# Biotech Daily

Monday May 20, 2019

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH EVEN: ORTHOCELL UP 6%; ANTISENSE DOWN 11%**

*** LONGAS MORPHOSEQ FOR DNA SEQUENCING; NICK MCCOOKE CEO**

*** FDA APPROVES LBT APAS INDEPENDENCE**

*** KAZIA, ALLIANCE PARTNER ON GDC-0084 FOR BRAIN METASTASES**

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*** JASON COLQUHOUN, 0971224 BC BELOW 5% IN THC**

*** OCH ZIFF EXITS TOTAL BRAIN**

*** CYNATA: DR BROOKE REPLACES DR CHIPLIN; HIRES DR LIPE**

*** IMUGENE APPOINTS DR JENS ECKSTEIN DIRECTOR**

*** BOTANIX APPOINTS VINCE IPPOLITO EXECUTIVE CHAIRMAN ON $400k PA**

## MARKET REPORT

The Australian stock market was up 1.74 percent on Monday May 20, 2019, with the ASX200 up 110.8 points to 6,476.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and five were untraded. All three Big Caps fell.

Orthocell was the best, up three cents or 6.1 percent to 52 cents, with 8.9 million shares traded. Volpara climbed 5.6 percent; Pro Medicus improved 4.8 percent; Medical Developments was up 3.5 percent; Compumedics, Cynata, Mesoblast and Universal Biosensors rose more than two percent; Kazia, Proteomics, Starpharma and Telix were up more than one percent; with Ellex and Nanosonics up by less than one percent.

Antisense led the falls, down 0.6 cents or 10.7 percent to five cents, with 1.3 million shares traded. Oncosil lost 9.0 percent; Immutep shed 6.7 percent; Alterity, Clinuvel and Neuren retreated five percent or more; Avita, Optiscan and Prescient fell more than four percent; Benitec was down 3.85 percent; Opthea shed 2.1 percent; Cochlear and Dimerix were down more than one percent; with CSL, Paradigm, Polynovo, Resmed down by less than one percent.

## LONGAS TECHNOLOGIES PTY LTD

The Sydney-based Longas says its Morphoseq ‘next generation [DNA] sequencing’ will save researchers time and money identifying disease targets.

Longas chairman and Brandon Capital managing-director Dr Stephen Thompson told Biotech Daily that current next generation sequencing was able to analyse up to 150 to 300 base pairs of human DNA at a time, and the 23 human chromosomes were composed of about 3 billion base pairs of DNA.

“We have found an elegant way of stitching together the short-read sequences into accurate long-read sequences,” Dr Thompson said.

“We are using proprietary reagents and an algorithm to analyse the data rather than having to build new hardware, which other companies are doing, Dr Thompson said.

“What it means to our customers, the research community and anyone doing clinical genomics, is that it will be easier, faster and cheaper to understand disease such as mutations in cancer and mutations causing other diseases,” Dr Thompson said.

Dr Thompson said the current DNA sequencing market was worth $US6 billion and was growing at more than 10 percent a year, with Pacbio the market leader and in the process of being bought by the San Diego, California-based Illumina for $US1.2 billion.

In a media release, Longas said it was officially launching the Morphoseq long-read DNA sequencing technology and had appointed Nick McCooke as its chief executive officer.

Longas said that Mr McCooke was formerly the chief executive officer of the University of Cambridge-based Solexa Inc which was later acquired by Illumina for its next generation DNA sequencing technologies.

The company said that its Morphoseq technology was developed by a team led by its chief scientific officer and computational biologist Prof Aaron Darling.

Longas said Morphoseq converted “short-read sequencers into ‘virtual long-read’ sequencers, enabling finished-quality genome assemblies with high accuracy, including resolution of difficult-to-assemble genomic regions”.

The company said it was a spin-out from the University of Technology Sydney’s Ithree institute, funded by the Medical Research Commercialisation Fund managed by Brandon Partners and investment from its founders and directors, Prof Darling, Dr Catherine Burke and Prof Ian Charles.

“The rise of high-throughput, low cost DNA sequencing has made genome sequencing routine and affordable, but has come at the cost of read length,” Prof Darling said.

“It is very difficult for assembly methods to resolve genomic repeats that are longer than the read length,” Prof Darling said.

“But long repeats are present at many of the most clinically informative parts of genomes, such as drug resistance genes in bacteria and the [major histocompatibility complex] locus in humans,” Prof Darling said.

“The ability to accurately assemble and phase these into individual chromosomes for humans and microorganisms has important clinical and epidemiological applications,” Prof Darling said.

Longas said that Mr McCooke had been a non-executive director since 2015 and as chief executive officer would lead commercialization and industry partnering.

