Biotech Daily

Wednesday July 31, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: SYNTARA UP 13%; 4D MEDICAL DOWN 6%**

*** LUMOS RECEIPTS UP 137% TO $25.5m**

*** CANN RECEIPTS UP 10% TO $16.5m**

*** GENETIC SIGNATURES RECEIPTS DOWN 48% TO $10m**

*** MESOBLAST RECEIPTS DOWN 9% TO $10m**

*** RESONANCE RECEIPTS UP 87% TO $8.1m**

*** GENETIC TECHNOLOGIES RECEIPTS DOWN 9% TO $8.0m**

*** UNIVERSAL BIOSENSORS H1 RECEIPTS UP 78% TO $3.8m**

*** CHIMERIC RECEIPTS $5.5m FROM INTRODUCTION FEE**

*** CONTROL BIONICS RECEIPTS DOWN 3% TO $5.3m**

*** USCOM RECEIPTS UP 30% TO $3.7m**

*** AUDEARA RECEIPTS UP 16% TO $3.5m**

*** ANTERIS H1 RECEIPTS UP 14% to $2.5m**

*** CONTROL BIONICS RAISES $525k**

*** TELIX: FDA CITES 'STERILITY', REJECTS TLX250-CDX APPLICATION**

*** NEUROTECH 'NTI164 MARIJUANA FURTHER IMPROVES RETT SYNDROME'**

*** SYNTARA DOSES PHASE II SNT-5505 MYELOFIBROSIS TRIAL**

*** ALGORAE 'AI-116 MARIJUANA LOWERS GLUTAMATE TOXICITY, IN-VITRO'**

*** CURVEBEAM REQUESTS 'ENTITLEMENT OFFER' TRADING HALT**

*** TREASURE CENTURY DILUTED TO 8% OF CAMBIUM; APEX METRO 6%**

*** HERREID, HR GLOBAL INCREASE, DILUTED BELOW 5% OF IMRICOR**

*** TAI PHAN REPLACES INVION CO SEC CLAIR NEWSTEAD-SINCLAIR**

MARKET REPORT

The Australian stock market recovered 1.75 percent on Wednesday July 31, 2024, with the ASX200 up 139.1 points to 8,092.3 points.

Twenty-two of the Biotech Daily Top 40 companies were up, 12 were down, five traded unchanged and one were untraded. All three Big Caps were up.

Yesterday's 25 percent worst, Syntara, was today's best, up 0.4 cents or 13.3 percent to 3.4 cents, with 3.4 million shares traded. Resonance rose 5.7 percent; Atomo and Pro Medicus climbed more than four percent; Dimerix, Genetic Signatures, Nanosonics, Next Science, Opthea, Polynovo and Resmed were up three percent or more; Amplia, Clinuvel, Percheron and Proteomics rose two percent or more; Avita, Cyclopharm, Impedimed, Mesoblast, Micro-X, Orthocell, SDI and Starpharma were up more than one percent; with Cochlear and CSL up by less than one percent.

4D Medical led the falls, down three cents or 5.9 percent to 48 cents, with 1.8 million shares traded; followed by Paradigm, down 5.8 percent to 24.5 cents, with 1.35 million shares traded. Actinogen and Medadvisor fell more than four percent; Compumedics and Cynata lost more than three percent; Alcidion and Nova Eye shed more than two percent; Emvision and Telix were down one percent or more; with Neuren and Clarity down by less than one percent.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says customer receipts for the year to June 30, 2024 were up 137.2 percent to $US16,569,000 ($A25,472,000) compared to the prior corresponding period.
Lumos said receipts from sales of its Viradx and Febridx finger-prick blood tests for bacterial and viral infections as well as its services business for the three months to June 30, 2024 were up 153.5 percent to $US7,447,000, compared to the prior corresponding period.
The company said it had positive cash flow of $US3,475,000 for the three months, with cash and cash equivalents of $US6,479,000 at June 30, 2024 compared to $US3,015,000 at June 30, 2023.
Lumos fell half a cent or 9.6 percent to 4.7 cents with 7.5 million shares traded.

