



# Biotech Daily

Monday October 26, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: RESONANCE UP 3%; OPTISCAN DOWN 9%**
- \* **EISAI \$63m GLOBAL COGSTATE LICENCE**
- \* **FDA ORPHAN STATUS FOR ANTISENSE ATL1102 FOR DMD**
- \* **CLINUVEL: 'SCENESSE SAFE FOR 1<sup>st</sup> XP PATIENT'; REGULATORY HALT**
- \* **MAYNE SUBA-ITRACONAZOLE 'HIGHER UPTAKE AT LOWER DOSE'**
- \* **NOVA EYE - ALPHARET PTY LTD FOR 2RT LASERS, FDA IND**
- \* **PRESCIENT: US PATENT FOR PTX-100 BREAST CANCER BIOMARKER**
- \* **ADHERIUM TAKES \$3m VIBURNUM CONVERTIBLE NOTE**
- \* **VOLPARA, VELOZ EXPLAIN BREAST SCAN RESULTS**
- \* **NOXOPHARM ENROLS 1<sup>st</sup> COVID-19 TRIAL COHORTS**
- \* **CANN GLOBAL LAUNCHES MARIJUANA TABLETS IN AUSTRALIA**
- \* **AVECHO PLEADS SCHULTZ TO ASX 100% PRICE QUERY**
- \* **CYNATA 4.5m DIRECTOR 'INCENTIVE' OPTIONS AGM**
- \* **MESOBLAST 1.2m CEO PROF SILVIU ITESCU OPTIONS AGM**
- \* **BOD 500k DIRECTOR OPTIONS, 462k CEO RIGHTS AGM**
- \* **NANOSONICS CEO MICHAEL KAVANAGH 371k RIGHTS AGM**
- \* **DORSAVI 2.7m CEO SHARES, DIRECTORS OPTIONS IN LIEU AGM**
- \* **LIFE BIOSCIENCES DILUTED TO 19.9% OF ALTERITY**
- \* **BVF PARTNERS INCREASES, DILUTED TO 17.3% OF ACTINOGEN**
- \* **INVION APPOINTS ALISTAIR BENNALLACK DIRECTOR**
- \* **BIO-MELBOURNE 'COVID-19 PROGRESS UPDATE' SYMPOSIUM**

## MARKET REPORT

The Australian stock market fell 0.18 percent on Monday October 26, 2020, with the ASX200 down 11.4 points to 6,155.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell and eight traded unchanged.

Resonance was the best, up 0.5 cents or 3.1 percent to 16.5 cents, with 1.5 million shares traded. Avita, Impedimed, Orthocell and Polynovo rose two percent or more; Cochlear, Genetic Signatures, Nova, Opthea and Pharmaxis were up one percent or more; with Clinuvel, CSL, Starpharma and Telix up by less than one percent.

Optiscan led the falls, down one cent or 9.1 percent to 10 cents, with 2.3 million shares traded. Osprey lost 8.3 percent; Proteomics fell five percent; Imugene was down 3.3 percent; Alterity, Antisense, Compumedics, Cynata, Neuren, Next Science, Paradigm, Uscom and Volpara shed two percent or more; Dimerix, Medical Developments, Nanosonics, Prescient and Universal Biosensors were down more than one percent; with Mesoblast, Pro Medicus and Resmed down by less than one percent.

## COGSTATE

Cogstate says Eisai Co will pay \$US15 million (\$A21.1) upfront and at least \$US30 million in royalties for a global licence to its digital cognitive assessment technology.

Cogstate said the upfront fees under the 10-year licence would be payable within 45 days, and Cogstate would retain the rights to market the cognition tests for clinical trials.

In August, the company said Tokyo's Eisai would link its Nouknow brain health self-assessment tool to the Easiit application for dementia (BD: Aug 3, 2020).

Today, Cogstate said the agreement would cover development, sales, marketing and distribution in healthcare and other markets, excluding clinical trials.

The company said Eisai would aim for first commercial sales within one year in the US, within three years in Europe and within four years in China.

Cogstate said the resulting data would be jointly owned by the companies.

Cogstate was up 17.5 cents or 22.0 percent to 97 cents.

## ANTISENSE THERAPEUTICS

Antisense says the US Food and Drug Administration has granted orphan drug designation for ATL1102 for Duchenne muscular dystrophy (DMD).

Antisense said ATL1102 met the primary endpoint of safety and tolerability in a nine-patient phase II study of adolescent non-ambulant patients (BD: Dec 17, 2019).

Last month, the company said the FDA granted rare paediatric disease designation to ATL1102 for Duchenne muscular dystrophy (BD: Sep 30, 2020).

