Biotech Daily

Wednesday December 6, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 14%; AMPLIA DOWN 8%**

*** POLYNOVO RECORD $9.5m MONTHLY REVENUE**

*** LUMOS STARTS US VIRADX, FEBRIDX SALES**

*** MICROBA COMPLETES $21m INVIVO ACQUISITION**

*** IMUGENE TO START PHASE II PD1-VAXX COLORECTAL CANCER TRIAL**

*** IMUGENE WINS EU PD1-VAXX PATENT**

*** INVEX EGM APPROVES $14m CAPITAL RETURN**

*** MERCHANT TAKES 6% OF NEUROTECH**

*** HYDRIX LOSES DIRECTOR JOANNE BRYANT**

*** PHARMAUST APPOINTS DR CAROL WORTH, JOHN CLARK**

MARKET REPORT

The Australian stock market was up 1.65 percent on Wednesday December 6, 2023, with the ASX200 up 116.8 points to 7,178.4 points. Nineteen Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and one was untraded. All three Big Caps rose.

Cynata was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 21,869 shares traded, followed by Polynovo up 13.0 percent to $1.52, with 3.5 million shares traded. Avita climbed 5.4 percent; Actinogen, Clinuvel and Prescient improved more than four percent; Curvebeam and Dimerix were up more than three percent; 4D Medical, Cochlear, Cyclopharm, Nanosonics and Neuren rose more than two percent; CSL, Mesoblast, Orthocell, Paradigm, SDI and Telix were up more than one percent; with Pro Medicus, Proteomics and Resmed up by less than one percent.

Amplia led the falls, down 0.6 cents or 8.1 percent to 6.8 cents, with 4,400 shares traded. Alcidion, Atomo and Clarity fell more than four percent or more; Pharmaxis/Syntara, Starpharma and Volpara were down more than three percent; Next Science and Universal Biosensors shed more than two percent; Imugene and Opthea were down one percent or more; with Emvision and Medical Developments down by less than one percent.

POLYNOVO

Polynovo says it has record monthly sales of its Novosorb burn wound treatment for November, with $8.8 million in sales and $9.5 million in revenue.

Polynovo said that US sales for the month were up 74 percent to $6.1 million compared to November 2022, with sales in Australia, Hong Kong, India, Ireland, the Middle East, Singapore and the UK up 290 percent to $2.7 million.

The company said the total group revenue for the month of $9.5 million included about $700,000 from the US Department of Health and Human Services' Biomedical Advanced Research and Development Authority (Barda).

Polynovo chair David Williams said "sales are lumpy and will remain so as we expand our geographic footprint and surgeons explore different uses for Novosorb MTX and BTM".

"Nevertheless, the direction of sales is clear and lumpiness is our friend because it reflects growth from $3.3 million in June 2021 to $8.8 million in November 2023," Mr Williams said.

"I expect more lumpiness from our entry into India, Finland, Hong Kong, Turkey, and Canada," Mr Williams said.

"As impressive as sales growth is, it reflects the impressive growth in hospitals being supplied, surgeons using the product, patients being treated and the large number of surgeon-initiated trials and publications," Mr Williams said.

Polynovo chief executive officer Swami Raote said that Novosorb BTM had been used to treat more than 34,900 patients.

Polynovo was up 17.5 cents or 13 percent to $1.52 with 3.5 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has begun US commercial operations for its Viradx three-in-one rap respiratory infection test and its Febridx bacterial respiratory test.

In September, Lumos said it had received a US Clinical Laboratory Improvement Amendments (CLIA) waiver for its Viradx Covid-19, influenza A and B rapid point-of-care test, giving the test emergency use authorization in the US (BD: Sep 11, 2023).

Today, the company said that with a CLIA waver Viradx could be used in 260,000 clinics in the US.

Lumos said that its first Viradx test lot had been released on November 21, 2023, with pre-orders received, initial stocking orders shipped, about $US150,000 ($A228,129) in sales revenue and reimbursement for the test established and confirmed.

The company said it had eight distributor agreements for Viradx for primary care, urgent care, employee health and student health, as well as an expansion plan that hoped to include an additional eight more distributors.

In July, Lumos said it had US Food and Drug Administration clearance to market its Febridx rapid, point-of-care, finger-prick, blood test "as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from nonbacterial etiology in patients presenting in urgent care or emergency care settings" (BD: Jul 3, 2023).

Today, the company said it had received pre-orders for Febridx and expected to begin sales in late December, with nine distributor agreements in place and two-to-three more planned.

Lumos said Febridx was able to be used in about 10,000 US laboratories for "moderately complex settings" and there were multiple paths to securing a full CLIA waiver which would allow its use in 260,000 clinics.

