



Biotech Daily

Monday April 9, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: COMPUMEDICS UP 6%; AIRXPANDERS DOWN 51%**
- * **AUSBIOTECH: 'R&D TAX INCENTIVE CAP WILL DAMAGE SECTOR'**
- * **BOTANIX COMPLETES CANNABIDIOL BTX1204 ECZEMA TRIAL ENROLMENT**
- * **OSPREY AGM FOR 2.4m DIRECTOR OPTIONS**
- * **ORTHOCELL EGM FOR 7.5m DIRECTOR, CFO OPTIONS**
- * **RESAPP REQUESTS 'TRIAL UPDATE' TRADING HALT**
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- * **DRH, DAVID HANNON REDUCE, DILUTED TO 6% OF NOXOPHARM**
- * **AIRXPANDERS SCOTT DODSON GOES, SCOTT MURCRAY INTERIM; SALES**
- * **SUDA APPOINTS DAVID PHILLIPS DIRECTOR**
- * **ANTEO LOSES CEO DR STEFAN ENDERLING, GAINS CHRISTOPHER PARKER**
- * **CELLMID 5th MIDKINE SYMPOSIUM IN MUNICH**

MARKET REPORT

The Australian stock market was up 0.35 percent on Monday April 9, 2018 with the ASX200 up 20.0 points to 5,808.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded. All three Big Caps were up.

Compumedics was the best, up two cents or 6.25 percent to 34 cents with 71,550 shares traded, followed by Acrux up 6.1 percent to 17.5 cents with 466,729 shares traded. Uscom climbed five percent; Immutep improved 4.35 percent; Orthocell and Osprey were up more than three percent; Bionomics and Impedimed rose more than two percent; Clinuvel, Cochlear, CSL and Telix were up more than one percent; with Neuren, Resmed and Viralytics up by less than one percent.

Airxpanders led the falls, down 20.5 cents or 51.25 percent to 19.5 cents with 8.1 million shares traded. Avita and Universal Biosensors lost five percent or more; Ellex fell 4.1 percent; Opthea lost 3.6 percent; Actinogen, Benitec, Factor, Mesoblast, Optiscan and Psivida shed more than two percent; with Medical Developments, Polynovo, Pro Medicus and Starpharma down by less than one percent.

AUSBIOTECH

Ausbiotech says the sector will be damaged if the Federal Treasury pushes ahead with plans to cap the Research and Development Tax Incentive.

Ausbiotech said that Federal Treasurer Scott Morrison had “flagged an overhaul of the [Tax Incentive] in the coming May Budget which will seek to restore the ‘integrity of the program’ after accusations of ‘mining of tax incentives’ and ‘arbitrary use’”.

Ausbiotech chief executive officer Glenn Cross said the R&D Tax Incentive had been “critical to Australia’s success in attracting more investment for the commercialization of medical research because it stretches our medical-research dollars further”.

“By fostering a strong Australian medical technology, pharmaceutical and life sciences [research and development] sector, we are encouraging the long-term investment in Australia that creates highly-skilled jobs, attracts clinical trials and grows the economy we need,” Mr Cross said.

Ausbiotech said that the overhaul would “include unwelcome and potentially damaging changes on the refundable components of the program: a \$4 million annual cap and a lifetime cap of \$40 million”.

“If the Government is concerned about misuse of the program, then why not clamp down on misuse and preserve the policy intent?” Mr Cross asked. “How is capping the program a rationale solution?”

“This cap is going to wind back the five percent annual growth Australia is achieving in clinical trials and the related jobs that we have seen in Australia since the scheme began,” Mr Cross said.

Ausbiotech said that 17 percent of ASX-listed life sciences companies that claimed the refundable component would be affected immediately, with potential flow-on to their research and development programs and another nine percent were in the danger zone. The industry organization said that if the Federal Government insisted on a \$4 million annual cap, the sector should be carved-out for protection, as measures to limit the R&D Tax Incentive would inequitably harm biotechnology-based research and development, which made-up about eight percent of claims and had a record of compliance.