The company said Mr McCooke was a director of Evonetix and Bioventix and previously held board and executive positions in the UK, Belgium, US and Japan, with Biogazelle, Oxford Cancer Biomarkers, Pronota, Rapigene, Innovex, Quintiles and Celltech.

According to his Linkedin profile Mr McCooke holds a Bachelor of Science and a Master of Science from the University of Birmingham, England, and a Master of Business Administration from London Business School.

Longas is a private company.

## LBT INNOVATIONS

LBT says the US Food and Drug Administration has approved its 510k application for its automated plate assessment system (APAS) Independence instrument.
Last December, LBT said it had filed the application to the FDA for the APAS Independence (BD: Dec 21, 2018).
Today, the company said the approval was a milestone and it was “not aware of any other competing products cleared by the FDA for similar applications, making the APAS Independence the only commercially available instrument for the automatic reading of culture plates in the US”.
LBT said the APAS could process more than 200 culture plates per hour.
The company said there were more than 1,500 laboratories that exceeded the daily volume that would make the investment in an APAS Independence attractive.
LBT chief executive officer Brent Barnes said the FDA clearance was “a hugely exciting development as it secures LBT’s first mover advantage with the only FDA cleared Class II commercial product of its kind available for sale”.
“The focus now is on ramping up commercialisation activities in the region to convert interest into early sales,” Mr Barnes said.
LBT was in a trading halt for this announcement and last traded seven cents.

## KAZIA THERAPEUTICS

Kazia says it will conduct 150-patient phase II trial of GDC-0084 for brain metastases with the US Alliance for Clinical Trials in Oncology Foundation, its fourth trial of GDC-0084.
Kazia said the Boston-based Alliance was a cancer research network sponsored by the National Cancer Institute and the Alliance-run multi-centre study would investigate GDC-0084 with several other targeted cancer therapies for brain metastases.
Kazia said the four studies were: its own phase II clinical trial for glioblastoma; a phase II study with the Dana-Farber Cancer Institute for breast cancer that spread to the brain; a phase I study with the St Jude Children’s Research Hospital for childhood brain cancer; and the Alliance study, with the last three substantially funded by other parties.
The company said the Alliance study was expected to begin recruitment by the end of 2019 and take about two years to complete.
Kazia said it would provide support, including a grant and the study would be conducted under an investigator-led investigational new drug application with the US Food and Drug Administration, and Alliance would assume the primary regulatory responsibilities.
Principal investigator and Harvard Medical School medicine professor Prof Priscilla Brastianos said there was an urgent need to find better treatments for patients with brain metastases and “we hope this study will help us identify a new treatment paradigm”.
Kazia said that depending on the genetic profile of their tumor, patients would be allocated to receive either abemaciclib, entrectinib or GDC-0084.
The company said that up to 30 percent of patients with metastatic cancer would develop secondary tumors in the brain and there were about 200,000 new cases of brain metastases each year in the US alone, with average survival from three to 27 months.
The company said that only patients with a genetic alteration in the PI3K pathway would receive GDC-0084 and it was expected that about one third of the patients would be in this group, while patients with other genetic mutations would receive either abemaciclib, a CDK inhibitor approved for certain forms of breast cancer, or entrectinib a Trk/ALK inhibitor, which has not yet been approved by the FDA.
Kazia was up half a cent or 1.1 percent to 45 cents.

## NOXOPHARM

Noxopharm said that 11 of 16 prostate cancer patients have had prostate specific antigen (PSA) response when treated with NOX66 and 177Lu-PSMA-617.
Noxopharm said that five of eight patients treated at the 400mg dose of NOX66, or Veyonda, and six of eight patients treated at the 800mg dose had a PSA response "defined as a greater than 50 percent overall reduction in PSA.
The company said that the rate of 68.75 percent for the 11 responders compared "favorably with PSA response rates of 177Lu-PSMA-617 alone, ranging between 31 and 61 percent, in 10 published trials".
Last year, Noxopharm said it had been approved to increase the number of patients in its phase I trial of NOX66 for late-stage prostate cancer to 32 patients with metastatic castrate-resistant prostate cancer and no remaining treatment options and they would receive a combination of Lu-PSMA, or 177-lutetium-prostate-specific membrane antigen-617, and NOX66 with safety and prostate-specific antigen responses the main end-points (BD: Sep 5, 2018).
Noxopharm was up 10 cents or 18.2 percent to 65 cents with 1.1 million shares traded.

## ALCIDION

Alcidion says it has signed a contract worth about $700,000 for a proposed national child digital health record (CDHR) trial with two New South Wales health districts.
Alcidion said the initiative would provide a digital record of children's health and development information, currently captured in hard copy 'baby books'.
The company said the estimated total value of the contract was $700,000, to be recognized over the project in the 12 months to June 30, 2020.
Alcidion said it would deliver an operational child data hub and a New South Wales health jurisdictional translator would take information from operational systems and provide it to the hub.
Alcidion fell 0.3 cents or three percent to 9.6 cents with 5.05 million shares traded.

