Biotech Daily

Tuesday June 11, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYNATA UP 10%; SYNTARA DOWN 8%**

*** FEDERAL $15m FOR LONG COVID-19**

*** ARTRYA, CONE HEALTH 1.2m OPTION SALIX CORONARY DEAL**

*** MYNDBIO OFFERS $52.5m FOR IDT**

*** QBIOTICS DOSES PHASE II TIGILANOL TIGLATE SARCOMA TRIAL**

*** RECCE COMPLETES HIGHEST DOSE PHASE I/II R327 COHORT**

*** ONCOSIL: 'PANCOSIL' TRIAL DOSES 5th PATIENT**

*** HERAMED 'TERMINATES' FEMBRIDGE HERACARE PARTNERSHIP**

*** RACE: FDA EXTENDS BISANTRENE AML ORPHAN DRUG STATUS**

*** ORTHOCELL FILES SMRTGRAFT TENDON REPAIR TO TGA**

*** NEUROSCIENTIFIC: 'FDA RESPONDS TO EMTINB FOR GLAUCOMA'**

*** ANGLO AUSTRALIAN, BARINGS, CHEMICAL DILUTED IN CYCLOPHARM**

*** EMYRIA LOSES CFO JOSEPH OHAYON; APPOINTS SIMON KEMP CLINICAL**

*** PIERS LEWIS REPLACES AUSCANN DIRECTOR BRETT MITCHELL**

*** MATHEW WATKINS REPLACES ATOMO CO SEC SALLY MCDOW**

MARKET REPORT

The Australian stock market fell 1.33 percent on Tuesday June 11, 2024, with the ASX200 down 104.6 points to 7,755.4 points. Eight of the Biotech Daily Top 40 were up, 25 were down, six traded unchanged and one was untraded. All three Big Caps fell.

Cynata was the best, up three cents or 10 percent to 33 cents, with 468,420 shares traded. Mesoblast climbed 3.35 percent; Emvision and Medadvisor rose more than two percent; Compumedics, Medical Developments and Pro Medicus were up more than one percent; with SDI up by 0.6 percent.

Syntara led the falls, down 0.2 cents or eight percent to 2.3 cents, with 2.1 million shares traded. Both Curvebeam and Universal Biosensors lost 7.1 percent; Nanosonics shed six percent; 4D Medical, Alcidion and Telix fell more than four percent; Avita and Imugene fell more than three percent; Actinogen, Dimerix, Micro-X, Neuren, Nova Eye, Paradigm, Polynovo and Starpharma shed two percent or more; Amplia, Clinuvel, Cochlear, Impedimed, Percheron, Proteomics and Resonance were down more than one percent; with CSL, Cyclopharm, Genetic Signatures and Resmed down less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will invest about $14.5 million in 12 grants for research to improve our understanding of the impacts of long Covid-19 in Australia.

A media release from the Minister for Health and Aged Care Mark Butler said the grants were part of the Medical Research Future Fund's $50 million Post-Acute Sequalae of Covid-19 Research Plan, with research to begin in 2025.

The Government said the recipients would "generate knowledge to support new diagnostic and therapeutic approaches for people with long Covid-19, co-led by [general practitioners] and primary care and fast-track how to best support people living with it".

The Federal Government said research would include; "the impact on [patient's] … physical and mental health and social and emotional wellbeing; the population-wide and health system impacts; the cause, progression and factors that influence prognosis; and national trials to rapidly assess and fast-track therapies".

The Government said it would additionally invest up-to $28 million within two years under the MRFF Research Plan to "ensure health systems meet the needs of people living with longCovid-19, including high-quality and equitable access".

Mr Butler said the Government recognized "the long-term impacts of Covid-19, including for those who experience prolonged symptoms following an acute Covid-19 infection".

ARTRYA

Artrya says healthcare provider Cone Health will non-clinically validate and use its Salix coronary anatomy system, for a potential 1,180,000 "performance options".

Artrya said the Greensboro, North Carolina-based Cone Health would non-clinically validate and integrate Salix into its workflow while it continued the US Food and Drug Administration 510(k) process.

The company said that with Cone Health it would "develop and expand the specific use cases for Artrya's software products across five hospitals, six ambulatory care centres, three outpatient surgery centres, eight urgent care centres, two retirement communities, and more than 120 physician practices across North Carolina".

