



Biotech Daily

Monday October 22, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: DIMERIX UP 10%; AIRXPANDERS DOWN 12%**
- * **ONE WEEK TO AUSBIOTECH MELBOURNE, BRISBANE CONFERENCES**
- * **MEMPHASYS, ANOVA TO VALIDATE FELIX SPERM SEPARATOR**
- * **IMAGION RIGHTS OFFER RAISES \$411k OF HOPED-FOR \$4.3m**
- * **KAZIA, DANA-FARBER TRIAL GDC-0084 FOR BREAST CANCER TO BRAIN**
- * **ANTISENSE INVENTOR DR FRANK BENNETT SHARES \$4m PRIZE**
- * **RESAPP REQUESTS 'SMARTCOUGH-C-2 TRIAL' TRADING HALT**
- * **INVICTUS: CAPSTONE SUPPLEMENT MANUFACTURE FOR US LAUNCH**
- * **ACTINOGEN TO CLOSE XANAMEM ALZHEIMER'S TRIAL RECRUITMENT**
- * **PETER MANLEY REPLACES GENETIC SIGNATURES CFO MARK LANGAN**
- * **INVITROCUE: PROF IYER ADVISOR CHAIR, CSO DR DASGUPTA GOES**
- * **LBT LOSES 12-MONTH DIRECTOR MATTHEW MICHALEWICZ**
- * **ERLYN DALE, WINTON WILLESEE REPLACE CRESO CO SEC SARAH SMITH**
- * **NOXOPHARM APPOINTS DR GREG VAN WYK CMO**

MARKET REPORT

The Australian Stock Market fell 0.58 percent on Monday October 22, 2018 with the ASX200 down 34.6 points to 5,904.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and six were untraded. All three Big Caps fell.

Dimerix was the best, up one cent or 10.0 percent to 11 cents with 301,244 shares traded. Benitec and LBT climbed more than nine percent; Universal Biosensors rose 8.9 percent; Avita and Optiscan improved more than six percent; Prescient was up 5.5 percent; Imugene climbed 4.55 percent; Bionomics was up three percent; Opthea rose 2.5 percent; with Factor and Volpara up more than one percent.

Airxpanders led the falls, down one cent or 12.35 percent to 7.1 cents, with 1.5 million shares traded. Impedimed lost 10.2 percent; Actinogen fell 7.8 percent; Orthocell was down 6.25 percent; Immutep, Mesoblast, Neuren and Telix fell more than four percent; Paradigm and Resmed lost more than three percent; Clinuvel, Cochlear, Nanosonics and Starpharma shed more than two percent; CSL, Pharmaxis, Polynovo and Pro Medicus were down more than one percent; with Ellex down by 0.8 percent.

AUSBIOTECH

Ausbiotech says Biotech Invest event will be in Melbourne on next Tuesday, October 30, followed by its national conference in Brisbane from October 31 to November 2.

Ausbiotech said the Biotech Invest and partnering seminar provided companies an opportunity to present to, and meet, the investment community.

The industry organization said that the up to 40 companies would present to an expected 350 investors, including representatives from pharmaceutical companies.

Ausbiotech said that delegates would be able to use the online Bioinvest Partnering System to plan meetings.

The organization said that last year's national conference had more than 980 delegates from 18 countries and this year's conference was expecting more than 1,200 delegates and would feature an inaugural "early stage investment event".

Ausbiotech chief executive officer Lorraine Chiroiu said that "this year we are helping to service new areas of the pipeline and will be hearing pitches from a wide range of pioneering companies".

"At the National Conference we will hear from those at the beginning of their funding journey and at the Australia Biotech Invest and Partnering we will meet those who are further down the path to success," Ms Chiroiu said.

Ausbiotech said that keynote speakers included CSL chief medical officer Dr Charmaine Gittleton, Walter and Eliza Hall Institute director, Prof Doug Hilton; Pfizer, head of oncology external science and innovation Dr Denis Patrick and Endpoints editor in chief John Carroll.

