Biotech Daily

Thursday July 4, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH UP: SYNTARA UP 14%; CYNATA DOWN 9%**

*** COMPUMEDICS RAISES $1.9m**

*** DIMERIX OPENS PHASE III DMX-200 FSGS TRIAL TO ADOLESCENTS**

*** ISLAND TO FILE RESULTS, TRIAL FDA PROTOCOLS; INITIATE SITE**

*** LUMOS: HENRY SCHEIN AUSTRALIA, NZ FEBRIDX DISTRIBUTOR**

*** ECHO IQ: SCIMAGE TO USE ECHOSOLV ON PLATFORM**

*** PERENNIAL REDUCES TO 7% OF MEDADVISOR**

*** REGAL FUNDS TAKES 7% OF RADIOPHARM**

*** JP MORGAN, AFFILIATES TAKE 5% OF RADIOPHARM**

*** CYNTEC TAKES 19.99% OF CAMBIUM**

*** MELBOURNE SECURITIES TAKES 5.7% OF HERAMED**

*** PRESCIENT APPOINTS DR GAVIN SHEPHERD DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.19 percent on Thursday July 4, 2024, with the ASX200 up 91.9 points to 7,831.8 points. Sixteen of the Biotech Daily Top 40 were up, 14 were down, eight traded unchanged and two were untraded. All three Big Caps were up.

Syntara was the best, up 0.3 cents or 13.6 percent to 2.5 cents, with 2.5 million shares traded. Nova Eye climbed 11.6 percent; Mesoblast was up 8.25 percent; Prescient improved 6.4 percent; Actinogen rose 4.8 percent; Cyclopharm, Emvision and Imugene were up more than three percent; Alcidion, Curvebeam, Genetic Signatures, Medadvisor and Starpharma rose two percent or more; Cochlear, Nanosonics and Percheron were up more than one percent; with CSL, Neuren and Resmed up by less than one percent.

Yesterday's best, Cynata, led the falls, down 2.5 cents or 8.6 percent to 26.5 cents, with 165,257 shares traded. Next Science lost 7.1 percent; Pro Medicus shed 5.1 percent; 4D Medical and Impedimed fell more than four percent; Medical Developments and Micro-X shed more than two percent; Immutep and Polynovo were down more than one percent; with Avita, Clinuvel, Proteomics, SDI and Telix down by less than one percent.

COMPUMEDICS

Compumedics says it has raised $1.9 million at 28.0 cents a share in a placement to fund the US rollout of its Somfit home sleep test.
Compumedics said the issue price was a 10 percent discount to the 15-day volume weighted average price prior to its trading halt, and the placement was “well supported by new and existing, professional and sophisticated investors”.
The company said its directors had committed to subscribe for about $50,000 of the placement, subject to shareholder approval.
Compumedics said the funds allowed it to employ up-to six new sales staff in the US during the next six months as it rolled-out its Somfit home sleep test business there.
The company said PAC Partners Securities was the sole lead manager to the raise and would be paid fees “on normal commercial terms, which is up-to six percent of the value of the new securities issued”.
Earlier this year, Compumedics said revenue for the six months to December 31, 2023 was up 37.5 percent to $26,414,000, it had turned the prior period’s net loss to a profit of $141,000 and had cash of $3,670,000 (BD: Feb 29, 2024).
Later, the company said it expected record revenue for the year to June 30, 2024 of more than $46 million and a profit due to a “strong sales performance” (BD: May 23, 2024).
Compumedics had been in a trading halt and was untraded at 34 cents.

DIMERIX

Dimerix says it will begin recruiting adolescents aged from of 12 to 17 years, in its phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS).
In 2022, Dimerix said it had recruited the first of 286 patients in the phase III trial of DMX200 for kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).
Earlier this year, the company said its paediatric investigation plan had UK Medicines and Healthcare Products Regulatory Agency (MHRA), US Food and Drug Administration and European Medicines Agency approval to open the trial to children between the ages of 12 and 17 years (BD: May 1, 2024).
Today, Dimerix said an independent data monitoring committee had confirmed the adolescent cohort would receive the same 120mg dose, administered orally and twice daily, that the adult cohort had received.
The company said the monitoring committee had considered interim safety and pharmaco-kinetic data, including simulations in adolescents, from the adult cohort of the trial taken at the first interim analysis point in March 2024.
In March, Dimerix said interim analysis of the first 72 randomized patients showed that DMX-200 reduced proteinuria more than placebo (BD: Mar 11, 2024).
Today, the company said the committee noted “the safety margin [of DMX-200] should allow [the] clinical study to proceed in this adolescent population using adult doses”.
Dimerix said about 15 specialist paediatric nephrology centres in the UK, US, Mexico, Brazil and Argentina were selected to recruit adolescent FSGS patients.
Dimerix chief medical officer Dr David Fuller said the positive recommendation of the committee to allow adolescent dosing, further extended “the strong safety profile and tolerability of DMX-200 when used in FSGS patients”.
“This is especially important as paediatric FSGS remains an area of high unmet need with limited therapeutic options and a high risk of progression to end-stage kidney disease,” Dr Fuller said.
Dimerix was unchanged at 47 cents with 18.3 million shares traded.

