



Biotech Daily

Monday December 14, 2020

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: ACTINOGEN UP 5%; IMMUTEP DOWN 22%
- * MEDICAL DEVELOPMENTS RAISES \$25m; SHARE PLAN CAPPED AT \$5m
- * TELIX, KANAZAWA START TLX591-CDX JAPAN ETHNICITY STUDY
- * ALCIDION \$2m SOUTH TEES NHS EXTENSION
- * AUSTCO \$1.3m SINGAPORE NURSE CALL CONTRACT
- * ANTISENSE WINS EU ORPHAN STATUS FOR ATL1102 FOR DMD
- * SAFETY DATA BOARD OKAYS ADALTA AD-214 DOSE ESCALATION
- * TELIX COMPLETES THERAPHARM, SOUTHAMPTON UNI DEALS
- * S&P PROMOTES 4DX, DEMOTES AVITA, RESAPP
- * EMVISION RECEIVES \$1.3m FEDERAL R&D TAX INCENTIVE
- * KAZIA RECEIVES \$1m FEDERAL R&D TAX INCENTIVE
- * STEMCELL RAISES \$1.9m
- * RHINOMED SARS-COV-2 SWAB EQUALS COMPARATOR
- * BOTANIX COMPLETES BTX1801 MRSA STUDY TREATMENT
- * ZELIRA APPOINTS HOPE MARIJUANA WASHINGTON DC DISTRIBUTOR
- * CELLMID: OURUI TO DISTRIBUTE HAIR, SKIN PRODUCTS IN CHINA
- * EMYRIA REQUESTS PLACEMENT TRADING HALT
- * SUDA REQUESTS CAPITAL RAISING TRADING HALT
- * EXOPHARM RELEASES 35.7m ESCROW SHARES
- * ANATARA UNMARKETABLE PARCEL FACILITY
- * PERENNIAL BELOW 5% IN 4D MEDICAL
- * JIMMY THOMAS, IVY PONNIAH BELOW 5% IN STEMCELL
- * IMEX LOSES CO-CO SEC PETER WEBSE; REENA MINHAS CO SEC

MARKET REPORT

The Australian stock market was up 0.26 percent on Monday December 14, 2020, with the ASX200 up 17.6 points to 6,660.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 23 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Actinogen was the best, up 0.1 cents or five percent to 2.1 cents, with 4.8 million shares traded. Impedimed improved four percent; LBT was up 3.7 percent; Nanosonics, Opthea, Orthocell, Pharmaxis and Polynovo were up more than one percent; with Neuren, Pro Medicus and Proteomics up by less than one percent.

Immutep led the falls, having closed last week up 27 cents or 96.4 percent to 55 cents, today retreating 12 cents or 21.8 percent to 43 cents, with 18.6 million shares traded. Optiscan lost 11.1 percent; Telix shed 7.2 percent; Medical Developments was down 6.9 percent; Avita, Kazia and Patrys were down five percent or more; Imugene and Osprey fell more than four percent; Oncosil, Paradigm and Uscom were down more than three percent; Amplia, Antisense, Clinuvel, Dimerix, Next Science and Universal Biosensors shed more than two percent; Cochlear, CSL, Mesoblast and Prescient were down more than one percent; with Cynata, Genetic Signatures, Resmed and Volpara down by less than one percent.

MEDICAL DEVELOPMENTS

Medical Developments says it has raised \$25 million in a placement at \$6.50 a share and will conduct a share purchase plan, capped at \$5 million, at the same price.

Medical Developments said the funds would be used to accelerate the commercial expansion of the inhaled methoxyflurane analgesic Pentrox, complete clinical studies and for general corporate purposes.

The company said director Christine Emmanuel had been allocated 0.4 percent or \$100,000 of the placement.

Medical Developments said that the record date for the share plan was December 11, with the offer opening on December 18, 2020 and closing on January 18, 2021.

Medical Developments fell 49 cents or 6.9 percent to \$6.61 with 712,107 shares traded.

TELIX PHARMACEUTICALS

Telix says Kanazawa University has begun a 10-patient, phase I trial of TLX591-CDx for imaging prostate cancer.

Telix said Ishikawa Prefecture-based Kanazawa University would conduct the trial using positron emission tomography (PET) using 68-gallium-prostate-specific membrane antigen 11 (Ga-PSMA-11).

