Biotech Daily

Wednesday November 23, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ANTISENSE UP 6.5%; EMVISION DOWN 11%**

*** CSL, UNIQURE WIN 1st FDA OK FOR HAEMOPHILIA B GENE THERAPY**

*** BRANDON LEADS $78m RAISE FOR MUNICH'S CATALYM**

*** VOLPARA H1 REVENUE UP 37% TO $16m; LOSS DOWN 38% TO $5m**

*** POLYNOVO COMPLETES $30m PLACEMENT**

*** VECTUS PLACEMENT FOR $3.5m; SHARE PLAN FOR $1m MORE**

*** LUMOS $2.3m HOLOGIC DEAL FOR 2 P-O-C TESTS**

*** HERAMED 1st HERACARE COMMERCIAL USE IN VICTORIA AT RWH**

*** MESOBLAST: 'REMESTEMCEL-L 51% 2-YEAR CHILD GVHD SURVIVAL'**

*** RACE US FDA PRE-IND 'POSITIVE' ZANTRENE GUIDANCE**

*** ACRUX 26% REMUNERATION REPORT 1st STRIKE**

*** MILFORD REDUCES TO 5.2% OF NEUREN**

*** ROBERT BRICE, JDB REDUCE TO 8.4% OF AUDEARA**

*** BVF DILUTED TO 11.6% OF BIONOMICS**

*** NEUROSCIENTIFIC APPOINTS CHAIR PAUL RENNIE INTERIM CEO**

MARKET REPORT

The Australian stock market was up 0.7 percent on Wednesday November 23, 2022, with the ASX200 up 50.5 points to 7,231.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Antisense was the best, up 0.6 cents or 6.45 percent to 9.9 cents, with 383,808 shares traded. Micro-X and Oncosil climbed four percent or more; Dimerix, Immutep and Prescient were up more than three percent; Avita, Cyclopharm, Genetic Signatures, Medical Developments, Pharmaxis, Pro Medicus, Proteomics and Telix were up more than one percent; with Cochlear, CSL, Nanosonics, Resmed and Starpharma up by less than one percent.

Emvision led the falls, down 23 cents or 11.2 percent to $1.82, with 68,139 shares traded. Polynovo lost 8.85 percent; Alcidion and Orthocell fell three percent or more; Impedimed, Imugene, Kazia, Next Science, Paradigm and Volpara shed more than two percent; Clinuvel, Mesoblast, Opthea and Universal Biosensors were down one percent or more; with Neuren down by 0.7 percent.

CSL

CSL say the US Food and Drug Administration has approved its Hemgenix, or etranacogene dezaparvovec-drlb, as the first gene therapy for haemophilia B.

In 2021, CSL said it had a $US450 million ($A583 million) agreement with Uniqure's for its AMT-061 gene therapy program for haemophilia-B (BD: Jun 25, 2020; May 6, 2021).

At the time, CSL said Uniqure would complete a 54-patient phase III trial of AMT-061 and scale-up manufacture while it would be responsible for regulation and commercialization.

Today, CSL said the FDA's approval of Hemgenix had been based on data from Uniqure's Hope-B trial demonstrating that factor IX activity increased 39 percent at six months post-treatment and remained stable at 36.7 percent at 24 months post-infusion.

CSL said Hemgenix reduces or eliminates the need for prophylactic therapy by helping patients to generate elevated and sustained levels of their own factor IX.

The company said that Hemgenix "generates elevated and sustained factor IX levels for years after a one-time infusion".

CSL said Hemgenix had been approved for adults with haemophilia B currently using a factor IX prophylactic, or with current and historical life-threatening haemorrhages, or repeated, spontaneous bleeding episodes.

CSL head of research and development and chief medical officer Dr Bill Mezzanotte said that "today's historic approval builds on our promise to put patients first in all that we do to discover, develop and deliver biotherapeutics and vaccines that meet their needs".

"With Hemgenix, we now offer a comprehensive portfolio of innovative medicines for haemophilia B, giving people living with the condition more choice in treatments and better and more durable control over their disease," Dr Mezzanotte said.

Uniqure chief executive officer Matt Kapusta said that the company had "always believed that gene therapy had the potential to provide transformative benefits to people living with haemophilia B and are excited that the haemophilia community will have a new, safe and effective treatment option available to them."

CSL was up 38 cents or 0.1 percent to $297.70 with 515,466 shares traded.

BRANDON CAPITAL

Brandon Capital says it has co-led a EUR50 million ($A77.6 million) raising for the Munich, Germany based Catalym for a phase II trial of its visugromab for solid tumors.

