



Biotech Daily

Tuesday June 28, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ORTHOCELL UP 30%; IMUGENE DOWN 10%**
- * **ORTHOCELL UP 50% ON BIOHORIZONS \$23.1m FOR STRIATE+ LICENCE**
- * **LUMOS RETAIL RIGHTS RAISE \$3.2m, TOTAL \$11.2m**
- * **AROVELLA: STRIDES ENDS SUMATRIPTAN AGREEMENT, 'NO COST IMPACT'**
- * **4D MEDICAL, I-MED 3-YEAR XV LVAS CONTRACT**
- * **IMRICOR, SIEMENS DEPLOY 3-D MRI CARDIAC MAPPING**
- * **MICROBA, G42 1st UAE MICROBIOME REPORTS**
- * **MEMPHASYS, MONASH IVF ENROL 1st FELIX STUDY COUPLE**
- * **CARDIEX FILES US FDA 510(k) PULSE MONITOR APPLICATION**
- * **BCAL, PRECION DEVELOP BLOOD TEST FOR BREAST CANCER**
- * **RACE: ZANTRENE WITH BRAF, MEK INHIBITORS KILLS MELANOMAS**
- * **CRESO: WEED POOL CANNABIS ORDERS \$12.4k MARIJUANA VAPES**
- * **MEDLAB REQUESTS CAPITAL RAISING EGM TRADING HALT**
- * **PLATINUM DILUTED BELOW 5% IN KAZIA**
- * **ONE FUNDS TAKES 6.6% OF IMRICOR**
- * **INCANNEX LOSES DR SUD AGARWAL; DR GEORGE ANASTASSOV; CTO**

MARKET REPORT

The Australian stock market was up 0.86 percent on Tuesday June 28, 2022, with the ASX200 up 57.6 points to 6,763.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 22 fell and three traded unchanged.

Orthocell was the best, climbing as much as 15 cents or 50 percent, before closing up nine cents or 30 percent at 39 cents, with 3.15 million shares traded. Both Oncosil and Volpara climbed 11.1 percent; Micro-X was up 8.3 percent; Amplia and Polynovo were up more than seven percent; Compumedics was up 6.7 percent; Opthea and Universal Biosensors improved more than four percent; Immutep, Impedimed and Prescient were up more than three percent; Pro Medicus rose 1.2 percent; with CSL, Nanosonics and Starpharma up by less than one percent.

Yesterday's 45.5 percent best, Imugene, led the falls, down 2.5 cents or 10.4 percent to 21.5 cents, with 71.2 million shares traded. Patrys lost 9.1 percent; Resonance retreated 8.1 percent; Paradigm was down 6.1 percent; Actinogen and Alcidion fell four percent or more; Antisense, Mesoblast and Uscom were down three percent or more; Avita, Next Science, Nova Eye and Pharmaxis shed more than two percent; Atomo, Clinuvel, Cynata and Emvision were down more than one percent; with Cochlear, Cyclopharm, Kazia, Neuren, Proteomics, Resmed and Telix down by less than one percent.

ORTHOCELL

Orthocell climbed as much as 50 percent on news that Biohorizons has paid \$23.1 million for a licence to the intellectual property for its Striate+ for bone and soft tissue repair.

Orthocell said it would grant the Birmingham, Alabama-based Biohorizons Implant Systems Inc an exclusive world-wide licence for its Striate+ resorbable collagen membrane, used for dental guided bone and tissue regeneration procedures.

The company said it would supply Biohorizons its two patent families covering a collagen scaffold for cell growth and a method for producing a collagen membrane, associated patent applications, improvements and know-how, and the Striate+ trademark.

The company said the 25-year supply and distribution agreement would give Biohorizons exclusive marketing and distribution rights of Striate+ and that it would manufacture and supply Biohorizons with “quantities of Striate+ products that embody the licenced [intellectual property]”.

Orthocell managing-director Paul Anderson said Biohorizons was a provider of dental implant and tissue regenerative products “with specialist capabilities and resources to expand the marketing, promotion and supply of Striate+ worldwide”.

“The agreements ... [are] a significant milestone for Orthocell and provide further external commercial and technical validation of the Celgro collagen scaffold platform, from which the Striate+ dental products were developed,” Mr Anderson said.