The organization said the conference would host trade exhibitions, networking events and a partnering platform for delegates to facilitating collaboration and partnership opportunities with other attendees.

For more information and to register go to www.ausbiotechinvestment.com.au and www.ausbiotechnc.org or contact events@ausbiotech.org.

MEMPHASYS

Memphasys says the Stockholm, Sweden-based Anova Karolinska will conduct in-vitro assessments of its Felix sperm separation device.

Memphasys said the memorandum of understanding with Anova was the first of "a number of leading international andrology and [in-vitro fertilization] clinics" to assess the device.

The company said that Anova Karolinska would carry out clinical studies to assess the Felix device in its male infertility centre.

Memphasys said that the Anova Karolinska team would be led by the head of andrology laboratory Dr Lars Björndahl and would work with Felix co-inventor the University of Newcastle New South Wales Prof John Aitken on the clinical validation of the Felix device in a clinical setting.

The company said that Anova and Prof Aitken would work to validate the Felix system and confirm its application and efficacy in separating spermatozoa under clinical conditions from a range of clinical samples of human semen.

Memphasys said the first clinical versions of the device were expected to be available for clinical testing by April 2019, with Conformité Européenne (CE) mark approval for a European and Australian launch by the end of 2019.

Memphasys was up 1.9 cents or 59.4 percent to 5.1 cents with 175.8 million shares traded.

IMAGION BIOSYSTEMS

Imagion says its non-renounceable, one-for-two rights issue at four cents a share raised \$410,924 of a hoped-for \$4.3 million a (BD: Sep 20, 2018).

The company said that of the 107,147,608 shares available in the offer, it received applications for 10,273,098 shares leaving a shortfall of 96,874,510 shares, to which it reserved the right to place to sophisticated and professional investors within three months, with the Perth-based Pamplona Corporate as lead manager to the placement.

In September, Imagion said the funds would be used for a first-in-human study of its nanoparticles for the detection of cancer at the Houston, Texas-based MD Anderson Cancer Centre in early 2019 (BD: Sep 10, 2018).

Imagion was untraded at 4.1 cents.

KAZIA THERAPEUTICS

Kazia says that with the Dana-Farber Cancer Institute it will trial GDC-0084 for breast cancer that has spread to the brain in up to 49 women.

Earlier this month, Kazia said it would collaborate with the Memphis, Tennessee-based St Jude Children's Research Hospital in a 41-patient, phase I trial of GDC-0084 for paediatric brain cancer, in parallel with the 200-patient phase II trial of GDC-0084 for adults with newly-diagnosed glioblastoma multiforme (BD: Mar 29, Oct 3, 2018).

Today, the company said that the Boston-based Dana-Farber Institute would recruit between 22 and 49 patients for an open-label, phase II trial of GDC-0084 in combination with Herceptin, or trastuzumab, in patients with HER2-positive breast cancer that had metastasized to the brain.

Kazia said the trial was expected to take up to three years and the company would provide support including study drug and a grant.

The company said that about 20 percent to 30 percent of early-stage breast cancers were HER2-positive and these patients were generally treated with Herceptin, but breast cancer could spread, or metastasize, to other parts of the body, and in up to half of these cases it spreads to the brain.

Kazia said breast cancer brain metastases were "often highly resistant to Herceptin, in contrast to the original tumor" and there was a substantial need for new therapies.

The company said that research suggested that the PI3K pathway might be a part of the resistance mechanism, and there was "a sound rationale to explore GDC-0084, a brain-penetrant PI3K inhibitor, as a potential treatment for patients with breast cancer that has metastasized to the brain".

Kazia chief executive officer Dr James Garner said the company "strongly believe in the potential for GDC-0084 to bring benefit to patients with other forms of brain cancer beyond glioblastoma".

The company said that the first part of the study would be an open-label, single-arm study seeking preliminary evidence of efficacy for GDC-0084 in 12 patients in cohort A; and if there was evidence of response then an additional 25 patients would be recruited.

