

# Biotech Daily

Monday October 28, 2019

# Daily news on ASX-listed biotechnology companies

- \* ASX FLAT, BIOTECH UP: ORTHOCELL UP 16%; RESONANCE DOWN 10%
- \* GENETIC SIGNATURES RAISES \$35m, PLAN FOR \$2m MORE
- \* KAZIA RAISES \$4m
- \* PHARMAXIS: 'FDA LARGER CLINICIAN STUDY, 1 MONTH DELAY'
- \* FEDERAL \$50k CYNATA CORONARY ARTERY DISEASE GRANT
- \* GENETIC SIGNATURES RECEIVES \$2.1m FEDERAL R&D TAX INCENTIVE
- \* ZELDA NAME CHANGE TO 'ZELIRA', 37.5m DIRECTOR OPTIONS AGM
- \* RESONANCE 12m DIRECTOR OPTIONS AGM
- \* RHINOMED 10m DIRECTORS OPTIONS AGM
- \* RESAPP 3m CEO, DIRECTOR INCENTIVE OPTIONS AGM
- \* BIOXYNE 36m M-D PERFORMANCE RIGHTS AGM
- \* BENITEC 5m DIRECTOR OPTIONS AGM
- \* ACRUX 2.7m '50% IN LIEU' DIRECTORS RIGHTS AGM
- \* ALTHEA LAUNCHES CBD100 IN AUSTRALIA
- \* CANN GLOBAL OPENS LAOS MARIJUANA SUBSIDIARY
- \* DAVID DAGLIO TAKES 6.5% IN TOTAL BRAIN
- \* APHRIA REDUCES TO 5.25% IN ALTHEA
- \* POLYNOVO APPOINTS CSL'S DR ROBYN ELLIOTT DIRECTOR
- \* AUSCANN TO LOSE DR MAL WASHER, CHERYL EDWARDS
- \* NOXOPHARM APPOINTS CHAIR DR GRAHAM KELLY INTERIM CEO
- \* EXOPHARM APPOINTS DR CHRISTOPHER BALDWIN CCO, ON \$330k
- \* GENETIC SIGNATURES LOSES 16-YEAR DIRECTOR PHILLIP ISAACS

# MARKET REPORT

The Australian stock market edged up 0.02 percent on Monday October 28, 2019, with the ASX200 up 1.5 points to 6,740.7 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and two were untraded.

Orthocell was the best, up 8.5 cents or 15.6 percent to 63 cents, with 8.9 million shares traded.

Cynata and Paradigm climbed 10 percent or more; Oncosil was up 9.5 percent; LBT improved 6.9 percent; Pharmaxis and Prescient were up five percent or more; Alterity, Compumedics, Dimerix and Osprey improved four percent or more; Volpara was up three percent; Optiscan, Polynovo, Resmed and Starpharma rose more than two percent; Cochlear, Medical Developments, Nanosonics and Next Science were up more than one percent; with Pro Medicus up by 0.5 percent.

Resonance led the falls, down 1.5 cents or 10.3 percent to 13 cents, with 3.7 million shares traded.

Proteomics lost 7.1 percent; Antisense, Genetic Signatures, Mesoblast, Opthea and Patrys fell more than four percent; Immutep and Kazia were down more than three percent; Avita, Impedimed and Neuren shed more than two percent; with Clinuvel and CSL down by less than one percent.

# **GENETIC SIGNATURES**

Genetic Signatures says it has raised \$35 million in a placement at 98 cents a share, and hopes to raise a further \$2 million through a share plan.

Genetic Signatures said the 98 cents share price was a 9.3 percent discount to the last closing price on October 23, 2019.

The company said that investors included the Sydney-based Perennial Value Management and Regal Funds Management.

Genetic Signatures said that the funds would be used for commercial expansion in Europe and the USA, further regulatory approvals to products, additional product development and working capital.

The company said it planned to raise a further \$2 million in a share plan for shareholders on the record date of October 25, opening about November 4, 2019, with investors able to apply for up-to \$30,000 in shares each.