Artrya said post-FDA 510(k) clearance it would expand access to Salix for clinicians and patients across Cone Health's North Carolina network, with Cone the third agreement it had signed in the US, and that the three providers performed a combined 30,000 coronary computed tomography angiography scans a year (BD: Nov 20, 2023; Mar 12, 2024).

The company said 500,000 options would vest on completion of test integration into picture archiving and communication system (PACS) and electronic medical records (EMR), with a further 680,000 options vesting annually over four instalments, exercisable withing five years of issue at the 5-day volume-weighted average price at issue.

Artrya chief executive officer Mathew Regan said the partnership was the company's third agreement as the company enters the US market once FDA approval was granted.

"The three hospital groups we have engaged, Cone Health, Tanner Health Systems and Northeast Georgia Health System, were specifically chosen for their expertise in cardiovascular care and market share across two large states on the US east coast," Mr Regan said. "Collectively, these agreements mean Salix will be integrated into 15 hospitals and multiple cardiovascular and outpatient clinics across three states as we progress with FDA approval."

"This is a deliberate approach to get final testing and validation scale on the Artrya system, allowing us to reduce the sales cycle post-FDA clearance by ensuring hospitals can immediately start using Salix once it is approved," Mr Regan said.

Artrya fell half a cent or two percent to 25 cents.

IDT AUSTRALIA

IDT says it has received a non-binding offer to be acquired by Melbourne's Myndbio Pty Ltd for 15.0 cents a share, valuing it at about $52.5 million.

According to IDT's most recent notification, prior to last week's announcement of a $7 million rights issue at 9.0 cents a share, the company had 350,189,149 shares on issue (BD: Jun 4, 2024).

Last week, IDT said it had received a non-binding indicative proposal "as part of its ordinary course of business" from Melbourne's Myndbio Pty Ltd in relation to a potential acquisition of all the shares in IDT (BD: Jun 4, 2024).

Today, the company said Mynd "had been granted access to due diligence information on a non-exclusive basis to progress the discussions subject to customary non-disclosure and standstill provisions".

IDT said "at this stage it is proposed that, if the proposal proceeds, it would be implemented by way of a scheme of arrangement".

The company said the proposal was "subject to a number of conditions including completion of satisfactory completion of due diligence, negotiation and execution of an implementation agreement and board approvals".

IDT said the discussions with Mynd were preliminary and there was "no certainty that these discussions will result in any binding transaction or that any offer would be made at a price within a range that would be recommended by the IDT board".

IDT fell half a cent or four percent to 12 cents with 1.5 million shares traded.

QBIOTICS GROUP

Qbiotics says it has dosed all 10 patients in its phase IIa trial of intra-tumoral tigilanol tiglate for soft tissue sarcoma, with the final patient completing 28-day follow-up.

Last year, Qbiotics said it had treated the first of 10 patients in the open-label, single-arm, preliminary efficacy trial in the US; and earlier this year, said tigilanol tiglate had received US Food and Drug Administration orphan drug designation status for soft tissue sarcoma (BD: Jun 13, 2023, Feb 16, 2024).

Today, the company said tigilanol tiglate was "a small molecule targeting a range of solid tumors" and that the drug was registered and marketed as a cancer drug for animals under the trade name Stelfonta, in the US, Europe, the UK and Australia.

Qbiotics said the primary endpoint of the study was drug efficacy measured as the proportion of patients achieving more than or equal to a 30 percent reduction in tumor volume assessed by ultrasound compared to baseline.

Qbiotics said the secondary endpoints were safety and pharmaco-kinetics, with exploratory endpoints including local rate of recurrence at the injection site at six months post-treatment, and assessment of tumor response in biopsy samples.

The company said it expected trial results in early 2025.

Qbiotics' executive director Dr Victoria Gordon said the recruitment of the study was "a key milestone in the company's development of its lead oncology asset".

"I would especially like to acknowledge the support of our principal investigators and their teams, as well as, the Qbiotics' clinical team, for their careful planning, oversight and input in reaching this achievement," Dr Gordon said.

Qbiotics is a public unlisted company.

