



Biotech Daily

Monday June 5, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: COMPUMEDICS UP 18%; GENETIC SIGNATURES DOWN 7%**
- * **ONEVENTURES \$15m FOR IMMVIRX; \$10m MORE TO GO**
- * **DIMERIX RIGHTS, NOTES RAISE \$8.7m**
- * **IDT 'FIRM COMMITMENTS' FOR \$5m; PLAN FOR \$2m MORE**
- * **STARPHARMA: MALAYSIA APPROVES VIRALEZE NASAL SPRAY**
- * **BLUE CROSS BLUE SHIELD COVERS IMPEDIMED L-DEX**
- * **ONCOSIL APPROVAL FOR PANCOSIL PANCREATIC CANCER TRIAL**
- * **CHIMERIC STARTS CHM1101 GLIOBLASTOMA TRIAL**
- * **BOTANIX: DONG WHA SOUTH KOREA SOFPIRONIUM BROMIDE DISTRIBUTOR**
- * **S&P ADDS COGSTATE TO ALL TECHNOLOGY INDEX**
- * **PACIFIC EDGE REQUESTS 'NOVITAS REIMBURSEMENT' TRADING HALT**
- * **NUHEARA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **AROVELLA REQUESTS 'CAPITAL RAISE' TRADING HALT**
- * **PHARMAUST REQUESTS 'MND TRIAL RESULTS' TRADING HALT**
- * **HERAMED REQUESTS 'PARTNERSHIP CLARIFICATION' TRADING HALT**
- * **MESOBLAST APPOINTS DIRECTOR DR PHILIP KRAUSE ADVISER**
- * **KAZIA APPOINTS EBRU DAVIDSON DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.00 percent on Monday June 5, 2023, with the ASX200 up 71.2 points to 7,216.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and one was untraded. All three Big Caps were up.

Compumedics was the best, up three cents or 17.65 percent to 20 cents, with 123,224 shares traded, followed by Immutep up 17.3 percent to 30.5 cents, with 7.3 million shares traded. Impedimed improved 14.3 percent; Cynata climbed 11.5 percent; Avita was up 8.2 percent; Nova Eye rose 7.1 percent; Micro-X was up five percent; Pro Medicus improved 4.8 percent; Clinuvel climbed 3.7 percent; Actinogen, Mesoblast and Volpara rose more than two percent; Cochlear, Nanosonics and Telix were up more than one percent; with CSL and Resmed up by less than one percent.

Genetic Signatures led the falls, down 3.75 cents or 6.7 percent to 52 cents, with 244,866 shares traded. Medical Developments and Neuren lost six percent or more; Atomo, Next Science, Proteomics and Universal Biosensors were down more than five percent; Opthea fell 4.1 percent; Alcidion, Pharmaxis and Starpharma were down more than three percent; Kazia and Orthocell shed more than two percent; Emvision and Paradigm were down more than one percent; with Cyclopharm down by 0.5 percent.

IMMVIRX PTY LTD

Immvirx says that Oneventures has committed \$15 million of a \$25 million series B raising to support its development of viral immune-therapies for cancer.

Immvirx said the funding would provide a runway for the next two years.

In April, Immvirx said it had dosed the first of up-to 27 patients in its phase Ia dose escalation and expansion trial of its oncolytic virus IVX037 for colorectal, gastric and ovarian cancer (BD: Apr 12, 2023).

Immvirx chief executive officer and co-founder Dr Malcolm McColl told Biotech Daily at that time that the phase Ia part of the trial was likely to take until April 2024, to be followed by an up-to 45-patient phase Ib trial to establish the dosing regimen when combined with an immune checkpoint inhibitor.

Dr McColl was the chief executive officer of Viralytics when the company was sold to Merck Inc (Merck Sharp and Dohme) for \$502 million for its Cavatak oncolytic immunotherapy (BD: Feb 22, Jun 4, 2018).

Dr McColl said that the former Viralytics chief scientific officer Prof Darren Shafren was the Immvirx chief scientific officer.

Today, the Newcastle, New South Wales-based Immvirx said that along with Oneventures \$15 million commitment, "several existing substantial investors including Acorn Capital [had] placed bids to participate in the offer.

The company said that funds would be used for pre-clinical and clinical trials to further develop and expand its pipeline as well as manufacturing and corporate and business "Against the backdrop of what's been a difficult capital market for biotechnology companies, it is testament to the work of our team thus far, and a significant vote of confidence from Oneventures to lead this round of funding," Dr McColl said.

"We are thrilled to welcome Oneventures to the register and appreciate the strong ongoing support of our existing shareholders," Dr McColl said.

"The new funds will enable us to accelerate the development of our innovative oncolytic viral immune-therapies and bring us closer to our goal of transforming outcomes for patients with some of the most prevalent cancer types," Dr McColl said.

The company said that Oneventures principal Dr Jeannie Joughin would join its board of directors and that Bell Potter Securities was the corporate advisor to the transaction.

Immvirx is a private company.

