Biotech Daily

Thursday November 7, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NEUREN UP 8.5%; CURVEBEAM DOWN 11%**

*** NEUREN $380m 9-MONTH DAYBUE SALES TRIGGERS $76m PAYMENT**

*** QUEENSLAND UNI, VICEBIO RESPIRATORY VIRUS VACCINE TRIAL**

*** TRIVARX 'NEW DEPRESSION MEB-001: 87% SENSITIVE, 69% SPECIFIC'**

*** ARCHER REDUCES BIOCHIP SIZE 97%**

*** RHYTHM RECEIVES $3.2m FEDERAL R&D TAX INCENTIVE**

*** RECCE AGM 25.6% REM REPORT 2nd STRIKE; BOARD SPILL FAILS**

*** RECCE EGM 100% APPROVES CAPITAL REDUCTION**

*** BLUEFLAG, ALLAN MOSS INCREASE, DILUTED TO 5.5% OF AMPLIA**

*** QBIOTICS APPOINTS MARK FLADRICH CHAIR**

*** TWO WEEKS TO AUSBIOTECH, MTP CONNECT SUMMIT**

MARKET REPORT

The Australian stock market was up 0.33 percent on Thursday November 7, 2024, with the ASX200 up 26.8 points to 8,226.3 points. Twelve of the Biotech Daily Top 40 companies were up, 18 fell, nine traded unchanged and one was untraded.

Neuren was the best for a second day in a row (see below), up $1.13 or 8.5 percent to $14.40, with 1.2 million shares traded. Aroa climbed 5.3 percent; Nova Eye and Resonance were up more than three percent; Avita, Cyclopharm and Polynovo rose more than two percent; with 4D Medical, Impedimed, Mesoblast, Nanosonics, Pro Medicus and Starpharma up by one percent or more.

Curvebeam led the falls, down 1.2 cents or 10.9 percent to 9.8 cents, with 723,613 shares traded. Universal Biosensors lost 7.4 percent; Immutep shed 6.9 percent; Amplia was down 5.2 percent; Actinogen and Clarity fell more than four percent; Medical Developments and Opthea were down more than three percent; Dimerix, Micro-X, Paradigm, Resmed and Syntara shed more than two percent; Orthocell and Proteomics were down more than one percent; with Clinuvel, Cochlear, CSL, EBR, Emvision and SDI down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says nine-month sales of Daybue for Rett syndrome were $US251.7 million ($A380 million), triggering a $US50 million ($A76 million) milestone payment.
Last year, Neuren said the US Food and Drug Administration approved Acadia Pharmaceuticals Daybue, or trofinetide, for Rett syndrome (BD: Mar 13, 2023).
Today, Neuren said nine-month Daybue sales exceeded the full-year threshold to trigger the payment, which it expected to receive by April 2025 after finalizing full year sales.
The company said it received $13.2 million in royalties for the three months to September 30, 2024 taking its nine-months royalties to $37.5 million, following Acadia's net sales for Daybue for the three months up 36 percent to $US91.2 million.
Yesterday, Neuren said it expected one-third of the proceeds from Acadia's $US150 million sale of the rare paediatric disease priority review voucher (BD: Nov 6, 2024).
Today, the company said it expected revenue, including royalties, sales milestone payments and its priority review voucher proceeds, for the year to December 31, 2024 to be between $216 million and $218 million.
Neuren quoted Acadia saying that "guidance for net sales in 2024 narrowed to $US340 million to $US350 million".
In August, Neuren said that Acadia sales guidance was between $US340 million and $US370 million (BD: Aug 7, 2024).
Neuren was up $1.13 or 8.5 percent to $14.40 with 1.2 million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says spin-out company Vicebio Ltd will conduct an up-to 120-patient, phase I trial of its vaccine for two respiratory viruses.
The University of Queensland said the London, England-based Vicebio had licenced molecular clamp technology developed at the University to produce a vaccine candidate for respiratory syncytial virus (RSV) and human meta-pneumo-virus (hMPV).
The University said its commercialization company Uniquest "exclusively licenced the clamp technology to Vicebio for non-epidemic use".
Vicebio's website said it raised $100 million in September 2024 for the bivalent vaccine phase I trial, to assess its safety and immunogenicity compared to a recently licenced RSV vaccine.
Vicebio said the clamp stabilized "viral glycol-proteins in their highly immunogenic 'prefusion' conformation, crucial for eliciting strong protective immune responses".
"This innovative approach enables the production of highly effective vaccines that are easy to manufacture and will be available in ready-to-use prefilled syringes," Vicebio said.
The University of Queensland said both the RSV and hMPV viruses caused "respiratory tract diseases which may be severe, especially in children under the age of five, in adults and the elderly as well as in immune-compromised individuals".
The University said the trial hoped to recruit 120 older adults aged 60 to 83 years.
The University of Queensland the trial was being conducted by the University of the Sunshine Coast's clinical trials network at three sites in Southeast Queensland.
The University said virology researcher and co-inventor of the molecular clamp, Prof Keith Chappell was Vicebio's principal scientist.
Prof Chappell said that "both RSV and hMPV infections have surged throughout Australia in recent years and there is a real need to explore new proactive protection and prevention options".
Vicebio chief executive officer Dr Emmanuel Hanon said the vaccine candidate "could be a turning point in reducing the burden of disease associated with respiratory viruses".