RECCE PHARMACEUTICALS

Recce says it has dosed six-patients with 4,000mg of R327 at an infusion rate of 20 minutes in its phase I/II trial for urinary tract infection and, or urosepsis.
Last month, Recce said it had dosed the first volunteers at the highest rate of 4,000mg intra-venous dose over 20-minutes following identification of 4,000mg over 30-minutes as "the potential optimum infusion time" (BD: Apr 26, May 15, 2024).
Today, the company said a safety committee would evaluate the data from the six-subject cohort, with preliminary results expected "in near weeks".
Recce said the data was expected to be used for a phase II efficacy trial.
Recce chief executive officer James Graham said the company had "successfully reached a new milestone in this trial by administering a 4,000mg dose over a fast 20-minute infusion to all subjects, the highest dosage achieved so far in this clinical trial".
"This is a significant step forward in bringing us closer to establishing R327 as a leading treatment for those suffering from [urinary tract infection and, or urosepsis," he said.
Recce fell 2.5 cents or 4.4 percent to 54 cents.

ONCOSIL MEDICAL

Oncosil says the fifth patient has been dosed in the up-to 20-patient, investigator-initiated 'Pancosil' trial of its pancreatic cancer device.
Last year, Oncosil said it had ethics approval for a 15-patient, investigator-led trial of percutaneously applied radiotherapy for pancreatic cancer (BD: Jun 5, 2023).
Today, the company said the trial was designed to assess the safety and feasibility of computed tomography-guided percutaneous radio-nuclide therapy using its device in patients with non-progressive, locally-advanced pancreatic cancer.
Oncosil said the milestone was "an important step towards understanding the potential benefits of this innovative treatment approach".
The company said the next step involved a protocol amendment to remove the requirement for mandatory general anaesthesia, which would improve patient comfort and expedite recruitment, subject to ethics approval.
Oncosil was unchanged at half a cent with 8.4 million shares traded.

HERAMED

Heramed says its partnership with Fembridge has been terminated with immediate effect "following both parties being unable to agree on revised commercial terms".
Last year, Heramed said the Winfield, West Virginia's Fembridge would use its Heracare foetal heart monitor in a "comprehensive maternity care solution" and earlier this year, said it would pay Fembridge $US40,000 a month retainer, $US7,083 a month for marketing and further payments subject to milestones to develop a "scalable, seamless and comprehensive maternity care solution" (BD: Dec 18, 2023; Mar 13, 2024).
Today, Heramed said its "new executive team sought to amend the terms of the Fembridge partnership, in particular the exclusivity over the US market and the performance measures tied to the monthly retainer in order to improve the commerciality of the agreement and ensure mutual benefit".
Heramed managing-director Anoushka Gungadin said although the termination of the partnership was disappointing, the company was "determined to continue to execute its commercialization strategy with strategic partners who share its vision and can provide the necessary support to drive the adoption of Heracare".
Heramed was up 0.6 cents or 37.5 percent to 2.2 cents.

RACE ONCOLOGY

Race says the US Food and Drug Administration (FDA) has extended orphan drug designation for its RC220 re-formulation of bisantrene for acute myeloid leukemia.
Race said FDA orphan drug status was first granted to Update Pharma Inc, for the RC110 formulation of bisantrene and then transferred to it in 2017 (BD: Aug 27, 2015).
Race chief executive officer Dr Daniel Tillett said the company continued "to advance bisantrene as a novel treatment for [acute myeloid leukaemia], however being able to leverage the additional regulatory and guidance support from the FDA that [orphan drug designation] provides is very welcome".
Race was up 11.5 cents or 6.4 percent to $1.90 with 627,989 shares traded.

