

Biotech Daily

Thursday August 24, 2017

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ACRUX UP 8%, NANOSONICS DOWN 7%
- * CLINICAL GENOMICS HAILS 25m BOWEL CANCER TEST KITS
- * MRFF 1st GRANTS FOR ANTIMICROBIAL RESISTANCE, CLINICAL TRIALS
- * ONE WEEK TO APPLY FOR STC \$160k MEDTECH'S GOT TALENT
- * NOXOPHARM RAISES \$5.5m
- * NANOSONICS REVENUE UP 53% TO \$67.5m, PROFIT UP 2,134% TO \$26m
- * SOMNOMED REVENUE UP 12% TO \$49m, PROFIT TO \$3.5m LOSS
- * CRYOSITE REVENUE UP 0.3% TO \$10m, PROFIT DOWN 26% TO \$225k
- * POLYNOVO REVENUE UP 8% TO \$4m, LOSS UP 64% TO \$5m
- * IMPEDIMED: 'INDEPENDENT STUDY BACKS L-DEX FOR LYMPHOEDEMA'
- * SIX MONTHS TO ACRUX, ELI LILLY AXIRON APPEAL DECISION
- * OBJ EXPLAINS \$3.5m STAFF, CONSULTANT PERFORMANCE MILESTONES
- * CONSONANCE TAKES 6% OF SIRTEX
- * BLUECHIIP APPOINTS BLAIR HEALY DIRECTOR

MARKET REPORT

The Australian stock market slipped 0.14 percent on Thursday August 24, 2017 with the ASX200 down 8.3 points to 5,745.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and three were untraded.

Acrux was the best, up two cents or 8.2 percent to 26.5 cents with 101,132 shares traded. Admedus climbed 6.5 percent; Cellmid improved 4.2 percent; Clinuvel, Cochlear, Pharmaxis, Pro Medicus, Psivida and Starpharma rose one percent or more; with Medical Developments, Mesoblast and Sirtex up by less than one percent.

Nanosonics led the falls, despite increased revenue and profit, down 17 cents or 7.2 percent to \$2.19 with 7.8 million shares traded. Compumedics and Uscom lost more than five percent; Airxpanders, Benitec, Bionomics and Living Cell fell four percent or more; ITL and Orthocell were down more than three percent; Actinogen, Genetic Signatures, Impedimed, Osprey, Polynovo and Viralytics shed two percent or more; Avita, Neuren, Oncosil, Resmed and Universal Biosensors were down more than one percent; with CSL and Ellex down by less than one percent.

CLINICAL GENOMICS TECHNOLOGIES

Clinical Genomics says it has celebrated "a remarkable milestone after manufacturing its 25 millionth test kit for bowel cancer screening".

Clinical Genomics said the kit was developed in Australia, and based on the faecal immune-chemical test (FIT) methodology, was distributed as Insure FIT and locally as Colovantage Home through Australian doctors and pharmacies.

The company said that the US Multi-Society Task Force said that faecal immune-chemical tests, along with colonoscopy, were recommended as first tier tests for screening for colorectal cancer.

Clinical Genomics said its tests were preferred by both doctors and patients, due to the design and ease of use with a brush sampling technology to detect the presence of blood in water from the toilet bowl, instead of the user having to collect a stool or faecal sample, a requirement normally associated with other at-home collection methods.

The company said that bowel cancer was "one of the leading causes of cancer-related deaths worldwide, accounting for more than 700,000 deaths each year".

Clinical Genomics is a private company.

FEDERAL GOVERNMENT, MEDICAL RESEARCH FUTURE FUND

The Federal Department of Health says the Medical Research Future Fund's first two competitive grants for antimicrobial resistance and clinical trials opened today. The Department said the grants would be run by the National Health and Medical Research Council and would draw on its application and assessment processes. A Department media release said the grants for antimicrobial resistance research aimed "to stimulate research on novel and innovative methodologies, such as genomics, to determine antimicrobial resistance profiles and transmission within and to/from residential aged care facilities" and the research would assist promote and develop "optimal and appropriate antimicrobial use in residential aged care facilities".

The Department said that grants for "lifting clinical trials and registries capacity ... [would] stimulate clinical trial and registry activity with priority to be given to under-researched health priorities, such as rare cancers and rare diseases", with innovative trial designs and recruitment strategies and the application of precision medicine would be encouraged. The media release said that more information about the application process was available at: https://www.nhmrc.gov.au/grants-funding/apply-funding/medical-research-future-fund.

VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER (STC) AUSTRALIA

The Victoria and Federal Government-funded STC says applications close for the \$160,000 national 'Medtech's Got Talent' program on September 1, 2017. STC said the innovation talent quest also funded by MTP Connect was in its "fourth and largest year", it had expanded from Victoria-only to a national program and was seeking aspiring medical technologies entrepreneurs and innovators" (BD: Jul 25, 2017). STC said that contestants would receive support to develop an investible start-up pitch,

develop a go-to-market strategy and initiating commercial activities, with more than \$160,000 in cash prizes plus critical support, such as mentoring from Australia's leading commercialization and technology experts.

The organization said that the program culminated in 'investor deal pitch' on March 20, 2018 when the five finalists pitch to seed-stage investors, with the most investible team receiving an additional \$40,000.

For details, eligibility and to apply, go to: visit <u>www.medtechchallenge.com</u>.

NOXOPHARM

Noxopharm says it has raised \$5,500,000 in a placement to sophisticated and institutional investors at 33 cents a share.

Noxopharm said that the funds would enable it to accelerate the clinical development of NOX66 for cancer.

Noxopharm fell four cents or 9.3 percent to 39 cents.

NANOSONICS

Nanosonics says record revenue for the 12 months to June 30, 2017 was up 53.3 percent to \$67,507,000, with net profit after tax up 2,134.1 percent to \$26,158,000. Nanosonics said that North American revenue from its Trophon EPR probe cleaning systems increased 59.6 percent to \$62,305,000, Europe was up 57.7 percent to \$1,673,000 and the Asia Pacific region improved 30.4 percent to \$3,507,000. Nanosonics said research and development spending increased 30 percent to \$9,488,000 or 14.05 percent of revenue.

The company said that net tangible asset backing per share was up 28.3 percent to 24.46 cents, with diluted earnings per share up 2,165.0 percent from 0.04 cents to 8.70 cents. The company said it had cash and cash equivalents of \$62,989, 000 at June 30, 2017, compared to \$48,841,000 at June 30, 2016.

Nanosonics fell 17 cents or 7.2 percent to \$2.19 with 7.8 million shares traded.

<u>SOMNOMED</u>

Somnomed says revenue for the 12 months to June 30, 2017 was up 12.0 percent to \$49,451,210 with last year's \$165,005 net profit after tax turned to a \$3,508,883 loss. Somnomed said its core mouth guard anti-snoring device business improved but its direct-to-patient Renew Sleep Solutions start-up losses were \$4.1 million.

The company said that net tangible asset backing per share fell 11.1 percent to 36.04 cents for the year to June 30, 2017, diluted earnings per share of 0.32 cents turned to a diluted loss per share of 6.23 cents and it had cash and cash equivalents of \$14,210,321 at June 30, 2017 compared to \$17,632,252 at June 30, 2016.

Somnomed was up 30 cents or 9.2 percent to \$3.55 with 607,652 shares traded.

CRYOSITE

Cryosite says revenue for the 12 months to June 30, 2017 was up 0.3 percent to \$10,163,000 with net profit after tax down 25.5 percent to \$225,000.

Cryosite said that the market for private cord blood and tissue collection was "static, if not declining" and it would licence that business to Cell Care.

The company said that revenue from contract good manufacturing practice of specialized cell therapy products was "slightly down" with biorepository services down 17 percent, but consumer biologics revenue was up 3.8 percent.

The company said that no final dividend would be paid this year, following an unfranked dividend of 0.5 cents last year and an interim unfranked dividend of 0.5 cents.

The company said that diluted earnings per share fell 25.0 percent to 0.48 cents at June 30, 2017, with net tangible asset backing per share down 6.7 percent to 5.6 cents.

Cryosite said that it had cash and cash equivalents of \$5,089,110 compared to \$3,651,581 at June 30, 2016.

Cryosite was unchanged at 16.5 cents.

POLYNOVO

Polynovo says that revenue for the 12 months to June 30, 2017, was up 8.3 percent to \$3,759,032 with net loss after tax up 63.5 percent to \$5,006,014.

Polynovo said that revenue primarily came from its US Biomedical Advanced Research and Development Authority (BARDA) contract supplemented by initial sales of its biodegradable temporizing matrix (BTM) wound treatment.

The company said that diluted loss per share was up 45.0 percent to 0.87 cents, net tangible assets per share was down 34.8 percent to 1.5 cents, with cash and cash equivalents of \$5,496,609 at June 30, 2017, compared to \$10,746,691 at June 30, 2016. Polynovo fell half a cent or 2.6 percent to 18.5 cents.

IMPEDIMED

Impedimed says an independent study of 206 patients, co-authored by two of its staff, supports using its L-Dex for the early detection of subclinical lymphoedema.

Impedimed said that the Bethpage, New York-based Dr David Kaufman, a professor of surgery at New York University Medical Center, sought to examine the impact of a prospective surveillance protocol utilising bio-impedance spectroscopy (BIS) to detect breast cancer-related lymphoedema at a sub-clinical, reversible stage.

