Biotech Daily

Monday August 19, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 8.5%; AVITA DOWN 3%**

*** CONTROL BIONICS WINS US NEURONODE REIMBURSEMENT**

*** OPTISCAN, MINNESOTA UNI ANIMAL CANCER STUDY**

*** NOXOPHARM TO START SOF-SKN HUMAN TRIAL IN 2025**

*** FIRETRAIL INCREASES, DILUTED TO 11% OF CURVEBEAM**

*** ILWELLA DILUTED TO 8% OF CURVEBEAM**

*** FISHER & PAYKEL LOSES CHAIR SCOTT ST JOHN; MARK CROSS DIRECTOR**

*** RESMED APPOINTS CHRISTOPHER DELOREFICE DIRECTOR**

*** MEDADVISOR LOSES DIRECTORS BRETT MAGUN, SANDRA HOOK**

MARKET REPORT

The Australian stock market was up 0.12 percent on Monday August 19, 2024, with the ASX200 up 9.3 points to 7980.4 points.

Sixteen of the Biotech Daily Top 40 companies were up, 14 fell and 10 traded unchanged.

Compumedics was the best, up 2.5 cents or 8.5 percent to 32 cents, with 168,780 shares traded.

Amplia improved 7.7 percent; Clarity climbed 4.5 percent; 4D Medical, Alcidion, Cynata and Prescient rose more than two percent; Aroa, Emvision, Impedimed, Medical Developments, Opthea, Orthocell and Telix were up one percent or more; with Clinuvel, Cochlear, CSL and SDI up by less than one percent.

Avita led the falls, down eight cents or 2.9 percent to $2.72, with 141,628 shares traded; followed by Nanosonics down 2.8 percent to $2.75, with 1.35 million shares traded.

Curvebeam, Dimerix and Nova Eye shed more than two percent; Cyclopharm, Medadvisor, Mesoblast, Micro-X and Polynovo were down more than one percent; with Neuren, Pro Medicus, Proteomics, Resmed and Resonance down by less than one percent.

CONTROL BIONICS

Control Bionics says its Neuronode has a US Centers for Medicare and Medicaid code qualifying it for $US4,299.75 ($A6,432) in reimbursement, from October 1, 2024.
Control Bionics said Neuronode was eligible under the Healthcare Common Procedure Coding System (HCPCS) level II code E2513 “Accessory for speech generating device, electro-myographic sensor” recognized augmentative and alternative communication devices.
The company said Neuronode used “electro-myographic signals and three-dimensional spatial movements to provide precise control over speech generating devices”.
Control Bionics said the HCPCS code would allow healthcare providers to report the use of Neuronode, making it “simpler to process claims and enhancing patient access”.
The company said it and its US customers had “been reimbursed for the Neuronode for many years” through a general ‘Accessories’ code, which reduced its gross margins.
Control Bionics said the HCPCS code would allow for “the direct billing of all the components provided” as part of the Neuronode device product.
The company said it was “difficult to project” the financial impact of the reimbursement but, based on historical results, if the code had been in place from July 1, 2023 and all insurers were paid out to the maximum recommended by Medicare, it would have led to about $US400,000 in revenue and margin for the year to June 30, 2024.
Control Bionics said it expected that Neuronode having its own code, rather than being bundled in the existing accessory code, would result in increased sales.
The company said the code could help it build a distribution model for the US, with 16,000 people in the US diagnosed with either motor neuron disease or cerebral palsy each year, conditions which accounted for about 50 percent of its US customers a year.
Control Bionics said it would begin discussions for Neuronode to be covered as an in-network device with private insurers but securing in-network could be time-consuming and so could not provide guidance on the time it would take to attain full coverage for the US.
Control Bionics chief executive officer Jeremy Steele said the reimbursement code marked “a significant milestone” and would enhance accessibility, making it easier for patients to obtain the necessary support and devices through their insurance provider.
Control Bionics rose 1.7 cents or 22.4 percent to 9.3 cents with 1.2 million shares traded.

OPTISCAN IMAGING

Optiscan says that with the Minneapolis’ University of Minnesota it will research the use of its endo-microscopic imaging system for cancer detection, in animals.
Optiscan said the agreement with the University of Minnesota College of Veterinary Medicine included a trial of the clinical applications of its digital confocal laser endo-microscopic imaging system, with an initial focus on cancer research in companion animals, such as cats and dogs.
The company said the planned research and testing would provide the necessary data for US Food and Drug Administration clearance of its imaging platform for use in veterinary medicine.
Optiscan said the agreement would combine its technology with the University’s “extensive research capabilities, veterinary facilities and expertise […] and faculty” but did not mention the commercial terms of the deal.
Optiscan said two of the most common cancer types in both cats and dogs were breast and oral cancers, and that these cancer types showed a “strategic alignment” to the medical conditions it was focused on in human oncology.
Optiscan fell half a cent or 2.4 percent to 20 cents.