CANN GROUP

Cann says receipts from customers for the year to June 30, 2024 were up 10.3 percent to $16,507,000, compared to the previous corresponding period.
Cann said customer receipts from sales of its marijuana dried flower, oil and pharmaceutical products were down 34.4 percent to $3,330,000 for the three months to June 30, 2024, compared to the prior corresponding period.
The company said it had a cash burn of $5,337,000 for the three months, with cash and cash equivalents of $1,639,000 at June 30, 2024 compared to $764,000 at June 30, 2023, leaving it with 0.5 quarters of available funding.
Cann said expenditure in the three months included several non-recurring payments, it was expecting a $1.8 million Federal Research and Development Tax Incentive and cash receipts were expected to increase in subsequent quarters".
Cann was up 0.1 cents or 2.6 percent to 3.9 cents with 3.2 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says customer receipts for the year to June 30, 2024 fell 48.2 percent to $9,895,000, compared to the prior corresponding period.
Genetic Signatures said that customer receipts from sales of its Easyscreen diagnostics for gastro-intestinal infections and respiratory infections, including Covid-19, for the three months to June 30, 2024 were down 37.8 percent to $2,155,000.
Genetic Signatures interim chief executive officer Dr Neil Gunn told Biotech Daily the reduced revenue was due to the withdrawal of its main respiratory product from Australia for a “large part” of the year and “the significance of today’s announcement is that we are back up to historical level of respiratory sales within a very short period of time post [Therapeutic Goods Administration] approval and re-entry to the Australian market”.
Last year, Genetic Signatures said its Easyscreen respiratory pathogen detection kit was not consistently detecting influenza B “in a small portion of low viral concentration samples” with sales impacted for the three months to October (BD: Aug 25, 2023).
Today, the company said it had a cash burn of $3,326,000 for the three months, with cash and equivalents of $36,252,000 at June 30, 2024 compared to $16,349,000 the prior year.
Genetic Signatures was up three cents or 3.9 percent to 80 cents.

MESOBLAST

Mesoblast says customer receipts for the year to June 30, 2024 fell 9.4 percent to $US6,776,000 ($A10,440,000), compared to the previous corresponding period.
Mesoblast said customer receipts from royalties on sales of Temcell for graft-versus-host disease in Japan fell 37.6 percent to $US1,144,000 for the three months to June 30, 2024, compared to the prior corresponding period.
The company said it had a $US10,241,000 cash burn for the three months, with cash and equivalents of $US62,960,000 at June 30, compared to $US71,318,000 the prior year.
Mesoblast was up 1.5 cents or 1.5 percent to $1.02 with 13.9 million shares traded.

RESONANCE HEALTH

Resonance says receipts from customers for the year to June 30, 2024 were up 87.1 percent to $8,110,000, compared to the previous corresponding period.
Resonance said customer receipts from its magnetic resonance imaging-based liver and heart diagnostics as well as its clinical research services were up 225.9 percent for the three months to June 30, 2024 to $3,774,000, compared to the prior corresponding period.
The company said it was $2,042,000 cash flow positive for the three months, with cash and equivalents of $6,854,000 at June 30, 2024, compared to $6,362,000 the prior year.
Resonance was up 0.3 cents or 5.7 percent to 5.6 cents with 2.8 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says customer receipts for the year to June 30, 2023 were down 9.1 percent to $7,972,000 compared to the previous corresponding period.
Genetic Technologies said sales of its Genetype genomic risk tests were up 8.7 percent to $2,266,000 for the three months to June 30, 2024.
The company said it had a cash burn of $3,254,000 for the three months, with cash and cash equivalents of $1,021,000 at June 30, 2024 compared to $7,853,000 at June 30, 2023, leaving it with 0.4 quarters of available funding.
Genetic Technologies was up 0.1 cents or 2.3 percent to 4.4 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says customer receipts for the six months to June 30, 2024 were up 77.7 percent to $3,757,000, compared to the prior corresponding period.
Universal Biosensors said receipts from sales of its biosensors for oncology, coagulation, women's health and fertility, water testing and the wine industry rose 100.2 percent to $2,535,000 for the three months to June 30, compared to the prior year.
The company said it had a positive cash flow of $566,000 for the three months, with cash and equivalents of $17,031,000 at June 30, 2024 compared to $16,644,000 the prior year.
Universal Biosensors was unchanged at 14 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has posted maiden receipts from customers for the year to June 30, 2024 of $5,475,000.
Last year, Chimeric said Imugene would pay a $US3 million introduction fee for acquiring Precision Biosciences' azer-cel technology (BD: Aug 16, 2023).
Today, the company said it had a cash burn of $5,949,000 for the three months, with cash and cash equivalents of $3,053,000 at June 30, 2024 compared to $5,370,000 at June 30, 2023, leaving it with 0.5 quarters of available funding.
Chimeric said expenditure for the three months included a one-off $3 million payment, and that it believed it could "raise sufficient capital based on the success of previous capital raises and the continued development of the company's projects".
Chimeric fell 0.3 cents or 14.3 percent to 1.8 cents with 3.1 million shares traded.

