



# Biotech Daily

Wednesday July 10, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: TELIX UP 12%; ANTISENSE DOWN 11%**
- \* **AIRXPANDERS: 'TGA LYMPHOMA FEAR MAY SUSPEND AEROFORM'**
- \* **BARD1 RIGHTS RAISE \$2.5m; TOTAL \$7.5m**
- \* **MEDIBIO TO RAISE \$4m IN PLACEMENT, SHARE PLAN**
- \* **CARDIEX: US EXPANDS BLOOD PRESSURE GUIDELINES; BENEFIT**
- \* **DIMERIX COMPLETES DMX-200 FSGS RECRUITMENT**
- \* **TOTAL BRAIN, 3 UNNAMED US COMPANIES PARTNER FOR MONITORING**
- \* **FACTOR BOARD SPILL GROUP WITHDRAWS SPILL REQUEST**
- \* **NEUROSCIENTIFIC RELEASES 1.16m ASX ESCROW SHARES**
- \* **AUSTRALIAN ETHICAL TAKES 16% OF COGSTATE**
- \* **DAGMAR DOLBY INCREASED, DILUTED TO 15% OF COGSTATE**
- \* **TOM GRANGER, ANACACIA, WATTLE BELOW 5% IN COGSTATE**
- \* **REGAL FUNDS TAKES 15% OF VISIONEERING**
- \* **WILLOUGHBY, HISHENK, ABOLAKIAN TAKE 17.5% OF KAZIA**
- \* **MACQUARIE BELOW 5% IN PATRYS; MASON STEVENS**

## MARKET REPORT

The Australian stock market was up 0.36 percent on Wednesday July 10, 2019, with the ASX200 up 24.1 points to 6,689.8 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and two were untraded. All three Big Caps rose.

Telix was the best, up 16 cents or 11.7 percent to \$1.53, with 1.6 million shares traded. Neuren and Paradigm climbed eight percent or more; Pro Medicus was up 6.5 percent; Clinuvel, Dimerix, Immutep, LBT, Opthea and Resonance improved four percent or more; Cochlear and Compumedics were up more than three percent; Cynata and Mesoblast rose two percent or more; Benitec, Ellex and Resmed were up more than one percent; with CSL, Cyclopharm, Nanosonics, Starpharma and Volpara up by less than one percent.

Antisense led the falls, down half a cent or 10.6 percent to 4.2 cents, with 348,641 shares traded. Polynovo lost 6.6 percent; Kazia, Orthocell and Patrys fell four percent or more; Oncosil was down 3.8 percent; Avita, Pharmaxis and Prescient shed more than two percent; with Genetic Signatures, Medical Developments, Osprey and Proteomics down by more than one percent.

## AIRXPANDERS

Airxpanders says that due to lymphoma fears, the Australian Therapeutic Goods Administration has proposed the suspension of its Aeroform breast tissue expander. Airxpanders said a decision had not been made to suspend the device from the Australian Register of Therapeutic Goods, which would halt sales and distribution of Aeroform in Australia for six months.

The company said the notice was the result of a TGA review of all textured breast implants on the Register, which tested relevant breast implants along with statistical and clinical analysis concerning the incidence of breast implant associated anaplastic large cell lymphoma and the implants associated with those cases.

Airxpanders said that although the notice said there had been no cases of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) associated with Aeroform, "the TGA considers that there are grounds to conclude that the potential risk of BIA-ALCL associated with the device outweighs any benefits of the device".

The company said it and its Australian sponsor Emergo Australia could make submissions in response to the notice by July 24, 2019, after which the TGA would make a decision which might require a recall and the removal of all remaining products from the market. Airxpanders said a recall "would only apply to product that is awaiting to be implanted and there is not a recommendation to remove implanted products".

Airxpanders chief executive officer Frank Grillo said the company was "very disappointed to see this notice".

"There have been zero cases of BIA-ALCL associated with the Aeroform device which is indicated for implantation for no more than six months," Mr Grillo said.

"According to literature reviews the median time of implantation of a breast implant and the onset of BIA-ALCL is eight years," Mr Grillo said.

"Due to the limited history of Aeroform in Australia, TGA has preliminarily concluded that any link between the device and BIA-ALCL is yet to be seen in Australia," Mr Grillo said.

"We believe the Aeroform tissue expander is safe, effective and provides a level of convenience highly desired by patients and their surgeons," Mr Grillo said.

"In addition, due to the much shorter implantation time we do not believe a tissue expander should be evaluated in the same manner as a permanent breast implant," Mr Grillo said.

"Regardless of the outcome of the notice, Airxpanders continues to work diligently to bring Aeroform Smooth Shell to the market as expeditiously as possible," Mr Grillo said.