NOXOPHARM

Noxopharm says it plans to start its first human trial of its Sofra drug candidate SOF-SKN for cutaneous lupus erythematosus (CLE)-related skin disease “in early 2025”.
Noxopharm said the trial, titled Heracles or ‘harnessing endogenous regulators against CLE study’ would be conducted in Australia, allowing it to maximize rebates from the Federal Government’s Research and Development Tax Incentive program.
The company said part one of the trial would administer a single dose of SOF-SKN before a safety review, followed by a second cohort of participants receiving a higher dose before a safety review, continually until a maximum dose had been reached.
Noxopharm said the second part of the trial would involve “several groups of volunteers, again in a sequential manner, each receiving multiple doses”.
The company said SOF-SKN was a “first-in-class oligo-nucleotide TLR7/8 antagonist” that could potentially treat the cause of CLE instead of merely controlling symptoms.
Noxopharm said the development of SOF-SKN was the “first step in leveraging … the Sofra [drug development] platform to tackle the much larger autoimmune disease market in areas such as rheumatoid arthritis”.
The company said it expected the first safety readouts to be available “four-to-six weeks” after completing dosing, with data expected to be ready by 2026.
Noxopharm said it was finalizing the specific SOF-SKN formulation to be used, while also selecting a phase I trial unit, designing the trial protocol, preparing its ethics submission, developing its investigator’s brochure and building the trial database.
The company said it hoped to transition to a follow-on trial for lupus patients “at a number of specialist centres in Australia”.
Noxopharm chief executive officer Dr Gisela Mautner said the trial marked “the return of Noxopharm to the small group of ASX-listed Australian companies that have made it to the clinical trial stage”.
“It is a major milestone that we have achieved in record time,” Dr Mautner said.
“At the big picture level, we very much see this as just the first chapter in developing the Sofra platform across larger markets,” Dr Mautner said.
Noxopharm was up 0.6 cents or 7.3 percent to 8.8 cents.

CURVEBEAM A.I.

Firetrail Investments Pty Ltd says it has increased its shareholding in Curvebeam and been diluted from 39,244,484 shares (12.26%) to 43,210,324 shares (11.25%)
The Brisbane-based Firetrail said that between August 31, 2023 and August 14, 2024 it bought, sold and transferred shares, with the single largest purchase 14,573,241 shares on February 16 for $3,206,113, or 22.0 cents a share.
Last week, Curvebeam said it had raised $7.9 million at 18 cents a share in a $2.0 million placement and $5.9 million one-for-six, institutional rights offer, with a further $2.0 million placement and $3.6 million retail rights offer to go (BD: Aug 14, 2024).
Curvebeam fell half a cent or 2.6 percent to 18.5 cents.

CURVEBEAM A.I.

Ilwella Pty Ltd says its substantial 30,370,786 share-holding in Curvebeam has been diluted from 9.49 percent to 8.34 percent.
The Sydney-based Ilwella said that on August 14, 2024 its shareholding was diluted due to the issue of placement shares and rights issue (see above).

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel Healthcare says it has appointed Mark Cross as a director, effective from October 1, 2024, with chair Scott St John to be replaced by Neville Mitchell.
Fisher & Paykel said Mr St John would retire form the board form the close of its annual general meeting on August 28, 2024, and it had elected current director Neville Mitchell as its replacement chair.
The company said the New Zealand-based Mr Cross was chair of Chorus, Xero and a board member and investment committee chair of the New Zealand Government's Accident Compensation Corporation and had been chair of Milford Asset Management as well as director of Z Energy, Genesis Energy and Argosy Property.
Fisher & Paykel said Mr Cross had held executive positions at Deutsche Bank in London and Sydney, as well as Lloyds Corporate Finance and Southpac Corp in Australia and New Zealand.
Fisher & Paykel said Mr Cross would chair its audit and risk committee and would "fill the vacancy on the board upon Mr St John's retirement at the end of August".
Fisher & Paykel slipped two cents or 0.07 percent to $29.96 with 348,194 shares traded.

RESMED

Resmed says it has appointed Christopher DelOrefice as a non-executive director, effective from today.
Resmed said Mr DelOrefice was currently Becton, Dickinson and Co chief financial officer, and had worked for Johnson & Johnson, Astrazeneca, Applied Extrusion Technologies Films and Ametek.
The company said Mr DelOrefice held a Bachelor of Science and a Master of Business Administration from the Philadelphia-based Villanova University.
Resmed fell 14 cents or 0.4 percent to $33.97 with 986,754 shares traded.

MEDADVISOR

Medadvisor says non-executive directors Brett Magun and Sandra Hook will retire, effective from August 28 and at its annual meeting in November, 2024, respectively.
Medadvisor said additional board members were recruited during a "board refresh process" in 2023 to ensure diversity of skills and maintenance of governance standards, but that "after a planned period of transition" the board would reduce to "align with the company's market capitalization".
Last year, the company said it had appointed Kate Hill as non-executive director, with substantial shareholder Cotiviti's director Mr Magun to replace Raeann Grossman, effective on May 24, 2023 (BD: May 26, 20023).
Medadvisor chair Linda Jenkinson said "on behalf of the board, I sincerely thank both Ms Hook and Mr Magun for their significant contributions to Medadvisor".
"They have played a critical part along the Medadvisor pathway to profitability and also in supporting our ongoing governance uplift process," Ms Jenkinson said.
Medadvisor fell half a cent or 1.1 percent to 44.5 cents.