



Biotech Daily

Monday September 11, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PARADIGM UP 8%; MICRO-X DOWN 9%**
- * **RECCE PLACEMENT RAISES \$8m; RIGHTS OFFER FOR \$3m MORE**
- * **ANTEOTECH PLAN RAISES \$688k OF HOPED-FOR \$2m; TOTAL \$4.7m**
- * **PACIFIC EDGE FILES CXBLADDER MEDICARE LCD SUBMISSION**
- * **CORRECTION: PAINCHEK**
- * **IMUGENE: 'POSITIVE FDA FEEDBACK' FOR CD19 CAR MANUFACTURING**
- * **LUMOS VIRADX COVID, 'FLU TEST WINS FDA EMERGENCY USE**
- * **BCAL: 20 LIPIDS FOR BREASTEST FOR BREAST CANCER**
- * **GENETIC TECHNOLOGIES UNDISCLOSED GRANT FOR CANCER-RISK TRIAL**
- * **GENETIC TECHNOLOGIES: NATA OKAYS 3 MORE DISEASES ON TEST**
- * **BIOTRON PLEADS SCHULTZ TO ASX 24% RISE QUERY**
- * **FIREBRICK REQUESTS 'TRIAL RESULTS' TRADING HALT**
- * **AUSTRALIAN ETHICAL INCREASES, DILUTED TO 11% OF SOMNOMED**
- * **GZ FAMILY DILUTED BELOW 5% OF LUMOS**
- * **NAOS REDUCES, DILUTED TO 25% OF BTC HEALTH**
- * **CHAIR DR RICHARD, KAREN TREAGUS DILUTED TO 9% OF BTC HEALTH**
- * **GARY DOHERTY REPLACES EBR CFO FRANK HETTMANN**

MARKET REPORT

The Australian stock market was up 0.5 percent on Monday September 11, 2023 with the ASX200 up 35.6 points to 7,192.3 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, and seven traded unchanged. All three Big Caps fell.

Paradigm was the best, up 5.5 cents or 8.3 percent to 71.5 cents, with 928,843 shares traded. Pharmaxis climbed 5.4 percent; Starpharma was up 3.7 percent; Next Science and Orthocell rose more than two percent; Antisense, Mesoblast, Neuren and Opthea were up more than one percent; with Nanosonics up by 0.5 percent.

Micro-X led the falls, down one cent or 8.7 percent to 10.5 cents, with 376,248 shares traded. Actinogen lost 8.3 percent; SDI fell 7.4 percent; Dimerix shed 6.15 percent; Kazia lost 5.7 percent; Alcidion, Emvision and Proteomics fell four percent or more; Atomo, Cyclopharm, Cynata and Imugene were down more than three percent; 4D Medical and Impedimed shed more than two percent; Avita, Immutep, Medical Developments, Prescient and Telix were down more than one percent; with Clinuvel, Cochlear, CSL, Genetic Signatures, Polynovo, Pro Medicus and Resmed down by less than one percent.

RECCE PHARMACEUTICALS

Recce says it has commitments for an \$8 million placement at 44 cents a share, and hopes a one-for-26, non-renounceable entitlement will raise a further \$3 million. Recce said the 44 cents a share price was a 35.0 percent discount to the five-day volume weighted average price of 67.6 cents a share.

The company said the entitlement offer would have a record date of September 14, and would open on September 15 and close on September 27, 2023.

Recce said \$6 million would be used for its phase I/II urinary tract infection trial, phase II burn wound infection trial and phase II diabetic foot infection trial, with the balance for its pre-clinical portfolio, manufacturing costs, US expansion and general working capital. The company said that Canaccord Genuity (Australia) was the lead manager to the placement, with Ord Minnett as co-manager.

Recce fell 13 cents or 20 percent to 52 cents with 1.6 million shares traded.

ANTEOTECH

Anteotech says its share purchase plan has raised \$688,125 of a hoped-for \$2.0 million at 3.2 cents a share, taking the total raised with the placement to \$4,688,125.

In July, Anteotech said it had commitments for \$4.0 million in a placement at 3.2 cents a share and hoped to raise \$2.0 million through a share plan (BD: Jul 26, 2023).

Today, the company said the share plan subscriptions included \$120,000 from eligible company directors.

Anteotech said the share plan included one attaching option for every two shares purchased, exercisable at 6.4 cents within three years.

Anteotech fell 0.1 cents or 3.3 percent to 2.9 cents with 2.9 million shares traded.

PACIFIC EDGE

Pacific Edge says it has written submissions on the draft local coverage determination (LCD) that proposed US Medicare non-coverage for its Cxbladder cancer tests.

In July, Pacific Edge said its Medicare administrative contractor Novitas had delayed implementing a 'local coverage determination' that would have removed US Medicare cover for its Cxbladder-urine based bladder cancer tests, after warning some patients may have to pay (BD: Jul 6, 2023).

