Biotech Daily

Monday July 15, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ACTINOGEN UP 8.5%; ATOMO DOWN 11%**

*** OPTHEA RETAIL RIGHTS RAISE $56m; TOTAL $227m**

*** NANOSONICS EXPECTS REVENUE UP 2.4% TO $170m**

*** IMMURON RECORD UNAUDITED TRAVELAN SALES UP 174% TO $4.9m**

*** RECCE $2.95m R327 US GRANT**

*** OPTISCAN INVUE BREAST CANCER STUDY APPROVED**

*** CURVEBEAM WINS FDA ENHANCED HIRISE APPROVAL**

*** PHARMAUST MONEPANTEL JOINS PHASE II/III HEALEY MND TRIAL**

*** DORSAVI COMPLETES NORTON HEALTHCARE SENSOR STUDY**

*** ALTERITY REQUESTS 'TRIAL DATA' TRADING HALT**

*** BCAL EGM 44% OPPOSE PLACEMENT SHARES**

*** PERENNIAL TAKES 5% OF IMMUTEP**

*** FIL (FIDELITY) TAKES 9.3% OF TRIVARX**

*** ONCOSIL APPOINTS HUNTER HALL'S PETER HALL DIRECTOR**

*** ARCHER LOSES CEO DR MOHAMMAD CHOUCAIR; DR SIMON RUFFELL CTO**

*** HERAMED, UTS SIGN 5-YEAR RESEARCH AGREEMENT**

MARKET REPORT

The Australian stock market was up 0.73 percent on Monday July 15, 2024, with the ASX200 up 58.3 points to 8,017.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 were down and nine traded unchanged. All three Big Caps were up.

Actinogen was the best, up 0.6 cents or 8.45 percent to 7.7 cents, with 15.0 million shares traded; followed by Next Science, up two cents or 8.3 percent to 26 cents, with 165,543 shares traded. Amplia climbed 6.45 percent; Nanosonics was up 5.1 percent; Avita rose 4.9 percent; Medadvisor and Micro-X were up more than three percent; Cochlear, Opthea and Resmed rose two percent or more; Alcidion, Nova Eye, Pro Medicus and Resonance were up more than one percent; with CSL, SDI and Telix up by less than one percent.

Atomo led the falls, down 0.3 cents or 10.7 percent to 2.5 cents, with 766,512 shares traded; followed by Immutep, down 3.5 cents or 9.9 percent to 32 cents, with 11.5 million shares traded. Curvebeam, Proteomics and Starpharma lost more than six percent; Impedimed fell 4.4 percent; Dimerix, Imugene and Paradigm were down more than three percent; Emvision, Mesoblast and Prescient shed more than two percent; Cyclopharm was down 1.8 percent; with Clarity, Clinuvel, Neuren and Polynovo down by less than one percent.

OPTHEA

Opthea says it has raised $55.85 million at 40 cents a share in its one-for-1.22, fully-underwritten retail rights offer, taking the total raised to $227.31 million.
Last month, Opthea said it had raised $10 million in an institutional placement and $161.46 million in the institutional component of its rights offer at 40.0 cents a share, with a retail offer for $55.9 million to follow (BD: Jun 12, 14, 2024).
Today, the company said retail investors had taken up about 13.1 percent of the offer, with the remaining shortfall shares to be subscribed for by the underwriter MST Financial Services Ltd, or sub-underwriters.
Opthea said participants in the capital raising received one option for every three shares subscribed for, exercisable at $1.00 each until June 30, 2026.
Opthea was up one cent or 2.7 percent to 38 cents with 5.5 million shares traded.