Kazia said that it would study the response of certain biomarkers to GDC-0084 using tissue samples from surgical resection in 10 to 12 patients in an exploratory cohort B.

The company said that the principal investigator was Dana-Farber Institute oncologist Dr Jose Pablo Leone and the study would be overseen by the Institute's head of metastatic breast cancer Dr Nancy Lin.

Kazia said the study was conditional on approval from the Institute's review board and was expected to recruitment by early 2019.

Kazia was unchanged at 38.5 cents.

ANTISENSE THERAPEUTICS

Antisense says the first named inventor on the original ATL1102 patents Dr Frank Bennett will share the \$US3 million (\$A4.2 million) Breakthrough prize in life sciences.

Antisense said that Ionis Pharmaceuticals head of research Dr Bennett shared the award with Cold Spring Harbor Laboratory's Prof Adrian Krainer "for the development of an effective antisense oligonucleotide therapy for children with the neurodegenerative disease spinal muscular atrophy".

On its website, the Breakthrough Prize Foundation said that with its sponsors Sergey Brin, Priscilla Chan and Mark Zuckerberg, Ma Huateng, Yuri and Julia Milner and Anne Wojcicki, it had awarded \$US22 million (\$A30.9 million) to nine researchers in life sciences, fundamental physics and mathematics.

The Foundation said that Dr Bennett and Prof Krainer "built upon their discoveries about antisense technology and the natural process of RNA splicing to produce the first drug to treat [spinal muscular atrophy] Nusinersen, marketed by Biogen as Spinraza", which was approved by the US Food and Drug Administration in 2016.

The Foundation said the work "paved the way for the possibility of new therapies using gene silencing modalities for Huntington's, [amyotrophic lateral sclerosis], spinocerebellar ataxias, Parkinson's and Alzheimer's".

The Foundation said the prizes would be presented on November 4, 2018 and broadcast live by National Geographic.

For more information go to: <https://breakthroughprize.org/News/47>.

Antisense was up 1.7 cents or 34.0 percent to 6.7 cents with 92.6 million shares traded.

RESAPP

Resapp has requested a trading halt "pending the release of an announcement regarding its US Smartcough-C-2 study results and analysis".

Trading will resume on October 24, 2018 or on an earlier announcement.

Resapp last traded at 22 cents.

INVICTUS BIOPHARMA

Invictus says that the Ogden, Utah-based Capstone Nutrition has begun manufacturing its sports and dietary supplements and food additives.

Invictus said that sales of its branded nutraceutical and sports nutrition products in "the high-growth US heart health and sports nutrition markets will generate revenues to fund clinical studies in high-value prescription medicines aimed at major human illnesses with large unmet medical needs".

The company said that Capstone was a leading US food additive contract manufacturer which was US Food and Drug Administration, current good manufacturing practice and Australian Therapeutic Goods Administration certified.

Invictus said that the first manufacturing run was expected to produce 60,000 packaged servings of each of its NE1-Elite and NE1-Heart products to support a US commercial launch, and help secure US distribution and start discussions with distributors.

Invictus executive chairman Dr Glenn Tong said that "after six years of research and development, the start of manufacturing is an important milestone in the development and expansion of the business".

"Sales of our nutraceutical products will underpin our future growth and the development of clinical studies for a number of promising prescription drug candidates," Dr Tong said.

Invictus is a public unlisted company.

ACTINOGEN MEDICAL

Actinogen says it will close recruitment to its phase II Xanadu trial of Xanamem for Alzheimer's disease on October 26, 2018.

Actinogen said that with 169 patients enrolled to date, it expected to enroll more than the planned 174 patients.

Actinogen chief executive officer Dr Bill Ketelbey said the company was "delighted to have reached this important milestone in our Xanadu trial".

Actinogen fell 0.4 cents or 7.8 percent to 4.7 cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed Peter Manley as its chief financial officer, effective from today October 22, 2018.