Melbourne's Brandon said that it co-led the series C financing with the Paris-based Jeito Capital and participation from existing investors Forbion, Novartis Venture Fund, Vesalius Biocapital III, Bayern Kapital, Biogeneration Ventures and Coparion.

Brandon Capital said that the funds would support the clinical development of visugromab, "a humanized monoclonal antibody engineered to neutralize the tumor-produced growth differentiation factor-15 (GDF-15) … [which] acts as a key regulator of immune cell activation and as an inhibitor of immune cell infiltration into the tumor tissue".

Catalym chief executive officer said Dr Phil L'Huillier said the "success of our series C financing, based on strong clinical data, is a further validation that visugromab is emerging as a new anti-cancer immune-therapeutic drug with the potential to transform the immuno-oncology landscape".

Brandon said the phase II program was based on "efficacy and durability results in advanced, last-line patients in phase I" and positive responses in the GDF-15 antibody-mediated human effector cell relocation phase II trial, evaluating visugromab with an anti-programmed death-1 (PD1) antibody in patients with advanced solid tumors.

The company said that Brandon partner Dr Jonathan Tobin and Jeito partner Dr Andreas Wallnoefer would be appointed Catalym directors.

VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the six months to September 30, 2022 was up 37.0 percent to $NZ16,884,000 ($A15,677,000), with net loss after tax down 37.9 percent to $NZ5,286,000 ($A4,908,000).
Volpara said annual recurring revenue from provision of its mammography software and related services had increased to $NZ29.0 million.
The company said that software-as-a-service generated $NZ11,948,000, software maintenance $NZ3,338,000 and capital sales $NZ659,000, with $NZ745,000 from lung contracts.
Volpara said its diluted loss per share fell 33.3 percent to 2.0 NZ cents and it had cash and cash equivalents of $NZ10,909,000 at September 30, 2022 compared to $NZ12,269,000 at September 30, 2021.
Volpara fell 1.5 cents or 2.3 percent to 65 cents.

POLYNOVO

Polynovo says it has completed a $30 million placement at $1.90 a share, and hopes to raise a further $20 million from directors and a non-underwritten retail share plan.
Polynovo announced the capital raising yesterday (BD: Nov 22, 2022).
Polynovo fell 18.5 cents or 8.85 percent to $1.905 with 3.8 million shares traded.

VECTUS BIOSYSTEMS

Vectus says it has “firm commitments” to raise $3.5 million in an institutional placement at 80 cents a share.
Vectus said the proceeds would be used to accelerate its phase Ib clinical trial for VB0004, for the prevention and reversal of fibrosis in the heart and kidneys, as well as development of other compounds and working capital.
The company said it hoped to raise a further $1 million in a retail share plan at the same price, with a record date of November 22, 2022.
Vectus was untraded at 96 cents.

LUMOS DIAGNOSTICS

Lumos says it will receive $US1.5 million ($A2.3 million) from the Marlborough, Massachusetts-based Hologic for the development of two women’s health tests.
Lumos said that the two programs focused on an undisclosed rapid point-of-care test and were expected to be completed “by the middle of 2023”.
Lumos chief executive officer Doug Ward said the company had “a long-standing commercial relationship with Hologic and are delighted to be awarded these two services agreements to assist with the development of their women’s health products”.
“I believe that strategic relationships which leverage Lumos’ [intellectual property] and know-how are likely to be a critical component of Lumos’ business plans going forward, so it is particularly pleasing that Hologic has been sufficiently impressed with our previous work to award us these two new services agreements,” Mr Ward said.
Lumos fell 0.3 cents or 5.7 percent to five cents with 1.4 million shares traded.

HERAMED

Heramed says that a private clinic at Melbourne's public Royal Women's Hospital will be the first Victorian clinic to use its Heracare connected maternity platform.
Heramed said that 'Melbourne Mothers' was Prof Vinay Rane's obstetrics and gynaecology clinic at Frances Perry House, which was part of Ramsay Health Care but housed at the Royal Women's Hospital.
Heramed said that it would earn $169,000 from 250 Heracare licences and a similar number of Herabeat foetal heart-rate monitors, to 250 mothers who would take part in the initial commercial rollout, lasting eight months.
The company said that on completion of the rollout, it expected to enter a long-term agreement for an annual purchase of up-to 1,500 Heracare and Herabeat licences.
Heramed was up half a cent or 3.45 percent to 15 cents.

