Biotech Daily

Tuesday July 2, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SDI UP 10%; ACTINOGEN DOWN 8%**

*** MAYNE PHARMA PAYS $38m TO SETTLE CLASS ACTION**

*** SDI UNAUDITED SALES UP 3% TO RECORD $111m**

*** FEDERAL $20m FOR AND HEALTH DIGITAL RESEARCH**

*** RECCE TO RAISE $10m IN PLACEMENT, SHARE PLAN**

*** IMMURON FILES IMM529 PRE-IND APPLICATION TO FDA**

*** ACTINOGEN LAST PHASE II XANAMEM DEPRESSION PATIENT VISIT**

*** RADIOPHARM ENDS LIND PARTNERS DRAW-DOWN FACILITY**

*** COMPUMEDICS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NICOLE KELSEY REPLACES AVITA CO SEC DONNA SHIROMA**

*** RACE APPOINTS PROF DANIEL VON HOFF ADVISOR**

*** PATRICIA VANNI REPLACES ALLEGRA CO SEC ROBYN SLAUGHTER**

*** JENNIFER VOON REPLACES ALGORAE CO SEC MARIA CLEMENTE**

MARKET REPORT

The Australian stock market fell 0.42 percent on Tuesday July 2, 2024, with the ASX200 down 32.5 points to 7,718.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 were down, six traded unchanged and two were untraded. All three Big Caps fell.

SDI was the best, up 7.5 cents or 9.6 percent to 85.5 cents, with 408,014 shares traded. Cyclopharm and Syntara climbed more than four percent; 4D Medical, Curvebeam, Emvision, Impedimed and Medadvisor rose more than two percent; Polynovo, Proteomics, Starpharma and Telix were up more than one percent; with Micro-X and Pro Medicus up by less than one percent.

Actinogen led the falls, down 0.5 cents or 7.7 percent to six cents, with 19.0 million shares traded; followed by Imugene, down 7.3 percent to 5.1 cents with 53.9 million shares traded. Immutep and Mesoblast lost six percent or more; Atomo fell four percent; Cynata, Paradigm and Prescient were down more than three percent; Alcidion, Clarity, Next Science and Nova Eye shed two percent or more; Amplia, Avita, Cochlear and Genetic Signatures were down more than one percent; with Clinuvel, CSL, Dimerix, Neuren and Resmed down by less than one percent.

MAYNE PHARMA GROUP

Mayne Pharma says it will pay $38 million to settle a class action.
In 2021, Mayne said it had been served with a class action by Phi Finney McDonald for the plaintiff and on behalf of all persons who acquired an interest in shares and/or American depositary receipts between November 24, 2014 and December 15, 2016, to be held at the Supreme Court of Victoria (BD: Aug 3, 2021).
Today, the company said the proceedings related to “alleged misleading or deceptive conduct and breaches of continuous disclosure obligations in respect of alleged anti-competitive conduct in the US that was previously the subject of investigations by the US Department of Justice and the Office of the Attorney General in the State of Connecticut”.
The company said the settlement was “without any admission of liability by Mayne Pharma, both with respect to the alleged underlying anti-competitive conduct in the US, and the alleged misleading or deceptive conduct and breaches of continuous disclosure obligations and is subject to court approval”.
Mayne said the agreement to settle was “a commercial decision made in the best interests of Mayne Pharma shareholders” and allowed it to avoid “the distraction and significant expense of a lengthy trial, and to remain focused on driving growth and shareholder value through its core commercial business”.
In 2016, Mayne said it was co-operating with a US Department of Justice investigation after receiving a subpoena seeking information into the marketing, pricing and sales of its generic products, particularly its generic Doryx, or doxycycline hyclate, delayed-release tablets and potassium chloride powders (BD: Nov 4, 2016).
Later that year, the company said that multiple US states had filed anti-trust proceedings against it and several other companies selling generic-branded medicines in the US District Court of Connecticut (BD: Dec 16, 2016).
Last year, Mayne said the US Department of Justice dismissed its last pending criminal indictment of a separate company and had not indicated that it intended to bring criminal or civil claims against it (BD: Nov 30, 2023).
Today, the company said $4.7 million of the settlement would be covered by insurance, with the remainder to be paid from its cash reserve, and it held cash and marketable securities of $146.8 million at December 31, 2023.
Mayne said the settlement amount was “in full and final settlement of the proceeding including interest, litigation costs, and the plaintiff’s legal fees”.
Mayne Pharma fell 23 cents or five percent to $4.41 with 397,624 shares traded.