Genetic Signatures fell five cents or 4.6 percent to \$1.03.

### **KAZIA THERAPEUTICS**

Kazia says it has raised \$4 million through a placement to institutional, professional, and sophisticated investors at 40 cents a share.

Kazia said the share price was a 14 percent discount to the last closing price on October 23, 2019.

The company said the funds would be used to progress the development of GDC-0084 for brain cancer and Cantrixil for ovarian cancer to data readouts in 2020, as well as to provide working capital.

Kazia fell 1.5 cents or 3.2 percent to 45 cents.

# **PHARMAXIS**

Pharmaxis says the US Food and Drug Administration requires partner Chiesi to expand a Bronchitol for cystic fibrosis, "human factor study" delaying approval one month.

In June, Pharmaxis said the US Food and Drug Administration required a small study of clinicians to approve Bronchitol for adult cystic fibrosis patients, which was expected to be completed by the end of 2019 with the FDA review of the Bronchitol new drug application to be completed by April 2020 (BD: Jun 20, 2019).

Pharmaxis chief financial officer David McGarvey told Biotech Daily in June that clinicians needed to ensure that patients did not have airways reactions to Bronchitol's active ingredient, mannitol, and said the study required that "a small number of clinicians need to demonstrate that the new instructions are simple and easy to follow".

Today, the company said that the FDA requirement for the Parma, Italy-based Chiesi Group to expand the study meant that Chiesi had added an additional month to its timetable and the FDA review of the Bronchitol new drug application was expected to be completed "in the second quarter of 2020", or between April 1 and June 30, 2020. Pharmaxis said that if Bronchitol was approved by the FDA, it would receive a \$US10 million (\$A14.7 million) milestone payment on the supply of Bronchitol for the US commercial launch and mid-to-high teen percentage royalties on in-market net sales. The company said it would manufacture and be the exclusive supplier of Bronchitol for the US, with Bronchitol approved and sold in Europe, Russia, Australia and other countries. Pharmaxis was up one cent or five percent to 21 cents.

# CYNATA THERAPEUTICS

Cynata says it has been awarded a Federal Government Innovation Connections grant for Cymerus stem cell technology for coronary artery disease.

Cynata said that coronary artery disease was the narrowing or blockage of the arteries in the heart and caused the majority of cardiac arrests and about one-third of all deaths in people over the age of 35 years in developed countries.

The company said it would match the Innovation Connections grant and the funds would be used to continue research at Sydney's University of New South Wales led by Prof Kristopher Kilian.

Cynata said that the initial project identified optimal cell culture matrices, which primed its stem cells to secrete factors that stimulated new blood vessel growth, or angiogenesis. The company said that positive effects were demonstrated in-vitro and were maintained after the cells were frozen and then thawed, which was "of significant importance from a commercialization perspective".

Cynata said the new project would profile the pro-angiogenic factors released from the primed mesenchymal stem cells, establish the ability of primed cells to promote new blood vessel formation in-vivo, followed by in-vivo safety and efficacy in a pre-clinical animal model, which was expected to be completed by the end of 2020.

Cynata was up 12 cents or 10 percent to \$1.32.

# **GENETIC SIGNATURES**

Genetic Signatures says it has received \$2,146,943 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Genetic Signatures said the rebate related to research and development expenditure for the year to June 30, 2019.

# **ZELDA THERAPEUTICS**

Zelda says shareholders will vote to change the company name, issue stock for the merger with Ilera Therapeutics, and issue 37,500,000 directors' performance rights. Earlier this month, Zelda said it would merge with the Philadelphia, Pennsylvania-based Ilera Therapeutics LLC to form Zelira Therapeutics, a "to develop clinically validated cannabis medical products" (BD: Oct 9, 2019).

Today, the company said it would propose to change the company name to Zelira Therapeutics and grant 113,601,290 shares and 725,240,644 performance rights as consideration for the acquisition of Ilera Therapeutics.

