Biotech Daily

Tuesday October 31, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ONCOSIL UP 8%; ADMEDUS DOWN 11%**

*** FEDERAL GOVERNMENT LAUNCHES $200m CSIRO INNOVATION FUND**

*** VICTORIA RESEARCH ACCELERATION FUND $3m FOR 13 PROJECTS**

*** VAXART TAKES OVER AVIRAGEN (BIOTA)**

*** ADHERIUM Q1 DELIVERS 7.5k SMARTINHALERS, 6.2k TO ASTRAZENECA**

*** BIONOMICS RECRUITS PHASE I BNC101 COLORECTAL CANCER TRIAL**

*** BOTANIX READY FOR CANNABIDIOL BTX1204 ATOPIC DERMATITIS TRIAL**

*** IMPEDIMED APPOINTS REGIONAL HEALTH FOR SOZO AUSTRALIA, NZ**

*** UK PHOENIX TO DISTRIBUTE RHINOMED MUTE**

*** LBT HAS TWO QUARTERS CASH, DESPITE PROJECTED BURN**

*** PRO MEDICUS TO LOSE 7-YEAR DIRECTOR RODERICK LYLE**

*** CLARITY APPOINTS PROF RICHARD WAHL ADVISOR**

MARKET REPORT

The Australian stock market fell 0.17 percent on Tuesday October 31, 2017 with the ASX200 down 10.1 points to 5,909.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Oncosil was the best, up one cent or eight percent to 13.5 cents with 2.4 million shares traded. Volpara climbed 7.3 percent; Cyclopharm was up 6.4 percent; Osprey improved 5.4 percent; Bionomics was up 4.6 percent; Medical Developments, Pharmaxis and Polynovo were up more than three percent; Factor Therapeutics rose two percent; with Compumedics, ITL, Nanosonics and Starpharma up more than one percent.

Admedus led the falls, down three cents or 11.3 percent to 23.5 cents with 1.9 million shares traded. Living Cell lost 9.1 percent; Benitec shed seven percent; Dimerix fell five percent; Cellmid and Viralytics were down more than four percent; Actinogen, Avita, Impedimed, Neuren and Prima were down more than three percent; Resmed fell 1.3 percent; with Clinuvel, Cochlear, CSL, Mesoblast, Pro Medicus and Sirtex down by less than one percent.

FEDERAL GOVERNMENT

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Federal Acting Minister for Industry, Innovation and Science Senator Michaelia Cash says the$200 million CSIRO Innovation Fund has made its first investments.

A spokesperson for the Minister said the amount made available in the first round of funding was undisclosed.

Media releases from the Federal Government and the CSIRO said that Main Sequence Ventures would manage the CSIRO Innovation Fund, with the first four recipients including the Brisbane-based Maxwell MRI, which was combining "deep learning with modern medical imaging … [to make] cancer diagnosis faster, more affordable and more accurate, starting with prostate cancer".

The other recipients were University of Sydney spin-out Q-CTRL to control errors in quantum computing, Sydney's Morse Micro to develop very low energy wireless devices and Sydney's Intersective developing technology for education.

"As part of the Turnbull Government's National Innovation and Science Agenda, the CSIRO Innovation Fund is designed to ensure our world-class research can be turned into the jobs and economic growth of the future," Ms Cash said.

The media releases said that Main Sequence Ventures would support "new spin-out and start-up companies, and [those] engaged in the translation of research generated in the Australian publicly-funded research sector".

CSIRO chief executive Dr Larry Marshall said the Fund and Main Sequence Ventures would help develop Australia's ideas and ensure a share of the rewards.

"Australia has never been short of great ideas, but the value is rarely captured domestically," Dr Marshall said. "It needs the horsepower of Australia's national science agency behind it."

The media releases said that the first Main Sequence Ventures investments in Q-CTRL, Morse Micro, Intersective and Maxwell MRI were expected to create more than 60 jobs.