DIMERIX

Dimerix says it has raised \$5.2 million in a rights issue at 8.0 cents a share, and \$3.5 million in a convertible securities agreement.

Last month, Dimerix said it hoped to raise \$12 million through an \$8.56 million partially-underwritten, one-for-three, entitlement offer and a convertible notes agreement of up-to \$12 million with Mercer Street Global Opportunity Fund (BD: May 4, 2023).

At that time, the company said about \$4.06 million of the offer was underwritten, with substantial shareholder Peter Meurs and directors Dr Nina Webster and Dr Sonia Poli committing to full entitlement uptake and sub-underwriting of a portion of shortfall.

Today, Dimerix said the entitlement offer received subscriptions for \$3,142,260 and the underwriters subscribed or procured subscriptions for \$2,063,699 of the shortfall.

Dimerix said it proposed to issue 11,363,636 options to Mercer, subject to approval.

The company said the funds raised would continue its phase III trial of DMX200 for focal segmental glomerulosclerosis past first interim data, including clinical, inclusion of paediatric patients, manufacturing and partnering activities.

Dimerix was unchanged at 6.8 cents.

IDT AUSTRALIA

IDT says it has “firm commitments” for a placement to raise \$5.0 million at 6.5 cents a share, with a share purchase plan of up-to \$2.0 million to follow.

IDT said the offer price of 6.5 cents was a 23.7 percent discount to the 15-day volume weighted average price.

The company said it had not determined the terms and timing of the share plan.

IDT chair Mark Simari said the funds would “strengthen the company’s balance sheet and provides IDT with the financial capacity to achieve ... growth objectives”.

The company said it had appointed Taylor Collison Ltd as sole lead manager and bookrunner for the placement.

IDT fell 2.8 cents or 29.2 percent to 6.8 cents with 2.2 million shares traded.

STARPHARMA

Starpharma says Malaysia has approved the sale and marketing of its anti-viral nasal spray Viraleze for influenza viruses, rhinoviruses and respiratory syncytial virus.

Starpharma said its Viraleze had been well received in Vietnam, Hong Kong and Macau.

The company said that it was continuing discussions with potential commercial partners in Malaysia as well as other parts of Asia.

Starpharma said that with Malaysian approval it had registrations for Viraleze in more than 35 countries and it was available in pharmacies, shops and online in certain markets.

Starpharma chief executive officer Dr Jackie Fairley said Viraleze would “be available immediately to consumers in Malaysia through an online webstore” and the company had plans to make the product available locally through retail outlets including pharmacies.

“We are encouraged by the positive uptake of Viraleze in Asia and look forward to launching the product in Malaysia as soon as practicable,” Dr Fairley said.

Starpharma fell 1.5 cents or 3.85 percent to 37.5 cents.

IMPEDIMED

Impedimed says that the Jacksonville-based Florida Blue is the first Blue Cross Blue Shield plan to cover its L-Dex bio-impedance spectroscopy lymphoedema test.

In 2010, Impedimed said it had two insurance contracts for the L-Dex to assess lymphoedema in breast cancer patients, with Integrated Health Plan and National Preferred Provider Network with 13.5 million members (BD: Aug 25, 30, 2010).

Today, Impedimed said Florida Blue had amended an existing lymphoedema policy to include broad coverage of its L-Dex test and the policy was not limited to breast cancer but included all US Food and Drug Administration cleared indications for L-Dex.

Impedimed said the reimbursement rates were expected to be in excess of rates seen under previously reported medical policies.

Impedimed said that “large regional payors like Florida Blue are a key step in gaining broad national coverage and this published policy continues the domino effect we expect to see in the coming weeks and months”.

Impedimed managing-director Richard Valencia said that coverage for the bio-impedance spectroscopy testing by a Blue Cross Blue Shield company was a “significant milestone”.

“We continue to expect to achieve critical mass of covered lives through the US in short order,” Mr Valencia said.

“Even in advance of critical mass, our sales pipeline is the strongest it has ever been, and we are already reaping some short-term rewards,” Mr Valencia said.

Impedimed was up two cents or 14.3 percent to 16 cents with 11.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has ethics approval for a 15-patient, investigator-initiated trial of percutaneously applied radiotherapy for advanced pancreatic cancer.

Oncosil said the trial would be led by Prof Marc Besselink at the Netherlands-based Amsterdam University Medical Centers.

The company said the trial would study the delivery of the device when inserted directly through the skin into the tumor under computed tomography scan guidance, or percutaneously, rather than the endoscopically guided by ultrasound.

Oncosil said the trial would begin recruitment by July 2023, and the outcome was expected to increase the number of medical professionals who could deliver the device to patients.

Oncosil said it would provide the doses for the trial at no cost and would make a “modest contribution to study personnel”.

Oncosil managing director Nigel Lange said that “expanding the number of specialties capable of implanting the Oncosil device will assist the company in gaining wider appeal amongst key opinion leaders”.

Oncosil was up 0.1 cents or 8.3 percent to 1.3 cents with 11.5 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has begun an up-to 32 patient, multi-site, two-part, phase Ib trial of CHM1101 for progressive glioblastoma multiforme brain cancer.