NANOSONICS

Nanosonics says it expects revenue from its Trophon ultrasound probe cleaning systems for the year to June 30, 2024 to be up 2.4 percent to $170 million.
Last year, Nanosonics said revenue for the year to June 30, 2023 was up 38 percent to $165,993,000, with net profit after tax up 431 percent to $19,883,000 (BD: Aug 22, 2023).
Today, the company said it sold an unaudited 3,850 Trophon units in the 12-month period, including 2,340 installed base units and 1,510 upgrade units.
Nanosonics said total units placed in the six months to June 30, 2024 were up 24 percent to 2,130 units, compared to the previous period.
The company said it installed 1,240 base units and upgraded 890 units in the six months to June 30, 2024, up 13 percent and 44 percent compared to the prior period, respectively.
Nanosonics said that “despite ongoing market challenges associated with hospital capital budget constraints in its major market of North America” it improved its sales conversion timeline in the six months to June 30, 2024, with total units placed in the region up 28 percent in the second half of the year to 1,850 units.
Nanosonics chief executive officer Michael Kavanagh said “despite a challenging market environment, the growth opportunity for Trophon remains significant”.
“With a growing pipeline for both new installed base and upgrades, it was pleasing to see the sales conversion timelines improve in the second half, which resulted in significant growth … for capital unit sales,” Mr Kavanagh said.
Nanosonics was up 16 cents or 5.1 percent to $3.31 with 4.9 million shares traded.

IMMURON

Immuron says record unaudited sales of Travelan for traveler’s diarrhoea for the year to June 30, 2024, is 174 percent to $4.9 million.
Immuron said Australian sales rose 236 percent to $3.7 million for the year, compared to $1.1 million in the year to June 30, 2023, with sales in the three months to June 30, 2024 up 209 percent to $1.0 million.
The company said that US sales were up 74 percent to a record $1.1 million for the year to June 30, 2024, compared to $600,000 in the year to June 30, 2019.
Immuron chief commercial officer Flavio Palumbo said the company’s “investment to drive awareness of the Travelan brand has seen continued strong sales results in Australia”.
“We were incredibly pleased to achieve record US sales,” Mr Palumbo said.
Immuron was up 0.9 cents or 10.5 percent to 9.5 cents with 1.45 million shares traded.

RECCE PHARMACEUTICALS

Recce says the US Department of Defense has granted it $US2 million ($A2.95 million) to accelerate development of its R327 gel for burn wound infections.

Recce said the funding was from the US Department of Defense Congressionally-Directed Medical Research programs and would be used to evaluate R327 as a gel-based treatment, or R327G, for burn wound infections and minimize the onset of bacteraemia complications, such as sepsis.

The company said the project's main aim was "to establish the potential for R327G products to be used in a far forward military setting" or point-of-injury.

Recce said the US Department of Defense granted its application as "outstanding".

Recce chief executive officer James Graham said the US Department of Defense decision was "a testament to the unique profile of Recce technology and the high quality of research and development conducted".

Recce fell half a cent or 1.1 percent to 45.5 cents.

OPTISCAN IMAGING

Optiscan says it has ethics approval from the Royal Melbourne Hospital for a 50-patient, in-vivo breast cancer imaging study using its Invue imaging microscope.

Last month, Optiscan said it had released its Invue microscope for providing "real-time, digital pathology access" to surgeons during surgery, and that the device could be used in cancer diagnosis and treatment (BD: Jun 4, 2024).

Today, the company said the study would assess the "clinical workflow and real-time imaging capability" of its Invue precision surgery imaging device.

Optiscan said the device would be used during surgery "to collect in-vivo imaging data of the surgical cavity intra-operatively after tumor removal to determine clearance of the tumor in real-time".

The company said the study would use intravenous fluorescein sodium as a contrast agent and would "assess the uptake of the contrast dye and the dynamics of imaging normal and cancerous breast tissue".

Optiscan said it would recruit patients undergoing breast conserving cancer surgery, or lumpectomy procedures, at Melbourne's Frances Perry House at the Royal Women's Hospital, the Epworth Hospital and the Royal Melbourne Hospital.

The company said the study was based on "new data from recent analyses of breast cancer lumps imaged ex-vivo … using topical acriflavine dye showing complete concordance between Optiscan's confocal imaging and gold standard histopathology'.

In 2018, Optiscan said it began the first part of a trial of its confocal laser endo-microscope to assess the surgical margin in patients undergoing breast cancer conservation surgery, and later, said results showed the device was "comparable" to histopathology when imaging breast cancer margins (BD: Oct 15, 2018; Sep 19, 2023).

Today, Optiscan chief executive officer Prof Camile Farah said "the non-interventional study design will allow the research team the opportunity to gather imaging data without the procedure interfering with standard-of-care".

"Once this stage is completed, we anticipate progressing to further recruitment with an interventional protocol," Prof Farah said.