Zelda said it would issue chairman Harry Karelis, chief executive officer Dr Richard Hopkins and director Jason Peterson 12,500,000 performance rights each, at 0.01 cents each, to be granted within one month following the annual general meeting.

The company said the rights would vest on the achievement of revenue milestones. Zelda said shareholders will vote to adopt the remuneration report, elect directors Jason Peterson, Osagie Imasogie, Oludare Odumosu and Lisa Gray, ratify the prior issue of options and shares, and approve amendments to the constitution.

The meeting will be held at Blackwall Legal, Level 26, 140 St Georges Terrace, Perth Western Australia, on November 28, 2019 at 10am (AWST).

Zelda fell 0.1 cents or 1.4 percent to 6.9 cents.

# **RESONANCE HEALTH**

Resonance says shareholders will vote to issue 3,000,000 options each to chairman Dr Martin Blake and directors Dr Travis Baroni, Mitchell Wells and Simon Panton. Resonance said it proposed to grant each director 3,000,000 options exercisable in three equal tranches at 15 cents, 17.5 cents and 20 cents, vesting when the company share price reached the exercise price, and expiring on November 28, 2022.

Resonance said investors would vote to adopt the remuneration report, re-elect directors Dr Baroni and Dr Panton, ratify the prior issue of 20,000,000 shares to Acuity Capital, ratify employee share scheme shares and adopt the employee share plan.

The meeting will be held at the University of Western Australia Water Sports Complex Car Park, 23 Hackett Drive, Crawley, Perth on November 28, 2019 at 10am (AWST). Resonance fell 1.5 cents or 10.3 percent to 13 cents, with 3.75 million shares traded.

# RHINOMED

Rhinomed says investors will vote to issue 10,000,000 options to directors Michael Johnson, Ron Dewhurst, Brent Scrimshaw and Eric Knight.

Rhinomed said it would propose to issue chief executive officer Mr Johnson 5,000,000 options, chairman Mr Dewhurst and Mr Scrimshaw 2,000,000 options each, and Mr Knight with 1,000,000 options.

The company said the options were exercisable at 145 percent of the volume weighted share price in the five-day period prior to the annual general meeting, vesting immediately and expiring within four years.

Rhinomed said shareholders would vote to adopt the remuneration report, to re-elect Mr Dewhurst, ratify the prior issue of 21,289,992 shares at 22 cents a share, approve the 10 percent placement capacity and the long-term incentive plan.

The meeting will be held at the Tom Wills Room, Great Southern Stand, Level 2, Melbourne Cricket Ground on November 29, 2019 at 9.30am (AEDT). Rhinomed was untraded at 26.5 cents.

# **RESAPP HEALTH**

Resapp says shareholders will vote to grant 975,000 incentive options to chief executive officer Dr Tony Keating and 2,000,000 director incentive options.

Resapp said it proposed to grant 975,000 options to Dr Keating exercisable at 21 cents, a 20 percent premium of the 20-day volume weighted average price prior to the date of his contract of employment, and expiring within five years of the issue date.

The company said Dr Keating's options would vest in three equal tranches on Conformité Européenne (CE) mark approval, US Food and Drug Administration clearance and the commercial release of the company's hardware product.

Resapp said it would grant 500,000 directors incentive options each to chairman Dr Roger Aston, Dr Keating and directors Chris Ntoumenopoulos and Nathan Buzza, exercisable at 43 cents each, a 50 percent premium to the 20-day volume weighted average price before October 10, 2019.

The company said the options would vest on issue and expire on October 9, 2022.

Resapp said shareholders would vote to adopt the remuneration report, re-elect director Dr Aston, re-approve the employee incentive plan, ratify the issue of consultancy options and device development agreement shares, and approve the 10 percent placement capacity.

The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 28, 2019 at 10am (AEDT).

Resapp fell one cent or 2.9 percent to 34 cents, with 1.7 million shares traded.

# **BIOXYNE**

Bioxyne says shareholders will vote to cancel the 40,000,000 performance rights issued to managing-director Nam Hoat Chua and issue 36,000,000 rights instead.

