Biotech Daily

Monday July 15, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 8%; ACTINOGEN DOWN 10%**

*** VICTORIA'S INNOVATION MINISTER MARTIN PAKULA TALKS BIOTECH**

*** TELIX: FDA GUIDANCE FOR ZIRCON TLX250-CDX KIDNEY CANCER TRIAL**

*** TELIX 'CAPITAL RAISING' TRADING HALT**

*** IMUGENE BUYS CITY OF HOPE, VAXINIA CF33 ONCOLYTIC VIRUS**

*** OSPREY: H1 CUSTOMER RECEIPTS UP 67% TO $1.8m**

*** RHINOMED: 'PRONTO VAPOR DILATORS WIN CE MARK'**

*** OVENTUS: 1st 'MATERIAL CONTRACT' WITH UNNAMED US GROUP**

*** PHARMAUST ETHICS APPROVAL FOR DOG CANCER TRIAL**

*** BOTANIX: 'AB2367 KILLS CLOSTRIDIUM DIFFICILE IN-VITRO'**

*** MICRO-X TO BUILD ITS CARBON NANOTUBE X-RAY TUBES**

*** ADHERIUM WINS FDA 510(K) CLEARANCE FOR HAILIE SENSORS**

*** COGSTATE CHAIR MARTYN MYER, FAMILY INCREASE, DILUTED TO 15%**

*** WILLIAM GARNER TAKES 18.8% OF RACE**

*** RACE CEO PETER MOLLOY DILUTED BELOW 5%**

MARKET REPORT

The Australian stock market fell 0.65 percent on Monday July 15, 2019, with the ASX200 down 43.5 points to 6,653.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded.

Impedimed was the best, up one cent or eight percent to 13.5 cents with 2.4 million shares traded. Alterity (Prana) and Medical Developments climbed more than seven percent; Universal Biosensors improved 4.2 percent; Oncosil was up 3.9 percent; Ellex, Kazia, Neuren, Osprey and Volpara rose more than two percent; Benitec, Compumedics and Genetic Signatures were up more than one percent; with CSL, Cynata and Opthea up by less than one percent.

Actinogen led the falls for the second trading day in a row, down 0.1 cents or 10 percent to 0.9 cents, with 17.6 million shares traded. Dimerix fell 9.1 percent; Antisense and Imugene shed more than six percent; Polynovo lost 5.5 percent; LBT fell four percent; Mesoblast and Optiscan were down more than three percent; Avita, Nanosonics, Orthocell, Paradigm, Pharmaxis and Prescient shed more than two percent; Clinuvel fell 1.2 percent; with Cochlear, Cyclopharm, Pro Medicus and Resmed down less than one percent.

VICTORIA GOVERNMENT

The Minister for Racing, Job, Innovation, Trade, Tourism, Sport and Major Events is not an easy person to pin down.

We rescheduled the interview several times to avoid clashes with Parliamentary sittings and other events, but finally caught up this morning, with both Biotech Daily and the Minister celebrating weekend Australian Rules football wins.

(The Minister in charge of Melbourne's Parkville-centred biotechnology world is a Carlton supporter.)

Mr Pakula says that the Victoria Government has made major investments, not just in the Parkville Precinct and Monash University, under the previous Governments of Steve Bracks and John Brumby, but more recently under the Daniel Andrews Governments, including the Peter MacCallum Comprehensive Cancer Centre, the Olivia Newton John Cancer Research Centre, the expansion of research facilities at Footscray's Western General Hospital, the establishment of the Monash Heart Hospital, the development of the Medtech Actuator, support for the establishment of Biocurate and a collaboration with Johnson & Johnson to support innovation at Monash University.

"We've supported the Actuator through Launchvic, we've supported Biocurate," Mr Pakula said.

"We announced in the Budget support for the Australian Drug Discovery Centre at the Walter and Eliza Hall Institute, we announced support for the Aikenhead Centre for Medical Discovery at St Vincent's Hospital and through Launchvic and through our support for some of the start-ups in the [medical technologies] space, through support for the Actuator and Biocurate, we're hoping we'll see some real outcomes in terms of getting some of these small start-ups to the next stage," Mr Pakula said.