The media releases said that the Fund comprised $70 million from the Federal Government, $30 million from CSIRO's WLAN program and private sector investment, with a target total value of $200 million.

VICTORIA GOVERNMENT

The Victoria Government says it has provided $3 million to 13 medical research projects to "fast-track breakthroughs in health and medical research".

In a media release, the Victoria Minister for Health Jill Hennessy said the inaugural round of the Victorian Medical Research Acceleration Fund invested $3 million in projects to "fast-track the translation of early stage health and medical research into everyday clinical practice and patient care".

The Government said that the process was overseen by the Science Medical Research and Technology Ministerial Advisory Panel of scientists, academics, clinicians and industry experts.

The media release said that the projects leveraged funding from philanthropic, industry and international sources, meaning a further $7 million would be invested in Victoria's leading medical research sector.

Ms Hennessy said the projects "show exactly why Victoria is at the forefront of ground-breaking medical research across the globe".

The media release said that the grants ranged from $500,000 to $97,403 across a range of disease, with the complete list of recipients available at: https://www.premier.vic.gov.au/new-research-to-fast-track-medical-breakthroughs/.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA)

Aviragen says it will merge with the privately held Vaxart Inc which was developing oral recombinant vaccines to become Vaxart Inc.

Vaxart chief executive officer Dr Wouter Latour said the transaction “gives us the opportunity to build on the positive phase II challenge study results we announced recently for our influenza oral tablet vaccine, as well as the excellent results we obtained in the safety and immunogenicity studies with our norovirus vaccine”.

“Additionally, it will provide us access to Aviragen's antiviral assets, including their BTA074 phase II program for the treatment of condyloma caused by [human papillomavirus] which is on track to complete enrolment this quarter and to report top-line safety and efficacy data in the second quarter of 2018,” Dr Latour said.

Aviragen chief executive officer Dr Joseph Patti said that following a comprehensive review of alternatives, the transaction with Vaxart would “complement Aviragen's focus on infectious diseases and position us to create both near and long-term value”.

Aviragen said the agreement was determined by assigning $US60 million to Aviragen for its assets and $US90 million in value for Vaxart's assets, so Vaxart's security-holders would own about 60 percent of the combined company and Aviragen investors 40 percent.

Aviragen said it would reduce its workforce by six to a total of 10 full-time employees, who would complete the BTA074 phase II clinical trial and assist with the transition.

In 2012, Biota moved from the ASX to the Nasdaq to merge with Nabi Pharmaceuticals for its $US54 million in cash, later settling for $US27 million, and was renamed Biota Pharmaceuticals and then renamed Aviragen (BD: Apr 23, Sep 18, Oct 26, 30, Nov 2012).

Following its move to the US, Biota lost its $US231 million contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to further develop its laninamivir anti-influenza drug with BARDA citing “concerns about the project with regard to the product manufacturing, clinical study enrolment pace, costs, and contractor performance” (BD: Apr 1, 2011; Apr 30, May 1, May 9, 2014).

It is believed that about 10,000 Australian based Biota investors still hold shares in Aviragen with only several hundred establishing US accounts and selling their shares.

Last night on the Nasdaq, Aviragen fell 15.0 US cents or 18.1 percent to 68 US cents (88.6 Australian cents, equivalent to 11.1 cents prior to the Biota-Nabi merger, when it was trading around $A1.00), with 15.1 million shares traded.

ADHERIUM

Adherium says it has delivered 7,500 of its asthma compliance devices with 6,200 devices delivered to Astrazeneca alone, in the three months to September 30, 2017.

In a teleconference, Adherium chief executive officer Arik Anderson said that Astrazeneca was funding the engineering projects and software support and the company expected to 25,000 devices this financial year.

Mr Anderson said that Adherium had receipts from customers of $622,000 for the three months to September 30, 2017, up 92.0 percent compared to $324,000 for the previous corresponding period and $213,000 for the three months to June 30, 2017.