The company said the study would “obtain preliminary Japanese ethnicity data in order to demonstrate to the Japanese Pharmaceutical and Medical Devices Agency (PMDA) that the targeting and bio-distribution of TLX591-CDx is comparable to the rest of the world in order to facilitate planning discussions for product approval in Japan”.

Telix said that the Japan had 70,000 prostate cancer patients a year with the number expected to rise over coming years.

Telix fell 27 cents or 7.2 percent to \$3.48 with 1.1 million shares traded.

[ALCIDION GROUP](#)

Alcidion says England's South Tees National Health Service has extended its management services contract by \$2.0 million to include internet cloud systems. Alcidion said the Middlesbrough-based South Tees NHS extension for internet cloud services hosted on Microsoft Azure took the total contract to \$11.3 million over five years. In November, the company said it had a \$9.5 million deal with the South Tees NHS to integrate its Miya Precision to digitize patient care and records and its Better Openep to digitize prescription and medicine administration (BD: Nov 9, 2020).

Today, the company said the addition of the Smartpage would provide "clinical team communication and collaboration capabilities to the Miya Precision [product], enabling integrated secure alerting and escalation within and between clinical teams at South Tees".

Alcidion was up 1.5 cents or 7.9 percent to 20.5 cents with 1.3 million shares traded.

[AUSTCO HEALTHCARE \(FORMERLY AZURE HEALTHCARE\)](#)

Austco says it has a \$1.3 million contract to update the Tacera Nurse Call platform at the two hospitals in Singapore.

Austco said that the 700-bed Ng Teng Fong General Hospital and the 400-bed Jurong Community Hospital chose its Tacera software because it was "the only nurse call [product] on the market that delivers [voice over the] internet protocol to the patients' bedside and provides a foundation for future products and services".

The company said the two hospitals were the first in Singapore "to be designed and built together from the ground up as an integrated healthcare development".

"They deliver patient-centred services in a seamless and integrated manner for better patient care, greater efficiency and convenience," Austco said.

The company said that all beds would have the Tacera product.

Austco was up 1.3 cents or 14.1 percent to 10.5 cents.

[ANTISENSE THERAPEUTICS](#)

Antisense says the European Commission has granted orphan drug designation for ATL1102 for the treatment of Duchenne muscular dystrophy (DMD).

In August, Antisense said it applied to the European Medicines Agency for orphan drug designation for ATL1102 for Duchenne muscular dystrophy and on October won orphan drug designation from the US Food and Drug Administration along with the September grant of rare paediatric disease status (BD: Aug 31, Sep 30, Oct 26 2020).

Today the company said the "orphan status in the EU brings development and marketing incentives, such as reduced fees on scientific advice and marketing authorization application, and market exclusivity in Europe for 10 years upon regulatory approval of ATL1102 with an additional two years of exclusivity for its paediatric use in DMD".

Antisense managing-director Mark Diamond said that "the incentives that come from such designations including marketing exclusivity periods will be of very significant commercial value, should ATL1102 be successful in its progress through development and ultimately achieve marketing approval".

Antisense fell 0.2 cents or 2.1 percent to 9.2 cents with 8.1 million shares traded.

[ADALTA](#)

Adalta says it will extend the healthy volunteer part A of its phase I study of AD-214 for fibrosis “to explore encouraging results from cohorts studied to date”.

Adalta said it had treated 34 healthy volunteers with AD-214 or placebo at doses ranging from 0.01mg/kg to 10mg/kg.

The company said the safety management committee found no adverse safety events of clinical concern and approved dose escalation to 20mg/kg, the maximum planned dose.

Adalta said a secondary endpoint was the extent and duration of receptor occupancy, the percentage of target receptors on some circulating white blood cells occupied by AD-214. The company said that high levels of receptor occupancy were “generally required for therapeutic effect” and the time occupancy remained high indicated likely therapeutic dosing intervals, with longer intervals generally more convenient and lower cost.

Adalta said the study had shown a dose dependent increase in both the duration of white blood cell receptor saturation, with and the time receptor occupancy above 50 percent.

The company said that blinded data from the 5mg/kg and 10mg/kg cohorts showed that receptors remained saturated for three days after infusion of AD-214 and remained at more than 55 percent and 86 percent, respectively, at seven days after infusion.

Adalta head of clinical product development Dr Claudia Gregorio-King said that “if repeated in [idiopathic pulmonary fibrosis] patients, these results are strongly supportive of longer dosing intervals in future clinical studies than currently planned”.

The company said that it would submit a protocol amendment to enable receptor occupancy in the final healthy volunteer cohort to be investigated at two and three-weeks following infusion.

