Biotech Daily

Monday May 6, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMMUTEP UP 8%; IMUGENE DOWN 6%**

*** SOMNOMED RETAIL RIGHTS RAISE $16.8m; TOTAL $22.6m**

*** IDT: VICTORIA 'PARTIALLY FUNDS' $3.8m ADC FACTORY**

*** LUMOS TRIGGERS $604k HOLOGIC MILESTONE PAYMENT**

*** NEUROTECH: 'NTI164 FURTHER IMPROVEMENTS FOR RETT SYNDROME'**

*** PYC: 'VP-001 IMPROVES 1 PATIENT'S RETINAL SENSITIVITY'**

*** CYCLOPHARM TECHNEGAS CPT CODE, INSURANCE, CONTRACTS, DATA**

*** PERCHERON: W.H.O. RENAMES ATL1102 'AVICURSEN'**

*** RMIT, SIGNATURE ORTHO, MELBOURNE UNI RESEARCH AGREEMENT**

*** GENETIC TECHNOLOGIES, WELLWORKS SALES, MARKETING DEAL**

*** GOODBYE VOLPARA**

*** IMAGION POTENTIAL 2nd STRIKE, BOARD SPILL AGM**

*** ECS LOSES FOUNDER ALEX KEACH; ALEX KEACH SELLS 50m SHARES**

*** POLYNOVO APPOINTS LIOR HAREL CO SEC, GENERAL COUNSEL**

MARKET REPORT

The Australian stock market was up 0.7 percent on Monday May 6, 2024, with the ASX200 up 53.4 points to 7,682.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one, Volpara, was untraded.

Immutep was the best, up 3.5 cents or 8.05 percent to 47 cents, with 7.4 million shares traded. Genetic Signatures, Mesoblast, Genetic Signatures and Syntara climbed more than six percent; Opthea was up 5.7 percent; Clarity and Starpharma improved more than four percent; Proteomics and Resonance were up more than three percent; Nanosonics rose 2.55 percent; Cochlear and Impedimed were up one percent or more; with Clinuvel and Neuren up by less than one percent.

Imugene led the falls, down 0.5 cents or 6.1 percent to 7.7 cents, with 33.9 million shares traded. Alcidion, Emvision, Paradigm and Prescient fell more than four percent; 4D Medical, Actinogen, Amplia, Cyclopharm, Medical Developments, Nova Eye and Universal Biosensors lost more than three percent; Cynata, Dimerix and SDI shed more than two percent; Orthocell, Polynovo, Pro Medicus and Telix were down more than one percent; with Avita, CSL and Resmed down by less than one percent.

SOMNOMED

Somnomed says it has raised about $16.8 million at 21 cents a share in its one-for-1.01, fully-underwritten retail entitlement offer, taking the total raised to $22.6 million.
In April, Somnomed said the institutional offer raised $7.5 million, with an up-to about $16.8 million retail offer to follow (BD: Apr 10, 2024).
Today, the company said about 70 percent of the retail offer was raised from eligible investors, with the remainder taken up by the underwriters and TDM Growth Partners.
Somnomed said Wilsons Corporate Finance was sole lead manager, bookrunner and underwriter to the entitlement offer.
Somnomed was up half a cent or 2.4 percent to 21.5 cents.

IDT AUSTRALIA

IDT says the Victoria Government will “partially fund” a $3.8 million antibody-drug-conjugate (ADC) manufacturing factory developing clinical trial materials.
IDT said antibody-drug-conjugates were “smart drugs that target cancer cells and have greatly reduced side-effects in non-cancerous cells”.
The company said the undisclosed grant from the Victorian Industry Investment Fund, part of the Victorian Jobs and Investment Fund, would assist build the factory in Boronia.
IDT said the facility would “further enhance [its] … competitive advantages in high potent and high containment manufacturing [and] provide a growth catalyst for its advanced therapies business and cement the company’s market leadership position as the go-to manufacturing partner”.
The company said the State funding would be in three tranches over 12-months.
IDT chief executive officer Paul McDonald said the facility was “a strategically important asset for our nation and for our company … [and would] put Victoria at the heart of Australia’s sovereign capability to manufacture the latest cutting-edge drugs, while providing a significant growth catalyst for our fledging [advanced therapies] business.”
IDT was up 0.65 cents or seven percent to 9.9 cents.

