 in shares which would require shareholder approval at the 2016 AGM.

Paradigm said the funds would be used to accelerate the Alphavirus program through phase II trials for Ross River virus and chikungunya virus, strengthen the balance sheet for licencing and partnering discussions, further clinical development programs including asthma and working capital.

Mr Rennie said that the capital raising provided “the financial strength and flexibility to accelerate its various clinical programs and in particular bring forward entering phase II human clinical trials for Ross River virus and Chikungunya virus”.

“By the start of ... 2017 Paradigm will be in four phase II clinical trials with results from the hay-fever and bone marrow oedema phase II trials expected around June 2017,” Mr Rennie said.

Paradigm said that shareholders could subscribe for up to \$15,000 in shares at 48 cents each in the share plan which had a record date of October 17, would open on 28 October 28 and close on November 17, 2016.

Paradigm was up four cents or 7.8 percent to 55 cents.

ALLEGRA ORTHOPAEDICS

Allegra says it has a conditional placement agreement to raise \$755,117 from related party Robinwood Investments Pty Ltd.

Allegra said the placement of 9,438,957 shares at eight cents each would require approval at the annual general meeting to be held on November 30, 2016.

The company said that Robinwood was a substantial shareholder with 21,391,879 shares or 33.50 percent of its issued shares and if the placement was approved, Robinwood would increase to 42.15 percent and with associates would have 43.76 percent.

Allegra said Robinwood was controlled by its director and majority shareholder Dr Nicholas Hartnell whose father Anthony Hartnell was a director of Allegra.

The company said that Robinwood provided a loan of \$1 million on commercial terms in June 2016, which is currently drawn down to \$700,000 and was due for repayment on December 30, 2016 (BD: Jun 30, 2016).

Allegra said the proceeds would be used for on-going operations, general working purposes and to meet its obligations including the repayment of the loan.

Allegra was untraded at 14 cents.

IMPEDIMED

Impedimed says that the Mayo Clinic with the Atlantic Health System would use its Sozo device in a feasibility study for monitoring patients with heart failure.

Impedimed said the study would provide data for the final design of a pivotal trial of the body composition test.

The company said that the study at the Mayo Clinic in Rochester and Atlantic Health System in New Jersey was led by Lancaster General Hospital clinical research medical director Dr Roy Small who was also a member of its medical advisory board.

Impedimed was up five cents or 3.3 percent to \$1.585.

GENETIC SIGNATURES

Genetic Signatures says its Easyscreen sexually transmitted infection (STI) detection kit has 100 percent concordance with traditional and confirmatory methods.

Genetic Signatures said that preliminary results of a clinical validation trial presented at the National HIV Reference Laboratory molecular diagnostics workshop in Melbourne today showed that the Easyscreen STI detection kit allowed the simultaneous identification of 12 of the most significant and commonly encountered STIs with 100 percent concordance with traditional and confirmatory methods.

The company said that the assay offered improved accuracy and sensitivity and additional STI pathogens were identified over existing testing techniques.

Genetic Signatures said that the presentation, entitled 'Evaluation of a new 3Base Assay for Screening of Sexually Transmitted Infections' was given by Melbourne's St Vincent's Hospital's Dr Damien Stark

Genetic Signatures chief executive officer Dr John Melki said that the rate of sexually transmitted co-infection was high and the trial showed that 25.9 percent of the patient samples had mixed infections with two or more pathogens detected, requiring an assay that could simultaneously screen for a large number of disease targets.

Genetic Signatures fell one cent or 1.8 percent to 55 cents.

ORTHOCELL

Orthocell says it has ethics approval for a 20-patient study of its Celgro collagen scaffold for nerve regeneration in severed nerves of the hand and upper limb.

Orthocell said that the primary objective of the study was to demonstrate the safety, tolerability and effectiveness of Celgro when used as a conduit to guide and promote the surgical repair of peripheral nerve injuries.

The company said the Perth, Western Australia-based St John of God Hospital study of patients who had injured one or more peripheral nerves would begin by the end of 2016. Orthocell said that peripheral nerve injury affected 20 million people in the US each year, costing about \$US150 billion in annual health care.

Principal investigator and orthopaedic surgeon Dr Alex O'Beirne said the study had "the potential to improve patient outcomes by allowing for a suture-less repair to the damaged nerve, to guide nerve regeneration and accelerate the healing process".

Orthocell managing-director Paul Anderson said that the study "validates Celgro as a unique platform technology for soft tissue repair".

Orthocell fell one cent or 2.4 percent to 41 cents

CLINUVEL

Clinuvel says the National Institute for Health and Care Excellence (NICE) has recommended Scenesse be evaluated under the single technology appraisal procedure. Clinuvel said that it in a NICE workshop it had proposed Scenesse (afamelanotide 16mg) for erythropoietic protoporphyria be evaluated under the highly specialized technology program for its introduction in England.

The company said the highly specialized technology program only considered drugs for very rare conditions and a review by NICE recommended to the UK Department of Health that Scenesse be evaluated under the single technology appraisal procedure

Clinuvel said it would participate in the scoping phase for the single technology appraisal after which the formal phases could begin.

