



Biotech Daily

Monday April 17, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ACTINOGEN UP 8%; ATOMO DOWN 10%**
- * **TELIX Q1 REVENUE \$100.1m**
- * **CONTROL BIONICS: 'WORLD'S 1st AUTONOMOUS DRIVING WHEELCHAIR'**
- * **CORRECTION: MEDADVISOR**
- * **IMEX \$750k GRUPO AVIDANTI COLOMBIA RADIOLOGY CONTRACT**
- * **IMMUTEP INVESTIGATOR-LED PHASE II EFTI FOR SARCOMA TRIAL**
- * **TELIX PROOF-OF-CONCEPT TAKES OLARATUMAB TO PHASE I TRIAL**
- * **AROVELLA 'ALA-101 ANTI-TUMOR EFFECT, IN MICE'**
- * **OSTEOPORE APPOINTS MAJETON SINGAPORE DISTRIBUTOR**
- * **EMVISION MILESTONE TRIGGERS \$600k STROKE ALLIANCE GRANT**
- * **BTC: AVANOS HALTS ACUTE PAIN PRODUCTS; HITS NTA BACKING**
- * **PROTEOMICS RENEWS ISO STANDARDS FOR PROMARKERD LAUNCH**
- * **RADIOPHARM: TERTHERA TO SUPPLY TERBIUM-161**
- * **RECCE PHASE I/II R327 TRIAL ETHICS APPROVAL**
- * **STARPHARMA DOSES DEP-CABAZITAXEL PATIENTS**
- * **ISLAND FILES RESPONSE TO FDA ISLA-101 CLINICAL HOLD**
- * **AVITA \$1.2m DIRECTOR SHARES, \$523k OPTIONS AGM**
- * **CRESO 131m SHARES, 752m OPTIONS, \$2.8m NOTES EGM**
- * **PATRYS WINS 2 US DEOXYMAB PATENTS**
- * **PHARMAUST RECEIVES 10k MONEPANTEL TABLETS**
- * **CRYOSITE APPOINTS LUIS ANTONIO DIRECTOR**
- * **SUSAN PARK REPLACES BOTANIX CO SEC SIMON ROBERTSON**

MARKET REPORT

The Australian stock market was up 0.27 percent on Monday April 17, 2023, with the ASX200 up 19.9 points to 7,381.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Actinogen was the best, up 0.5 cents or 8.1 percent to 6.7 cents, with 598,849 shares traded. Dimerix climbed five percent; Alcidion, Genetic Signatures, Oncosil and Starpharma improved more than four percent; Compumedics, Imugene and Neuren were up more than three percent; Micro-X, Impedimed, Telix and Volpara rose more than two percent; Avita and Emvision were up more than one percent; with Clinuvel, Cochlear, CSL, Cyclopharm, Pro Medicus and Resmed up by less than one percent.

Atomo led the falls, down 0.4 cents or 10.3 percent to 3.5 cents, with 1.9 million shares traded. Patrys lost 6.25 percent; Prescient was down 5.1 percent; Paradigm, Proteomics and Resonance fell four percent or more; Amplia, Nova Eye and Pharmaxis were down more than three percent; Antisense, Next Science and Polynovo shed more than two percent; with Mesoblast down by one percent.

TELIX PHARMACEUTICALS

Telix says that revenue from Illucix sales and pre-commercial sales for the three months to March 31, 2023 rose 26.7 percent to \$100.1 million compared to the prior three months. Telix said that sales of its Illucix kit for prostate cancer imaging were up 26.95 percent to \$97.5 million compared to the prior three months.

In February, the company said revenue for the year to December 31, 2022 was up from \$7,596,000 in 2021 to \$160,096,000 with \$149,700,000 from sales and licencing of its Illuccix prostate cancer diagnostic imaging kit (BD: Feb 28, 2023).

Today, Telix said the Illucix label had been expanded to include patient selection for prostate specific membrane antigen (PSMA)-directed radio-ligand therapy.

Telix was up 16 cents or 2.1 percent to \$7.89 with 1.6 million shares traded.

CONTROL BIONICS

Control Bionics says it will launch “the world’s first autonomous driving wheelchair module” using its Nanonode thought-to-computer technology on Wednesday April 19, 2023.

Control Bionics said that when installed on a power wheelchair, Drove helped people move about their home environment without using the joystick.

The company said Drove was developed with Deakin University’s Applied Artificial Intelligence Institute and would provide “a whole new level of safe and reliable independence at home”.

