Biotech Daily

Thursday October 20, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: EMVISION UP 6%; USCOM DOWN 11%**

*** TELIX Q1 REVENUE UP 724% TO $55.3m**

*** NEUREN EARNS ACADIA $16m MILESTONE ON TROFINETIDE NDA**

*** RADIOPHARM INSTITUTIONS RAISE $5.5m; RETAIL $4.5 UNDERWRITTEN**

*** HYDRIX RETAIL RIGHTS RAISE $1.3m; TOTAL $3.4m**

*** CLINUVEL DOSES 1st SCENESSE FOR VITILIGO PATIENT**

*** SERVATUS ORAL BACTERIA TRIAL FOR RHEUMATOID ARTHRITIS**

*** PROTEOMICS $2m JOINT WESTERN AUSTRALIA DIAGNOSTICS FACTORY**

*** MICROBA, SYNLAB EXPAND DISTRIBUTION DEAL**

*** ACTINOGEN RECEIVES $4.2m FEDERAL R&D TAX INCENTIVE**

*** IMUGENE RELEASES 106m VOLUNTARY ESCROW SHARES**

*** AVITA $2.4m CEO, DIRECTORS' SHARES, OPTIONS AGM**

MARKET REPORT

The Australian stock market fell 1.02 percent on Thursday October 20, 2022, with the ASX200 down 69.4 points to 6,730.7 points. Seven of the Biotech Daily Top 40 were up, 25 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Envision was the best, up eight cents or 6.25 percent to $1.36, with 35,405 shares traded. Kazia climbed 5.9 percent; Actinogen and Antisense improved more than four percent; Dimerix was up 3.2 percent; with Alcidion and Impedimed up by more than one percent.

Uscom led the falls, down 0.7 cents or 10.8 percent to 5.8 cents, with 102,288 shares traded. Medical Developments and Starpharma lost seven percent or more; Immutep, Nanosonics, Oncosil and Telix were down six percent or more; Clinuvel, Prescient and Pro Medicus fell five percent or more; Opthea was down 4.5 percent; Avita, Cochlear, Mesoblast, Next Science and Paradigm were down more than three percent; Compumedics, Imugene, Nova Eye, Pharmaxis and Resmed shed more than two percent; Atomo, CSL, Cyclopharm, Cynata, Polynovo and Proteomics were down more than one percent; with Neuren down by 0.3 percent.

TELIX PHARMACEUTICALS

Telix says sales of its Illucix kit for prostate cancer imaging for the three months to September 30 are up 145.8 percent to $55.3 million compared to the previous quarter.
Telix said that receipts from customers for the three months to September 30 were up 718.9 percent to $44,525,000, compared to the previous three months $5,437,000.
In July, Telix posted its first commercial revenue saying it expected $22.5 million from sales of its Illucix prostate cancer diagnostic imaging agent between the April 4 launch and June 30, 2022 (BD: Jul 21, 2022).
Telix Americas chief executive Kevin Richardson said “sales have continued to increase each month, and we have continued to gather pace since reimbursement came into effect on July 1”.
Telix fell 43 cents or 6.7 percent to $6.00 with 2.8 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says Acadia has paid a $US10 million ($A16 million) after the US Food and Drug Administration accepted the new drug application of trofinetide for Rett syndrome.
In 2018, Neuren said Acadia Pharmaceuticals paid a $US10 million upfront fee for an exclusive licence for trofinetide in North America (BD: Aug 22, 2018).
Today, the company said the San Diego, California-based Acadia made the payment after the FDA accepted for review its new drug application, granted priority review, and assigned a Prescription Drug User Fee Act (PDUFA) action date of March 12, 2023.
Neuren said that if the application was approved by the FDA, the next milestone payment would be US$40 million, payable following the first US commercial sale of trofinetide.
The company said that in addition, it would be eligible for “double-digit percentage royalties on net sales of trofinetide in North America, plus milestone payments of up to $US350 million on achievement of a series of four thresholds of total annual net sales, plus one third of the market value of a Rare Pediatric Disease Priority Review voucher if awarded by the FDA upon approval of the NDA” estimated at $US33 million.
Neuren said it retained all rights to trofinetide for all countries outside North America and had a fully paid-up, irrevocable licence for use in those countries of the data generated by Acadia in its regulatory process.
Neuren fell one cent or 0.1 percent to $7.51 with 180,109 shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has raised about $5.5 million in the institutional part of its 14 cent a share rights offer, with Bell Potter to underwrite the retail offer to $4.5 million.
Yesterday, Radiopharm said it hoped to raise $10 million from the institutional and retail components of the entitlement offers (BD: Oct 19, 2022).
Today, the company said that Bell Potter Securities had “committed to fully underwrite the retail component of the entitlement offer of approximately $4.5 million”.
Radiopharm said the funds raised would provide it with runway through to the end of 2023, accounting for five phase I trials it expected to have underway by early next year, as well as later stage trials for Pivalate.
Radiopharm executive chair Paul Hopper said the company would have $36.9 million in cash and looked forward to 2023 when “we expect to have five phase I clinical trials underway” and progressed Pivalate into late-stage US trials, subject to a positive meeting with the US Food and Drug Administration.
Radiopharm fell 3.5 cents or 21.2 percent to 13 cents with 4.3 million shares traded.