"This product will no longer have a textured shell," Mr Grillo said.

Mr Grillo said the company expected US Food and Drug Administration clearance shortly and aimed for Conformité Européenne (CE) mark later this year.

Airxpanders was in an extended suspension and last traded at 3.5 cents.

## BARD1 LIFE SCIENCES

Bard1 says its partly-underwritten one-for-10 rights offer had applications for \$1,318,544 in shares of the \$2.5 million available, taking the total raised to \$7.5 million.

Last month, Bard1 said it raised \$4.97 million in a placement to investors including Merchant Opportunities Fund, David Williams and Jeffrey Emmanuel and expected to raise \$2.5 million in a rights issue (BD: Jun 18, 2019).

Today, the company said Merchant Corporate Advisory would place any unallocated shortfall shares, with \$200,000 of shares underwritten by companies controlled by directors Max Johnston and Philip Powell.

Bard1 fell 0.1 cents or 3.85 percent to 2.5 cents with 4.4 million shares traded.

## MEDIBIO

Medibio says it expects to raise \$4 million in a placement and share plan at one cent a share, a 51.6 percent discount to the July 4 five-day volume weighted average price.

Medibio said it had commitments for a two-stage \$3.5 million placement, subject to shareholder approval and would offer a share plan, which was underwritten to \$520,000.

The company said eligible shareholders would be offered one free attaching option for each new share, exercisable at three cents a share by December 1, 2021.

Medibio said the share plan would be underwritten by the Perth-based CPS Capital Group and the record date would be July 9, with the offer opening on July 22 and closing on August 20, 2019.

Medibio said the funds would be used for its US Food and Drug Administration de-novo application, to commercialize its Illumen cardiac rhythm-based test for mental health and to finalize its revised Conformité Européenne (CE) mark.

The company said CPS Capital Group was the lead manager to the placement.

Medibio said that two cent per share convertible note holders had agreed to early conversion at the one cent placement price, receiving one option for each share and reducing the company's contingent liabilities by about \$2.75 million.

Medibio fell half a cent or 26.3 percent to 1.4 cents with 16.9 million shares traded.

## CARDIEX

Cardiex says US guidelines have expanded ambulatory blood pressure monitoring and lowered the blood pressure threshold, expanding its potential market.

Cardiex said the US Centers for Medicare and Medicaid Services guidelines (CMS) would include masked hypertension in ambulatory blood pressure monitoring (ABPM).

The company said the threshold for blood pressure (BP) for hypertension would be lowered from 140mmHg systolic over 90mmHg diastolic (140/90) to 130/80.

Cardiex said this would increase access for ambulatory blood pressure measurement technologies such as its Sphygmocor system and Oscar 2.

Cardiex chief executive officer Craig Cooper said the new guidelines and expansion of Medicare coverage emphasized "the value of precise hypertension management and the growing need for more accurate technology to monitor blood pressure and related cardiovascular disease".

"Our expectation is that policy decisions such as the recent announcement by CMS will further support our sales growth objectives in both our existing and new product development," Mr Cooper said.

Cardiex was up 0.3 cents or 11.5 percent to 2.9 cents with 4.5 million shares traded.

## DIMERIX

Dimerix says it has completed recruitment of its 10-patient phase IIa trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS).

In February, Dimerix said it had recruited seven of 10 patients in the double-blind, randomized, placebo-controlled, crossover study to evaluate safety and efficacy of DMX-200 in patients receiving Irbesartan (BD: Feb 27, 2019).

Today, the company said patients would receive 16 weeks of DMX-200 and 16 weeks of a placebo, with a 6-week washout period.

Dimerix said it expected the first patient to complete treatment in August 2019, with results by July 2020.

Dimerix was up half a cent or 4.8 percent to 11 cents.

## TOTAL BRAIN

Total Brain says it has partnered with three unnamed US organizations to measure brain capacity, mental conditions and improve productivity of 70,000 employees.

Total Brain was up 0.3 cents or 12.5 percent to 2.7 cents.

## FACTOR THERAPEUTICS

Factor says the dissident investor group that were involved in the March board spill call and renewed the call in June have withdrawn their second board spill request.

Last month, Factor said it received a second call to remove chair Dr Cherrell Hirst, directors Dr Christian Behrenbruch, John Michailidis and Dr David Brookes, and appoint Darren Paul Olsen, Joshua John Wellisch and Shaun Menezes (BD: Jun 25, 2019).

The company said it had received a Notice under Section 249D of the Corporations Act 2001 requesting a meeting from Richsham Nominees Pty Ltd, DC & PC Holdings Pty Ltd, Alitime Nominees Pty Ltd and Pamela Christine Neesham.