Ausbiotech said the Government recognised the sector as one of Australia’s strongest and most competitive, with its contribution to gross domestic product significant and growing. The organization said the main benefit of the Tax Incentive was the timing and up-front payment, when companies in tax-loss had their highest research and development costs. Ausbiotech said the immediate benefit to Australia was increased high-skilled jobs and technology value creation, and later, commercialization revenues returning further benefit. The organization said that relative to most other sectors, the timeline to commercialization of medicines and vaccines was long, up to 15 years, and very expensive with an average of \$1.5 billion to \$2.2 billion spent per approval, with significant scientific and regulatory hurdles to reach sales to patients.

Ausbiotech said that a \$40 million lifetime cap would disadvantage companies developing life-saving and life-changing technologies.

The organization quoted an Australian Bureau of Statistics report that annual research and development expenditure by businesses fell by more than \$2 billion or 12 percent a year between 2013-’14 and 2015-’16, the latest period for which data was available.

Ausbiotech said that research and development expenditure was “at levels not seen since the global financial crisis”.

The organization said that the life sciences sector was “bucking this trend in most part due to the [Tax Incentive] and clearly demonstrating the success of the policy intent of the program and the National Innovation and Science Agenda”.

“Why threaten this success?” Ausbiotech asked.

BOTANIX PHARMACEUTICALS

Botanix says it has completed enrolment of 36 patients in its phase Ib trial of synthetic cannabidiol BTX1204 for atopic dermatitis, or eczema, with results expected by July 2018. Botanix said that the randomized, double-blind, placebo-controlled trial was designed to evaluate the safety and assess for any treatment effects of BTX1204 in patients with mild-to-moderate atopic dermatitis, treated over four weeks.

The company said that BTX1204 was being developed as a new treatment for mild to moderate eczema, which targeted "multiple pathologies involved in the development of the disease" and was delivered using its Permetrex drug delivery technology.

Botanix executive director Matt Callahan said the company was "very pleased to complete enrolment of the [21-patient] BTX1204 atopic dermatitis patient study, which comes on the heels of the successful phase Ib study for acne" (BD: Jan 29, 2018).

"Our focus is now to finalize the clinical testing phase of the study and ensure the data is available as planned [by July] 2018," Mr Callahan said.

Botanix said it was able to accelerate the completion of the BTX1204 study as it used the same active drug and topical application platform as lead acne product BTX1503.

The company said it planned to file an investigational new drug (IND) application to the US Food and Drug Administration following completion of the study, for a multi-centre phase II BTX1204 safety and efficacy study to begin by the end of 2018.

Botanix said it would continue to develop its broader pipeline including its lead acne treatment BTX1503.

The company said it was preparing an investigational new drug application for BTX1503 and was on-track to begin a phase II study by July 2018 in the US and Australia.

Botanix fell half a cent or four percent to 12 cents with 6.3 million shares traded.

OSPREY

Osprey says it will vote to grant directors 2,352,166 options over Chess depository interests (CDIs), increase the incentive plan by 60 percent and ratify a prior share issue. Osprey said it proposed to grant options over 725,000 US shares, equivalent to 1,450,000 CDIs to chief executive officer Michael McCormick, options over the equivalent to 356,000 CDIs to chairman John Erb and options over the equivalent to 122,500 CDIs to director Neville Mitchell, with 25 percent of their options vesting on January 8, 2019 and the rest to vest in equal monthly installments over 36 months.

The company said that the options would be exercisable at the closing price of the CDIs on the date of the grant and within 10 years.

The company said it would vote to grant options over the equivalent to 423,666 CDIs to director Sandra Lesenfants, of which 25 percent would vest on June 20, 2018, and the remainder to vest in equal monthly installments over 36 months, also exercisable at the closing price of the CDIs on the date of the grant and within 10 years.

The company said it proposed to increase the incentive plan by 5,151,500 CDIs or 60.0 percent to 13,804,300 CDIs, vote to ratify the prior issue of 55,464,076 CDIs and approve the 10 percent placement capacity.