Control Bionics was untraded at 16 cents.

CORRECTION: MEDADVISOR

Friday’s edition erroneously said that Medadvisor’s in-pharmacy scheduling of vaccines had facilitated 67 million vaccines under government-sponsored pandemic programs.

The correct number was 6.7 million vaccinations.

The Friday sub-editor was channelling her Bill Gates 5-G at the time and has been sent back to the factory, through the chem trails, for re-programming.

Medadvisor was unchanged at 26 cents.

IMEX HEALTH SERVICES

Imex says it has a \$750,000 contract with Grupo Avidanti for radiology reporting and interventional radiology procedures at its hospital in Soacha, Bogota, Colombia. Imex said the initial one-year agreement with Grupo Avidanti, a subsidiary of Brazilian asset management fund Patria Investments, would use its enterprise software and contribute \$1 million in annual recurring revenue by its second year.

The company said there was no minimum expenditure required, services were expected to begin this month and the contract had automatic renewal provisions.

Imex chief executive officer Dr Germán Arango said it was an “important contract” as Grupo Avidanti was “rapidly growing across Colombia and elsewhere in [Latin America]”. “Our ambition is to grow with them and to expand our new partnership throughout their network of hospitals,” Dr Arango said.

Imex was up 3.5 cents or 5.9 percent to 62.5 cents.

IMMUTEP

Immutep says it will provide efti, or imp321, for an investigator-led, up-to 40 patient, open-label phase II trial in combination with radiotherapy for soft tissue sarcoma.

Immutep said the trial was funded by the Warsaw, Poland-based Maria Skłodowska-Curie National Research Institute of Oncology, with a Polish government grant, and the company would supply eftilagimod alpha, or efti, and technical support at no cost.

The company said soft tissue sarcoma was an orphan disease, with a high unmet medical need and poor prognosis and the trial would be the first time efti would be studied as a neo-adjuvant for non-metastatic cancer prior to surgery.

Immutep chief executive officer Marc Voigt said “efti’s unique potential to help safely drive superior clinical efficacy for cancer patients, with and without the use of chemotherapy” was attracting “increasing attention from industry and academia”.

“We are delighted to see efti and pembrolizumab, which together have led to deep and durable responses in several difficult-to-treat advanced solid tumors, being combined with radiotherapy for the first time,” Mr Voigt said.

Immutep was unchanged at 24.5 cents with one million shares traded.

TELIX PHARMACEUTICALS

Telix says pre-clinical work on the radio-labelled olaratumab has been “sufficiently encouraging” to take it to a diagnostic and therapeutic radiation trial for sarcoma.

Last year, Telix said it would pay Eli Lilly and Co \$US5 million for the rights to radio-labelled forms of its olaratumab antibody for cancer (BD: Apr 11, 2022).

Today, the company said it had shown proof-of-concept for olaratumab as a radiotherapy candidate for cancer and it would progress to in-human studies for soft tissue sarcoma.

Telix said olaratumab was originally developed as a monoclonal antibody targeting platelet-derived growth factor receptor alpha (PDGFRA) but was withdrawn by Eli Lilly after a phase III trial failed to improve patient survival.

The company said the ability of olaratumab to target PDGFRA in the micro-environment of soft tissue sarcoma tumors made it a high-potential radio-pharmaceutical candidate.

Telix said it has assigned the therapy formal candidate status and called the diagnostic version TLX300-CDx and the therapeutic version TLX300.

Telix chief scientist Dr Michael Wheatcroft said olaratumab would be evaluated in a study “designed to inform both the potential efficacy and safety profile of this research candidate as a therapeutic”.

AROVELLA THERAPEUTICS

Arovella says ALA-101 shows “significant” anti-tumor effect in mice and could have the potential to be an off-the-shelf treatment for leukaemias and lymphomas.

Arovella said ALA-101 used modified invariant natural killer T (INKT) cells expressing a chimeric antigen receptor (CAR) that targeted CD19, an antigen found on the surface of several cancer types.

The company said the study showed ALA-101 was effective in mouse models of human B-cell acute lymphoblastic leukaemia, with tumor burden after 26-days 90 percent lower compared to the control group.

Arovella said that the ALA-101 dosed mice had a significantly enhanced survival compared to untreated controls ($p < 0.005$).