Today, Antisense said orphan drug designation was for companies that developed drugs for the effective treatment of rare diseases and provided incentives including tax credits towards the cost of clinical trials, a waiver of US prescription drug filing fees and seven years of orphan product exclusivity on authorization.

Antisense chief executive officer Mark Diamond said the designation was "a very significant commercial milestone for the company ... [providing] a cost reduction and regulatory streamlining mechanism" with additional intellectual property protection for along with seven years of marketing exclusivity from generic competition.

Antisense fell 0.25 cents or 1.96 percent to 12.5 cents with 6.6 million shares traded.

### CLINUVEL PHARMACEUTICALS

Clinuvel says the integrity of the skin in its first xeroderma pigmentosum (XP) patient was unaffected in a 42-day special access program of Scenesse or afamelanotide.

Clinuvel said xeroderma pigmentosum patients exhibited extreme deficiency in repair of ultraviolet (UV)-provoked damage to the DNA helix within the nucleus of skin cells, which if left unrepaired replicated and significantly increased the risk of skin cancers.

In a separate announcement, the company requested a trading halt pending an announcement “regarding a decision by a regulatory authority regarding its evaluation of Scenesse” for erythropoietic protoporphyria.

Trading will resume on October 28, 2020 or on an earlier announcement.

Clinuvel was up four cents or 0.2 percent to \$21.95 with 90,557 shares traded.

### MAYNE PHARMA GROUP (FORMERLY HALCYGEN GROUP)

Mayne says its Suba-itraconazole has a higher uptake with a 35 percent lower dose than conventional itraconazole for endemic fungal infection.

Mayne said a randomized controlled trial showed that Suba-itraconazole recorded higher itraconazole serum levels at each time point with no increase in common adverse events. The company did not disclose whether the drug was effective for fungal infections.

In 2018, Mayne said that the US Food and Drug Administration had approved Suba-itraconazole, to be marketed as Tolsura, 65mg capsules for certain systemic fungal infections in adults.

In 2008, the then Halcygen said it had filed an investigational new drug application for Suba-intraconazole with the FDA (BD: Nov 29, 2007; May 14, 2008).

Today, the company said the new data was presented at Infectious Disease Week 2020, which was held virtually from October 21 to 25, 2020.

Mayne fell half a cent or 1.5 percent to 32 cents with 3.3 million shares traded.

### NOVA EYE MEDICAL (FORMERLY ELLEX MEDICAL LASERS)

Nova Eye says it has established a subsidiary company, Alpharet Pty Ltd to support the commercial development of its retinal rejuvenation therapy (2RT) laser.

Nova Eye said the 2RT laser was a minimally invasive nano-pulse ophthalmic laser therapy for clinically significant macular oedema and age-related macular degeneration, for which no treatment existed in its early stages.

The company said 2RT was currently approved in Europe for both indications and for clinically significant macular oedema in the US.

Nova Eye said Alpharet would prioritize the US regulatory pathway for 2RT, including the filing of an investigational device exemption with the US Food and Drug Administration for a major clinical study, and find a partner to fund the study.

Last year, the then Ellex said that a four-year follow-up of 183 patients showed that its 2RT had a “rejuvenating” impact on the retina and potential for early intervention, following the 2018 results from the 292-patient Lead trial which missed its primary endpoint (BD: Sep 21, 2018; Jul 8, 2019).

Today, the company said the new study would aim to provide statistically significant clinical evidence that 2RT delayed the progression of intermediate AMD.

Nova Eye said Alpharet was established to delineate its 2RT development from its core business, which was focused on glaucoma treatment technologies.

Nova Eye was up half a cent or 1.5 percent to 33 cents.

## [PRESCIENT THERAPEUTICS](#)

Prescient says it has been granted a US patent for a biomarker to identify patients most likely to respond to treatment with its PTX-100 for breast cancer.

Prescient said the patent, titled 'Methods for inducing tumor regression and inhibiting tumor growth, and inducing apoptosis in breast tumors with geranylgeranyl transferase-1 inhibitors', would protect its intellectual property until 2031.

The company said it had licenced the p27 biomarker from the Tampa, Florida-based Moffitt Cancer Centre as a companion diagnostic with PTX-100, on the basis that patients with low levels of p27 would be more likely to respond to PTX-100 (BD: Feb 9, 2015).

Prescient fell 0.1 cents or 1.6 percent to six cents with 1.6 million shares traded.

## [ADHERIUM](#)

Adherium says Perth's Viburnum Funds has issued a \$3 million convertible note and the will "explore potential future funding ... for device and sensor development".

Adherium said the funds would support development and initial commercialization of its Hailie sensor technology, previously known as the Smartinhaler, and software platform and software and hardware development with the Melbourne-based Planet Innovation.