Lumos fell 0.9 cents or 12.3 percent to 6.4 cents with 22.8 million shares traded.

MICROBA LIFE SCIENCES

Microba says it has completed the up-to $21.2 million acquisition of the Gloucestershire, England-based Invivo Clinical, effective on December 5, 2023.
In October, Microba said it would buy Invivo Clinical, a microbiome testing business with products including vaginal, oral and urinary testing, for $12.5 million and up-to $8.7 million in earn-out, with a $20 million rights offer to fund it (BD: Oct 19, 2023).
Today, the company said “acquiring a market leading position, customer and geographical base in the UK, together with [major shareholder] Sonic Healthcare, provides deep access to the entire UK healthcare market”.
Microba was unchanged at 22 cents.

IMUGENE

Imugene says it will conduct an up-to 44-patient, phase II trial of its PD1-Vaxx vaccine for operable colorectal cancer at six sites in Australia and four in the UK.
Imugene said the primary objective of the study would be to determine pathological response rates by measuring tumor size.
The company said secondary objectives were the safety of its programmed-death-1 (PD1)-Vaxx therapy, evaluating biomarkers, objective response rates and overall survival.
Imugene said patients diagnosed with operable colorectal cancer would be enrolled beginning next year and treated with PD1-Vaxx before surgery.
The company said it expected to take about 18 months to enrol all the patients, which was with the University of Southampton, the Royal Surrey Hospital National Health Service Foundation Trust and the Australasian Gastro-Intestinal Trials Group.
Imugene managing-director Leslie Chong said study costs were “partially funded, being investigator sponsored studies, and fall within current cash flow forecasts”.
Imugene fell 0.1 cents or 1.1 percent to 9.2 cents with 89.8 million shares traded.

IMUGENE

Imugene says the European Patent Office has granted it a patent for its PD1-Vaxx cancer treatment, covering its manufacturing and method of treatment.
Imugene said the patent, titled ‘Human PD1 Peptide Vaccines and Uses Thereof’, would protect its intellectual property until March 28, 2038.
The company said that PD1-Vaxx was currently in clinical development for non-small cell lung cancer and would be trialed for colorectal cancer next year (see above).
Imugene said that corresponding applications were pending in Canada, China, Hong Kong, India, South Korea, Brazil and Australia and the patent had received a notice of grant in the US and Japan.

INVEX THERAPEUTICS

Invex says its extraordinary general meeting voted 99.98 percent in favor of the return of $14.0 million in capital to shareholders.
Earlier this year, Invex closed its phase III Presendin idiopathic intracranial pressure, trial due to limited market opportunity and costs and the uptake of GLP-1 receptor antagonists for obesity and later said it would return $14.0 million (BD: Jun 28, Aug 21, Nov 1, 2023).
Today, Invex said the effective date for the capital return was December 6, the record date would be December 11, with payment on December 18, 2023.
Invex was up one cent or 4.2 percent to 25 cents.

NEUROTECH INTERNATIONAL

Merchant Funds says it has increased its substantial shareholding in Neurotech from 36,402,227 shares (5.01%) to 53,424,419 shares (6.03%).
The Perth-based Merchant Funds said it bought, sold and transferred shares between November 2022 and November 2023, with the single largest purchase of 5,257,012 shares in May 2023 for $254,830, or 4.85 cents a share.
Neurotech was unchanged at six cents.

HYDRIX

In an appendix 3Z, Joanne Bryant said she had resigned as a director of Hydrix, effective on November 13, 2023.
Hydrix announced Ms Bryant's resignation in the October notice of annual general meeting.
Biotech Daily apologizes for missing this news.
Hydrix fell 0.1 cents or 5.3 percent to 1.8 cents.

PHARMAUST

Pharmaust says it has appointed Dr Carol Worth as chemistry, manufacturing and controls operations manager and John Clark as clinical operations manager.
Pharmaust said Dr Worth had been quality manager at its wholly-owned subsidiary Epichem, chief technical officer at Suda Pharmaceuticals and Solbec Pharmaceuticals, and had led product development programs at Thermalife International and Pharmasolv Laboratories.
According to her Linkedin page, Dr Worth held a Master of Science from the UK's University of Salford and a Doctor of Philosophy from the University of Western Australia.
The company said Mr Clark had more than 20 years of experience in running clinical trials and had been the senior project manager at a clinical research organization, and had held clinical operations roles.
Pharmaust said Mr Clark held a Bachelor Science from Bristol's University of the West of England.
Pharmaust was up one cent or 10 percent to 11 cents with 2.1 million shares traded.