Later that month, the company said Novitas did not consider Cxbladder tests "medically reasonable and necessary" the threshold for US coverage (BD: Jul 28, 2023).

Today, Pacific Edge said it that its Cxbladder triage, detect and monitor tests should retain coverage based on its clinical value to patients, clinicians and healthcare payers.

Pacific Edge chief executive Dr Peter Meintjes said there was "no new information in these submissions, but they provide further context of a sensitive process and show the weight of opinion supporting the arguments for continued Medicare coverage".

The company said the material in the submissions included its medical rebuttal of Novitas' evidentiary review of the clinical evidence supporting Cxbladder tests, letters from three US urological associations, a submission providing a critique on the structure and approach of Novitas' local coverage determination and an open letter from 13 key urological opinion leaders.

Pacific Edge said written submissions closed September 9, 2023, and that Novitas and First Coast Service Options might take up-to a year from the original publication date on July 27 to withdraw or finalize the local coverage determination.

Pacific Edge was untraded at nine cents.

CORRECTION: PAINCHEK

Friday's article on Painchek had several small errors of fact.

The pain-detecting software picks up nine facial expressions not five, as reported; and the company has 700 aged care facilities under contract rather than "providers", with 300 beds in the UK, rather than 800 beds.

Painchek told Biotech Daily that Leecare Solutions is a partner in Australia and the UK, while Telstra Health is a partner in Australia only.

The errors were made by the alleged "fact-checking" Friday sub-editor, who said they were deeply pained by the experience but like TE Lawrence, chose not to show it.

The Painchek software application had not trouble differentiating the truth.

The sub-editor does not possess a Brough Superior motorcycle, nor a job at Biotech Daily. Painchek was unchanged at 2.8 cents.

IMUGENE

Imugene says it has "positive feedback" from the US Food and Drug Administration to improve the manufacturing process of its azer-cell therapy for blood cancers.

Last month, Imugene said it would pay Precision Biosciences up-to \$US227 million (\$A352 million) for its allogeneic, azercabtagene zapreleucel 'azer-cell' CD19 chimeric antigen receptor T-cell (Car T) therapy for autologous Car T-cell relapsed patients with blood cancers (BD: Aug 16, 2023).

Today, the company said the improved manufacturing process allowed for "increased robustness, consistency and scalability".

Imugene said the manufacturing process gave it the "potential to start a pivotal study in 2024 and become the first approved allogeneic Car T-cell therapy for cancer".

Imugene managing director Leslie Chong said having "FDA support on the manufacturing process that could be used for a pivotal trial is an extremely important milestone ... as it improves the overall robustness and scalability of the product."

Imugene fell 0.2 cents or 3.3 percent to 5.9 cents with 33.7 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has US Food and Drug Administration emergency use authorization for its Viradx Covid-19, influenza A and B rapid point-of-care test.

Lumos said the nasal swab test simultaneously tested for acute respiratory infections caused by the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), influenza A and influenza B viruses, with results within 15 minutes.

The company said it had received a US Clinical Laboratory Improvement Amendments (CLIA) waiver, meaning the test was of "insignificant risk for an incorrect result".

Lumos said that the FDA requested "some post-marketing studies that may require additional investment".

Lumos said it intended to offer the Viradx test to healthcare providers in the US through its sales channel for other point-of-care products for women's health, sexually transmitted diseases and infectious diseases.

The company said the inclusion of Viradx would expand the products available in the US along with tests for chlamydia, gonorrhoea and, later this year, its Febridx product.

Lumos managing director Doug Ward said the emergency authorization was "an important addition to the suite of products that we will offer healthcare professionals through our recently established US sales channel".

Lumos was up 0.1 cents or 1.05 percent to 9.6 cents with 44.2 million shares traded.

BCAL DIAGNOSTICS

Bcal says it has confirmed 20 lipids, or fats, that will form the basis of its Breastest blood test for the detection of breast cancer, to be launched in 2024.

Bcal said the Breastest was based on changes in the lipid, or fat, composition in the blood of women who developed breast cancer and the test could detect the sum of the changes that defined a breast cancer signature.

The company said that to identify the specific breast cancer lipid signature it compared lipid profiles in samples of blood from more than 2,000 biopsy-confirmed breast cancer patients and health control subjects.

Bcal said the transformation of cells from normal to cancer was driven in part, and accompanied by, changes in the production and metabolism of some classes of lipids and it was these changes that constituted the Breastest lipid signature.

The company said it had applied for a patent for the 20-lipid signature.

Bcal executive chair Jayne Shaw said that confirming the identity and locking down the breast cancer signature lipids was “a crucial step towards providing the Breastest to the clinical community involved with the screening, care and management of breast cancer patients”.