"The Actuator helps to bring together the work that the research institutions and the university sector are doing, with some of the ideas that young entrepreneurs come up with, and to provide some guidance and support to bring those ideas to commercialization," Mr Pakula said.

"It's about bringing ideas with research capability and a bit of funding support to help some of these start-ups on their way," Mr Pakula said.

Mr Pakula said the Budget included $150 million for a Victorian Jobs and Investment along with $250 for the Business Growth Fund, which would provide loans for companies with a lack of access to capital.

Mr Pakula quoted former Victoria Premier and Treasurer, now chairman of Biocurate, John Brumby saying that "you need a lot of different ideas going through the system to get one or two hits – companies that are actually going to take off, develop a product and become commercially viable".

“I recognize that disruption creates – and we’ve seen so much already – a real need for us to be on the ground floor of whatever is going to be the next wave of big employment-creating technology.

“Some of that is medical and biotech and some of it is in other forms of innovation,” Mr Pakula said.

“But the thousands of jobs rather than fives and tens of jobs tend to be where these companies are created, rather than when a city just has a branch office.

“So, we want to be the place where ideas flourish and where they get to commercialization and where companies start, so that we have great employment outcomes for young people.”

Mr Pakula cited CSL as “the anchor” of the biotechnology industry, or what the State Government calls the biotechnology “precinct”.

“They’re constantly investing in new technology. Vaccines technology is changing rapidly and they are at the forefront of that.

“The fact that they are there. They are one of the largest employers in the precinct.

“They draw skilled people toward them. They’re a magnet for smart graduates and people interested in medical technology and pharmaceuticals,” Mr Pakula said.

Next steps in innovation

Mr Pakula said he recently had discussions with Launchvic chief executive officer Kate Cornick about what would be the next step in the evolution of her organization and the general innovation agenda.

“We have so far invested very heavily in early stage start-ups and we’re thinking about whether we should be focusing slightly more heavily on mature start-ups, those that are looking to scale-up, rather just start-up,” Mr Pakula said.

He said that the $250 million Victoria Business Growth Fund would ensure that businesses had access to capital to move from being small enterprises to medium and larger enterprises.

“It’s often that lack of access to capital that holds businesses back.”

“I’m sure that there’ll be heavy demand for that capital that’s available.”

Mr Pakula said that the Minister for Precincts Gavin Jennings was looking at how Government could help to determine how precincts like Parkville, Fisherman’s Bend and Arden-Macauley grow-up.

“We want to make sure that these precincts have the kind of characteristics necessary to ensure that they do become a good eco-system,” Mr Pakula said.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has provided regulatory guidance for its phase III 'Zircon' trial of TLX250-CDx for imaging clear cell renal cancer.
Lats year, Telix said it had begun its 250-patient, Zircon, phase III imaging trial of TLX250, or 89-zirconium-girentuximab, for clear cell renal cancer (BD: Oct 23, 2018).
Today, the company said the FDA meeting was "successful and the company received clear guidance and support from the FDA to submit the regulatory package in the US".
Telix said the FDA "positively commented on the suitability of the company's product development strategy to attain eventual marketing authorization in the US, subject to review of the final clinical data from the Zircon study and approval of an acceptable [biologics licence application] submission".
The company said "the FDA clarified the scope of manufacturing data … including supporting stability studies and data to support product safety and efficacy".
Telix said it agreed with the FDA's suggestion "to request a waiver for additional non-clinical reproductive and developmental toxicity studies, reflecting the average "post-reproductive" age of patients typically administered the product".
Telix chief executive officer Dr Christian Behrenbruch said the meeting "paves the way for inclusion of US patients into the ZIRCON study".
"Telix also received valuable guidance in relation to attaining product approval for TLX250-CDx in the US," Dr Behrenbruch said.
Separately, Telix requested a trading halt "pending an announcement regarding a proposed capital raise".
Trading will resume on July 17, 2019 or on an earlier announcement.
Telix last traded at $1.67.

