



# Biotech Daily

Tuesday April 17, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH FLAT: IMPEDIMED UP 5%; USCOM DOWN 10%**
- \* **FDA CLEARS IMPEDIMED SOZO FOR BILATERAL LYMPHOEDEMA**
- \* **MAYNE US LAUNCH OF 200mg AMIODARONE FOR ARRHYTHMIA**
- \* **NOXOPHARM NOX66 PROSTATE CANCER TRIAL ENROLS 2<sup>nd</sup> COHORT**
- \* **CRESO WITHDRAWS 1.8m DIRECTOR, EVERBLU RIGHTS, OPTIONS**
- \* **SG HISCOCK TAKES 5% OF SOMNOMED**

## MARKET REPORT

The Australian stock market was flat on Tuesday April 17, 2018 with the ASX200 up 0.2 points to 5,841.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

Impedimed was the best, up 3.5 cents or 5.2 percent to 70.5 cents with 260,406 shares traded.

Dimerix climbed 4.35 percent; Avita was up 3.5 percent; Compumedics, Prana and Volpara rose more than two percent; Telix was up 1.6 percent; Cochlear, Optiscan and Pro Medicus were up more than one percent; with Clinuvel, CSL, Ellex, Medical Developments, Nanosonics, Resmed, Sirtex and Starpharma up by less than one percent.

Uscom led the falls, down 2.5 cents or 10.2 percent to 22 cents with 4,942 shares traded.

Benitec lost 7.1 percent; Airxpanders was down 6.25 percent; Psivida fell 5.2 percent; Admedus, LBT, Pharmaxis and Universal Biosensors were down more than three percent; Bionomics, Polynovo and Reva shed more than one percent; with Neuren and Viralytics down by less than one percent.

## IMPEDIMED

Impedimed says the US Food and Drug Administration has issued 510(k) clearance for its Sozo body composition diagnostic for bilateral lymphoedema in arms or legs.

Impedimed said that the clearance was to market Sozo “as an aid in the clinical assessment of bilateral lymphoedema in adult patient’s arms or legs”.

The company said that the clearance “greatly expands the available market for our technology”.

“Of the approximately one million new cancer cases per year in the US alone which put survivors at risk of limb lymphoedema, only 25 percent of them are breast cancers,” Impedimed said.

“The other 75 percent are pelvic-area cancers or melanoma, which most often put survivors at risk of bilateral lymphoedema,” the company said.

Impedimed said that Sozo with its unilateral and bilateral bio-impedance spectroscopy L-Dex allowed clinicians “to monitor all of these survivors with confidence, effectively quadrupling the total available market”.

The company said that the previous L-Dex U400 device was not capable of assessing bilateral lymphoedema.

Impedimed chief executive officer Richard Carreon said that the company was “excited for this new clearance and what it means for the patients we serve”.

“Now Sozo is able to aid in the clinical assessment of lymphoedema in the upper and lower extremities for both women and men who are at-risk of developing this debilitating chronic disease due to their cancer care,” Mr Carreon said.

“This is a significant advancement in our goal to play a greater role in the broader cancer market,” Mr Carreon said.

“This, our third 510(k) clearance in under 12 months for the Sozo platform, follows our recent clearance for monitoring fluid levels in heart failure patients, achieving yet another important regulatory milestone in our journey of providing a new and improved model of care, across the patient care continuum,” Mr Carreon said.

Impedimed said that the Sozo diagnostic used its bio-impedance spectroscopy technology to perform a full scan of 256 frequencies to provide detailed and accurate information on the fluid status of patients.

The company said that studies had shown detectable differences in extra-cellular fluid using its devices as low as 36ml in limbs and 100ml in whole-body measurements.

Impedimed was up 3.5 cents or 5.2 percent to 70.5 cents.

## MAYNE PHARMA GROUP

Mayne Pharma says it has launched 200mg amiodarone tablets for life-threatening recurrent ventricular arrhythmia the US.

Mayne said that Amiodarone was a generic alternative to Cordarone and the launch complemented the existing amiodarone product range of 100mg and 400mg dose strengths.