LUMOS DIAGNOSTICS

Lumos says it will receive $US400,000 ($A604,000) from Hologic Inc in milestone payments for completing the first phase of development for its foetal fibronectin test.
Earlier this year, Lumos said the Marlborough, Massachusetts-based Hologic Inc would pay it up-to $US10 million ($A14.9 million) to improve their women’s health products and adapt them for use with Lumos’ platform (BD: Jan 21, 2024).
Today, the company said that a foetal fibronectin test was a pre-term test kit for diagnosing pre-term deliveries in pregnancies.
Lumos said that the annual US pre-term birth market was about 2.5 million tests a year and its tests were reimbursed at $US64.41 each.
Lumos said phase one included product definition and planning, with $US200,000 already recognized and the remaining $US200,000 to be received by July 2024; the second phase, showing the assay’s feasibility to detect biomarkers, would trigger a $US600,000 payment, with prototype delivery triggering a $US3.7 million final payment.
Lumos managing-director Doug Ward said achieving the milestone was “excellent validation of the project work completed by the Lumos team, whilst providing additional strength to the company balance sheet through further project funding and a positive outlook on the likelihood of Lumos delivering on subsequent phase”.
Lumos was up 0.4 cents or 8.2 percent to 5.3 cents with seven million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says analysis of its 14-patient, phase I/II trial of marijuana-based NTI164 shows improvement and behavior improvement in Rett syndrome patients (p = 0.001).
Last month, Neurotech said the trial showed a “statistically significant clinical improvement in Rett syndrome patients” (p = 0.04) (BD: Apr 17, 2024).
Today, Neurotech said the further analysis showed a further improvement in the primary endpoint of clinical global impression score at 12 weeks compared to baseline, with a mean difference of 0.4 in nine Rett-specific measures (p = 0.009).
The company said 13 patients (93.0%) of patients showed improvement at 12 weeks of orally dosed NTI164 treatment, with eight patients (57.1%) minimally improved, four patients (28.6%) much improved, one patient (7.1%) very much improved and one patient (7.1%) showing no change.
Neurotech said NTI164 showed “significant improvements in communication skills, mental alertness, socialization, eye contact and anxiety” which would likely form the basis of registration-directed studies.
The company said further improvements were shown in secondary endpoints including the clinical global severity of illness score (p = 0.009) and impact of childhood neurological disability scale (p = 0.004).
Neurotech said one serious adverse event of urticaria, or hives, was reported during the 12-week treatment with no patients reporting diarrhoea and two patients experiencing nausea and, or vomiting.
The company said all patients were enrolled in the 52-week extension phase, and it was seeking regulatory advice to conduct a further registration-directed clinical trial.
Neurotech executive director Dr Thomas Duthy said the “fulsome data set reported today represents a very rapid translation of our strong conviction on the anti-neuroinflammatory and neuroprotective effects of NTI164 applied to a third paediatric neurological population, Rett Syndrome, where safe and effective therapies are urgently needed”.
“The level of improvement we have observed in these girls after 12 weeks of treatment is remarkable in the context of the excellent safety profile of NTI164 where just a single serious event recorded and adverse events were minor and manageable relative to the observed standard therapy in the US,” Dr Duthy said.
Neurotech fell 0.9 cents or 9.9 percent to 8.2 cents with 16.1 million shares traded.

PYC THERAPEUTICS

PYC says one patient in its single-ascending dose study of VP-001 for retinitis pigmentosa type 11 has shown “potential signs of early improvement in … retinal sensitivity”.
Earlier this year, PYC said it had dosed the third and final cohort of three patients in its phase I single dose escalating trial of VP-001 for the childhood disease retinitis pigmentosa type 11 (RP11) (BD: Feb 28, 2024).
Last week, the company said it had conducted a safety review of the first three doses of 3.0 micrograms, 10 micrograms and 30 micrograms studied in the trial, with a fourth cohort expected to receive the final 75 microgram dose by June (BD: Apr 29, 2024).
Today, the company said the study showed no treatment emergent serious adverse events across all three patient cohorts were reported; and one patient at an earlier stage of disease progression in the 30 microgram cohort showed early improvement in retinal sensitivity at four and eight week follow-up.
The company said the trial was expected to support a planned registrational trial in 2024 and a potential new drug application in 2027.
PYC was up half a cent or 4.8 percent to 11 cents with 9.1 million shares traded.