SDI (PREVIOUSLY SOUTHERN DENTAL INDUSTRIES)

SDI says it has record unaudited sales for the year to June 30, 2024, up 3.2 percent to $111.4 million, compared to the previous corresponding period.
SDI said it expected net profit after tax to be between $9.5 million to $10.0 million compared to $7.1 million in the prior corresponding period.
The company said the improvement in receipts from customers for its dental products compared to the prior corresponding period “reflected a strong increase in European sales, offset by the continued reduction in amalgam sales”.
SDI said during the 12 months “product margins increased by 490 [basis points], reflecting further improvements in logistic costs, operational efficiencies, regional market performance, product mix and favorable currency movements”.
The company said its operating expenses continued “to be well managed, despite continued inflationary pressures”.
SDI was up 7.5 cents or 9.6 percent to 85.5 cents.

FEDERAL GOVERNMENT, AUSTRALIA'S NATIONAL DIGITAL HEALTH INITIATIVE

The Federal Government says the Medical Research Future Fund has awarded AND Health $19.75 million to invest in the commercialization of digital health research.

A media release from the Minister for Health and Aged Care Mark Butler said Australia's National Digital (AND) Health received $19.75 million through the Medical Research Future Fund's (MRFF) medical research commercialization initiative.

The Government said through AND Health's program six companies had been awarded a share of $3.75 million in "equity-free funding, alongside hands-on support by a network of experts to help them to scale their businesses".

According to the AND Health website, the $3.75 million would be invested in the next 16 months in a two-stage investment process, and that the recipients were Cape Bionics, Healthily, Navier Medical, Osara Health, Sydney Neuroimaging Analysis Centre and Touchstone Life Care.

Mr Butler said "the potential of Australian researchers and our digital health technology sector is unlimited".

"Investment is important, but so too is expert guidance to navigate the pathway from discovery to delivery for Australian patients," Mr Butler said.

"Through AND Health the Government is accelerating our brightest ideas to help reach our vision for fast and safe adoption of digital health technologies," Mr Butler said.

AND Health managing-director Bronwyn Le Grice said the investments would "support Australia's highest-potential digital health innovators to navigate the complex and evolving landscape of digital health commercialization, providing hands-on support and access to leading experts from around the globe".

"Access to capital and digital health experience remain critical barriers to commercialization and growth for digital health innovators in Australia," Ms Le Grice said.

"Whilst we have an increasing number of success stories growing internationally, this Australian Government funding is vital because companies at home still require support to navigate the valley of death and subsequent post-regulatory-approval viability gap," Ms Le Grice said.

More information is available at: https://bit.ly/4cpJous.

RECCE PHARMACEUTICALS

Recce says it has "firm commitments" to raise $8 million at 45 cents a share in a placement and hopes to raise $2 million in a share purchase plan at the same price.

Recce said the issue price was a 31.4 percent discount to the 30-day volume weighted average price of 57.3 cents, or a 20.4 percent discount to the 10-day volume weighted average price of 56.5 cents.

The company said $7.5 million of the funds would be used for its phase III clinical trial in Indonesia and two phase II trials in urinary tract infections and skin diseases, with $1.5 million to be used for an investigational new drug application to the US Food and Drug Administration and remaining $1 million for general working capital.

Recce said following the raise it would have cash of about $18.5 million before costs and expected to receive further non-dilutive funding of about $8.7 million from the US Department of Defence and its Federal Research and Development Tax Incentive.

Recce said Ord Minnett was sole lead manager and Evolution Capital was co-manager to the raise.

The company said the share purchase plan had a record date of July 1, would open on July 10 and close on July 31, 2024.

Recce fell 11 cents or 18.3 percent to 49 cents with 1.9 million shares traded.

IMMURON

Immuron says it has filed a pre-investigational new drug application to the US Food and Drug Administration for IMM-529 for Clostridioides difficile.

Last year, Immuron said it would manufacture its cow colostrum-derived IMM-529 to proceed with an FDA pre-investigational new drug submission for Clostridioides difficile (BD: Jun 22, 2023).

At that time, the company said Clostridioides difficile was an anaerobic, spore-forming bacillus associated with gastro-intestinal disease, with infection able to cause life-threatening diarrhea.

Today, the company said IMM-529 antibodies with standard-of-care antibiotics may help to clear infections and "promote a quicker re-establishment of normal gut flora, providing an attractive oral preventative for recurrent [Clostridioides difficile]".

Immuron said the antibodies had been shown to prevent disease by 80 percent ($p = 0.0052$), protect disease recurrence by 67 percent ($p < 0.01$) and treat primary disease by 78.6 percent ($p < 0.0001$) in pre-clinical models.

The company said it believed IMM-529 was "to date, the only investigational drug that has shown therapeutic potential in all three phases of [Clostridioides difficile]".

Immuron chief executive officer Steven Lydeamore said the company was "excited for our third therapeutic to be heading towards phase II clinical studies, demonstrating the utility of our technology platform".