TRIVARX (FORMERLY MEDIBIO)

Trivarx says initial data from a 295-patient subset of its phase II trial shows its “new algorithm” had 87 percent sensitivity and 69 percent specificity for depression.

Last year, the then Medibio said it had begun a 400-participant trial of its MEB-001 “sleep signal analysis” algorithm for current major depressive episodes at 14 US sleep centres; and in July, said it completed the trial (BD: Sep 4, 2023, Jul 10, 2024).

Earlier this year, the company said the 400-patient, phase II trial showed its MEB-001 algorithm identified depression from heart rate with 87 percent sensitivity and 72 percent specificity (BD: July 30, 2024).

Today, Trivarx said its “new algorithm” could accurately conduct sleep staging and screen for current major depressive episodes in subjects through a single channel electrocardiogram (ECG).

The company said the algorithm had “been developed and optimised to use only a single channel ECG providing heart rate and heart rate variability metrics which [could] be used in sleep staging and [current major depressive episode] screening”.

Trivarx said it had filed a provisional patent application covering the algorithm with the US Patent and Trademark Office, and it would “continue to advance discussions with multiple industry participants around collaboration and potential licencing”.

Trivarx chair David Trimboli said the “new algorithm follows a targeted [research and development] program undertaken by the company following the completion of its phase II … study utilizing MEB-001”.

“This pivotal trial also has the potential to lead to FDA clearance for MEB-001, which will further strengthen the commercialization opportunities and endorsement for both the company’s proprietary algorithms,” Mr Trimboli said.

Trivarx was up 0.4 cents or 26.7 percent to 1.9 cents with 30.85 million shares traded.

ARCHER MATERIALS

Archer says it has miniaturized its graphene field effect transistor (gFET) Biochip from 10mm by 10 mmm to 1.5mm by 1.5mm, or a 97 percent size reduction.

Earlier this year, Archer said it had designed a miniature version of its Biochip for applications in biotechnology (BD: Mar 11, 2024).

Later, the company said it began experiments to detect and monitor chronic kidney disease by detecting potassium on its Biochip (BD: Aug 27, 2024).

Today, Archer said the miniaturized Biochip was fabricated on a whole four-inch wafer, with 1,375 graphene field effect transistor chips, compared to the 45 chips produced using earlier designs in previous four-inch wafer fabrication runs.

The company said the wafer had been diced and assembled at its outsourced semiconductor assembly and testing partner, AOI Electronics in Japan, which included “moulding, dicing and lead frame design”.

Archer said the chips were currently undergoing testing at its factory, including home testing for chronic kidney disease.

Archer executive chair Greg English said the company was “pro-actively reducing device fabrication costs and paving the way for a wafer-scale run of over a thousand miniaturized gFET chips”.

“By working with Applied Nanolayers and AOI Electronics on the miniaturized gFET chips, we have successfully proved the fabless commercial model to support development of the Biochip and strengthen our relationships with semiconductor supply-chain partners,” Mr English said.

Archer was up 4.5 cents or 17.3 percent to 30.5 cents with 3.8 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has received $3.23 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Rhythm said the funds included $1.24 million for the year to June 30, 2023, as a second tranche following an amended tax filing, and its $1.94 million incentive for the year to June 30, 2024, with the proceeds to be used for a "second generation Colostat product for commercialization and to repay the current loan balance of $1.15 million".
In August, Rhythm said it had a $1.15 million loan and expected a $1.5 million Federal Research and Development Tax Incentive (BD: Aug 14, 2024).
Rhythm was up half a cent or 4.8 percent to 11 cents.