CYCLOPHARM

Cyclopharm says Technegas has received a unique reimbursement code, it has 10 contracts under review and data supports the use of Technegas in further indications.
Cyclopharm said the Center for Medicare Medicaid Services had approved a unique identifier code for the use of Technegas for diagnosing pulmonary embolism, from July 1, 2024, which would streamline the reimbursement process.
The company said that given Technegas pricing in the US was at a premium cost to existing products, it had applied for pass-through status through Medicare to allow clinical sites to be fully reimbursed for using Technegas for up-to three years.
Cyclopharm said it had issued 136 proposals and contracts for Technegas in the US, for more than 400 locations, with 10 contracts in the review stage, six contracts in committee stage and 103 proposals in early discussions.
The company said it had provided 12 proposals to the Veterans Administration Healthcare system and three to military hospital systems, which had a total of 120 nuclear medicine departments and 35 US-based hospitals.
Cyclopharm said it continued “to prioritize US opportunities through a focused engagement strategy” which included US clinical trial sites involved in its Technegas’ new drug application, with key opinion leaders and advocates supporting the application, along with approaching government and private health care groups and university affiliated teaching hospitals.
The company said it was expanding the indications for Technegas, including a study from the New South Wales-based University of Newcastle and the Hunter Medical Research Institute, titled ‘Ventilation Heterogeneity is a Treatable Trait in Severe Asthma’, published in the Journal of Allergy and Clinical Immunology: In Practice.
Cyclopharm said the study showed that in a population of severe asthmatics diagnosed using ventilation single-photon emission computed tomography, ventilation heterogeneity was “clinically significant, measurable and treatable”.
The company said the study concluded that using Technegas for imaging severe asthmatics with ventilation heterogeneity was “safe, fast and cost-effective”.
Cyclopharm managing-director James McBrayer said there were “clear and temporary reasons for a slower than anticipated rate of installations during the first few months since our landmark US [Food and Drug Administration] approval”.
“The company’s view of the total market potential for Technegas therefore remains unaltered,” Mr McBrayer said.
“We continue to be encouraged by excellent clinical support and interest received as we progress our rollout across a range of fronts throughout the US,” Mr McBrayer said.
“We expect that a favorable [Center for Medicare Medicaid Services] pass-through determination will accelerate the conversion from clinical demand to executed contracts,” Mr McBrayer said.
Cyclopharm fell seven cents or 3.9 percent to $1.73.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says the World Health Organisation has selected ‘Avicursen’ as the international non-proprietary name for its ATL1102 for Duchenne muscular dystrophy.
Percheron said it expected the name to be confirmed by the W.H.O. about May 2025 and it would continue to use the designation ATL1102 until it adopted ‘avicursen’ next year.
Percheron chief executive officer Dr James Garner said the selection of an international non-proprietary name was “an important regulatory milestone”
Percheron was unchanged at 7.7 cents.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY, SIGNATURE ORTHOPAEDICS THE UNIVERSITY OF MELBOURNE