Bioxyne said Mr Chua had been issued with 40,000,000 performance rights on August 3, 2017, none of which had vested.

The company said it would propose to issue Mr Chua with 36,000,000 performance rights, which would vest based on performance hurdles.

Bioxyne said shareholders would vote to adopt the remuneration report, re-elect chairman Anthony Ho as a director, and approve the 10 percent placement capacity.

The meeting will be held in the board room of RSM Australia, Level 13, 60 Castlereagh Street, Sydney on November 25, 2019 at 10am (AEDT).

Bioxyne was untraded at 1.9 cents.

### BENITEC

Benitec says shareholders will vote to grant executive director Megan Boston 5,000,000 options exercisable at 20.01 cents each, with five years.

Benitec said it proposed to grant the options to Ms Boston within five days following the meeting, and no later than 12 months after the meeting.

The company said the options would vest in three equal tranches annually following the grant date.

Benitec said shareholders will vote to adopt the remuneration report, re-elect director Ms Boston, approve a 10 percent placement capacity, ratify the prior issue of shares and warrants, and approve the issue of purchase warrants.

The meeting will be held at Grant Thornton, Collins Square, Tower 5, 727 Collins Street, Melbourne on November 29, 2019 at 10am (AEDT).

Benitec was unchanged at 5.1 cents.

# **ACRUX**

Acrux says shareholders will vote to grant directors a total of 2,733,330 rights in lieu of 50 percent of their remuneration at its annual general meeting.

Acrux said that following a request from 6.15 percent shareholder, Sydney's Samuel Terry Asset Management, it proposed that directors receive rights equivalent to 50 percent of their remuneration, to be issued at 18 cents each (BD: Apr 11, 2018).

The company said chairman Ross Dobinson would receive 983,334 rights, with directors Dr Timothy Oldham, Dr Simon Green and Dr Geoff Brooke to receive 583,332 each, vesting in three equal tranches between February 17, 2020 and November 16, 2022. The company said shareholders would vote to adopt the remuneration report, elect directors Dr Brooke, Dr Green and Norman Gray and approval the 10 percent placement capacity.

The meeting will be held at Pitcher Partners, Level 13, 664 Collins Street, Docklands, Melbourne on November 28, 2019 at 10am (AEDT).

Acrux was up half a cent or 2.3 percent to 22.5 cents.

# ALTHEA GROUP HOLDINGS

Althea says it has launched its full spectrum concentrated cannabidiol oral oil product, Althea CBD100, in Australia.

Althea said the oil was predominantly of cannabidiol (CBD), with small traces of terpenoids, flavonoids, other cannabinoids, and had less than 0.08 percent tetrahydrocannabinol (THC).

The company said given the demand for CBD-only products in the Australian medicinal marijuana market, especially for paediatric patients, it expected that Althea CBD100 would "substantially increase Althea's patient numbers".

Althea fell 1.5 cents or 3.75 percent to 38.5 cents, with 3.2 million shares traded.

# **CANN GLOBAL**

Cann Global says it has incorporated Cann Global Asia, based in Ban Tung, Laos to further its marijuana expansion in South East Asia.

Cann Global said Cann Global Asia would focus on broad-acre industrial marijuana cultivation and processing, indoor marijuana cultivation and processing operations in South-East Asia.

The company said it was the major shareholder with 55 percent of Cann Global Asia and partners David Evans and Christopher Waldron each held 22.5 percent of the company. Cann Global said that its Laos subsidiary was "seeking to provide extraction and manufacturing services for pharmaceutical grade products for retail in Thailand" and would make an announcement regarding Thailand by January 1, 2020.

Cann Global was up 0.2 cents or 8.7 percent to 2.5 cents, with 10.2 million shares traded.

# **TOTAL BRAIN**

David Daglio says he had become a substantial shareholder in Total Brain with 50,301,811 shares or 6.47% of the company.

The Boston, Massachusetts-based Mr Daglio said that in "the period up to and including" October 23, 2019 he acquired all 50,301,811 shares for an average of \$1,408,451 or 2.8 cents a share.