In April, Chimeric said it had ethics approval for the trial, and that part A would treat three to six patients to complete the phase I dose escalation confirmation trial at the Duarte, California City of Hope Cancer Centre (BD: Apr 26, 2023).

Today, the company said the trial of its CHM1101 chlorotoxin chimeric antigen receptor (CLTX Car) T-cell solid tumor treatment for brain cancer was open for enrolment at the Austin, Texas-based St David’s South Austin Medical Centre.

Chimeric said the trial would assess the safety and activity of CHM1101, and based on favorable results, it would enrol between 12 and 26 dose expansion cohort patients in part B of the trial, expected later this year.

Chimeric said that after successful completion of part B it intended to design and initiate a registration trial, in collaboration with regulatory feedback.

Chimeric chief executive officer Jennifer Chow said the multi-centre trial would enable the company to “advance the development of CHM1101 with recruitment across multiple [...] sites ... [and] accelerate the next phase of development if supported by the clinical results”.

Chimeric was up 0.2 cents or 5.3 percent to four cents with 1.2 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says Kaken Pharmaceutical Co has a sublicense and distribution agreement with Dong Wha to distribute sofipronium bromide for sweating in South Korea.

Botanix said Seoul’s Dong Wha Pharmaceuticals would commercialize its sofipronium bromide for primary axillary hyper-hidrosis, or excessive sweating, in South Korea.

The company said Kaken, and in turn Botanix, would receive a share of upfront payments from Dong Wha, along with milestone payments and royalties based on product sales.

Botanix said that at this stage it did not expect the revenue from the agreement to be material.

Botanix was up 1.5 cents or 16.7 percent to 10.5 cents with eight million shares traded.

COGSTATE

S&P Dow Jones Indices says Cogstate has been added to the All Technology Index, effective from June 19, 2023.

Cogstate fell 2.5 cents or 1.4 percent to \$1.735.

PACIFIC EDGE

Pacific Edge says it has requested a trading halt pending an announcement in relation to Novitas finalizing its proposal to cover the reimbursement of Cxbladder by Medicare.

Last week, Pacific Edge said Novitas must finalize or withdraw local coverage determination and a local coverage article for reimbursement of Cxbladder tests by June 9, 2023 (BD: Jun 2, 2023).

Trading will resume on June 7, 2023, or on an earlier announcement.

Pacific Edge was untraded at 38 cents.

NUHEARA

Nuheara says it has requested a trading halt “pending release of an announcement regarding a capital raising”.

Trading will resume on June 7, 2023, or on an earlier announcement.

Nuheara last traded at 14 cents.

AROVELLA THERAPEUTICS

Arovella says it has requested a trading halt “pending an announcement regarding a proposed capital raise”.

Trading will resume on June 7, 2023, or on an earlier announcement.

Arovella last traded at five cents.

PHARMAUST

Pharmaust says it has requested a trading halt “pending an announcement of interim analysis results from the motor neurone disease phase I/II clinical trial”.

Trading will resume on June 7, 2023, or on an earlier announcement.

Pharmaust last traded at 7.7 cents.

HERAMED

Heramed says it has requested a trading halt pending clarification of last week’s announcement of a strategic US employee rewards platform partnership.

On Thursday, Heramed said that said San Francisco’s Fond Perks would incorporate its Heracare foetal heart rate technology (BD: Jun 1, 2023).

The company said at that time that Fond Perks offered employees corporate rewards, and since US employees receive health insurance from their employers, Fond would incorporate its Heracare platform into its portfolio and make it available for its clients.

Trading will resume on June 7, 2023, or on an earlier announcement.

Heramed last traded at eight cents.

MESOBLAST

Mesoblast says it has appointed director Dr Philip Krause as a strategic advisor. Mesoblast said Dr Krause was formerly deputy director of the US Food and Drug Administration Office of Vaccines Research and Review and would advise the company on “regulatory strategies related to broadening out the remestemcel-L platform ... and the second-generation platform rexlemestrocel-L”.

Mesoblast chief executive officer Prof Silviu Itescu said Dr Krause had provided “invaluable input in the current biologics licence application for remestemcel-L in the treatment of children with [steroid-resistant acute graft versus host disease]”.

“We are very fortunate to be able to access [Dr Krause’s] expertise as we position our pipeline for further regulatory interactions,” Prof Itescu said.

Mesoblast was up 2.5 cents or 2.35 percent to \$1.09 with 1.4 million shares traded.

KAZIA THERAPEUTICS

Kazia says it has appointed Ebru Davidson as a non-executive director, effective from today.

Kazia said Ms Davidson was a corporate lawyer and was currently Qbiotics Group general counsel and was previously a partner at Thomson Geer Lawyers.

The company said Ms Davidson held a Bachelor of Science from the University of Melbourne and a Juris Doctor from the Gold Coast, Queensland Bond University.

Kazia fell half a cent or 2.9 percent to 16.5 cents.