Genetic Signatures chief executive officer Dr John Melki said that Mr Manley had a "wealth of senior financial leadership experience ... [and would] play a key role in allowing the company to deliver sustainable growth and pursue growth opportunities".

The company said that Mr Manley was previous chief financial officer and company secretary for Sirtex Medical and Atcor Medical, now Cardiex, and previously worked for Dow Chemical and Goodman Fielder.

Genetic Signatures said that chief financial officer Mark Langan would continue as an advisor for an extended hand-over period.

The company said that Mr Manley held a Bachelor of Business from the University of Technology Sydney.

Genetic Signatures was unchanged at 58 cents.

INVITROCUE

Invitrocue says it has appointed Prof Narayanan Gopalakrishna Iyer as medical advisory board chair and will terminate Dr Ramanuj Dasgupta as chief scientific officer.

Invitrocue said that Prof Narayanan Gopalakrishna Iyer would assume the role of chair with immediate effect, with Dr Dasgupta departing on November 30, 2018.

The company said that medical advisors provided guidance on the development of its patient-derived cancer organoids, or Onco-PDO, and the expansion of the personalized tumor test business.

Invitrocue said that Prof Iyer had been a member of the advisory board since 2017 and was currently the leader of the National Cancer Centre of Singapore's Cancer Therapeutics Research Laboratory and was a head and neck surgeon at the National Cancer Centre and Singapore General Hospital.

The company said that Prof Iyer was involved in research and led a number of research programs that aimed to determine prognostic factors in oral cancers, identifying the cause of head and neck cancers in young people and development of novel therapeutic strategies in treating these cancers.

Invitrocue said that Prof Iyer's research on the use of biomarkers to facilitate personalized patient-selection strategies was published in journals including Nature Medicine.

The company said that Prof Iyer held a Bachelor of Medicine and a Bachelor of Surgery from the National University of Singapore and a Doctor of Philosophy from England's University of Cambridge.

Invitrocue was untraded at 9.2 cents.

LBT INNOVATIONS

LBT says that non-executive director Matthew Michalewicz who was appointed in September 2017 has resigned, effective immediately (BD: Jun 5, 2017).

LBT said that Mr Michalewicz told the company he was “not in a position to contribute the necessary time to the company's affairs”.

LBT was up one cent or 9.5 percent to 11.5 cents.

CRESO PHARMA

Creso says it has appointed Eryln Dale and Winton Willesee as joint company secretaries, following the resignation of Sarah Smith.

Creso said that Ms Dale had experience in corporate governance and company administration having held positions as company secretary for a number of ASX listed public companies across a range of industries.

The company said that Ms Dale held a Bachelor of Commerce from Perth's Murdoch University.

Creso said that Mr Willesee was an experienced company secretary for ASX-listed and other companies across a range of industries and had been involved with ventures from early stage through to large capital development projects.

The company said that Mr Willesee held a Bachelor of Business from Perth's Edith Cowan University, a Master of Commerce and a Post-Graduate Diploma in Business from Perth's Curtin and a Graduate Diploma in Education from Perth's Notre Dame University.

Creso said that Mr Willesee and Ms Dale had worked with other marijuana companies listed on both the ASX and TSX, including MMJ Phytotech, and given the company's increased operations in Canada, were well placed to assist it.

Creso fell 8.5 cents or 14.4 percent to 50.5 cents with 1.9 million shares traded.

NOXOPHARM

Noxopharm says it has appointment Dr Greg van Wyk as its chief medical officer.

Noxopharm said that Dr van Wyk was “an experienced pharmaceutical industry physician who has led medical teams across Australasia and North-Western Europe”.

The company said that Dr Van Wyk had “postgraduate degrees in management and economics and experience ... across multiple therapeutic area” and brought clinical and business acumen to the role.

Noxopharm did not provide any further details.

Noxopharm fell three cents or 4.4 percent to 65 cents.