Total Brain was up 0.1 cents or two percent to 5.1 cents.

# ALTHEA GROUP HOLDINGS

Aphria says it had reduced its substantial shareholding in Althea from 110,090,361 shares (54.15%) to 12,250,000 shares (5.25%).

Previously, Althea said it had a commercial agreement with Aphria and in March, Althea said it had appointed Aphria president Jakob Ripshtein as a non-executive director representing Aphria (BD: Mar 7, 2019).

Last year, when Althea listed, Althea, its chief executive officer Josh Fegan and Aphria all said they held 71,590,361 shares or 35.21 percent of the company.

Last week, Althea said that Aphria would sell 36 million shares and the commercial relationship would continue.

Today, Aphria said it was no longer directly associated with Althea or Mr Fegan and between August 9 and October 22, 2019 it sold shares and was diluted in Althea, and on October 25 it sold 36,697,481 shares for \$14,687,992 or 40 cents a share.

Aphria said that as a result of the share sale, it "no longer had relevant interest" in the securities it held with Althea and Mr Fegan, as its holding was below 20 percent.

# **POLYNOVO**

Polynovo says it has appointed CSL executive Dr Robyn Elliott as a non-executive director, effective immediately.

Polynovo said Dr Elliott was a pharmaceutical professional with more than 30 years' experience, was currently CSL Behring's strategic expansion projects senior director, and was previously IDT's managing-director and began her career at DBL Faulding. Polynovo said that Dr Elliott had "a proven track record in product development, clinical trials, regulatory affairs, audits, quality management and operational strategy". The company said that Dr Elliott held a Bachelor of Science and Doctor of Philosophy from Melbourne's Monash University.

Polynovo was up six cents or 2.6 percent to \$2.38, with 1.5 million shares traded.

### **AUSCANN**

Auscann says chairman Dr Mal Washer has resigned as a director, with Cheryl Edwards appointed acting chair until her director term expires in January 2020.

Auscann said Dr Washer and Ms Edwards would retire as part of the company's board renewal and neither would seek re-election at the coming annual general meeting. The company it had begun the search for new directors and a new chair, including the appointment of a nominee from largest shareholder, Merchant Funds Management. Auscann has not announced the date of its 2019 annual general meeting. Auscann fell half a cent or 1.8 percent to 27 cents.

### NOXOPHARM

Noxopharm says chairman Dr Graham Kelly has replaced five-month chief executive officer Dr Greg van Wyk, who left the company in September (BD: Sep 24, 2019). Noxopharm said Dr Kelly would be the interim chief executive officer and would appoint "an Australian-based senior executive with a strong financial and business background". The company said that Dr Kelly would "remain as executive chairman on an annual salary of \$300,000 for the dual roles".

Noxopharm fell 2.5 cents or 6.3 percent to 37 cents.

# **EXOPHARM**

Exopharm says it has appointed Dr Christopher Baldwin as chief commercial officer, starting on \$330,000 a year, including compulsory superannuation.

Exopharm said Dr Baldwin previously worked for Haemonetics Corp, Terumo BCT, and McKinsey & Co.

The company said Dr Baldwin held a Doctor of Philosophy from England's University of Cambridge.

Exopharm said Dr Baldwin could receive yearly bonuses of up to \$33,000 and the smaller of \$75,000 or 75,000 shares based on key performance indicators.

Exopharm fell two cents or five percent to 38 cents.

# **GENETIC SIGNATURES**

Genetic Signatures says that director Phillip Isaacs will retire from the board following the company's annual general meeting on November 22, 2019.

Genetic Signatures said that Mr Isaacs had been appointed to the board in 2003 and had played an integral role in "transitioning the company from a private to a public entity" in 2015.

Genetic Signatures chairman Dr Nick Samaras thanked Mr Isaacs "for his immeasurable contribution to Genetic Signatures".

"I have always valued his counsel and he can be proud of the company he leaves behind," Dr Samaras said.