Immuron fell 0.1 cents or 1.2 percent to 8.2 cents.

ACTINOGEN MEDICAL

Actinogen says it had the final of 126 patient visits in its phase IIa trial of 10mg Xanamem for major depressive disorder, with top-line results expected in August 2024.

In 2022, Actinogen said it had treated the first of 160-patients in the phase IIa trial of its oral, cortisol synthesis inhibitor, Xanamem (BD: Dec 8, 2022)

Earlier this year, the company said it had enrolled all 167 cognitive impairment patients in the randomized, placebo-controlled trial (BD: Apr 22, 2024).

Today, Actinogen said the primary endpoint was the computerized Cogstate 'attention composite' test battery, which measured attention and working memory which had been shown to be a sensitive measure of Xanamem benefit in prior trials.

The company said secondary endpoints included the Montgomery-Asberg depression rating scale, an executive function cognitive composite, a memory function cognitive composite, proportions of responders and global clinical assessment scores.

Actinogen chief medical officer Dr Dana Hilt said that "any positive effects on cognition in this trial would confirm prior trial findings of cognitive enhancement and support the likelihood of future success in the on-going, 36-week, phase IIb 'Xanamia' trial in patients with Alzheimer's disease".

"We continue to observe the excellent safety profile for Xanamem and believe its low drug-drug interaction potential makes it an ideal candidate for use in multiple diseases and populations," Dr Hilt said.

"Cognitive impairment is a clinical deficit observed in many neurological and neuro-psychiatric disorders," Dr Hilt said.

"Therefore, Xanamem may have potential to have pro-cognitive and clinical benefit in a wide variety of disorders," Dr Hilt said.

Actinogen fell half a cent or 7.7 percent to six cents with 19.0 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has told Lind Partners that it intends to terminate its share subscription agreement and share purchase agreement, effective immediately.
Last week, Radiopharm said it had commitments to raise about $62.5 million at 4.0 cents a share in a placement, taking the total with the Lantheus placement at 5.0 cents a share to $70 million (BD: Jun 20, 25, 2024).
Earlier this year, Radiopharm said it had an up-to $12.5 million draw-down equity facility with New York's Lind Partners through a $1.2 million share subscription agreement and up-to $11.3 million share purchase agreement to be drawn down in monthly instalments of between $50,000 to $1 million (BD: Feb 6, 2024).
At that time, the company said it would pay an establishment fee of $25,000, 3.5 percent of the amount funded in each tranche and could terminate the agreement for a fee of $50,000, or for no fee after a minimum of $900,000 had been drawn down.
Today, Radiopharm did not disclose the amount it had drawn down from the facility prior to terminating the agreement.
Radiopharm was unchanged at 3.8 cents with 7.6 million shares traded.

COMPUMEDICS

Compumedics has requested a trading halt pending an announcement "in relation to a proposed capital raising".
Trading will resume on July 4, 2024, or on an earlier announcement.
Compumedics last traded at 34 cents.

AVITA MEDICAL

Avita says it appointed Nicole Kelsey as its chief legal and compliance officer and corporate secretary on July 1, 2024, following the retirement of Donna Shiroma.
Avita said Ms Kelsey had been Amyris Inc chief legal officer and secretary, Criteo SA general counsel and secretary and principal legal counsel for Medtronic Inc.
According to her Linkedin profile, Ms Kelsey held a Bachelor of Arts from Columbus' Ohio State University and a Doctor of Law from Chicago, Illinois' Northwestern University.
Avita fell four cents or 1.6 percent to $2.40 with 487,040 shares traded.

RACE ONCOLOGY

Race says it has appointed Prof Daniel Von Hoff to its clinical advisory board to consult on the development of its RC220 formulation of bisantrene.
Race said Prof Von Hoff was head of molecular medicine at the Translational Genomics Research Institute and City of Hope in Phoenix, Arizona, chair of cancer research at Phoenix, Arizona's Honor Health Clinical Research Institute and held a professorship at the Mayo Clinic site in Phoenix, Arizona.
According to his American Association for Cancer Research profile, Prof Von Hoff held a bachelor's degree from Waukesha, Wisconsin's Carroll College, and a Doctor of Medicine from New York's Columbia University.
Race fell 7.5 cents or 4.1 percent to $1.745.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says its company secretary Robyn Slaughter has resigned and was replaced by Patricia Vanni on July 1, 2024.
Allegra was in a suspension and last traded at 2.9 cents.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has appointed Jennifer Voon as its company secretary to replace financial services firm Atomic Group's Maria Clemente, effective immediately.
Algorae fell 0.1 cents or 9.1 percent to one cent with 1.6 million shares traded.