CONTROL BIONICS

Control Bionics says receipts from customers for the year to June 30, 2024 were down 3.0 percent to $5,310,000, compared to the previous corresponding period.
Control Bionics said sales of its Neuronode thought-to-computer technology for the three months to June 30, 2024 fell 26.9 percent to $968,000, compared to the prior year.
The company said it had a cash burn of $1,333,000 for the three months, with cash and cash equivalents of $1,058,000 at June 30, 2024 compared to $936,000 at June 30, 2023, leaving it with 0.79 quarters of available funding.
Control Bionics said it was expecting "an improvement in cash flows", with sales deferred due to delayed National Disability Insurance Scheme approvals and increased expenditure on Drove and Neurostrip development costs during the period.
The company said it had raised $525,000 and had "strong relations with potential investors to subscribe for additional capital in the company" (see below).
Control Bionics rose 0.9 cents or 16.4 percent to 6.4 cents with 1.1 million shares traded.

USCOM

Uscom says receipts from customers for the year to June 30, 2024 were up 30.35 percent to $3,732,000, compared to the previous corresponding period.
Uscom said receipts from sales of its digital, ultrasonic technologies for cardiovascular and pulmonary diseases for the three months to June 30, 2024 were up 23.45 percent to $1,537,000, compared to the prior corresponding period.
The company said it was $102,000 cash flow positive for the three months, with cash and cash equivalents of $2,520,000 at June 30, 2024 compared to $2,179,000 the prior year.
Uscom fell 0.3 cents or 16.7 percent to 1.5 cents.

AUDEARA

Audeara says that receipts from customers for the year to June 30, 2024 were up 16.1 percent to $3,539,000, compared to the previous corresponding period.
Audeara said that receipts for the three months to June 30, 2024, primarily from sales of its hearing devices, were up 66.4 percent to $982,000.
The company said it had a three-month cash burn of $867,000, with cash and equivalents of $1,268,000 at June 30, 2024 compared to $2,623,000 at June 30, 2023, leaving it with 1.5 quarters of available funding, but it expected cash inflows, deposits and new business and “remains confident in its ability to raise funds as and when needed”.
Audeara was up 0.2 cents or 6.25 percent to 3.4 cents.

ANTERIS TECHNOLOGIES

Anteris says receipts from customers for the six months to June 30, 2024 were up 14.3 percent to $2,475,000, compared to the previous corresponding period.
Anteris said receipts from sales of its Adapt anti-calcification tissue product for the three months to June 30, 2024 were up 77.0 percent to $1,280,000.
The company said it had a cash burn of $20,855,000 for the three months, with cash and cash equivalents of $10,844,000 at June 30, 2024 compared to $20,256,000 at June 30, 2023, leaving it with 0.5 quarters of available funding and last week raised $30 million.
Anteris was up 15 cents or one percent to $15.30.

CONTROL BIONICS

Control Bionics says it has raised $525,000 at 5.25 cents a share in a private placement to the Sydney-based Northstar Impact Funds.
Control Bionics said the issue price was a 0.1 percent discount to the 15-day volume weighted average price and a 4.5 percent discount to the last closing price.
The company said the funds would be used for general working capital purposes.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has rejected its biologics licence application for TLX250-CDx as an imaging agent for renal cell carcinoma.
Last month, Telix said it had filed a biologics licence application with the FDA for its radio-diagnostic TLX250-CDx for clear cell renal cell carcinoma (BD: Jun 3, 2024).
Today, the company said during the 60-day review process the FDA had identified a filing issue in the chemistry, manufacturing and controls package which related to showing “adequate sterility assurance during dispensing of TLX250-CDx in the radio-pharmacy production environment”.
Telix said that despite the FDA’s concerns “all process performance qualification batches submitted as part of the [biologics licence application] passed the sterility requirements of product release”.
The company said the FDA had required the issue to be resolved before the application could advance to a full review, and that it expected to be able to complete remedial actions within about 90 days and resubmit the application.
Telix said the delay was not material and there would be no impact on revenue forecasts or research and development expenditure for the year to June 30, 2024.
Telix fell 24 cents or 1.2 percent to $19.08 with 3.3 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says 20-week data from its 14-patient, phase I/II trial of NTI164 marijuana for Rett syndrome shows “further significant clinical improvements” ($p < 0.001$).

Earlier this year, Neurotech said the further analysis showed 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 ($p = 0.009$) (BD: May 6, 2024).

Today, the company said Clinical Global Impression – Improvement (CGI-I) scores at 20 weeks were 2.7, down from 3.1 at 12 weeks, with all patients improved ($p < 0.001$), compared to 13 (93.0%) at 12 weeks.

Neurotech said between 12-to-20 weeks, there was an additional CGI-I csore improvement of -0.4, “representing a significant, additional improvement of 13 percent ($p = 0.007$), which continues the downward trajectory of clinical improvement overall”.

The company said there was a 24 percent improvement in Rett Syndrome behavioral questionnaire (RSBQ) scores at 20 weeks ($p < 0.001$), with no further improvement in scores between week 12 and week 20.

Neurotech said the average RSBQ score at baseline was 44.6 compared to 31.2 at 12-weeks and 34.1 at 20 weeks.