ISLAND PHARMACEUTICALS

Island says it filed its revised phase II study protocol to the US Food and Drug Administration on July 3 and will conduct a trial site initiation visit on July 11, 2024.
Island said the proposed updated protocol for the phase II study was filed to the FDA as well as the final report from its single-ascending dose study of ISLA-101 for dengue fever.
Earlier this year, the company said its 24-subject, single-ascending dose study showed that ISLA-101 achieved the required levels of blood concentration; and last month, said computer models of the study had confirmed a “predicted ideal single dose” for a phase II clinical study (BD: Apr 16, Jun 3, 2024).
At that time, Island said the data “potentially obviates” the need to conduct a phase II trial at multiple doses, reducing the costs and resources needed, and that it would submit the modelling data to the FDA with the study protocol for the phase II study, including an expansion from pure prophylactic focus to a therapeutic arm.
Today, the company said the revised protocol intended to “eliminate the originally planned dose escalation strategy” for a single dose twice daily across multiple days, included a therapeutic arm in the study and expected to screen and enrol subjects in August 2024.
Island said it would conduct a site initiation visit with the Syracuse, New York-based State University of New York Upstate Medical University, the first step in opening the trial.
Island managing-director Dr David Foster said the investigational new drug application was open, it had its team and investigator lined-up, and when the protocol amendment process was concluded the company would move quickly to begin the dengue fever study.
Island fell 0.2 cents or 2.8 percent to seven cents.

LUMOS DIAGNOSTICS

Lumos says it has expanded its distribution deal with Henry Schein Medical to include selling its Febridx blood test for infections in Australia and New Zealand.
In 2023, Lumos said the New York-based Henry Schein Medical would sell its Febridx point-of-care, finger-prick blood test to differentiate bacterial from viral respiratory infections, in Spain, Portugal and the Netherlands; and in February, expanded the deal to include the US (BD: Jul 18, Aug 16, 2023; Feb 12, 2024).
Today, the company said it would sell the test through Henry Schein’s Regional Health Care Group but did not disclose the commercial terms of the agreement.
Lumos was up 0.6 cents or 19.35 percent to 3.7 cents with 11.9 million shares traded.

ECHO IQ

Echo IQ says Scimage will use the Echosolv cardio-vascular decision support system in its internet cloud image management and reporting platform for aortic stenosis.
Echo IQ said the Los Altos, California-based Scimage Inc provided “cloud-native enterprise image management, picture archiving and communication systems and image exchange solutions for the healthcare industry”.
The company said that the deal would give users of Scimage’s Picom-365 platform access to “high-quality, automated [artificial intelligence]-backed echocardiography assessments designed to facilitate faster and more accurate diagnosis”.
Echo IQ said 2,000 US sites used Scimage’s Picom-365 system and that Echosolv would be rolled out to “several key US cardiology practices and strategic hospitals” before 2025 and was expected to be available for assessments within three months.
Echo IQ was up one cent or 6.1 percent to 17.5 cents.

MEDADVISOR

Sydney's Perennial Value Management says it has reduced its substantial shareholding in Medadvisor from 65,708,521 shares (11.94%) to 40,409,181 shares (7.34%).
Perennial said it bought and sold shares on market between April 17 and July 3, 2024, with the single largest sale 12,048,397 shares for $6,010,945, or 49.9 cents a share.
Medadvisor was up one cent or 2.1 percent to 49 cents.

RADIOPHARM THERANOSTICS

Regal Funds Management Pty Ltd says it has become a substantial shareholder in Radiopharm with 75,246,901 shares, or 7.12 percent.
The Sydney-based Regal said that on July 1, 2024 it bought 75,246,901 shares for $3,009,876, or 4.0 cents a share.
Last week, Radiopharm said it had "firm commitments" to raise about $62.5 million at 4.0 cents a share in a placement, taking the total with the Lantheus placement to $70 million (BD: Jun 25, 2024).
Radiopharm fell 0.3 cents or 7.9 percent to 3.5 cents with 5.4 million shares traded.

RADIOPHARM THERANOSTICS

JP Morgan Chase & Co said with "its affiliates" it became a substantial shareholder in Radiopharm with 54,060,030 shares, or 5.11 percent.
The New York and Sydney-based JP Morgan said that between April 11 and July 1, 2024 it bought and sold shares, with the single largest purchase 52,025,494 shares on June 28 for $2,081,020, or 4.0 cents a share.
In its substantial shareholder notice, JP Morgan did not disclose the identity of its affiliates.

CAMBIUM BIO (FORMERLY REGENEUS)

The Taipei, Taiwan-based Cyntec Co Ltd says it has increased its Cambium holding from 62,966,489 shares (8.2%) to 238,435,861 shares (19.99%).
Cyntec failed to cite the consideration for the shares as required by the Corporations Act 2001, but said it participated "in the second capital increase and issue new shares" (sic).
In April, Cambium said it raised $3.48 million at 0.6 cents a share (BD: Apr 5, 2024).
Cambium was unchanged at 40 cents with two (2) shares traded.

HERAMED

Melbourne Securities Corporation Ltd says it has become a substantial shareholder in Heramed with 36,313,787 shares, or 5.73 percent.
Melbourne Securities said it bought the 36,313,787 shares in five transactions between May 22 and June 28, 2024, for $379,428, or 1.0 cent a share.
In May, Heramed said it would raise $2.35 million in convertible notes at $1 each, $350,000 in a placement at one cent a share and $50,000 from the issue of shares at one cent each to chair Tim Chapman, subject to approval (BD: May 10, 2024).
Heramed fell 0.1 cents or 3.7 percent to 2.6 cents.

PRESCIENT THERAPEUTICS

Prescient says it has appointed Dr Gavin Shepherd as an independent non-executive director, effective from today.

Prescient said Dr Shepherd had 25 years of experience in medicine, was a director of Lateral Pharma and was involved in the Medical Device Partnering Program at Adelaide's Flinders University and lectured at the Royal Australian College of General Practitioners training program in South Australia.

According to his Linkedin entry, Dr Shepherd held a Bachelor of Medicine and Bachelor of Surgery from Flinders University.

Prescient was up 0.25 cents or 6.4 percent to 4.15 cents.