Mayne chief executive officer Scott Richards said that “amiodarone tablets are one of the first products to be manufactured at our new Greenville, North Carolina manufacturing facility which was recently completed”.

“This new solid oral dose manufacturing facility quadruples the company’s US manufacturing capacity to well over one billion doses and importantly introduces significant capacity to manufacture potent compounds and new capability to manufacture modified-release bead/pellet products,” Mr Richards said.

Mayne was unchanged at 71.5 cents with 6.4 million shares traded.

## NOXOPHARM

Noxopharm says it has been approved to enrol the second cohort of four patients in its 16-patient combination trial of NOX66 with 177-lutetium radiotherapy for prostate cancer.

Noxopharm said the 177-lutetium prostate-specific membrane antigen (Lu-PSMA) in combination with NOX66 (Lupin) study at Sydney's St Vincent's Hospital second cohort was approved following a first cohort review that showed an absence of adverse events.

The company said the open label, single arm, phase I pilot study's first two cohorts would receive 400mg of NOX66 increasing to 800mg for the third and fourth cohorts.

Noxopharm said that 177Lutetium-PSMA-617 was "an emerging and promising form of treatment for late-stage, metastatic prostate cancer" delivering radiation directly to prostate cancer cells through an intravenous injection.

Co-principal investigator Prof Louise Emmett said that clinical experience with Lu-PSMA was limited and it "appears to work well in about 60 percent of patients, but the benefit appears of limited duration in some men" and he hoped NOX66 would extend the benefit.

Noxopharm said the treatment course was six monthly injections, with efficacy being determined at three and 12 months on the basis of scans to measure the number and size of tumors and pain scores, with blood prostate specific antigen levels measured monthly.

The company said that three of four patients in the first cohort showed a fall in prostate specific antigen levels of between 78 and 85 percent, but the fourth patient progressed.

Noxopharm said the study was expected to complete enrolment by August 2018 and to complete the 12-month follow-up by August 2019.

Noxopharm was up one cent or 1.3 percent to 80 cents.

## CRESO PHARMA

Creso says it has withdrawn the issue of 1,800,000 performance rights and options to related party Everblu Capital "as a result of the changes to market conditions"

In February, Creso said it would issue 3,350,000 shares to advisors, with 1,800,000 performance rights and options to Everblu (BD: Feb 13, 2018).

Creso said at that time that Everblu was contracted for 18 months from July 1, 2017 to introduce and assess potential acquisitions, collaborations and opportunities, and explore dual-listing for 1,800,000 performance rights, vesting on the first of six months from grant or the share price exceeding \$1.00 for five consecutive days, as well as 1,800,000 options, exercisable at \$1.00 within three years from issue.

The company said Everblu would also receive a \$10,000 monthly advisory fee for each capital raising via equity or debt as well as a four percent fee for managing and marketing each capital raising via equity and a fee of two percent, subject to shareholder approval.

The company said that Everblu chairman Adam Blumenthal was a Creso director.

Today, Creso said the issue of securities to Everblu was to satisfy part of its corporate advisory fee and "incentivise Everblu" and the purpose for issuing directors securities "was to motivate and reward [their] successful performance and retention".

Creso said the issues of rights and options were subject to shareholder and ASX regulatory approvals and it had been consulting the ASX to ensure the proposed securities were appropriate and equitable from an ASX perspective.

The company said the consultation took "a couple of months ... [and]" "as a result of the changes to market conditions during this consultation process, the ... board has resolved that it no longer intends to issue the performance rights or options to Everblu or the directors" with no additional advisory fees paid to Everblu or remuneration to directors as a replacement of the previously proposed securities.

Creso climbed three cents or 4.8 percent to 65 cents.

## SOMNOMED

SG Hiscock, Aidan Brooksby and Lochinvar Securities have become substantial shareholders in Somnomed with 3,000,803 shares or 5.11 percent.

The Collins Street Melbourne-based SG Hiscock said the shares were held by the Sydney-based HSBC Custody Nominees, and the Melbourne-based Lochinvar and Mr The company said that on October 31 and December 11, 2017 it acquired 400,000 shares for \$1,406,000 or \$3.515 a share.

Somnomed was up four cents or 1.3 percent to \$3.07.