"In this phase, collected images will guide surgeons in decision-making, determining tumor clearance or the need for additional tissue related to microscopic spread, before patient discharge," Prof Farah said. "This study represents a significant step in demonstrating the value Invue can deliver in managing and treating breast cancer."

Optiscan was up 3.5 cents or 17.95 percent to 23 cents.

CURVEBEAM A.I.

Curvebeam says it has 510(k) clearance for its Enhanced Hirise weight-bearing computed tomography imaging system from the US Food and Drug Administration.
Curvebeam said approval allowed it to sell the Enhanced Hirise system for Musculo-skeletal conditions in the US.
The company said the device could be used “in routine medical practice settings, allowing the final validation steps to be run on patients to ensure compatibility with custom knee and hip procedures, including robotic surgical systems”.
Curvebeam said the clearance permitted it to “executive on its commercial launch and expansion plans for the Enhanced Hirise platform in the US market”.
Curvebeam chief executive officer Greg Brown said the approval was “an important milestone that allows us to plan both the commercial launch of the Enhanced Hirise and validation of custom protocols for personalized knee and hip procedures, including robotic systems”.
“We are targeting this quarter to have multiple sites utilising the Enhanced Hirise for custom robotic surgeries,” Mr Brown said.
Curvebeam fell 1.5 cents or 6.4 percent to 22 cents with 1.75 million shares traded.

PHARMAUST

Pharmaust says Massachusetts General Hospital has accepted monepantel into its phase II/III Healey amyotrophic lateral sclerosis, or motor neuron disease platform trial.
Pharmaust said the US Food and Drug Administration-approved Healey trial at Boston’s Massachusetts General Hospital was a “large-scale collaboration across multiple clinical trial sites, industry partners and researchers to evaluate multiple drug candidates”, using a share master protocol, for the treatment of amyotrophic lateral sclerosis (ALS), or motor-neuron disease.
The company said that the trial would have more than 70 sites in the US and aimed to enrol 160 to 240 participants “per regimen” with a three-to-one active drug-to-placebo group ratio.
Pharmaust said drug candidates were chosen by a group of scientists and members of the Healey & AMG Center for ALS advisory committee.
The company said the trial design team would work with it “to develop a regimen specific protocol with information specific to monepantel”.
Pharmaust said that with bio-statisticians it would adapt the “regimen-specific statistical analysis plans, as necessary, to incorporate considerations specific to the monepantel study regimen”.
Pharmaust chief executive officer Dr Michael Thurn said the partnership was “a significant step forward in our efforts to develop monepantel as a viable treatment for ALS.”
“The collaboration with leading ALS experts and the streamlined regulatory support will accelerate our progress towards delivering a much-needed therapy for patients with ALS,” Dr Thurn said.
“While we had been exploring the potential to conduct the adaptive phase II/III Strike study globally, including at sites in Australia, the opportunity to be part of the Healey ALS platform trial via their US network of 72 clinical sites is substantial,” Dr Thurn said.
“This collaboration with the Healey ALS Platform Trial, with its streamlined regulatory support and engagement with leading ALS experts, is a critical advancement in our mission to offer a viable treatment for ALS,” Dr Thurn said.
Pharmaust was up 1.5 cents or 7.3 percent to 22 cents with 2.7 million shares traded.

DORSAVI

Dorsavi says it has completed its US clinical study of its wearable sensors with the Louisville, Kentucky's Norton Healthcare, with results to support its product line.
Dorsavi said the study, in Southern Indiana and Kentucky, generated about $100,000 in sponsored research support over 24-months.
The company said it collaborated with Norton Healthcare to research and investigate spinal motion and patterns of movement pre-and-post surgery, using its sensor technology and "artificial intelligence and machine learning algorithms".
Dorsavi said the study was led by Norton Healthcare's Dr Steven Glassman.
The company said it expected the study findings to be published in peer-reviewed journals and "discussed at medical conferences", with the results and timing to be determined by Dr Glassman and his team.
Dorsavi said the study would support research on its product line, "enhancing its top-tier client base and diversifying its revenue stream".
Dorsavi was up 0.3 cents or 27.3 percent to 1.4 cents.