Clinuvel was up seven cents or one percent to \$6.96.

COCHLEAR

Cochlear's annual general meeting passed all resolutions but saw significant dissent against the re-election of director Donal O'Dwyer.

Cochlear said that 8,580,508 votes (22.03%) opposed Mr O'Dwyer's re-election with 30,364,880 votes (77.97%) in favor, with resolutions on the remuneration report, the grant of 'performance rights' and options to chief executive officer Chris Smith and the re-election of director Yasmin Allen passed overwhelmingly.

The company's most recent Appendix 3B said that Cochlear had 57,412,688 shares on issue meaning that the opposition to Mr O'Dwyer amounted to 14.9 percent of the total shares on issue, sufficient to requisition extraordinary general meetings.

Cochlear was up 23 cents or 0.2 percent to \$136.90 with 135,972 shares traded.

IDT AUSTRALIA

IDT's annual general meeting passed all resolutions but saw significant dissent against two resolutions and the retirement of deputy chairman and 18-year director Geoff Lord.

IDT's results of meeting showed that the strongest percentage dissent was against a new employee share plan with 71,378,144 votes (83.4%) in favor and 14,246,127 votes (16.6%) against, but the increased placement capacity was opposed by 16,414,268 votes (12.0%) and supported by 120,115,378 votes (88.0%).

The re-election of director Dr Graeme Blackman, the remuneration report and the ratification of a prior share issue were passed by wider margins.

The company's most recent Appendix 3B said that IDT had 248,641,152 shares on issue meaning that the opposition to the placement capacity amounted to 6.6 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

IDT said that the resolution to re-elect Mr Lord was withdrawn prior to the meeting and Mr Lord "recently commenced a major new undertaking in the financial sector which will require a substantial commitment on his part, leading to his decision to retire".

IDT was up 1.5 cents or 7.1 percent to 22.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell annual general meeting will vote on a potential second strike board spill, the ratification of share issues and the re-election of two directors.

Last year, the Living Cell remuneration report was opposed by 25,591,800 votes (39.55%) with 39,115,572 votes (60.45%) in favor, providing the first trigger for a potential board spill at this year's annual general meeting (BD: Nov 13, 2015).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.

If the spill vote fails, the trigger is reset to no opposition.

Today, Living Cell said that shareholders would vote to ratify two previous share issues, exempt employee options from ASX Listing Rule 7.1 and re-elect directors Laurie Hunter and Robert Willcocks.

The meeting will be held at Sheraton on the Park, 161 Elizabeth Street, Sydney on November 16, 2016 at 10.30am (AEDT).

Living Cell was unchanged at 8.5 cents.

CSL

The Blackrock Group says it has returned to a substantial holding in CSL with 22,846,038 shares or 5.01 percent.

Blackrock said it bought shares in more than 600 small trades between June 15 and October 14, 2016.

In 2011 and 2012 Blackrock fell below the five percent substantial shareholder threshold acquiring 11,479,861 shares for an average price of \$32.67 a share and selling 13,549,559 shares for an average price of \$33.12 a share (BD: Jul 31, 2012).

CSL climbed \$1.02 or one percent to \$105.28 with 1.1 million shares traded.

LBT INNOVATIONS

Former LBT chief executive officer Lusia Guthrie and High Guthrie have sold 1,750,000 shares for \$1,212,845 or 69.3 cents a share.

Last week LBT's share price jumped 357.9 percent from 19 cents when it announced FDA approval for its automated plate assessment system on Monday October 10 to 87 cents on Friday October 14, 2016 (BD: Oct 10, 14, 2016).

Today, Ms Guthrie said that she sold shares on October 12, 13 and 14, 2016.

Ms Guthrie's previous substantial shareholder notice said that with Mr Guthrie and the Podlaska Superannuation Fund she held 5,063,334 shares or 5.1 percent of the company (BD: Jan 16, 2011).

LBT was up 7.5 cents or 10 percent to 82.5 cents with 13.9 million shares traded.

IMMURON

The Shepparton, Victoria-based Chris Retzos has directly and indirectly become a substantial shareholder in Immuron with 5,620,000 shares (5.33%).

Mr Retzos said the holding included shares held with Susie Retzos through the Retzos Family Superannuation Fund, Jaclyn Stojanovski through the Retzos Executive Superannuation Fund, Stephen Retzos, Melissa Martin and Westpark Operations Unit.

Mr Retzos said the shares were acquired between July 8 and October 4, 2016 in the company's rights issue at 25 cents a share (BD: May 31, Jul 5, Oct 4, 2016).

Immuron fell one cent or 2.7 percent to 35.5 cents.

BENITEC BIOPHARMA

Benitec says that Sakura Holloway was appointed joint company secretary with chief executive officer Greg West and left the company on October 11, 2016.

Benitec said that Mr West remained company secretary.

The company said it "inadvertently did not inform the market of the appointment of a joint company secretary at the time of appointment, due to the management restructure that was underway at the time [and] additional protocols have been put into place to ensure this does not occur again".

Benitec was up 0.3 cents or 3.3 percent to 9.3 cents.