HYDRIX

Hydrix says it has raised $1,292,822 in a one-for-two retail rights offer and shortfall facility at six cents a share, bringing the total raised to $3,366,409.
In September, Hydrix said it had raised about $2.07 million in a “fully subscribed” institutional component of the entitlement offer (BD: Sep 19, 2022).
Today, the company said the funds raised would support the services business’ growth, as well as the regulatory and marketing costs involved in its heart attack alert device.
Hydrix was untraded at 6.6 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first of up-to six-patients in its phase II trial of afamelanotide, or Scenesse, as a systemic monotherapy for vitiligo.
In May, Clinuvel said it had approval for an up-to six-patient study of sub-cutaneous 16mg afamelanotide in darker-skin vitiligo patients (BD: May 10, 2022).
Today, the company said patients would be dosed every two weeks for three months with a three-month follow-up, with the trial endpoint facial re-pigmentation.
Clinuvel head of North American operations Dr Linda Teng said the company expected to complete the treatment phase of the study by mid-2023, with results later in the year.
The company said that it planned late-stage vitiligo studies over the next 30 months and pending regulatory discussions and clinical results, the use of afamelanotide as both a monotherapy and combination therapy with narrow band ultra-violet B light (NB-UVB) would be pursued.
Clinuvel fell $1.05 or 5.5 percent to $18.05 with 58,999 shares traded.

SERVATUS LIMITED

Servatus says it will conduct a 45-patient “world-first human clinical trial” of its oral bacteria strains for rheumatoid arthritis.
Servatus said that its “live biotherapeutics” included selected specific bacteria strains that had shown the ability to modulate immune responses and regulate inflammatory signals.
The company said that the study was being conducted by the Sunshine Coast, Queensland Rheumatology Research Unit’s Prof Peter Nash, who was associated with the University of Queensland and Queensland’s Griffith University, and would assess the impact of the live bacteria on gut microbiome composition and function “and ultimately the association between a healthy gut and a reduction in the symptoms associated with [rheumatoid arthritis]”.
Servatus said that animal trials had “delivered very positive results”.
“We know the gut microbiome is important in the possible cause of, or one of the drivers for, rheumatoid arthritis and this is an exciting opportunity to test the beneficial effects of a novel live biotherapeutic,” Prof Nash said.
Servatus said its technology used “live bio-therapeutics derived from the human microbiome that has a different mode of action than existing drugs to suppress the production of inflammatory cytokines and improve the production of anti-inflammatory cytokines … [which were] secreted proteins that have a specific effect on the interactions and communications between cells”.
The company said that the trial would run for about 12 months, with final results expected by the end of 2023.
Servatus is a public unlisted company.

PROTEOMICS

Proteomics says with Bioplatforms Australia and the University of Western Australia it will invest $2 million over three years in a diagnostics factory.

Proteomics said Bioplatforms Australia would invest $1.7 million over the three years through the Federal Government's National Collaborative Research Infrastructure Strategy, with it and the University of Western Australia contributing $150,000 each.

The company said the project would increase capacity and throughput at the factory, taking its diagnostics capability to "industrial scale screening to explore biological markers across medicine, agriculture and the environment".

Proteomics managing-director Dr Richard Lipscombe said there were "clinical samples sitting in biobanks and sample repositories all over Australia that can be used to help combat chronic diseases".

"Similarly, analyzing seeds in national and international seed stores could help make breeding decisions that boost the world's agricultural output," Dr Lipscombe said.

"All these biological samples are a precious and limited resource," Dr Lipscombe said.

"By analyzing them faster and at greater scale we can accelerate the development of new precision diagnostic tests that could improve patient care or transform agriculture production," Dr Lipscombe said.

Proteomics fell 1.5 cents or 1.55 percent to 95 cents.

MICROBA LIFE SCIENCES

Microba says it will extend and expand its agreement with the Munich-based Synlab International GmbH for the distribution of its microbiome tests in Europe.

Microba said that under the expanded agreement, Synlab would distribute its tests in in Latin America as well as Europe and begin selling direct to consumers in an agreement to December 2028.

Microba head of services Bernie Woodcroft said "Synlab is the largest European clinical laboratory and medical diagnostic services company by revenue and number of tests, servicing around 100 million patients annually".

"Although progress was delayed by Covid-19, we have now laid the groundwork in Spain providing a blueprint for Synlab to expand into key countries they operate in," Mr Woodcroft said.

Microba was unchanged at 15.5 cents.

ACTINOGEN

Actinogen says it has received $4,165,402 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Actinogen said the rebate related to research and development expenditure for the year to June 30, 2022.

Actinogen was up half a cent or 4.2 percent to 12.5 cents with 3.6 million shares traded.

IMUGENE

Imugene says it will release 105,929,613 shares from voluntary escrow on October 26, 2022.

In its most recent filing, Imugene said it had 6,276,168,743 shares on issue, with no further shares in ASX or voluntary escrow.

Imugene fell half a cent or 2.9 percent to 17 cents with 9.15 million shares traded.

AVITA MEDICAL

Avita says shareholders will vote to issue $US1.5 million ($A2.4 million) in restricted stock units and options to four directors and chief executive officer James Corbett.

Avita said the annual general meeting would vote to issue $US1 million in options to chief executive officer James Corbett, vesting in four equal tranches, exercisable at $US5.64, being the share value at the date of issue and appointment, within 10 years.

The company said the meeting would vote to issue directors Lou Panaccio, Suzanne Crowe, Jeremy Curnock Cook, and Jan Stern Reed $US87,500 worth of restricted stock units and $US37,500 worth of options each, with the options exercisable at the company's share price on the date of grant, within 10 years.

Avita said the restricted stock units and options would vest 12 months after grant, with the options "subject to various performance or related criteria, including continuation of employment over the relevant vesting period".

Avita said shareholders would vote to elect as directors chair Mr Panaccio, Mr Corbett, Ms Crowe, Mr Curnock Cook and Ms Reed, the appointment of Grant Thornton as the company's accountant, the approval of amended bylaws, and an advisory vote to approve the company's compensation of its executive officers.

Avita fell 5.5 cents or 3.6 percent to $1.47.