Osprey's notice of meeting said shareholders would vote on the election of directors Ms Lesenfants, Dr Chris Nave and Andrew Jane.

The meeting will be held at Johnson Winter & Slattery, Level 34, 55 Collins Street, Melbourne on May 10, 2018 at 9am (AEST).

Osprey was up one cent or 3.6 percent to 29 cents.

ORTHOCELL

Orthocell says it will vote to grant directors and chief financial officer 7,450,000 options, approve a placement and allow directors to participate in the placement.

Orthocell said the extraordinary general meeting would vote to grant 2,300,000 options to director Paul Anderson, 1,850,000 options to directors Dr Stewart Washer and Matthew Callahan, 300,000 options to directors Prof Lars Lidgren and Qi Xiao Zhou, and 850,000 options to chief financial officer Nicole Telford, vesting in three equal tranches.

The company said the options would be exercisable with three years and at a 15 percent premium to the 5-day volume weighted average price on the date of grant.

Orthocell said the meeting would vote to amend the employee incentive plan to allow the board to determine whether participants could use a cashless facility to exercise options.

The extraordinary general meeting will be held at Building 191, Murdoch University, South Street, Murdoch, Western Australia on May 7, 2018 at 2pm (AWST).

Orthocell was up one cent or 3.4 percent to 30.5 cents..

RESAPP HEALTH

Resapp has requested a trading halt "pending the release of an update in relation to the company's clinical studies".

Trading will resume on April 11, 2018 or on an earlier announcement.

Resapp was up 2.5 cents or 16.7 percent to 17.5 cents with 4.9 million shares traded.

PHYLOGICA

Phylogica has requested a trading halt "pending an update to the market on the board and management of the company".

Trading will resume on April 11, 2018 or on an earlier announcement.

Phylogica last traded at 2.8 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a trading halt pending an announcement regarding a European Union medical marijuana contract and a capital raising.

Trading will resume on April 11, 2018 or on an earlier announcement.

MGC last traded at 7.5 cents.

NOXOPHARM

DRH Superannuation and David Hannon say they have reduced and been diluted in Noxopharm from 7,905,627 shares (7.76%) to 7,271,237 shares (6.245%).

The Sydney-based Mr Hannon said he acquired 685,000 shares on January 22, 2018 through the conversion of options for \$205,500, or three cents a share, and sold 143,890 shares in October and November of 2017 for \$86,000 or 59.8 cents a share and sold 1,175,500 shares on September 4, 2017 for \$941,000, or 80 cents a share.

Mr Hannon said he had been diluted due to the recent placement, which raised \$10.8 million at 90 cents a share (BD: Mar 23, 2018).

Mr Hannon said he received 1,424,808 free 'performance shares' on November 23, 2016, with Mr Hannon and RAH selling shares between September 21, 2016 and August 29, 2017 (BD: Sep 8, 2017).

Noxopharm fell one cent or 1.1 percent to 86.5 cents.

AIRXPANDERS

Airxpanders says that chief executive officer Scott Dodson has resigned with chief financial and operating officer Scott Murcray appointed interim chief executive officer. Airxpanders co-founder and chairman Barry Cheskin said that “bringing on a new [chief executive officer] at this time will help drive the business in this next phase, including refining and improving the effectiveness of our sales model while achieving operating cost efficiencies to reduce our quarterly cash burn and provide a clearer path to profitability”. In February, Airxpanders said that revenue for the year to December 31, 2017, increased 585.3 percent to \$US3,906,000 (\$A5,009,140), with net loss after tax up 33.0 percent to \$US28,983,000 (\$A37,182,290), with 80 percent of sales revenue for its breast reconstruction technology for post-mastectomy patients from the US and 20 percent from Australia (BD: Feb 28, 2018).

Today, Mr Cheskin said that the company’s “early experience in the US gives us a high degree of confidence in the strength of Aeroform and the long-term outlook for the business”.