Orthocell closed up nine cents or 30 percent at 39 cents with 3.15 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it raised about \$3.2 million in the retail component of its fully-underwritten entitlement offer at 19 cents a share, bring the total raised to \$11.2 million.

Earlier this month, Lumos said it had raised \$7,959,235 in the institutional component of its one-for-2.55 pro-rata, underwritten rights offer and expected to raise a further \$3.2 million in the underwritten retail rights offer (BD: Jun 6, 8, 2022).

The company said at that time that the offer price was a 22.4 percent discount to the last closing price of 24.5 cents a share, on June 1, 2022.

Today, Lumos said it had applications for about 1.7 million shares, raising about \$323,000, with about 250,000 additional shares, worth about \$47,500, accepted under the top-up facility.

The company said that about 15.3 million shares were not taken up under the retail offer, worth about \$2.9 million, and would be allocated to the sub-underwriters of the offer, including Planet Innovation which was expected to hold 32.4 percent of Lumos.

The company said the offer was fully-underwritten by joint lead managers, Bell Potter Securities and Wilsons Corporate Finance.

Lumos was up one cent or 6.9 percent to 15.5 cents.

AROVELLA (FORMERLY SUDA) THERAPEUTICS

Arovella says the Bangalore, India-based Strides Pharma will end its sumatriptan development licence and supply agreement due to “a change in market conditions”.

In 2018, the then Suda said Strides would pay \$1.4 million to commercialize and develop its SUD-001H oral spray of sumatriptan for migraines in the US (BD: Nov 8, 2018).

Today, Arovella said the termination would have no cost impact, nor immediate impact on revenue streams, and it had reviewed operations and restructured the reformulation group to match the reduced requirements for reformulation project work.

Arovella was up 0.2 cents or 9.1 percent to 2.4 cents with 2.2 million shares traded.

4D MEDICAL

4D Medical says it has an expanded three-year national contract with Sydney's I-Med Radiology Network for its XV lung ventilation analysis software (XV LVAS).

Last year, 4D said it would begin the second phase of its clinical pilot program with I-Med and said it had begun the commercial rollout of its XV LVAS at I-Med's Berwick, Victoria clinic (BD: Sep 1; Nov 23, 2021).

Today, the company said the expanded three-year agreement would deliver its lung imaging technology to selected clinics across I-Med's network of 250 clinics, including in Sydney, Melbourne, Adelaide, and Perth, and while it said it expected revenue to be material it did not disclose the commercial terms of the agreement.

4D managing-direct Prof Andreas Fouras said the agreement was "a significant milestone for the company".

"Expansion of our proven capability nationwide means many more people will be able to access the latest technology in respiratory imaging," Prof Fouras said.

"Beyond putting our innovative technology in the reach of more people, this deal represents a significant opportunity to drive revenue for the company... [and] additionally, this agreement creates a framework for the rapid commercialization of future 4D Medical products," Prof Fouras said.

I-Med chief executive officer Dr Shrey Viranna said the arrangement augmented I-Med's diagnostic imaging through access to 4D Medical's functional lung imaging technology.

4D was up 10 cents or 27.8 percent to 46 cents with 5.7 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has agreements with Siemens to deploy its three-dimensional (3-D) cardiac mapping systems on Siemens' magnetic resonance imaging platform.

Imricor did not disclose the commercial terms of the agreements with the Erlangen, Germany-based Siemens Healthcare GmbH but said it had an initial term ending December 31, 2026, which could be automatically extended by 12-month periods.

The company said the agreements allowed it to commercialize its 3-D mapping system for the Siemens platform "sooner than previously possible" and that it would provide Siemens invasive cardiovascular magnetic resonance sites an opportunity to participate in its planned ventricular tachycardia ablation clinical trial.

Imricor said the first agreement was a licence which provided the ability to interface its 3-D mapping system to Siemens magnetic resonance imaging (MRI) scanners, and that the second was a local coil agreement allowing its catheters to be recognized by new Siemens MRI scanners.

Imricor chair Steve Wedan said the agreements were "extremely significant to our business".