The company said that 206 consecutive patients at Dr Kaufman's clinic were prospectively monitored with the L-Dex diagnostic, including 30 at high-risk for developing lymphedema who had undergone axillary lymph node dissection.

Impedimed said that 9.8 percent of patients had an abnormally elevated L-Dex score, indicative of sub-clinical disease, at some point during their follow up, with that prevalence increasing to 23 percent for axillary lymph node dissection patients.

Impedimed said early intervention was a four-week regimen of an over-the-counter compression sleeve to prevent disease progression to a clinical and irreversible stage. The company said that none of the patients undergoing early intervention required complete decongestive physiotherapy for chronic, clinically detectable lymphoedema. The study, entitled 'Utilization of bioimpedance spectroscopy in the prevention of chronic breast cancer-related lymphedema' was published in Breast Cancer Research and Treatment and is at: https://link.springer.com/article/10.1007/s10549-017-4451-x.

The article concluded that the results "support prospective surveillance utilizing BIS initiated pre-operatively with subsequent post-operative follow-up measurements for the detection of subclinical [breast cancer-related lymphoedema]".

"Intervention triggered by subclinical [breast cancer-related lymphoedema] detection with an elevated L-Dex score was associated with no cases progressing to chronic, clinically detectable [breast cancer-related lymphoedema] even in very high-risk patients," the article concluded.

The study said that overall, 17 percent of patients had one high-risk feature, eight percent had two high-risk features and seven percent had three high-risk factors.

The published article said that median follow-up was 25.9 months and at last follow-up, no patients had developed chronic, clinically detectable, breast cancer-related lymphoedema. Impedimed chief executive officer Richard Carreon said the study reported "dramatically lower rates" of the chronic and irreversible affliction than reported in studies where patients had not been prospectively evaluated for breast cancer-related lymphoedema.

"This scientific validation of what I had previously believed to be true through my clinical experience, strengthens my resolve to offer this simple, accurate, and readily available surveillance tool to my patients," Dr Kaufman said.

Impedimed fell 1.5 cents or 2.4 percent to 61.5 cents.

<u>ACRUX</u>

Acrux says the Federal Circuit in Washington DC Court of Appeals has scheduled the Axiron patent appeal for October 5, 2017 (BD: Aug 23, 24, 2016; Aug 21, 2017). Acrux said a Federal Circuit decision was expected within six months. Acrux climbed two cents or 8.2 percent to 26.5 cents.

<u>OBJ</u>

OBJ says that \$3.54 million of salaries and consultants expenses were "a provision in the accounts for the expense of two ... performance milestones".

OBJ said that the milestones were approved at the 2014 annual general meeting and were required to be published in yesterday's Appendix 4E (BD: Aug 23, 2017).

The company said that the \$3.54 million figure was "based on the prevailing share price at the time shareholders approved the performance milestones in November 2014" when the company was trading around 9.5 cents.

OBJ said that its auditors took the view that the \$3.54 million figure should be published "based on independent legal advice ... that performance milestones 1 and 2 have been met, though these shares have not yet been approved ... to be issued".

OBJ was up 0.1 cents or 2.2 percent to 4.7 cents with 1.2 million shares traded.

SIRTEX MEDICAL

Consonance Capital Management says it has increased its substantial holding in Sirtex from 2,942,594 shares (5.13%) to 3,554,728 shares (6.20%).

The New York-based Consonance said that Goldman Sachs was a registered holder of the shares with Mitchell Blutt, Kevin Livingston and Benny Soffer as associated holders. Consonance said it bought shares between August 1 and 23, 2017 with the single largest acquisition yesterday August 23, of 142,297 shares for \$2,055,286 or \$14.44 a share. Sirtex was up nine cents or 0.6 percent to \$14.65 with 646,978 shares traded.

BLUECHIIP

Bluechiip says it has appointed Blair Healy as non-executive director, effective immediately.

Bluechiip said that Mr Healy had 17 years' experience in establishing, improving and selling technology companies, both publicly and privately.

The company said that Mr Healy graduated with a Bachelor of Engineering from the Canberra-based Royal Military College, Duntroon, and served in the Australian Army for eight years in technical and command positions, attaining the rank of Captain.

Bluechiip said Mr Healy was a systems engineering consultant in several large defence and public transport projects and worked for Fujitsu Telecommunications as research and development manager and Canada's Nortel Networks as business development and operations director for the Asia Pacific.

The company said that Mr Healy was previously Kusp chief executive officer and between 2008 and 2013 was the founder and managing-director of Cogent Energy and then Maxx Engineering managing-director.

Bluechiip was untraded at 2.8 cents.