“We appreciate Scott Dodson’s efforts in leading Airxpanders through the early clinical trials in Australia and the US, the initial public offering, [US Food and Drug Administration] clearance and the launch of Aeroform in Australia and the US,” Mr Cheskin said.

The company said it had begun a search for a new chief executive officer and had formed an operating advisory committee to assist during the transition period, consisting of Mr Cheskin and directors Greg Lichtwardt and Dennis Condon.

Airxpanders said the committee members had “substantial expertise in sales, marketing and executive management in the medical device and/or plastic surgery sector” and would help guide the management team to accelerate operational progress.

The company said it expected to announce its results for the three months to March 31 on April 27, 2018, “noting that, while the financial reports have not yet been finalized, worldwide sales were basically flat compared to the fourth quarter of 2017, with US sales up marginally”.

Airxpanders said it had a cash balance of \$US13.6 million at March 31, 2018, which was sufficient to fund its operations until the end of 2018.

Airxpanders fell 20.5 cents or 51.25 percent to 19.5 cents with 8.1 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has appointed David Phillips as a non-executive director, effective from April 6, 2018.

Suda said that Mr Phillips was previously an advisor to the board.

The company said that Mr Phillips had more than 30 years of experience in the health care industry, including 14 years in sales and marketing with Glaxo Wellcome, Cephalon, Oxford Molecular Group, and eight years with Glaxosmithkline corporate venture fund SR One.

Suda said that Mr Phillips was previously a director of Argenta Discovery, the Automation Partnership and Biofocus PLC.

The company said that at SR One Mr Phillips was involved in “a new function to incubate and spin-out technologies from [Glaxosmithkline] and in parallel investing in early-stage life science companies” and was involved in the monetization of a number of research and development operations and drug delivery technologies, including leading the team that divested Glaxosmithkline opiates business in Australia in 2015, and previously Mr Phillips was a senior investment manager at Bioscience Managers.

Suda was unchanged at 1.4 cents.

ANTEO DIAGNOSTICS

Anteo says that three-month chief executive officer Dr Stefan Enderling has resigned “for family reasons” and will be replaced by Christopher Parker on a short-term contract. Anteo said that Dr Enderling was appointed effective from January 1, 2018 and would support the company in any required transition arrangements and step down as chief executive officer on April 27, 2018.

The company said that Mr Parker’s appointment, effective from April 23, 2018 for three months, would allow it to conduct a considered search for a permanent chief executive officer.

Anteo said that Mr Parker had 20 years’ experience in the life sciences sectors predominately through a career with Roche Diagnostics, culminating as UK and Ireland managing-director.

The company said that Mr Parker previously worked in general management, marketing and business development in Canada, Asia and Australia targeting the centralized laboratory, decentralized point-of-care, molecular diagnostics and applied sciences markets.

Anteo said that Mr Parker would be paid \$23,400 a month including superannuation, and would be based at its Brisbane office.

Anteo fell 0.1 cents or 6.25 percent to 1.5 cents with 3.8 million shares traded.

CELLMID

Cellmid says it will hold its fourth midkine symposium in Munich, Germany, from May 3 to 5, 2018

Cellmid said that the symposium would be a meeting of key opinion leaders, clinicians and scientists involved in midkine research with experts representing a number of therapeutic and diagnostic fields.

The company said it previously held midkine scientific meetings in Sydney, Istanbul, Kyoto and Budapest which resulted in collaborations, including the most recently completed clinical studies carried out at the Sweden-based University of Gothenburg’s Sahlgrenska Academy, where researchers “demonstrated midkine association with prostate cancer progression and treatment resistance”.

Cellmid said that the event would be hosted by the team led by the Munich-based Ludwig Maximilian University’s Dr Ludwig Weckbach, which was Cellmid’s research partner based at the University’s Biomedical Centre and Department of Cardiology.

The company said the agenda included presentations on unpublished and patentable research, so the meeting and lectures would not be recorded.

Cellmid fell 1.5 cents or 3.4 percent to 43 cents.