A poster, presented at the American Association of Cancer Research meeting in Orlando, Florida, said the study concluded that INKT cells could be isolated from peripheral blood mononuclear cells with a high purity and be transduced to express CD19 CAR.

The poster also said that ALA-101 could be expanded to about 5000-fold, it was cytotoxic to certain tumor cells, displayed “excellent proliferative response”, prolonged survival and mediated anti-tumor activity, and had the potential to treat CD19 positive malignancies.

Arovella chief executive officer Dr Michael Baker said the statistically significant lifespan extension in an aggressive leukaemia animal model was “excellent data to indicate [the] product’s potency and support the ongoing development of ALA-101 and progression to human phase I clinical trials in 2024”.

Arovella was up one cent or 12.7 percent to 8.9 cents with 52.0 million shares traded.

OSTEOPORE

Osteopore says it has appointed Majeton Pte Ltd to distribute its dental and oral, maxillofacial products in Singapore.

Osteopore said Majeton was a Singapore-based sales, marketing and distribution company of therapeutics, medical devices and food additives in Southeast Asia, which was a wholly owned subsidiary of Essex Biotechnology.

The company did not disclose the commercial terms of the appointment, but said it was a three-year, exclusive agreement to distribute its products for guided bone regeneration, immediate implant loading and socket preservation.

Osteopore was up one cent or 10.5 percent to 10.5 cents.

EMVISION MEDICAL DEVICES

Emvision says its adaption of an ambulance version of its portable stroke device has triggered a \$600,000 milestone payment from the Australian Stroke Alliance.

In 2021, Emvision said it would receive a total of \$8 million funded by the Australian government’s Medical Research Future Fund, in staged payments over five-years, which would support the development and clinical validation of its planned first responder device for air and road ambulances (BD: Sep 16, 2021).

Last year, Emvision said it received a \$600,000 milestone payment from the Australian Stroke Alliance for its first responder helmet-based portable brain scanning device, and said a second-generation device was expected later that year (BD: Jun 27, 2022).

Today, the company said it received \$600,000 for the technical adaptation of the ultra-lightweight helmet system, with a computer-aided design, a miniaturized component prototyping and successful bench testing of the three-dimensional antenna array.

Emvision was up 2.5 cents or 1.5 percent to \$1.71.

BTC HEALTH

BTC Health says its Avanos Medical will discontinue supply of its acute pain infusion products to Australia and New Zealand from the middle of October 2023.

BTC said the product sales totaled \$6.7 million and accounted for about 80 percent of subsidiary BTC Speciality Health's revenue in the year to June 30, 2022.

The company said based on projected inventory levels it would meet demand for the products until April 2024 and intended to have "a comprehensive range of alternative drug delivery devices and accessories available" by that time.

BTC Health said the discontinuation of the Alpharetta, Georgia-based Avanos products would be negatively reflected in its subsidiary's annual financial results.

BTC Health said that given the discontinuation of the Avanos products the estimated fair value of its investments in its investee companies had been reduced from \$10.8 million to \$1.2 million, with the reduction to be shown in net tangible asset backings in the financial statements for the year to June 30, 2023.

The company also said as of March 31, 2023 it had \$2.1 million cash on hand, and was "taking immediate measures to preserve cash and maintain the necessary flexibility to transition [its subsidiary's] portfolio of medical products".

BTC Health fell 0.9 cents or 36.0 percent to 1.6 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the National Association of Testing Authorities (NATA) Australia and the British Standards Institution (BSI) have renewed its testing accreditation and certification.

Proteomics said its NATA ISO17025 accreditation and its BSI ISO13485 certification would benefit the launch of its Promarkerd test for predicting diabetic kidney disease and help its analytical testing services and other diagnostic tests under development.

The company said the ISO17025 demonstrated and promoted confidence in its laboratory standards and the ISO13485 ensured safety and quality management from the design and development to manufacture and sale of medical devices.

Proteomics managing-director Dr Richard Lipscombe said accreditation by the independent bodies showed testing, manufacturing and sales of its medical diagnostic tests were held to quality standards.

Proteomics fell four cents or four percent to 96 cents.

RADIOPHARM THERANOSTICS

Radiopharm says the Breda, Netherlands-based Terthera will supply terbium-161 for its phase I trial of RAD602 for brain cancer expected later this year.

Radiopharm said terbium-161 was a promising isotope for targeted cancer "due to its unique characteristics of radiation emitted" which included Auger electrons and short-range beta particles.