IMUGENE

Imugene says that through related company Vaxinia, it will acquire the City of Hope invented CF33 oncolytic virus technology to kill tumor cells.
Imugene said it would pay Vaxinia, whose major shareholder is Imugene executive chairman Paul Hopper, $462,500 in cash and $1,619,000 in shares, subject to conditions and shareholder approval.
The company said it would pay the Los Angeles-based City of Hope an undisclosed licencing fee, including upfront annual maintenance fees for the "exclusive world-wide rights to develop and commercialize" the CF33 oncolytic virus, funded through the company's current cash reserve.
Imugene said that CF33 was "a chimeric vaccinia poxvirus" from the laboratory of Prof Yuman Fong, a co-investor in Vaxinia and a former Viralytics executive.
The company said that Vaxinia would be eligible for further payments based on the achievement of milestones including US Food and Drug Administration investigational new drug approval and phase I clinical trial first patient dosing.
Imugene chief executive officer Leslie Chong said the company was "delighted to be able to licence such a promising next generation oncolytic virus in a competitive market place where big pharma companies are actively seeking [oncolytic virus] technologies".
"CF33 comes with robust intellectual property and long patent life, compelling pre-clinical efficacy and safety, and is anticipated to enter a phase I clinical trial in 2020," Ms Chong said.
Ms Chong told Biotech Daily that the patents would provide protection until 2037.
The company said it expected both acquisitions to be completed in September 2019.
Imugene fell 0.1 cents or 6.25 percent to 1.5 cents with 17.0 million shares traded.

OSPREY MEDICAL

Osprey says customer receipts from sales of its Dyevert Plus cardiac dye reduction system sales for the six months to June 30, 2019 was up 67.2 percent to $1,844,000.
Osprey said the three months to June 30 was the “19th consecutive quarter of unit growth for its dye saving technologies”.
According to its Appendix 4C quarterly report customer receipts for the six months to June 30, 2019 was up 67.2 percent to $1,844,000 compared to the previous corresponding period, with receipts from customers for the three months to June 30, up 64.7 percent to $990,000.
Osprey was up 0.2 cents or 2.7 percent to 7.5 cents with 2.3 million shares traded.

RHINOMED

Rhinomed says it has Conformité Européene (CE) mark for its Pronto rechargeable vapor release nasal dilator technology for sleep and decongestion.
Rhinomed said the CE mark allowed its Pronto Sleep and Pronto Clear products to be sold in Europe.
The company said the Pronto products were sold in 1,000 Walgreen pharmacies in the US and the Pronto range filled a demand in the congestion, cough, cold and allergy markets worldwide.
Rhinomed was up 1.5 cents or 6.1 percent to 26 cents.

OVENTUS MEDICAL

Oventus says it has its “first material contract with an unnamed American sleep medicine group” for its O2Vent platform for obstructive sleep apnoea.
Oventus said the group had eight clinical treatment sites in Texas, Arizona and New Mexico, with a minimum monthly quota of 20 devices to be delivered to patients, per site.
The company said it expected orders “to exceed these quotas once fully operational”.
Oventus said the agreement would be launched when the O2Vent Optima oral device had US Food and Drug Administration regulatory clearance.
Oventus chief executive officer Dr Chris Hart said the agreement was “the first we’ve announced in the US which will use our ‘lab in lab’ business model and one that we have signed in anticipation of FDA clearance of the company’s flagship device the O2Vent Optima”.
Dr Hart said contracts being negotiated in Canada where O2Vent Optima and Exvent were both cleared for sale.
Oventus was up 1.5 cents or 5.1 percent to 31 cents.

PHARMAUST

Pharmaust has it has ethics approval for its phase II clinical trial of monepantel tablets in dogs with B-cell lymphoma, starting by September 2019.
Pharmaust said the New South Wales Department of Primary Industry approved the trial of short-term anti-cancer efficacy and long-term anti-cancer maintenance.
In May, the company said a phase I trial showed that healthy beagles could be dosed with up to five tablets a day for nine days (BD: May 6, 2019).
The company did not confirm the number of dogs to be recruited or the dose the dogs would receive.
Pharmaust was up 0.3 cents or 6.0 percent to 5.3 cents with 1.1 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says that its cannabidiol antimicrobial platform and AB2367 program is effective against clostridium difficile in-vitro.