Adalta said that dosing of this final cohort would be deferred to January 2021 and design of part B of the study in idiopathic pulmonary fibrosis and interstitial lung disease patients continued and incorporating the new findings was not expected to result in any material changes to previously forecast milestones.

Adalta was up half a cent or four percent to 13 cents with 1.6 million shares traded.

[TELEX PHARMACEUTICALS](#)

Telex says it has completed its acquisition of Therapharm and with it an agreement for a data package from the University of Southampton for 90-yttrium-besilesomab.

Last month, Telex said it would pay up to EUR20.4 million (\$A33.05 million) plus royalties to acquire Therapharm from Scintec Diagnostic GmbH (BD: Nov 30, 2020).

Today, the company said the acquisition had been completed and with it, the intellectual property agreement with the University of Southampton for its 90-yttrium-besilesomab based therapeutic product for bone marrow conditioning.

The company said the product would be “used in patients undergoing haematopoietic stem cell transplant for the treatment of blood cancers and various related conditions.

[STANDARD & POORS DOW JONES INDICES](#)

Standard & Poor’s Dow Jones Indices says that 4DX has been promoted, while Avita and Resapp have been removed.

In its December indices rebalance S&P said that Avita was removed from the S&P ASX200, 4D Medical had been added to the S&P ASX All Technology Index, with Resapp removed from that index.

The S&P Dow Jones Indices said the changes were based on market capitalization alone, and would be effective from December 21, 2020.

EMVISION MEDICAL DEVICES

Emvision says it has received \$1,280,631 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Emvision said the rebate related to research and development expenditure for the year to June 30, 2020.

Emvision was up 24 cents or 8.4 percent to \$3.09 with 294,853 shares traded.

KAZIA THERAPEUTICS

Kazia says it has received \$1,018,448 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Kazia said the rebate related to research and development expenditure for the year to June 30, 2020.

Kazia fell seven cents or five percent to \$1.33.

STEMCELL UNITED

Stemcell United says it has issued 100,741,255 shares at 1.9 cents a share, raising \$1,914,084.

Last week, the company requested a trading halt for a placement (BD: Dec 10, 2020).

Today, in an announcement titled 'Proposed issue of securities' the company said the funds were for "working capital and to finance the hemp and sea grape projects in Singapore and Australia".

Stemcell said the investors were 180 Markets Pty Ltd and CS Third Nominees Pty Ltd.

Stemcell fell 0.8 cents or 28.8 percent to 2.3 cents.

RHINOMED

Rhinomed says an in-vitro study shows its Rhinoswab "is comparable to standard of care nasal swabs" for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Rhinomed said that the study at the Victorian Infectious Diseases Reference Laboratory, part of Melbourne's Peter Doherty Institute assessed Rhinoswab's ability to transfer high and low viral loads for testing compared to commercial comparators.

The company said that its Rhinoswab was comparable to the Copan Eswab "when artificially dipped into a neat saliva solution spiked with inactivated Sars-Cov-2, at both high and low virus burdens ... [and] the relative maximal volume recovered was also comparable between the devices".

Rhinomed chief executive officer Michael Johnson said the Laboratory "confirmed that the Rhinoswab can detect Sars-Cov-2" using laboratory-based reverse transcription-polymerase chain reaction (RT-PCR).

"This is a critical step in demonstrating that the Rhinoswab has a role to play in responding to the need for an easy-to-deploy, self-administered and effective sampling methodology," Mr Johnson said.

Rhinomed said it was continuing its research and development program to optimize the swab and understand its utility with clinical sample collection.

Rhinomed was up 2.5 cents or 15.6 percent to 18.5 cents.

[BOTANIX PHARMACEUTICALS](#)

Botanix says all 60 subjects have completed its phase IIa study of BTX1801 to eradicate nasal Staphylococcus aureus and methicillin-resistant Staphylococcus aureus.

Botanix said that the study of the synthetic cannabinoid was designed to test the ability of two different formulations of BTX1801 to eradicate or decolonise nasal carriage of Staphylococcus aureus and methicillin-resistant Staphylococcus aureus (MRSA) from the nasal cavity of healthy participants.

The company said that top-line data was expected early next year.

In August, Botanix said it hoped to complete the study by the end of 2020 and move to a pivotal study of patients undergoing surgery. (BD: Aug 12, 2020).

In April, the company said the US Food and Drug Administration had granted BTX1801 qualified infectious disease product (QIDP) status for the prevention of post-surgical infections.