The company said costs were "not material" and the three-year agreement could be extended for an additional two years.

Radiopharm chief executive officer Riccardo Canevari said a RAD602 trial would be "the first dose escalating radio-pharmaceutical study leveraging the strong therapeutic properties of terbium-161 in brain tumors".

"We believe that Radiopharm has achieved a strong competitive advantage from being the first company to do a phase I trial using this isotope, and securing supply of this relatively scarce isotope," Mr Canevari said.

Radiopharm was up half a cent or 2.9 percent to 17.5 cents.

RECCE PHARMACEUTICALS

Recce says it has ethics approval for its about 12-patient, phase I/II intravenous, faster infusion rate trial of R327 in healthy male and female patients.

Recce said the phase I/II trial would assess R327 at faster infusion rates in three cohorts of participants, with urine collected to measure the drugs anti-bacterial and concentration effects.

The company said it expected to dose its first patient at Adelaide's CMax clinical trial facility by July 2023 and the results would provide optimal dose levels for a phase II pre-sepsis trial of patients with uncomplicated urinary tract infections.

Recce was up half a cent or 2.2 percent to 71 cents.

STARPHARMA

Starpharma says it has dosed all 76 patients in its phase II trial of dendrimer enhanced product (DEP)-cabazitaxel for cancers with "encouraging efficacy signals".

Last year Starpharma said its then 25-patient, phase II trial of DEP-cabazitaxel for prostate cancer showed "highly encouraging anti-tumor activity" with a partial response for more than 45 weeks, and a stable or improved secondary metastatic bone disease for up to 45 weeks (BD: Sep 12, 2022).

The company said at that time that median progression-free survival was 3.9 months, 30 percent longer than previous published data for standard cabazitaxel at the same dose and 90 percent of evaluable patients achieved a reduction in prostate specific antigen, with 52 percent seeing a reduction of 50 percent or more.

Today, the company said the phase II trial used its DEP-cabazitaxel at sites in the UK and Australia to treat a variety of cancers.

Starpharma said its DEP-cabazitaxel was highly water soluble and did "not contain toxic detergent-like excipients associated with anaphylaxis and avoids the need for patients to pre-medicate with steroids".

Starpharma said following treatment with cabazitaxel tumor shrinkage and substantial tumor biomarker reductions were observed in prostate, ovarian, gastroesophageal, cholangiocarcinoma and head and neck cancer patients.

Starpharma was up two cents or 4.3 percent to 48.5 cents.

ISLAND PHARMACEUTICALS

Island says it has filed its response to the US Food and Drug Administration's feedback to its repurposing ISLA-101 for mosquito borne diseases.

In February, Island said the FDA had placed a "clinical hold" on its investigational new drug application for ISLA-101 for mosquito borne diseases and required a further "small" trial as well as protocol amendments (BD: Feb 1, 2023).

Today, the company said it had completed a draft protocol for the proposed single ascending dose study of its ISLA-101 for dengue fever, which included a clinical research organization and an analytical laboratory to test and analyze collected samples.

Island chief executive officer and managing director Dr David Foster said its next steps would be "navigating the remaining non-clinical hold issues raised in the original feedback to our [investigational new drug] submission".

"There remains a strong unmet need for dengue fever therapeutics," Dr Foster said.

"The Island team is dedicated to bringing ISLA-101 forward for the treatment of dengue fever and looks forward to updating the market as soon as possible," Dr Foster said.

Island was untraded at seven cents.

AVITA MEDICAL

Avita says its annual general meeting will vote to issue directors shares worth more than \$US819,000 (\$A1,221,000) and options worth \$US351,000 (\$A523,267)

Avita says its annual general meeting will vote to issue shares worth \$87,500 and options to acquire shares worth \$37,500 to each of six directors including chair Lou Panaccio, Prof Suzanne Crowe, Jeremy Curnock Cook, Jan Reed, Robert McNamara and Cary Vance. The company said the meeting would vote to issue each of Mr McNamara and Mr Vance \$147,000 in restricted stock units and options to acquire shares worth \$63,000; with 100,000 shares of US common stock, equivalent to 500,000 Chess depository instruments (CDIs) to chief executive officer James Corbett.

Avita said the meeting would vote to approve an amendment to the 2020 Omnibus Incentive Plan; approve the Employee Stock Purchase Plan; hold an “advisory vote to approve the compensation of ... named executive officers”; and to elect seven directors. Avita said the virtual meeting would be held on June 7, 2023 at 8am (AEST), or June 6, 2023 at 3pm (USPDT).