The company said a 44-patient trial of Neuren’s US Food and Drug Administration-approved trofenitide, marketed by Acadia as Daybue, showed a CGI-I score of 3.1 and a RSBQ change of -7.3.

Neurotech said eight patients (57.1%) were “very much/much improved” at 20 weeks compared to five patients (35.7%) of patients at 12 weeks.

The company said the 20-week data showed an improvement of 33 percent compared to baseline and a 23 percent improvement at 12 weeks.

Neurotech said there were no serious adverse events or adverse events reported between 12 weeks and 20 weeks and no weight loss.

Neurotech was up 0.6 cents or 8.6 percent to 7.6 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has dosed all 15 patients in its phase II trial of SNT-5505 with ruxolitinib for bone marrow cancer myelofibrosis.

Last year, the then Pharmaxis said five-of-nine patients in its open-label, phase II trial of the then PXS-5505 for bone marrow cancer myelofibrosis had shown bone marrow improvement (BD: Jul 12, 2023).

Later, the company said it had dosed the first of up-to 15 patients in the next study cohort of the trial of SNT-5505 with the Janus kinase inhibitor ruxolitinib following US Food and Drug Administration approval (BD: Dec 13, 2023).

Today, Syntara said the trial was being conducted at 19 sites in the US, Australia, South Korea and Taiwan, with interim results expected in “late 2024”.

The company said that “no drug-related dropouts nor any serious adverse reactions have been observed to date”.

Syntara said with the drug’s safety profile and interim data it expected to engage and discuss pivotal study design with the FDA by April 2025, with the full 12-month data set to be available by October 2025.

Syntara chief executive officer Gary Phillips thanked the haematology clinics, investigators and the clinical team “for achieving this significant milestone in such a timely fashion”.

“We now look forward to presenting our interim data later in the year,” Mr Phillips said.

Syntara was up 0.4 cents or 13.3 percent to 3.4 cents with 3.4 million shares traded.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says its AI-116 combination of donepezil hydrochloride and cannabidiol (CBD) for dementia “significantly reduces glutamate-induced toxicity”, in-vitro.
Earlier this year, Algorae said its marijuana-based AI-116 for dementia increased neuronal cell viability by 20.1 percent, in-vitro, outperforming the US Food and Drug Administration-approved therapy for dementia, donepezil, alone (BD: Apr 8, 2024).
Today, the company said its AI-116 combination of donepezil and cannabidiol exceeded the reduction of glutamate-induced toxicity compared to donepezil alone, in-vitro.
Algorae said that “elevated glutamate in neuroblastoma cells significantly contribute to the progression of dementia” through processes which were neurotoxic and resulted in cognitive decline and memory impairment.
The company said that “relative to glutamate-only treated control cells, AI-116 restored a mean of 53 percent of total relative cell viability, which exceeded the effect of either CBD or donepezil alone”.
Algorae said that AI-116 “significantly modulated expression of key genes” that were associated with one or more neurodegenerative disorders.
Algorae was up 0.1 cents or 11.1 percent to one cent with 48.7 million shares traded.

CURVEBEAM AI

Curvebeam has requested a back-to-back trading halt of two days, each, “to undertake an accelerated non-renounceable entitlement offer”.
Trading will resume on August 6, 2024, or on an earlier announcement
Curvebeam last traded at 23.5 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

The Seychelles-based Treasure Century Group Ltd says its 99,900,109 share-holding in Cambium was diluted from 13.04 percent to 8.37 percent following a capital raise.
Earlier this year, the then Regeneus said it raised $3.48 million at 0.6 cents a share to fund non-clinical studies of Elate Ocular and prepare for phase III trials as well as general working capital purposes (BD: Apr 5, 2024).
Cambium was untraded at a post-100-to-one consolidation 40 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

The Samoa-based Apex Metro Investments Ltd says its 69,175,904 share-holding in Cambium was diluted from 9.03 percent to 5.80 percent in a capital raise (see above).

IMRICOR MEDICAL SYSTEMS

Imricor says Warren Herreid’s and HR Global Investments’ separate substantial shareholdings have been diluted below five percent due to a capital raising.
Imricor said Mr Herreid, with KAHR Foundation increased and was diluted from 10,771,092 shares (6.96%) to 12,437,759 shares (4.93%).
The company said HR Global Investments increased and was diluted from 9,746,663 shares (6.11%) to 11,204,996 shares (4.44%).
Earlier this month, Imricor said it had raised $35 million in a placement of Chess depository interests and US shares at 52.0 cents per security (BD: Jul 19, 2024).
Imricor was unchanged at 58 cents.

INVION

Invion says Tai Phan will replace Clair Newstead-Sinclair as its company secretary, effective immediately, following Ms Newstead-Sinclair's resignation.

Invion fell 0.05 cents or 14.3 percent to 0.3 cents with 3.6 million shares traded.