RECCE PHARMACEUTICALS

Recce says its annual general meeting voted 25.59 percent for a second strike against its remuneration report, with the spill resolution defeated by 87.97 percent of the vote.
Last month, Recce said its annual general meeting would vote on its remuneration report and a potential second-strike board spill and the issue of 11,500,000 options to its board and management (BD: Oct 8, 2024).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings must vote on a board spill and if passed by more than 50 percent the directors must stand for re-election.
Today, the company said the remuneration report was opposed by 16,300,281 votes (25.59%) with 47,403,295 votes (74.41%) in favor.
Recce said the -election of Dr Alan Dunton and Alistair McKeough as directors both faced 20.70 percent opposition, with the issue of options to them opposed by 9.43 percent and 9.46 percent, respectively, 8.42 percent of the meeting voted against the issue of placement shares, and its placement capacity was opposed by 6.79 percent of the vote.
Recce said the remaining resolutions passed easily.
According to its most recent filing, Recce had 231,871,617 shares on issue, meaning that the 16,300,281 votes against the remuneration report amounted to about 7.0 percent of the company, sufficient to requisition extraordinary general meetings.
Recce was up half a cent or 1.1 percent to 47 cents.

RECCE PHARMACEUTICALS

Recce says 100.0 percent, or 7,454,424 votes, of its special general meeting voted to approve of a selective capital reduction.
Last month, Recce said a special general meeting would vote on a selective capital reduction to cancel all of its 8,754,423 class B performance shares (BD: Oct 8, 2024).

AMPLIA THERAPEUTICS

Allan Moss as director of Blueflag Holdings Pty Ltd says he has increased but been diluted in Amplia from 18,861,500 shares (6.94%) to 19,731,062 shares (5.51%).
Mr Moss said that with the Sydney-based Blueflag he bought 869,562 shares on November 6, 2024 in an entitlement offer for $100,000, or 11.5 cents a share.
Last week, Amplia said it raised $9.9 million in a placement and institutional rights offer at 11.5 cents a share, with a $3.1 million retail offer to follow (BD: Oct 30, Nov 1, 2024).
Amplia fell half a cent or 5.2 percent to 9.1 cents with 3.3 million shares traded.

QBIOTICS GROUP

Qbiotics says it has appointed director Mark Fladrich as its non-executive chair, following the death of Dr Susan Foden.

On Wednesday, Qbiotics said that “with profound sadness [it] announces the passing of Dr Foden, non-executive chair” (BD: Nov 5, 2024).

Today, the company said Mr Fladrich had more than 30 years of experience including 23 years with Astrazeneca as head of marketing, regional head in Germany, Australia and New Zealand as well as Southern and Western Europe.

Qbiotics said Mr Fladrich had been a director since May 20, 2024, and that prior to joining its board he was chief commercial officer of Grunenthal, a private German company specializing in pain management.

Qbiotics managing-director Stephen Doyle said the company was “grateful to Mr Fladrich for stepping into the chair role, following the recent passing of our former chair, Dr Foden”.

“Mr Fladrich’s extensive industry experience and commitment to our vision make him well-suited for leading the company, moving forward, building upon the strong legacy that Dr Foden has left behind,” Mr Doyle said.

Qbiotics is a public unlisted company.

AUSBIOTECH, MTP CONNECT

Ausbiotech and MTP Connect say they have released a discussion paper ahead of their biotechnology and medical technology summit, in Canberra.

Earlier this year, Ausbiotech and MTP Connect said they would conduct a one-day summit to focus on improving development strategies in Australia for biotechnology and medical technology, in Canberra on November 19, 2024 (BD: Sep 19, 2024).

Today, a joint media release from the industry organizations, said that they had released a discussion paper, titled ‘National Biotech and Medtech Development and Commercialisation Summit 2024’

Ausbiotech and MTP Connect said the joint discussion paper related to “Australian and global policy contexts, stubborn industry challenges, and barriers to achieving robust development and commercialization outcomes”.

The organizations said they were “encouraging the sector to participate in shaping the summit's conversation” and that those attending the summit should read the discussion paper in advance “and be ready to engage in the room on the day”.