Avita was up eight cents or 1.8 percent to \$4.61 with 303,934 shares traded.

CRESO PHARMA

Creso says its shareholders will vote on 21 resolutions relating to the issue of more than 130,831,574 shares, 752,021,794 options and \$2,777,750 in convertible notes.

Creso said that its extraordinary general meeting would vote to issue 30,000,000 options to unrelated lenders; 5,000,000 options to former chair Adam Blumenthal; 304,000,000 broker options to Everblu Capital of which Mr Blumenthal was the current chair; 4,315,790 options “to the 2020 lenders”; and 23,684,144 placement options;

The company said the meeting would vote to issue \$160,000 in adviser shares; convert the La Plata convertible notes; issue 4,612,320 shares and 4,612,320 options to Mr Blumenthal; issue 4,612,320 options to Everblu Capital; ratify the prior issue of 101,726,426 shares and 203,452,852 options to “the February participants”; ratify the prior issue of 1,700,000 SBC Notes with a face value of \$1.1111 each to SBC Global; approve the issue of 800,000 convertible notes with a face value of \$1.1111 each to SBC Global; issue 70,000,000 options to SBC Global; ratify the issue of 14,940,239 shares to Achievement Nominees Pty Ltd; ratify the issue of 3,842,098 shares to EAS Advisors; ratify the issue of 5,710,491 shares to Six Degrees Group Holdings Pty Ltd; 29,880,478 “February options” to Achievement Nominees Pty Ltd; 7,684,196 “February options” to EAS Advisors; 11,420,982 “February options” to Six Degrees; and ratify the prior issue of 53,358,712 options.

Creso said that the virtual meeting would be held on May 15, 2023 at 3pm (AWST).

Creso fell 0.1 cents or 9.1 percent to one cent with 5.7 million shares traded.

PATRYS

Patrys says the US Patent and Trademark Office has granted two patents relating to its deoxymab antibodies PAT-DX1 and PAT-DX3.

Patrys said the first patent, titled ‘Binding proteins 1’ protected its lead clinical deoxymab antibodies PAT-DX1 and PAT-DX3 until September 2039.

The company said the second patent, titled ‘Antibody-mediated autocatalytic, targeted delivery of nanocarriers to tumors’ would protect its deoxymab technologies as nanocarriers for the treatment of cancer until January 2039.

Patrys fell 0.1 cents or 6.25 percent to 1.5 cents with 6.5 million shares traded.

PHARMAUST

Pharmaust says it has received about 10,000 monepantel tablets ensuring availability for its phase I/II motor neuron disease trial.

Last month, Pharmaust said that it had enrolled the second cohort of six patients in its phase I/II trial of monepantel for motor neurone disease and amyotrophic lateral sclerosis (BD: Mar 30, 2023).

Today, the company said that, so far, patients had elected to remain on monepantel after day-29 of the trial, and it had sufficient quantity of tablets to commence one or more other human clinical trials.

Pharmaust was up 0.6 cents or 6.1 percent to 10.5 cents with 1.2 million shares traded.

CRYOSITE

Cryosite says it has appointed Luis Antonio as an independent non-executive director, effective from today.

Cryosite said Mr Antonio was previously Johnson and Johnson Medical Asia-Pacific head of finance, Wright Medical head of finance and was currently Paragon 28 Asia Pacific head.

The company said Mr Antonio held a Bachelor of Arts from University of New South Wales, a Bachelor of Arts from Wagga Wagga-based Charles Sturt University and a Master of Business Administration from Perth's Curtin University.

Cryosite was unchanged at 73 cents.

BOTANIX PHARMACEUTICALS

Botanix says Susan Park has been appointed company secretary replacing Simon Robertson who had been with the company since 2016.

Botanix said Ms Park had more than 25 years' experience as a company secretary and non-executive director in the corporate finance industry, and was currently company secretary to several other ASX listed companies.

The company said Ms Park held a Bachelor of Commerce from the University of Western Australia.

Botanix said Mr Robertson was stepping down from day-to-day company secretarial work for public companies.

Botanix executive chair Vince Ippolito said: "We cannot thank Simon enough for his contribution to Botanix over the last seven years."

"His insight and counsel have been invaluable," Mr Ippolito said.

Botanix fell 0.3 cents or 3.1 percent to 9.3 cents with 2.8 million shares traded.