Mr Anderson said the company was building its direct-to-consumer marketing system with its New Zealand electronic commerce website running and a marketing campaign underway.

Mr Anderson said the company had appointed chief financial officer Tim Marcotte and the head of marketing Vik Panda, who had taken control over the New Zealand direct-to-consumer program and was planning a US launch (BD: Sep 19, Oct 10, 2017).

Adherium fell 0.1 cents or 1.1 percent to nine cents.

BIONOMICS

Bionomics says it has complete recruitment in its up-to-60 patient, dose-escalation, phase I trial of anti-cancer stem cell drug BNC101 for metastatic colorectal cancer.
Bionomics said the open label, multi-centre, Australian trial aimed to demonstrate that BNC101 was safe, well-tolerated and able to delay disease relapse (BD: Apr 4, 2017).
Today, the company said BNC101 was an anti-LGR5 humanized, monoclonal antibody being developed to prevent or delay tumour recurrence by targeting LRG5 a cancer stem cell marker over-expressed in metastatic colorectal cancers and other solid tumor types.
Bionomics said that initial pharmaco-dynamic marker data was available and the recommended phase II dose level of 15mg/kg was confirmed.
The company said that target engagement had been demonstrated in patient tumor biopsy material and with no dose limiting toxicities or other significant safety issues, the phase I trial provided the first evidence confirming the mechanism-of-action in colon cancer patients through evaluation of gene expression in tumor biopsies.
Bionomics said that gene expression changes correlated with biopsy LGR5 expression.
The company said that colorectal cancer was the second most prevalent cancer type, with overall survival significantly behind other high occurrence cancers and a five-year survival rate of 12 percent with treatments having minimal therapeutic benefits.
Bionomics chief executive officer Dr Deborah Rathjen said the company was “very pleased that the recommended dose level of 15mg/kg has been confirmed and that BNC101 continues to be safe and well tolerated”.
“We anticipate that this data and further pharmaco-dynamic data from the clinical trial will be highly supportive of our ongoing out-licencing effort,” Dr Rathjen said.
Bionomics was up two cents or 4.6 percent to 45.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has ethics approval for an up-to 36 patient phase Ib trial of its synthetic cannabidiol BTX1204 for atopic dermatitis, delivered with its Permetrex technology.
Botanix said it was developing BTX1204 for mild to moderate atopic dermatitis, or serious eczema, which targeted multiple pathologies involved in the development of
The company said that the randomized, double blind, placebo-controlled safety and tolerability study would be begin at four Australian dermatology clinics immediately and was expected to be completed by July 2018.
Botanix said that the study would collect data on the improvement of atopic dermatitis lesions and symptoms of atopic dermatitis including itch, burning and stinging compared with the vehicle.
Botanix executive director Matt Callahan said the company was “very pleased to bring our second program into the clinic within 18 months of listing”.
“BTX1204 has the potential to provide a new solution to sufferers of atopic dermatitis which is safe and directly addresses the itch and inflammation, these patients endure,” Mr Callahan said.
Botanix said it could accelerate BTX1204 into the clinic based on its phase I study of BTX1503 for acne, which was completed in July 2017 because BTX1204 used the same active drug as BTX1503 (BD: Jul 3, 2017).
The company said that the ability to rapidly add new clinical programs which used synthetic cannabidiol and Permetrex was good for product development and partnering opportunities for the broader Botanix pipeline in psoriasis and other skin diseases.
Botanix fell 0.1 cents or 2.1 percent to 4.6 cents with 2.6 million shares traded.