Today, the Richsham Nominees and Pamela Christine Neesham, and Alitime Nominees said they had ceased their substantial shareholdings by ceasing to be associates.

Factor was unchanged at 0.4 cents with one million shares traded.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it will release 1,160,000 shares from ASX escrow on July 25, 2019.

According to its most recent Appendix 3B new issue announcement, Neuroscientific will have 55,882,595 shares available for trading, following the release from escrow, with a further 19,349,506 shares subject to ASX escrow until July 27, 2020.

Neuroscientific fell 1.5 cents or 4.7 percent to 30.5 cents with 2.7 million shares traded.

## COGSTATE

Australian Ethical Investment says it has become a substantial shareholder in Cogstate with 22,857,143 shares or 16.09 percent.

The Sydney-based Australian Ethical said it acquired the shares for \$4,000,000 or 17.5 cents a share in this week's \$4 million placement (BD: Jul 8, 2019).

Cogstate was up 2.5 cents or 16.1 percent to 18 cents.

## COGSTATE

Dagmar Dolby, as trustee for Dagmar Dolby Trust, says it has increased and been diluted in Cogstate from 19,776,389 shares (18.47%) to 21,391,389 shares (15.06%).

San Francisco's Dagmar Dolby said it acquired 1,615,000 shares for \$920,550 or 57 cents a share on September 5, 2018 and was diluted in the placement (BD: Jul 8, 2019).

## COGSTATE

Anacacia says it has been diluted below 5.0 percent in Cogstate, following the \$4 million placement to Australian Ethical Investment (BD: Jul 8, 2019).

In 2017, the Sydney-based Anacacia's portfolio manager Tom Granger said the company became a substantial shareholder with 6,246,216 shares or 5.5 percent as trustee for the Wattle Fund (BD: Dec 1, 2017).

Biotech Daily calculates that Anacacia retains 4.4 percent of Cogstate.

## VISIONEERING TECHNOLOGIES

Regal Funds Management says it has increased its substantial shareholding in Visioneering from 25,030,907 shares (9.24%) to 61,734,060 shares (15.47%). The Sydney-based Regal Funds said that between June 18 and July 5, 2019 it bought and sold shares, with the single largest sale 12,256,304 shares for \$661,949 or 5.4 cents a share and the single largest purchase 42,063,605 shares for \$1,892,862 or 4.5 cents a share. Last week, Visioneering said it raised \$5.8 million in a nine-for-19 rights issue at 4.5 cents a share (BD: Jul 1, 2019). Visioneering was unchanged at six cents.

## KAZIA THERAPEUTICS

Willoughby Capital, as trustee for Willoughby Capital Trust, says it has increased its holding in Kazia from 10,835,000 shares (17.4%) to 10,890,000 (17.52%). Last week, Hishenk said it held 10,835,000 shares or 17.4 percent of Kazia, with related parties MNA Family Holdings and Willoughby Capital acting for Willoughby Capital Trust (BD: Jul 4, 2019). Today, Willoughby said in a notice of change of interests signed by Stephen Abolokian that shares previously held by Hishenk would now be held by Willoughby. The Artamon, Sydney-based Willoughby said it acquired 7,220,000 shares in an off-market purchase on July 5, 2019 and Hishenk Pty Ltd sold 7,220,000 shares off market the same day. Willoughby said related party MNA Family Holdings acquired 55,000 shares for \$20,845 or 37.9 cents a share on market between June 26 and July 9, 2019. Kazia fell two cents or 4.65 percent to 41 cents.

## PATRYS

Sydney's Macquarie Group says it has ceased its substantial holding in Patrys selling shares at two cents a share in more than 750 small trades on July 5, 2019. Yesterday, Mason Stevens says it had ceased its substantial shareholding in Patrys, buying and selling shares in more than 70 transactions between August 2018 and July 2019. The Sydney-based Mason Stevens notice said that on July 5, 2019 it bought tens of millions of shares in more than 50 transactions with the single largest purchase 4,335,069 shares for \$101,874 or 2.35 cents a share; and sold 98,093 shares for \$100,929 or \$1.02 a share. The notice said "at the time of this notice Mason Stevens is advised of consolidated holdings (not specific trade information including consideration for each trade) from Bond Street Custodians (the custodian for Macquarie Investment Management) for securities that Mason Stevens Asset Management may acquire or dispose of as an investment manager". Biotech Daily believes the confusing announcements are related. Patrys fell 0.1 cents or 4.2 percent to 2.3 cents with 1.6 million shares traded.