## IDT AUSTRALIA

IDT says the Australian Office of Drug Control has granted it a medicinal cannabis manufacturing licence.
IDT said the licence would allow the manufacture of extracts and tinctures of marijuana and marijuana resin.
The company said its licence allowed the supply, packaging, transport, storage, possession, control and disposal of the drug.
IDT said its manufacturing and packaging facilities already had a good manufacturing practices (GMP) licence and a Poisons Licence for handling Schedule 8 and 9 drugs.
IDT chief executive officer Dr David Sparling said the company was "extremely pleased to have secured a medicinal cannabis manufacturing licence from the Office of Drug Control".
"With IDT's long-established facilities and expertise in GMP pharmaceutical manufacturing, a licence in our own right to manufacture medicinal cannabis products puts IDT in a very strong position in the exciting and rapidly growing global medicinal cannabis market," Dr Sparling said.
IDT was up 5.5 cents or 37.9 percent to 20 cents with 7.6 million shares traded.

## MEDADVISOR

Medadvisor says its joint venture with Zeullig Pharma has signed the Manila, Philippines-based Medexpress Drugstores as its first customer in Asia.
Earlier this month, Medadvisor began a joint venture with the Hong Kong-based Zuellig Pharma to extend its medication management service in Asia (BD: May 7, 2019).
Today, the company said Medexpress Drugstores was the leading hospital outpatient pharmacy chain and delivery service drugstore in the Philippines and had 1.5 million customers in 50 hospitals.
Medadvisor was up 0.3 cents or 5.4 percent to 5.9 cents with 1.7 million shares traded.

## CARDIEX

Cardiex says that with its subsidiary Inhealth Solutions it has partnered with China's Health160, for a pilot program to deploy its tele-health products in China.
Cardiex said it had signed a memorandum of understanding with Health160 to help pilot its service on its smartphone applications, which had 167 million registered users.
The company said that revenue would be shared between the parties and the program would refine pricing, marketing strategies and products.
Cardiex said that on completion of the pilot program, Health160 and Cardiex would establish commercial terms on a long-term strategic partnership.
Cardiex chief executive officer Craig Cooper said it was a "major step forward for the Cardiex China growth strategy as previously announced to the market."
"Inhealth's programs address a significant unmet need in China for an effective health management system which operates outside of China's current hospital-based system," Mr Cooper said.
Cardiex fell 0.2 cents or five percent to 3.8 cents with 11.6 million shares traded.

## G (GEVA) MEDICAL INNOVATIONS

G Medical hope to raise at least USD17,000,000 ($A24,570,907) and list its American depository shares on the Nasdaq under the symbol GMVD.
G Medical said the offer would begin on June 3, 2019 with a US roadshow and founder and chief executive officer Dr Yacov Geva has agreed to convert $US2 million of loan funds into ordinary shares subject to shareholder approval, as well as the recently general meeting-approved loan conversion of $US3,317,500 ($A4,793,874) to shares.
The company Medical said it would remain listed on the ASX.
G Medical said HC Wainwright was the underwriter and sole running manager of the US public offering.
Further details are available at: https://bit.ly/30tc3tZ.
G Medical fell two cents or 10.3 percent to 17.5 cents with 1.9 million shares traded.

## ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says that it expects the registration of the shares and warrants held by Life Biosciences to be complete on or about May 21, 2019.
Alterity said it expected 269,905,533 shares and 539,811,066 warrants to be released from escrow on June 3, 2019.
The company said that following release it would have 860,837,432 shares available for trading on the ASX.
Alterity fell 0.2 cents or five percent to 3.8 cents.

## STEMCELL UNITED

Stemcell says it has completed the acquisition of 51 percent of Yunnan Haufang Industrial Hemp Co for RMB3.8 million ($A794,357) and 21 million shares.
Stemcell chief executive officer Phillip Gu said the acquisition would allow the company “to be a … channel for foreign hemp markets to access China’s closed hemp market”.
Stemcell was unchanged at 1.7 cents.

## THC GLOBAL

Jason Colquhoun and 0971224 BC Ltd say they have reduced their holding below the five percent substantial, selling 3,000,000 shares for $1,500,000 or 50 cents a share.
In the substantial shareholder notice Mr Colquhoun and 0971224 BC Ltd said the shares were reduced in an “off-market transfers” between May 2 and 17, 2019.
According to THC’s most recent Appendix 3B new share issue announcement, the company has 134,745,072 shares on offer, meaning that 0971224 BC’s 6,700,000 shares amount to 4.97 percent of THC.
THC fell two cents or 4.35 percent to 44 cents.