ALTERITY THERAPEUTICS

Alterity has requested a trading halt pending an announcement "in relation to new data from an ATH434 clinical trial".
Trading will resume on July 17, 2024, or on an earlier announcement.
Alterity last traded at 0.5 cents.

BCAL DIAGNOSTICS

Bcal says its extraordinary general meeting passed all six resolutions but with 52,330,306 votes, or 43.85 percent, opposing the issue of placement shares.
Last month, Bcal said it had "firm commitments" to raise $10.5 million at 10 cents a share in a placement, which Biotech Daily calculated was a 42.85 percent discount to the 17.5 cent closing price on May 29, 2024 (BD: Jun 3, 2024).
In June, Bcal said an extraordinary general meeting would vote to approve the issue of 41,900,000 placement shares approve chair Jayne Shaw and directors Jonathan Trollip and Ronald Phillips' participation raise and the ratification of the prior issue of shares from a placement in November, 2023.
Today, the company said the issue of the placement shares was opposed by 52,330,306 votes (43.85%), with 67,018,765 votes (56.15%) in favor.
Bcal said the remaining resolutions were all passed easily.
According to its most recent filing, Bcal had 314,294,714 shares on issue, meaning that the 52,330,306 votes against the placement shares amounted to about 16.65 percent of the company, sufficient to requisition extraordinary general meetings.
Bcal fell two cents or 12.1 percent to 14.5 cents with 1.7 million shares traded.

IMMUTEP

Perennial Value Management Ltd says it has become a substantial shareholder in Immutep with 71,743,087 shares, or 5.04 percent.
The Sydney-based Perennial said that it acquired the shares between February 2 and June 13, 2024 with HSBC, Northern Trust, BNP Paribas and Citicorp, with the single largest purchase 3,985,845 shares on June 12 for $1,584,373, or 39.75 cents a share.
Immutep fell 3.5 cents or 9.9 percent to 32 cents with 11.5 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

FIL Limited (Fidelity) says it has increased its substantial shareholding in Trivarx from 32,809,220 shares (8.01%) to 42,502,362 shares (9.30%).
The Hong Kong-based FIL said that on May 7, 2024 it bought 9,693,142 shares for 2.5 cents a share.
Trivarx was up 0.1 cents or 2.9 percent to 3.6 cents with 2.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Peter Hall as a non-executive director, effective by "the end of August 2024".
Oncosil said the London-based Mr Hall was an Australian financier, media proprietor and philanthropist, and founding chief investment officer and chair of Hunter Hall Investment Management.
In past years, Hunter Hall Investment has invested in Avita, GI Dynamics, Mach 7 and Sirtex Medical (BD: Feb 10, Apr 26, Jun 20, Oct 13, 2017).
According to Mr Hall's Linkedin page, he held a Bachelor of Arts from the University of Sydney.
Oncosil was up 0.1 cents or 14.3 percent to 0.8 cents with 4.3 million shares traded.

ARCHER MATERIALS

Archer says its chief executive officer Dr Mohammad Choucair will resign in January 2025 and it has appointed Dr Simon Ruffell as its chief technology officer.
Archer said Dr Mohammad Choucair was the co-inventor of its quantum and biosensor technologies and that he was resigning "for personal reasons".
"Our transformation from mineral explorer to a semiconductor company focusing on quantum and medical diagnostics advanced technologies has placed Archer in a position of strength, which creates the ideal opportunity to hand over the leadership," Dr Choucair said.
Archer said Dr Ruffell was appointed engineering manager in February 2024, and had worked at Microsoft, Applied Materials and Semiconductor and the University of Sydney, and held a Masters of Electronic and Electrical Engineering from England's University of Surrey and a Doctor of Philosophy from Canada's University of Western Ontario.
Archer fell eight cents or 22.2 percent to 28 cents with 4.4 million shares traded.

HERAMED

Heramed says it has a five-year research partnership agreement with the University of Technology Sydney (UTS) in New South Wales for its foetal heartbeat monitor.
Heramed said the agreement with the University of Technology Sydney would "contribute to and build on its existing research collaborations with other leading universities".
Heramed chief executive officer Anoushka Gungadin said the company "was excited to work in partnership with UTS to advance models of care and wellbeing for women and babies".
Heramed was unchanged at 2.3 cents.