Botanix said that research conducted in collaboration with Monash University's Prof Dena Lyras showed that the marijuana-derived platform was effective against human and veterinary strains of the gram-positive bacteria Clostridium difficile and the "hypervirulent" epidemic strains ribotype 027 and ribotype 078.

The company said Clostridium difficile was "a gram-positive, spore-forming and toxin-producing bacterium that infects the intestinal tract, causing diarrhoea and in severe cases, life-threatening colitis".

Botanix chief executive officer Matt Callahan said the company was "overwhelmed by the potential this new data presents".

"Recently we announced the ground-breaking discovery that [methicillin-resistant staphylococcus aureus] superbugs do not develop resistance to cannabidiol, as part of our BTX1801 program," Mr Callahan said.

"Now we have shown cannabidiol is also an effective antibiotic against [Clostridium difficile], the bacteria that the US Centers for Disease Control and Prevention regards as a global threat requiring urgent and immediate action," Mr Callahan said.

Botanix was up three cents or 14.3 percent to 24 cents with 16.5 million shares traded.

MICRO-X

Micro-X says it will develop and manufacture its next generation of carbon nanotube x-ray tubes.

Earlier this month, Micro-X said the Paris-based Thales Group invested $10 million through a convertible note to fund its x-ray products and would contract Micro-X's engineering capability to build the core imaging system of Thales's high-speed airport checkpoint security system using carbon nanotubes cathodes (BD: Jul 2, 2019).

Today, the company said it had been developing its own carbon nanotube electron emitter to manufacture its x-ray tubes since 2017 and would no longer need to contract the emitter from a third party, Xinray.

Micro-X managing director Peter Rowland said that "the strategic and operational importance of having established and proven our own carbon nanotube and x-ray tube technology in-house cannot be overstated".

"We now have co-located with our product manufacturing in Adelaide, complete control of the technology which will shape our destiny with our current and future products as we develop and take to market the innovative x-ray products which only this technology can permit," Mr Rowland said.

Micro-X was up two cents or 7.7 percent to 28 cents.

ADHERIUM

Adherium says it has US Food and Drug Administration 510(k) clearance for its Hailie sensors for asthma and chronic obstructive pulmonary disease products.

Adherium said the FDA clearance was for over-the-counter sales of its Hailie sensors to be used with a range of existing inhalers.

The company said it was working with a number of parties in the US to commercialize its products further following the clearance.

Adherium was up 0.4 cents or 14.8 percent to 3.1 cents.

COGSTATE

Melbourne's Myer family has increased its holding in Cogstate from 18,493,214 shares to 21,467,786 shares but has been diluted from 17.27 percent to 15.11 percent.
The substantial shareholder notice said that between June 1, 2015 and July 8, 2019, Myer & Myer Pty Ltd, Myer Investments Pty Ltd, Max Myer, Edwina Myer, Lucy Myer and Martyn Myer bought shares and exercised options at prices ranging from 10.45 cents to 57 cents and were diluted in the recent $4 million placement (BD: Jul 8, 2019).
Cogstate was untraded at 21 cents.

RACE ONCOLOGY

William Garner says he has increased his substantial holding in Race from 11,634,166 (14.15%) to 16,414,927 (18.82%).
The substantial shareholder notice said on July 4, 2019 Mr Garner transferred 219,239 shares to non-related shareholders of a director related entity, and on July 12 acquired 5,000,000 shares through the conversion of 'performance' rights.
Race was untraded at five cents.

RACE ONCOLOGY

Race chief executive officer Peter Molloy says his 4,305,004 share-holding has increased but been diluted to below five percent.
Last year, Mr Molloy said his substantial holding had increased and been diluted from 4,020,000 shares (6.27%) to 4,278,593 shares (5.20%) (BD: Dec 24, 2018).
Today, Mr Molloy said he acquired 26,411 shares through an "in specie distribution of shares by Update Pharma", but was diluted to below five percent on July 12, 2019 due to the conversion of performance shares.
Biotech Daily calculates Mr Molloy retains 4.935 percent of Race.