## TOTAL BRAIN

The New York-based Och-Ziff Holding Corp says it has sold all of its 47,100,794 shares and ceased its substantial holding in Total Brain.
Och-Ziff said it became substantial in 2013, buying shares at 30 cents each and last week said it reduced to 47,100,794 shares (6.06%) (BD: Aug 19, 2013; May 9, 2019).
Today, Och-Ziff said it sold 47,100,794 shares for $1,292,922 or 2.7 cents a share.
Total Brain fell 0.2 cents or 6.7 percent to 2.8 cents with 7.5 million shares traded.

## CYNATA THERAPEUTICS

Cynata says Dr Geoff Brooke will replace Dr John Chiplin as a non-executive director and Dr Suzanne Lipe has been appointed as head of alliance management.
Cynata said Dr Brooke had 30 years of experience in the healthcare industry and was a founder and managing-director of venture capital firms, GBS Ventures and Medvest.
The company said that Dr Brooke held a Bachelor of Medicine and a Bachelor of Surgery from the University of Melbourne and also held a Masters of Business Administration from the Lausanne, Switzerland-based International Institute for Management Development (BD: Mar 1, 2019).
Cynata said Dr Lipe had worked in biotechnology and pharmaceuticals for more than 20 years and had a Bachelor of Science, a Bachelor of Laws and a Doctor of Philosophy from the University of Melbourne.
The company said it had promoted product development head Dr Kilian Kelly to chief operating officer (BD: Jan 19, 2014).
Cynata said Dr Brooke had been granted 300,000 options exercisable at $2.11 each by May 16, 2024, vesting in three tranches over two years.
The company said it would grant 375,000 options to Dr Lipe, 750,000 options to Dr Kelly, and 300,000 options to senior project manager Dr Lynne Atley exercisable at $1.75 each by May 16, 2022.
Cynata said Dr John Chiplin was appointed as a director in October 2014.
Cynata was up 2.5 cents or 2.1 percent to $1.20.

## IMUGENE

Imugene says it has appointed Dr Jens Eckstein as a non-executive director, effective from today, May 20, 2019.

Imugene said Dr Eckstein recently became managing partner of the Hamburg, Germany-based Apollo Ventures and was previously the president of SR One, the corporate venture capital arm of the Middlesex, UK-based Glaxosmithkline.

The company said Dr Eckstein was the co-founder and director at the Waltham, Massachusetts-based Palleon Pharmaceuticals and Boston's Decibel Therapeutics.

Imugene said Dr Eckstein had been chairman and director at Thrasos Therapeutics, a director at Zapprx, Gladius Pharmaceuticals, and Alios Biopharma, and, a general partner at TVM Capital.

The company said Dr Eckstein has more than 15 years venture capital experience funding early to clinical stage biopharmaceutical companies, including founding Action Potential Venture Capital and creating Onestart, the world's largest life science accelerator.

Imugene said Dr Eckstein held several issued patents and had authored a number of scientific publications.

The company said Dr Eckstein help a Doctor of Philosophy from Germany's University of Konstanz and Harvard University.

Imugene said that subject to shareholder approval it had agreed to issue 25,000,000 options to Dr Eckstein over 24 months, exercisable at between 4.0 and 4.5 cents each, expiring three years after approval.

Imugene was unchanged at 1.7 cents with 5.8 million shares traded.

## BOTANIX PHARMACEUTICALS

Botanix says it has appointed Vince Ippolito as executive chairman and president starting on $400,000 a year.

Botanix said Mr Ippolito had more than 30 years' experience in the pharmaceutical industry, including 20 years working in dermatology, and had developed and launched more than 20 dermatology products in the US.

Botanix said Mr Ippolito was currently a director of the Santa Barbara, California–based Senuva Medical, and prior to that was the Long Beach, California-based Dermavant Sciences president and chief operating officer.

The company said that previously Mr Ippolito was the Palo Alto, California-based Anacor Pharmaceuticals chief commercial officer and had worked for the Bridgewater, New Jersey-based Medicis Pharmaceutical.

The company said Mr Ippolito would be responsible for all commercial operations.

Botanix said Mr Ippolito would be issued with 15,000,000 options exercisable at the higher of the closing share price before the day of issue or the 7-day volume weighted average price of the shares trading before the day of issue, with 12,000,000 of the options subject to shareholder approval.

Botanix said that Mr Ippolito would be paid $200,000 a year while he worked part-time, with a $400,000 a year salary when he moved to full-time.

Botanix was unchanged at 11.5 cents with 4.1 million shares traded.