



Biotech Daily

Monday May 13, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ORTHOCELL UP 45%; LBT DOWN 12%**
- * **VOLPARA DENSITY 'EFFECTIVE IN BREAST CANCER RISK MODEL'**
- * **LIVING CELL: NTCELL SHOWS 'BENEFIT' FOR PARKINSON'S**
- * **BTC HEALTH PAYS \$6m FOR ADMEDUS INFUSION BUSINESS**
- * **AIRXPANDERS DUMPS REVENUE FORECAST; 2nd LOAN BREACH**
- * **FDA CLEARS SOMNOMED SOMNODENT AVANT**
- * **DIIS APPROVES IMAGION OVERSEAS R&D; EXPECTS \$1.7m**
- * **CORRECTION: NEXT SCIENCE**
- * **JOHN GLEESON TAKES 5% OF USCOM**
- * **REGAL FUNDS AGAIN REDUCE TO 11% OF VISIONEERING**

MARKET REPORT

The Australian stock market fell 0.21 percent on Monday May 13, 2019, with the ASX200 down 13.3 points to 6,297.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded.

Orthocell was the best, improving on last week's 282 percent rise, up 19 cents or 45.2 percent to 61 cents with 39.5 million shares traded.

Proteomics climbed 8.5 percent; Alterity, Optiscan and Pro Medicus were up more than six percent; Paradigm was up 5.5 percent; Kazia, Uscom and Volpara improved more than three percent; Clinuvel rose 2.9 percent; Avita, CSL, Dimerix and Mesoblast were up more than one percent; with Resmed up 0.4 percent.

LBT led the falls, down one cent or 12.2 percent to 7.2 cents, with 296,999 shares traded.

Osprey lost 7.7 percent; Impedimed fell 6.7 percent; Neuren, Prescient and Universal Biosensors shed more than two percent; Cochlear, Cynata, Nanosonics, Opthea and Pharmaxis were down more than one percent; with Compumedics, Ellex, Medical Developments, Starpharma and Telix down by less than one percent.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says a University of Virginia study shows its Volpara Density diagnostic software for breast density is effective in the Tyrer-Cuzick breast cancer risk model.

Volpara said its software measured breast density “automatically and objectively from a mammogram to generate a volumetric breast density score” which was a physical measurement of the breast tissue, instead of a radiologist making a visual assessment using the qualitative breast imaging-reporting and data system (BI-RADS) categorizations. The company said that the University of Virginia studied of 2,717 women, including 474 women diagnosed with invasive breast cancer and 2,243 controls.

The study, titled ‘A Case-Control Study to Add Volumetric or Clinical Mammographic Density into the Tyrer-Cuzick Breast Cancer Risk Model’ was published in the Journal of Breast Imaging and an abstract is available at: <https://bit.ly/2Vn0y3v>.

The abstract concluded that “the addition of volumetric and visual mammographic density measures to classical risk factors improves risk stratification”.

In a separate announcement, Volpara reported that the American Society of Breast Surgeons said that the Tyrer-Cuzick model was suitable for risk assessment, in an official statement, making recommendations on how to assess breast cancer risk with breast density as an input and how to act on the assessment.

Volpara chief executive officer Dr Ralph Highnam said the University of Virginia study showed that Volpara Density was “about equal to world experts in judging breast density ... [and did not] suffer from subjectivity and there are practical advantages to an automated system”.

Dr Highnam said that Volpara Density had been “in Tyrer-Cuzick for some time” the publication would assist in accelerating uptake and it was a “milestone” for the company. Volpara was up 5.5 cents or 3.4 percent to \$1.685.

[LIVING CELL TECHNOLOGIES](#)

Living Cell says that a two-year follow-up of its 18-patients, phase IIb study of NTCell for Parkinson’s disease shows non-statistically significant benefit over placebo.

Living Cell said the study had three groups of six patients, with two patients from each group having sham surgery, while the active cohorts received 40 microcapsules, 80 microcapsules and 120 microcapsules of the encapsulated pig brain choroid cell NTCell implanted on each side of the brain.

Last year, the company said there was a statistically significant difference at 80 weeks for the patients implanted with the 80-capsule dose ($p < 0.05$) (BD: Nov 2, 2018).

Today, Living Cell said that at 24 months post-implant the four people who received 80 capsules continued “to show a benefit as measured by the change in the Unified Parkinson’s Disease Rating Scale”, which was greater than the two in the placebo group, but not when compared to all the six placebo patients.

“Recipients of 40 capsules showed no difference from placebo,” Living Cell said.

The company said it was “seeking advice from both our statistician and a panel of internationally recognized experts on clinical studies in Parkinson’s disease to help interpret the data further”.

Living Cell chief executive officer Dr Ken Taylor said the company would confirm its strategy once it had the detailed analysis of the data.

“We anticipate that the input of our expert advisors in the coming weeks will shape our plans for the future of NTCell,” Dr Taylor said.

Living Cell fell 2.4 cents or 43.5 percent to 3.1 cents with 4.3 million shares traded.

[BTC HEALTH \(FORMERLY BIOTECH CAPITAL\), ADMEDUS](#)

BTC Health says it will buy the hospital infusion kit business from Admedus for \$6.3 million and hopes to raise \$8 million at eight cents a share to fund the acquisition.

In February, Admedus told the ASX it would divest its infusion business or raise funds if it did not have funds, and last week requested an extension to its voluntary suspension to finalize its re-capitalization plan (BD: Feb 20, May 7, 2019).

Today, BTC said the acquisition, through its subsidiary BTC Speciality Health Pty Ltd included the renewal of an eight-year exclusive distribution agreement with the Salt Lake City, Utah-based Summit Medical Products for the Ambit range of infusion pumps in Australia and New Zealand and a relationship with Melbourne's Sigma Healthcare, which would invest \$2 million in the \$8 million capital raising.