"We began developing our own 3-D mapping system in January with the intent to remove our reliance on third parties with respect to delivering such a mapping system and our development, in close collaboration with Siemens, continues to exceed our expectations," Mr Wedan said. "With the completion of the ... [agreements] we now have full control over the deployment of our 3-D mapping system to our customers who have Siemens' Aera or newer systems."

Mr Wedan said that 3-D prototypes would be used for research and clinical trial purposes, including a planned ventricular tachycardia ablation trial, with the goal of Conformité Européenne (CE) mark for the 3-D mapping system, at the same time as receiving ventricular tachycardia indications for the second-generation ablation catheter.

Imricor was up one cent or 6.7 percent to 16 cents with 1.4 million shares traded.

MICROBA LIFE SCIENCES

Microba says with Abu Dhabi's G42 Healthcare has delivered its first gut microbiome reports using its analysis platform for users in the United Arab Emirates.

The company said that in February 2022, it signed an agreement to enable a gut microbiome testing service to be developed by G42 Healthcare and made available to customers in the United Arab Emirates, Saudi Arabia, Bahrain, Kuwait, Oman and Qatar, but did not disclose the commercial terms of the agreement (BD: Feb 22, 2022).

Microba chief executive officer Dr Luke Reid said the company was "pleased to see our testing technology being delivered to customers in the [Gulf Cooperation Council] region via our market-leading distribution partners".

Microba fell three cents or 10.7 percent to 25 cents.

MEMPHASYS

Memphasys says with Monash IVF (in-vitro fertilization) Group, it has enrolled and treated the first couple in its 104-couple study of its Felix sperm separation device.

In December, Memphasys said with Monash IVF, it would conduct the trial at four sites in New South Wales and Victoria, with Mobius Medical as its contract research organization, to "statistically prove the Felix system is not inferior to either of the current commercial sperm separation techniques" (BD: Dec 9, 2021).

Today, the company said that the couples would be enrolled at seven Monash IVF sites, with the three additional sites joining the program by August 1, 2022, and that the study was expected to be completed by the end of December 2022.

Memphasys managing-director Alison Coutts said "the first patient enrolments into this clinical study are exciting".

"Memphasys, along with Monash IVF, are confident recruitment and treatment rates will increase especially with the additional three ... sites," Ms Coutts said.

Memphasys was unchanged at 3.6 cents.

CARDIEX

Cardiex says it has filed a 510(k) submission to the US Food and Drug Administration for its Conneqt Pulse dual blood pressure and arterial health monitor.

Cardiex said that subject to final FDA clearance, Pulse would be its first arterial health monitor, targeted at home health, remote patient monitoring and decentralized clinical trials, to be marketed to both clinicians and consumers.

The company said the Pulse device monitored arterial health parameters beyond traditional blood pressure, in order to provide "more advanced insights into cardiovascular health".

Cardiex did not say when it expected the FDA to respond to its submission.

Cardiex chief executive officer Craig Cooper said "the submission of our application for FDA clearance on the Pulse represents the most significant event for Cardiex in over 20 years when we were initially granted FDA clearance on our Sphygmocor technology".

"Pulse extends that legacy into new, significant markets and importantly, is set to redefine the diagnostic paradigm for the identification and treatment of vascular and arterial disease," Mr Cooper said.

"Traditionally, the level of technology incorporated in the Pulse was only available to specialist clinicians, research institutions, and pharmaceutical companies for clinical trials," Mr Cooper said.

Cardiex was up two cents or 6.9 percent to 31 cents.

BCAL DIAGNOSTICS

Bcal Diagnostics says it has an agreement with the Morrisville, North Carolina-based Precion Inc for the development of its blood-based test to detect breast cancer. Bcal did not disclose the commercial terms of the agreement but said it would work with Precion's laboratories to develop standardized commercial assays, based on the proprietary lipid biomarker signature identified by Bcal in the blood samples of early and late-stage breast cancer cohorts.

The company said the companies would validate the algorithm required for reporting results and carry out clinical studies in the US.

Bcal chief executive officer Dr John Hurrell said his company was "keen to work with Precion as we move our blood test for breast cancer further along the commercialization pathway and closer to benefiting breast cancer patients and women in general".