ORTHOCELL

Orthocell says it has applied for market approval for its Smrtgraft tendon repair device with the Australian Therapeutic Good Administration (TGA).
Orthocell said Smrtgraft was available in Australia under special access scheme and used to "wrap or to cover surgically repaired tendons … to protect the tendon and promote tendon cell migration and proliferation at the repair site".
The company said the filing followed its tendon regeneration study indicating Smrtgraft reduced the rate of treatment failure and the need for revision (BD: Dec 16, 2021).
Orthocell said Smrtgraft would be "the third revenue generating product to be launched by the company, in addition to Striate+ for dental bone regeneration and Remplir for peripheral nerve repair".
The company said Smrtgraft was manufactured at its factory in Western Australia, with a "geographical roll-out strategy for tendon and ligament repair devices in progress, starting with Australia and other key regulatory jurisdictions to follow".
Orthocell said it believed Smrtgraft would become a leading tendon repair device, with uptake driven by the surgeon's preference for high quality, easy-to-use devices that facilitate better patient outcomes and it was "well-positioned to achieve further international approvals for Smrtgraft in tendon and ligament repair".
Orthocell managing-director Paul Anderson said TGA approval was "an important stepping stone" to other markets, including the US.
Orthocell was unchanged at 36 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says following a meeting with the US Food and Drug Administration (FDA) it has clinical development and regulatory feedback for Emtinb for glaucoma.
Neuroscientific said the completion of a pre-investigational new drug (IND) meeting with the FDA was "an important milestone" as it provided regulatory clarity around its proposed phase I trial of Emtinb for adults with advanced glaucoma.
The company said it received "positive feedback from the FDA on its planned IND-enabling studies to further evaluate toxicology, pharmacokinetics and formulation optimization for intra-vitreal administration".
Neuroscientific executive director Tony Keating said the FDA had "answered a number of critical questions related to our non-clinical and clinical development program and provided us with a clear understanding of the design for our phase I trial".
"Furthermore, we confirmed with the FDA, the non-clinical intra-vitreal administration studies needed to complete an IND application," Mr Keating said.
Neuroscientific fell 0.4 cents or 8.5 percent to 4.3 cents.

CYCLOPHARM

The Anglo Australian Christian and Charitable Fund says its 13,211,332 share-holding in Cyclopharm has been diluted from 14.39 percent to 12.20 percent.
The 65 St Pauls' Churchyard, London-based Anglo Australian Christian and Charitable Fund said that between May 30 and June 4, 2024, it was diluted in an institutional share placement.
Last month, Cyclopharm said it hoped to raise $20 million in a placement at $1.42 a share and expected to raise $2 million in a share purchase plan (BD: May 24, 2024).
Cyclopharm fell one cent or 0.6 percent to $1.585.

CYCLOPHARM

Barings Acceptance Ltd says it has increased and been diluted in Cyclopharm from 11,433,424 shares (12.45%) to 11,444,962 shares (10.57%).
The 65 St Pauls' Churchyard, London-based Barings said that on February 19, 2021 it bought 11,538 shares for $29,999, or $2.60 a share and was diluted between May 30 and June 4, 2024 (see above).
In 2021, Cyclopharm said it had raised $3 million in a "significantly over-subscribed" share plan at $2.60 a share, taking the total raised to $33 million (BD: Feb 17, 2021).

CYCLOPHARM

Chemical Overseas Ltd says it has increased and been diluted in Cyclopharm from 9,176,470 shares (9.99%) to 9,188,008 shares (8.49%).
The 65 St Pauls' Churchyard, London-based Chemical Overseas said that on February 19, 2021 it bought 11,538 shares in a share purchase plan for $29,999, or $2.60 a share and was diluted between May 30 and June 4, 2024 (see above).

EMYRIA

Emyria says chief financial officer Joseph Ohayon has resigned, and it has appointed Simon Kemp as head of clinical operations.
Emyria said contingency arrangement had "been put in place to cover the role and duties vacated by Mr Ohayon".
The company said Mr Kemp was co-founder of Sleep Studies Australia and that as head of clinical operations he would "support Emyria's growth in clinical services and to enhance patient care".
Emyria fell 0.4 cents or 7.3 percent to 5.1 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has appointed Piers Lewis as a non-executive director, replacing Brett Mitchell who has resigned.
Auscann said Mr Lewis had more than 25 years of experience and was a director of Noronex, OD6 Metals and chair of Aurumin Ltd.
According to his Linkedin profile, Mr Lewis held a Bachelor of Commerce from Perth's University of Western Australia.
The company thanked "Mr Mitchell for his significant contribution".
Auscann was in a suspension and last traded at four cents.

ATOMO DIAGNOSTICS

Atomo says it has appointed Mathew Watkins as its company secretary, replacing Sally McDow who had resigned, effective from June 8, 2024.
Atomo said Mr Watkin's was from corporate services provider Vistra Pty Ltd.
Atomo was unchanged at 2.8 cents.