“Next steps involve the clinical validation of the test,” Ms Shaw said.

Bcal was unchanged at 9.8 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says the Federal Government has provided an undisclosed grant to fund a 600-patient multi-cancer polygenic risk score trial.

Genetic Technologies said the randomized, controlled trial would study “the clinical utility and cost-effectiveness of a multi-cancer polygenic risk score in general practice” which included a Genetype multi-test for cancer screening and possible treatment.

The company said the trial would implement the breast, colorectal, prostate and melanoma polygenic risk scores from its Genetype multi-test and would “assess patient and provider behavior and assess the economic impact of the resulting behavior”.

Genetic Technologies said it would receive funding to cover the supply of its genomics test kits and the analysis of the returned samples.

Genetic Technologies was unchanged at 0.25 cents with 7.9 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says the National Association of Testing Authority has approved the addition of pancreatic cancer, melanoma and atrial fibrillation to its Genetype test.

Last year, the company said its Genetype Multi-test had Australian accreditation and US Clinical Laboratory Improvement Amendments approvals (BD: Feb 21, 2022).

At that time, the company said the test provided a risk assessment for breast, ovarian, colorectal and prostate cancers as well as coronary artery disease and type 2 diabetes.

Earlier this year, Genetic Technologies said it had begun the phase two-roll out of its Genetype Multi-test in the US, which included risk assessments for melanoma, pancreatic cancer and atrial fibrillation as well as six existing indications (BD: Mar 27, 2023).

Today, Genetic Technologies said the test could perform nine individual disease risk assessments from one saliva sample.

Genetic Technologies chief executive officer Simon Morriss said the approval to showed the ability to be “a world leader of in delivering personalized risk assessments to enable preventative healthcare for a range of serious diseases”.

BIOTRON

Biotron has told the ASX that it is not aware of any information it has not announced, which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 24.2 percent from a low of 3.3 cents to 4.1 cents today and noted a "significant increase" in the trading volume.

Biotron was up 0.2 cents or 6.1 percent to 3.5 cents with 24.4 million shares traded.

FIREBRICK PHARMA

Firebrick says it has requested a trading halt "pending an announcement about the results of its phase III common cold trial".

Trading will resume September 13, 2023, or on an earlier announcement.

Firebrick was untraded at 33 cents.

SOMNOMED

Australian Ethical Investment says its substantial holding in Somnomed has been increased and diluted from 10,164,754 shares (12.28%) to 10,544,525 shares (10.64%). Australian Ethical said that between May 29 and June 30, 2023 it bought 379,780 shares for \$353,059, or an average 93.0 cents a share, and was diluted due to the issue of 16,319,922 shares by Somnomed on September 8, 2023.

Last week, Somnomed said it raised \$2.75 million in placements and \$7 million in an institutional rights offer at 60 cents a share (BD: Sep 4, 2023).

Somnomed was up one cent or 1.7 percent to 61 cents.

LUMOS DIAGNOSTICS

GZ Family Holdings says its substantial holding has been diluted below five percent in Lumos due to the issue of shares and the conversion of convertible notes.

The Sydney-based GZ Family Holding said it held 21,930,614 shares which were diluted on August 3 and 10, 2023.

Last month, Lumos said its share plan had raised \$690,000 of a hoped-for \$4.75 million, taking the total raised to \$5.44 million, and that the funds would be used to buy back the remaining convertible notes issued to Lind Global Fund II and SBC Global Investment Fund in January (BD: Aug 3, 2023).

BTC HEALTH

Naos Asset Management and related parties say they have reduced their holding in BTC and been diluted from 80,260,587 shares (28.48%) to 80,065,587 shares (24.70%).

The Sydney-based Naos said on September 7, 2023 it sold 195,000 shares for \$4,038, or 2.1 cents a share and was diluted due to the issue of placement shares.

Earlier this month, BTC said it had "binding commitments" for a \$887,816 placement at 2.1 cents a share with Kingfisher Medical, Tau Medical and GLK Medical (BD: Sep 1, 2023).

BTC was untraded at 2.4 cents.

BTC HEALTH

BTC chair Dr Richard Treagus says he and his wife have had their 29,376,000 shares substantial holding diluted from 10.42 percent to 9.06 percent (see above).

[EBR SYSTEMS INC](#)

EBR says it has appointed Gary Doherty as its chief financial officer replacing Frank Hettmann, effective from today.

EBR said Mr Doherty had previously been chief financial officer at Acutus Medical and group plant controller at Volcano Corp.

The company said Mr Doherty held a Bachelor of Science in business administration from the San Diego State University.

EBR said that the current chief financial officer Frank Hettmann would remain with the company until November 30 to assist the transition.

EBR fell one cent or 1.2 percent to 84 cents.