In April, the company said it had contracted Planet Innovation to develop inhaled drug adherence devices and software for remote asthma monitoring (BD: Apr 21, 2020).

Adherium fell 0.1 cents or 4.2 percent to 2.3 cents with 3.1 million shares traded.

## [VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says it has partnered with the Valencia, California's Sheila R Veloz Breast Centre to provide breast images to explain mammography screening results to women.

Volpara said that with the Veloz Breast Centre it would provide breast images to women to explain the results of their mammograms.

The company said that women currently received text-heavy follow-up letters following mammography and that including the images and explanation of breast composition and other could make it easier for women to understand their breast health.

Volpara chief executive officer Dr Ralph Highnam said the project was "the first step in empowering women with more personalized information about their breast health, and in particular about their breast composition".

Dr Highnam said that patient letters following mammography were "too complex ... [and] carefully constructed imagery can convey far more than just words".

Volpara fell three cents or two percent to \$1.47.

## [NOXOPHARM](#)

Noxopharm says it has enrolled six patients in the first two cohorts of its phase Ib study of Veyonda or NOX66 for Covid-19.

In April, Noxopharm said that idronoxil, the active ingredient in Veyonda, inhibited a key pathway involved the cytokine storm resulting from Sars-Cov-2 infection and it would seek US Food and Drug Administration guidance for a Covid-19 trial (BD: Apr 1, 21, 2020).

Today, the company said it would administer 400mg of Veyonda to the first cohort, 600mg to the second cohort, and following a safety review planned for early November, would administer 800mg to three patients and 1,200mg to three patients in the next two cohorts, and then the trial would be expanded to 30 patients and the targeted 1,800mg dose.

Noxopharm fell 1.5 cents or three percent to 49 cents.

### CANN GLOBAL

Cann Global says its Canntab Therapeutics joint venture has launched its formulation of medical marijuana tablets in Australia.

Cann Global said it had an import permit and an initial order for six products, including two tetrahydrocannabinol (THC) only products, two cannabidiol (CBD) only products and two THC and CBD blends.

The company said Canntab manufactured and distributed hard pill cannabinoid formulations in multiple doses and timed-release combinations and the current path to patients in Australia was through the special access scheme B and authorized prescriber schemes.

Cann Global was up 0.1 cents or 20 percent to 0.6 cents with 67.5 million shares traded.

### AVECHO BIOTECHNOLOGY

Avecho has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 100 percent from 0.8 cents on October 21, 2020 to 1.6 cents on October 23 and noted a significant increase in the trading volume. Avecho fell 0.3 cents or 21.4 percent to 1.1 cents with 28.9 million shares traded.

### CYNATA THERAPEUTICS

Cynata says its annual general meeting will vote to issue 4,500,000 "incentive" options to directors.

Cynata said it would issue 2,000,000 options to independent non-executive chairman Dr Geoff Brooke, 1,500,000 options to managing-director Dr Ross Macdonald, with 300,000 options each to independent directors Dr Paul Wotton, Dr Stewart Washer and Dr Darryl Maher and 100,000 options to company secretary Peter Webse.

The company said the options would be exercisable at 97 cents, a 45 percent premium to the five-day volume weighted average price to August 17, 2020, within five years.

Cynata said the meeting would vote to adopt its remuneration report, re-elect Dr Washer and Dr Maher as directors, ratify the issue of placement shares, approve the 10 percent placement facility and replace its constitution.

The virtual meeting will be held on November 24, 2020 at 11:30am (AEDT). Register at: [https://us02web.zoom.us/webinar/register/WN\\_yHhYmE6dQ7KPWa2TBMvMaQ](https://us02web.zoom.us/webinar/register/WN_yHhYmE6dQ7KPWa2TBMvMaQ).

Cynata fell two cents or 2.4 percent to 81.5 cents.

### MESOBLAST

Mesoblast says its annual general meeting will vote to issue to chief executive Prof Silviu Itescu 1,200,000 options exercisable at \$3.41 each within seven years.

Mesoblast said the milestone-based options would form part of the long-term incentive component of Prof Itescu's remuneration, with 50 percent vesting on achievement of clinical and commercialization performance and 50 percent vesting on achievement of financial and business hurdles.

The company said the meeting would vote to adopt the remuneration report, re-elect Donal O'Dwyer as a director and ratify the issue of shares.

The virtual meeting will be held on November 24, 2020 at 11am (AEDT) at: <https://agmlive.link/MSB20>.

Mesoblast fell one cent or 0.3 percent to \$3.15 with 4.1 million shares traded.

## BOD AUSTRALIA

Bod says investors will vote to issue 500,000 options to director Akash Bedi and 462,238 long term incentive rights to chief executive officer Joanne Patterson.