IMPEDIMED

Impedimed says it has appointed the Sydney-based Regional Health Care Group as its exclusive Sozo distributor for Australia and New Zealand.
Impedimed said that Regional Health Care would be responsible for the sale of its Sozo bio-impedance body composition systems with its L-Dex lymphoedema diagnostic technology.
The company said it would provide Regional Health Care marketing and training materials and assist in other marketing efforts.
Impedimed chief executive officer Richard Carreon said the agreement was “a strategic partnership for the longer term with Regional Health Care Group playing a key role in working with us to build the business across a number of chronic disease markets”.
Regional Health Care general-manager Stephen Doorey said that Sozo platform was “a truly exciting medical technology that is well proven, accurate and will help many patients around the world”.
Impedimed fell 2.5 cents or 3.3 percent to 73.5 cents.

RHINOMED

Rhinomed says the Calverton, Nottingham UK-based Phoenix Healthcare will distribute its Mute nasal dilators through its network of independent pharmacy chains.
Rhinomed said that all four products including the trial pack and three Mute sizes would available.
The company said that Phoenix distributed to independent pharmacies and groups including Numark with a network of 3,500 pharmacies and Rowland which had 500 shops and an online presence.
Rhinomed was up half a cent or 2.8 percent to 18.5 cents.

LBT INNOVATIONS

LBT says its expected cash burn for the three months to December 31, 2017 would be $7,801,584 with cash at September 30, 2017 of $2,474,160.
LBT chief executive officer Brent Barnes told Biotech Daily that the company would have higher than unusual payments to begin sales of its automated plate assessment system (APAS), with sales expected to begin in January 2018.
LBT said that along with $2,474,160 at September 30, it received a $4,198,256 Research and Development Tax Incentive in October, with $2.37 million reimbursements expected from joint venture partner Clever Culture Systems AG and $2 million from its placement to China’s Autobio Diagnostic Co (BD: Oct 9, 27, 2017).
LBT was unchanged at 31 cents.

PRO MEDICUS

Pro Medicus says that director Roderick Lyle will retire at the conclusion of its annual general meeting on November 14, 2017.
Pro Medicus said that Mr Lyle had accepted the role of chair in the education sector and a directorship of a foreign-listed mining company and would no longer have sufficient time for the company at a level that shareholders expected and deserved.
The company said that Mr Lyle was appointed a director in November 2010 and had “contributed greatly to the development of the company’s strategy”.
Pro Medicus fell one cent or 0.15 percent to $6.70.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Prof Richard Wahl to its scientific advisory group.

Clarity said that Prof Wahl was the St Louis, Missouri-based Washington University School of Medicine Department of Radiology chairman and Mallinckrodt Institute of Radiology director.

The company said that Prof Wahl was "a world leader in the field of targeted radiopharmaceuticals for diagnosing and treating cancer" with an emphasis on positron emission tomography and multi-modality imaging, enabling precision diagnosis of cancers and other diseases.

Clarity said that Prof Wahl was "one of the inventors of radio-immunotherapy of lymphoma, which is a combination of radiotherapy and immunotherapy that facilitates targeted treatments and an inventor of US Food and Drug Administration-approved medical devices, including radio-nuclide guided biopsy.

The company said that Prof Wahl was previously Johns Hopkins University's professor of nuclear medicine.

Clarity said that Prof Wahl held a Doctor of Medicine for Washington University St Louis, held 18 radiology patents and published more than 400 peer-reviewed scientific papers and several books.

The company said that Prof Wald had received numerous awards and was previously chairman of the American Board of Nuclear Medicine and was elected as a member of the US National Academy of Medicine in 2015.

Prof Wahl said that "Clarity has made a significant contribution to the development and use of copper radio isotopes for diagnosis and therapy of cancer and other serious diseases".

"I am very excited about the potential of copper to answer a number of the limitations of radiopharmaceuticals today," Prof Wahl said.

Clarity's executive chairman Dr Alan Taylor said "Richard is a world leader in the radiopharmaceuticals space and we are very excited to have someone of his calibre joining our scientific advisory board".

"Not only his experience in clinical trials and product development will be invaluable to Clarity, his central location in St Louis will allow us to explore and implement a broader manufacturing and clinical trials site to industrialise our technology in the US," Dr Taylor said.

Clarity is a public unlisted company.