Today, Botanix said “80 percent of all post-surgical infections are caused by the patient infecting themselves through spreading [Staphylococcus aureus] and MRSA resident in their own nasal cavity”, with one in three people carrying the bacteria in their nose.

The company said nasal decolonization was a commonly used method for preventing surgical site infections, “but overuse of the widely available antibiotic Bactroban has led to significant increase in the development of bacterial resistance to antibiotics”.

Botanix executive chair Vince Ippolito said there had not been a new class of antibiotic for the treatment of gram-positive bacteria in more than 30 years and serious Staphylococcus aureus and MRSA infections had become “very difficult to treat”.

Botanix was up half a cent or four percent to 13 cents with 7.5 million shares traded.

[ZELIRA THERAPEUTICS \(FORMERLY ZELDA THERAPEUTICS\)](#)

Zelira says Alternative Solutions LLC will distribute its Hope medical cannabis products in Washington DC.

In 2019, the then Zelda said it would merge with Ilera to form Zelira Therapeutics, which would grant it access to the Hope portfolio for autism (BD: Nov 20, 2019).

Today, the company said it would receive an upfront fee and ongoing royalties from sales. Zelira was up 0.6 cents or 6.1 percent to 10.5 cents with 53.5 million shares traded.

[CELLMID](#)

Cellmid says its Advangen subsidiaries have appointed Ourui Health Management to distribute its Ju-Ju and Lexilis anti-aging hair and skincare products in China.

Cellmid chief executive officer Maria Halasz said that the 10-year agreement was expected to contribute up to 40 percent of the company’s revenue by June 30, 2023.

The company said that the Hong Kong-based Ourui must order a minimum of 500,000 units of the two products in the first year and 1,000,000 units in the second year, followed by double digit percentage annual purchase increases.

Cellmid was up one cent or 9.5 percent to 11.5 cents with 2.7 million shares traded.

[EMYRIA](#)

Emyria has requested a trading halt pending an announcement “regarding a proposed placement of securities”.

Trading will resume on December 16, 2020 or on an earlier announcement.

Emyria last traded at 8.5 cents.

SUDA PHARMACEUTICALS

Suda has requested a trading halt "pending an announcement in relation to a potential capital raise".

Trading will resume on December 16, 2020 or on an earlier announcement.

Suda last traded at four cents.

EXOPHARM

Exopharm says that 35,661,570 shares will be released from ASX escrow on December 18, 2020.

According to Exopharm's most recent Appendix 2A new share announcement, after the release there would be 139,413,667 shares available for trading with no further shares in ASX escrow.

Exopharm fell one cent or 2.8 percent to 35 cents.

ANATARA LIFESCIENCES

Anatara says it has instituted an off-market, share buy-back facility for holders of unmarketable parcels of shares at the December 11, 2020 record date.

Anatara said that a holding valued at less than \$500 was considered to be an "unmarketable parcel" of shares.

The company said that based on the closing price of 19 cents a share at the record date, an unmarketable parcel of Anatara shares was any holding of 2,631 shares or fewer.

Anatara said the facility would allow eligible shareholders to sell their shares to the company at 17.8 cents a share, without brokerage or fees.

The company said that investors could opt-out or increase their holding to more than 2,631 shares by the close of business on February 5, with the buy-back planned for February 9, 2021.

Anatara was untraded at 19 cents.

4D MEDICAL

Perennial Value Management says it has reduced its holding in 4D Medical to below the five percent substantial level

The Sydney-based Perennial said that between August 28 and December 9, 2020 it bought and sold shares with the single largest sale on September 30, 2020 of 1,220,669 shares for \$2,070,572 or \$1.70 a share.

4D was up three cents or 1.4 percent to \$2.18.

STEMCELL UNITED

Jimmy Thomas and Ivy Ponniah say they have reduced their holding in Stemcell United to below the five percent substantial level.

The Melbourne-based Mr Thomas said 16,322,420 shares were sold for \$461,749 or an average price of 2.8 cents a share.

In October, Mr Thomas and Ms Ponniah said they had reduced their holding in to 33,562,420 shares (5.23%) (BD: Oct 30, 2020).

Biotech Daily calculates that they continue to 17,240,000 shares or hold 2.57 percent of the company.

IMEX HEALTH SERVICES

Imex said says Peter Webse has resigned as joint company secretary, effective from December 12, 2020, with Reena Minhas continuing as sole company secretary. Imex fell 2.5 cents or 1.5 percent to \$1.625.