BTC executive chairman Dr Richard Treagus told Biotech Daily that the \$6.3 million purchase price would deliver a business unit with annual revenue of about \$7 million increasing at 14 percent a year, with \$800,000 of customers payments owing and \$950,000 in stock along with the transfer of employees including infusion business unit head Glenn Gilchrist and nine sales staff, and included \$1.75 million of working capital.

In its media release to the ASX, BTC said it would not acquire the rights to the Arcomed and Leventon range of infusion pumps which would remain with Admedus.

The company said the sale was expected to be finalized on May 31, 2019, subject to conditions including the funding through a private placement and share purchase plan.

Dr Treagus said the acquisition was "transformative" and brought "established revenues, a quality range of innovative hospital products and an experienced national sales and specialist education team".

"This gives the BTC Health group a platform for growth which can be leveraged to deliver strong organic growth and provide the capability and capacity for the introduction of new products from the BTC health pipeline," Dr Treagus said.

Admedus chief executive officer Wayne Patterson said the company restructure would enable it "to improve working capital management and reduce cash burn through reduction in headcount and focus on the Adapt portfolio".

Admedus is in an extended suspension and last traded at six cents.

BTC is in a trading halt for the capital raise and last traded at 8.5 cents.

[AIRXPANDERS](#)

Airxpanders says it does not expect to meet its 2019 forecast revenue of US\$11.5 million to US\$14 million (A\$16.5 million to A\$20.0 million).

Airxpanders said the change in the forecast revenue for its Aeroform post-mastectomy breast expansion system was due to the "recently announced organizational restructure" and it was not able to provide a revised revenue guidance.

Earlier this month, the company said it would reduce its workforce by about 45 percent, cutting expenditure by 33 percent to reduce costs and increase sales (BD: May 2, 2019).

Today, Airxpanders said it expected to "breach its minimum net revenue covenant for April under its debt facility with Oxford Finance LLC" and was in discussion with Oxford in relation to the previous and current breach (BD: Mar 29, Apr 2, 2019).

Airxpanders chief executive officer Frank Grillo said he was looking forward "to working with Cowen regarding our evaluation of strategic alternatives for the company".

Last week, Airxpanders said it had hired the New York-based Cowen Inc as an independent financial adviser (BD: May 9, 2019).

"We have a great product, loyal customers and enthusiastic patients," Mr Grillo said.

Airxpanders was in a suspension and last traded at 3.5 cents.

SOMNOMED

Somnomed says the US Food and Drug Administration has provided 510k clearance for its Somnodent Avant mouthguard anti-snoring device.

Somnomed said the Somnodent Avant has been developed for “precise fit and unsurpassed patient comfort” with an easy-to-use friendly adjustment mechanism.

The company said Somnodent Avant had a greater efficacy over previous products in its range.

Somnomed chief executive officer Neil Verdal-Austin said the company had “invested significant time and resources to ensure that our new digital manufacturing process will enhance and improve the quality of the range of Somnodent products”.

Somnomed was untraded at \$1.755.

IMAGION BIOSYSTEMS

Imagion says the Federal Department of Industry Innovation and Science has approved its off-shore claims for the Research and Development Tax incentive.

Imagion said it received the finding for expenditure from January 1, 2018 until December 31, 2020 of Australian and overseas research and development on its magnet-based imaging technology for detection of human epidermal growth factor receptor 2 (HER2) breast cancers.

The company said it expected to receive a Tax Incentive of about \$1.7 million for the financial year to December 31, 2018.

Imagion was untraded at 2.3 cents.

NEXT SCIENCE

In Friday’s edition reporting that Next Science would release 2,270,294 shares from ASX escrow on May 25, 2019, an incorrect number was given for quoted shares on the ASX.

A Next Science spokesperson told Biotech Daily that following the release of the shares, the company would have 104,884,253 quoted shares on the ASX, of which 39,823,525 were held in voluntary escrow; with a further 73,630,322 unquoted shares on issue and remaining in ASX escrow, along with 650,000 unquoted partly paid shares on issue and subject to voluntary escrow.

The mistake was made by the Friday Escrow Shares sub-editor, who has been sent home to revise her add-ups and subtracts.

Next Science climbed 16 cents or 7.7 percent to \$2.23 with 499,904 shares traded.

VISIONEERING TECHNOLOGIES

Regal Funds Management says that it has reduced its holding in Visioneering, again, this time from 29,793,065 shares (12.39%) to 27,458,740 shares (11.04%).

The substantial shareholder notice said that Regal Funds sold the shares between February 25 and March 28, 2019, with the single largest sale 380,638 shares for \$34,410 or 9.0 cents a share.

Regal Funds said that on March 29, 2019 it bought 30,000 shares for \$2,070 or 6.9 cents a share and the late notice was due to third-party “data feed issues”.

The company said that it last increased its holding in Visioneering in August 2018 to 33,106,832 shares (13.44%), buying 11,111,111 shares for \$2,000,000 or 18 cents a share, but since then has been reducing its holding (BD: Aug 21, 2018; Feb 27, 2019).

Visioneering was up 0.1 cents or 1.45 percent to 7.0 cents.

USCOM

The Sydney-based John Gleeson says he has become a substantial shareholder in Uscom with 7,013,679 shares or 5.1 percent.

Mr Gleeson said that he bought the shares between January 14 and April 12, 2019 with the single largest purchase 500,000 shares for \$69,759 or 13.95 cents a share.

Uscom was up half a cent or 3.2 percent to 16 cents.