MESOBLAST

Mesoblast says overall survival in children with acute graft versus host disease (GvHD) treated with its remestemcel-L is 51 percent at two years post-treatment.
Mesoblast said that its results compared with 25 percent to 38 percent overall survival at two years in published studies for children or adults with GvHD "who received best available therapy or the only approved agent in adults"
In 2018, Mesoblast said 38 of 55 children (69.1%) in its open-label, phase III trial of remestemcel-L for acute GvHD survived to 180 days (BD: Sep 20, 2018).
Today, the company said the four-year observational cohort survival study was performed by the Center for International Blood and Marrow Transplant Research on 51 evaluable children with GvHD in its phase III trial.
Mesoblast said that overall survival was 63 percent at one year, 51 percent at two years, and 49 percent at three years, compared to 40 to 49 percent in best available treatment survival at year one, and 25 to 38 percent survival in best available treatment at year two.
The company said the long-term data was "a key component of its biologics licence resubmission to the US Food and Drug Administration" for remestemcel-L in children with acute graft versus host disease under 12 years.
In 2020, Mesoblast fell as much as 44.7 percent to $2.81 on news that the US Food and Drug Administration required a further trial of Remestemcel-L for graft versus host disease (BD: Oct 2, 2020).
Mesoblast fell one cent or one percent to 98.5 cents with 1.4 million shares traded.

RACE ONCOLOGY

Race says it has received "positive guidance" from the US Food and Drug Administration at a pre-investigational new drug application meeting for Zantrene.
In 2019, Race said the US Food and Drug Administration had placed a clinical hold on its investigational new drug application of Bisantrene (Zantrene) for acute myeloid leukaemia (BD: Apr 24, 2022).
Today, Race said that the FDA had indicated that the clinical hold issues raised in 2019 had been satisfactorily addressed, and had confirmed that the 505(b)(2) pathway was a viable route through which Zantrene might gain regulatory approval.
The company said it had "no current plans to undertake any clinical trials in the US, [but] receiving timely guidance from the FDA provides valuable commercial optionality as Race's clinical activities and partnership discussions continue to advance".
Race was up four cents or 1.8 percent to $2.30.

ACRUX

Acrux says its annual general meeting voted a remuneration report first strike with 20,144,078 votes (25.78%) against and 57,997,889 votes (74.22%) in favor.
Acrux said that a proposal to grant four directors $181,700 in “performance rights” faced 20,631,141 votes (25.37%) against and 60,704,656 votes (74.63%) in favor.
The 10 percent placement facility was opposed by 20.16 percent, with the re-election of Dr Geoff Brooke opposed by 17.15 percent of the meeting.
According to its most recent filing, Acrux had 286,191,484 shares on issue, meaning that the votes against the performance rights amounted to 7.2 percent of the company, sufficient to requisition extraordinary general meetings.
Acrux was unchanged at 6.7 cents.

NEUREN PHARMACEUTICALS

Auckland’s Milford Asset Management says it has reduced its substantial holding in Neuren from 8,041,925 shares (6.236%) to 6,771,157 shares (5.174%).
Milford said that between April 27, 2022 and November 22, 2022, it bought and sold shares, with the largest sale 354,666 shares on September 9, citing both $2,255,676 and $2,252,292 as the receipts, or about $6.36 and $6.35 a share respectively.
Neuren fell six cents or 0.7 percent to $8.56 with 290,541 shares traded.

AUDEARA

Brisbane’s Robert Price and JDB Services say they have reduced their substantial holding in Audeara from 11,165,726 shares (9.71%) to 9,715,950 shares (8.43%).
Mr Brice and JDB Services) said that between June 8 and November 22, 2022, they sold shares, with the largest sales 200,000 shares for $25,970, or 13.0 cents a share on July 5 and 200,000 shares for $17,982 or 9.0 cents a share on November 22, 2022.
Audeara fell half a cent or 5.75 percent to 8.2 cents.

BIONOMICS

San Francisco, Grand Cayman and New York based BVF says its 170,089,885 shares substantial holding in Bionomics has been diluted from 12.99 percent to 11.58 percent.
Last week, Bionomics said that it expected to raise $US5 million ($A7.4 million) on the Nasdaq in an underwritten offer at $US7.80 ($A11.59) per ADS (BD: Nov 17, 2022).
Bionomics fell 0.1 cents or 1.7 percent to 5.9 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed chair Paul Rennie interim chief executive officer, effective immediately.
In September, Neuroscientific said that chief executive officer and managing-director Matt Liddelow had resigned, effective immediately (BD: Sep 9, 2022).
Today, the company said Mr Rennie’s remuneration would “remain unchanged”, but he would be granted 2,000,000 performance rights, vesting on a phase I trial ethics approval.
Neuroscientific was up half a cent or five percent to 10.5 cents.