Bcal was up 1.6 cents or 26.7 percent to 7.6 cents.

RACE ONCOLOGY

Race says Zantrene, or bisantrene dihydrochloride, has synergy with BRAF and MEK inhibitors for treating melanoma, in-vitro and in mice.

Race said that Zantrene, when used in combination with BRAF and MEK protein kinase inhibitors improved the killing of human melanoma cells and better targeted melanoma in organoid and animal tumor models.

The company said that Zantrene in combination with vemurafenib, a BRAF inhibitor, significantly slowed the growth of human melanoma tumors in mice.

Race said that a patent protecting these findings had been submitted and if granted, would be valid until 2042.

Race chief scientific officer Dr Daniel Tillett said the "exciting preclinical results offer an alternative path to use Zantrene in the clinic to help advanced melanoma patients who are unable to tolerate, or are unresponsive to immunotherapy".

"The synergy that has now been observed with a diverse range of kinase inhibitors suggests possibilities for the clinical use of Zantrene in combination with kinase inhibitors far beyond melanoma," Dr Tillett said.

Race was up 3.5 cents or 1.9 percent to \$1.885.

CRESO PHARMA

Creso says it has received its first order worth \$CA11,088 (\$A12,439) for its Ritual Gold vaporizer products from Weed Pool Cannabis Cooperative.

Creso said that its Windsor, Nova Scotia-based, subsidiary Mernova Medicinal would provide the Saskatoon, Saskatchewan Weed Pool Cannabis with 40 cases of one gram Lemon Haze vaporizers, which used marijuana 'trim' and other biomass not suitable for retail sale.

Creso was unchanged at 3.7 cents with 7.3 million shares traded.

MEDLAB CLINICAL

Medlab has requested a trading halt pending the release of an "announcement of an extraordinary general meeting to approve [a] capital raising".

Trading will resume on June 30, 2022 or on an earlier announcement.

Medlab was up 0.4 cents or 9.1 percent to 4.8 cents.

[KAZIA THERAPEUTICS](#)

Sydney's Platinum Investment says it has ceased its substantial holdings in Kazia after it was diluted due to the release of 4,072,660 shares on June 20, 2022.

Last year, in its most recent substantial shareholder notice, Platinum said it held 7,084,856 Kazia shares (5.60%) (BD: Apr 9, 2021).

Last week, Kazia applied for the quotation of the 4,072,660 shares through its Oppenheimer "at the market" equity draw-down facility, with the shares selling at 60.956 US cents (87.97 Australian cents) (BD: Jun 10, 2022).

Kazia fell half a cent or 0.8 percent to 61.5 cents.

[IMRICOR MEDICAL SYSTEMS](#)

Sydney's One Funds Management says it has increased its substantial share-holding in Imricor from 7,180,000 shares (5.05%) to 9,500,000 shares (6.63%).

One Funds said that between September 4, 2020 and June 21, 2022 it bought and sold shares, with the largest purchase on September 10, 2021 of 1,500,000 shares for \$1,500,000 or \$1.00 a share.

[INCANNEX HEALTHCARE](#)

Incannex says Dr George Anastassov will replace Dr Sud Agarwal as a director and it has appointed Lekhram Changoer as chief technology officer.

Incannex said that Dr Agarwal's resignation would "alleviate potential future conflict of interest issues pertaining to work undertaken by Melbourne's Cannvalate Pty Ltd, Dr Agarwal's medicinal cannabis advisory firm".

The company said that Dr Agarwal's "key contribution ... was his strategic vision and foresight to originate Incannex's proprietary cannabinoid combination drugs, IHL-42X, IHL-216A and IHL-675A".

Incannex said that Dr Anastassov was the managing-director of the Scottsboro, Alabama-based Apirx Pharmaceuticals, the medical marijuana company it acquired last month (BD: May 12, 2022).

Incannex said that Mr Changoer was a co-founder of Apirx and would join the company as its chief technology officer to develop and implement science and technical strategies for clinical and commercial manufacturing of pharmaco-therapies.

Incannex fell 2.5 cents or 9.4 percent to 24 cents with 5.8 million shares traded.