RMIT says it will work with Signature Orthopaedics and the University of Melbourne to develop “materials, designs and methods in orthopaedic implants and devices”.
An RMIT media release said the partnership connected each party’s research capabilities in biomedical engineering, health, medicine, technology development and design.
The Institute said the agreement complemented its investments in medical technology training and skills development, as well as the University of Melbourne and grants from the Victorian Government.
RMIT said it would announce the first projects under the partnership in the “coming months”.
The Institute said the Sydney-based Signature Orthopaedics was the “only manufacturer of implantable orthopaedic devices in Australia” under its own brand, as well as for other well-known brand devices including hip and knee joint replacements, spinal, osseointegration, osteosynthesis and soft tissue repair implants.
RMIT said due to increased demand for orthopaedic implant products, Signature Orthopaedics had opened additional manufacturing and distribution facilities in Europe and North America.
Signature Orthopaedics chief executive officer Declan Brazil said the partnership would focus on collaborative research and development in specific areas of clinical and technological innovation.
“Together we will develop a clinical test bed for new materials, designs and methods in orthopaedic implants and devices, and connect our joint talent to amplify scientific and industry leadership across Australia’s growing [medical technology] sector,” Mr Brazil said.
“This partnership’s goal is to bring to market new and personalised medical implant technologies that can improve health outcomes and quality of life,” Mr Brazil said.
Signature Orthopaedics is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a sales and marketing agreement with the West Chester, Pennsylvania Wellworks for You Inc for its Genetype risk assessment tests.
Genetic Technologies said Wellworks would include its Genetype tests in its “employee wellness solutions for organizations and businesses across the US, providing direct access to more than two million personnel”.
The company said the partnership was “a pivotal milestone” and that assuming an initial adoption rate of two percent it expected to sell 40,000 units in the first year and up-to 100,000 tests in the third year.
Genetic Technologies was unchanged at 12 cents.

VOLPARA HEALTH TECHNOLOGIES

The ASX says it suspended Volpara from the close of trading on May 3, 2024 following the approval of the Lunit Inc scheme to buy the company for $295.7 million.
On Friday, Volpara said it was its last day of trading and that it would delist from the ASX on May 22, 2024, following the New Zealand High Court approval of its acquisition by Seoul, South Korea’s Lunit Inc for $1.15 a share (BD: May 3, 2024).
Volpara last traded at $1.145.

IMAGION BIOSYSTEMS

Imagion says its annual general meeting will vote on the remuneration report and, potentially, a second-strike board spill.

Last year, Imagion said its annual general meeting passed all resolutions but voted a remuneration report 'first strike' with 44,624,043 votes (25.20%) against and 132,434,432 votes (74.80%) in support (BD: May 25, 2023).

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 if passed by more than 50 percent the directors must stand for re-election. If the spill vote fails, the trigger is reset to no opposition.

Imagion said investors would vote to elect directors Michael Harsh and Mark Van Asten.

The meeting will be held online and in-person at K&L Gates, Level 25, 525 Collins Street, Melbourne on May 31, 2024, at 10am (AEST).

Imagion was in a suspension and last traded at 7.3 cents.

ECS BOTANICS HOLDINGS

ECS says founder and former managing director Alex Keach has resigned and has sold 50,000,000 shares of his 100,253,739 share-holding at 1.5 cents each.

ECS said Mr Keach had resigned "to pursue other interests" and that due to "personal financial circumstances" Mr Keach sold a portion of his holding in a structured sell down managed by Bell Potter Securities Ltd.

The company said that sale included 3,333,333 shares to chair Jeremy King and 6,666,667 shares to managing-director Nan-Maree Schoerie.

According to Commsec, ECS is a "medicinal cannabis cultivator and manufacturer located in North West Victoria" and had traded between 7.0 cents and 1.7 cents.

ECS said Mr Keach founded ECS in 2018, was managing-director until June 2022 and his "experience, leadership, vision and drive were significant factors in establishing [it] as a trusted and leading medicinal cannabis business".

ECS said it did not intend to replace Mr Keach.

ECS was unchanged at 1.9 cents with 5.2 million shares traded.

POLYNOVO

Polynovo says it has appointed Lior Harel as general counsel and company secretary, replacing chief financial officer Jan-Marcel Gielen, effective from today.

Polynovo said that Mr Gielen would continue as chief financial officer.

Polynovo said Mr Harel was most recently commercial director and company secretary of Optima Technology Group and had been company secretary of Vitura, then Cronos Australia, chief legal counsel at Seek as well as having worked as a lawyer for Arnold Bloch Leibler.

The company said that Mr Harel held a Bachelor of Arts and Bachelor of Law from the University of Melbourne.

Polynovo fell four cents or 1.9 percent to $2.05 with 1.1 million shares traded.