Bod said Mr Bedi's options would be exercisable at 140 percent of the 105-day volume-weighted average price (VWAP) within three years of issue and form part of his pay.

The company said Ms Patterson's incentive rights would vest in two equal tranches by June 30, 2022 and 2023, subject to a 59 cent 10-day volume weighted average price (VWAP) by June 30 2021 and an 82 cent 10-day VWAP by June 30, 2022.

Bod said the annual general meeting would vote to adopt the remuneration report, re-elect director George Livery and approve an additional 10 percent placement capacity.

The virtual meeting will be held on November 25, 2020 at 10:30am (AEDT) at:

<https://agmlive.link/BDA20>.

Bod fell half a cent or 0.96 percent to 51.5 cents.

## NANOSONICS

Nanosonics says investors will vote to issue chief executive officer Michael Kavanagh 162,410 performance rights and 208,884 share appreciation rights.

Nanosonics said the annual general meeting would vote to issue Mr Kavanagh 19,112 free rights as a short-term incentive and 143,298 performance rights and 208,884 share appreciate rights as a long-term incentive.

The company said that, pending performance hurdles, the short-term rights would vest on August 31, 2021 and held as restricted shares until August 31, 2022.

Nanosonics said the 208,884 share appreciation rights would be exercisable at \$6.0436 a share, with the total rights exercisable until September 30, 2027.

The company said the long-term rights would vest on September 30, 2023 and would be subject to an exercise restriction period of one year from the vesting date.

Nanosonics said it would also vote to elect Steve Sargent, Marie McDonald and Dr Lisa McIntyre as directors, adopt the remuneration report and to re-insert a proportional takeover provision in its Constitution.

The virtual meeting will be held on November 24, 2020 at 11am (AEDT) at:

<https://web.lumiagm.com/366404283>.

Nanosonics fell six cents or 1.1 percent to \$5.42 with 1.5 million shares traded.

## DORSAVI

Dorsavi says its annual general meeting will vote to issue 2,707,286 shares to managing director Dr Andrew Ronchi and issue options to directors in lieu of pay.

Dorsavi said the shares to Dr Ronchi would be in lieu of cash and entitlements of \$75,804.

The company said investors would vote to grant options to non-executive directors Gregory Tweedly, Dr Ashraf Attia, Caroline Elliott and Dr Michael Panaccio in lieu of fees.

The company said the options would be exercisable at a 50 percent premium to the 10-day volume weighted average price for five years and the number of options would be determined by dividing fees owing to the director for each three-month period.

Dorsavi said it would also vote to approve the issue of 57,856,882 placement shares, receive financial statements and reports, re-elect Mr Tweedly as a director, approve a 10 percent placement facility and to adopt its remuneration report.

The meeting will be held on November 27, 2020 at 9am virtually and to register, email

[brendan@casegovernance.com.au](mailto:brendan@casegovernance.com.au).

Dorsavi fell 0.02 cents or 0.5 percent to 3.9 cents with 3.4 million shares traded.



### [ALTERITY THERAPEUTICS \(FORMERLY PRANA BIOTECHNOLOGY\)](#)

Life Biosciences says its 269,905,533 share-holding in Alterity has been diluted from 24.88 percent to 19.9 percent.

The Boston, Massachusetts-based Life Biosciences said that it was diluted on October 23, 2020 following the \$35 million placement at 3.7 cents a share (BD: Oct 16, 2020).

In December 2018, the then Prana said it had raised \$44.6 million from Life Biosciences and in 2019 an extraordinary general meeting approved the company taking control of Prana and changing the name to Alterity (BD: Jan 20, Mar 6, Apr 5, 2019).

Alterity fell 0.1 cents or 2.6 percent to 3.7 cents with 12.7 million shares traded.

### [ACTINOGEN MEDICAL](#)

BVF Partners LP says it has increased and been diluted in Actinogen from 217,200,000 shares (19.43%) to 239,927,273 shares (17.27%).

The San Francisco-based BVF said that on October 22, 2020 it acquired 22,727,273 shares for \$500,000 or 2.2 cents a share in the \$6 million oversubscribed institutional private placement (BD: Oct 15, 2020).

BVF said that on June 5, 2019 it acquired 5,583,063 shares off-market for \$66,997 or 1.2 cents a share, which it sold for the same price on June 7, 2019.

Actinogen was unchanged at 2.2 cents with 5.3 million shares traded.

### [INVION](#)

Invion says it has appointed Alistair Bennallack as a non-executive director, effective from October 22, 2020.

Invion said Mr Bennallack was currently the chief executive officer of Village Roadshow Theme Parks Asia and previously a member of the Village Roadshow executive committee, the company's chief financial officer and business general manager.

Invion said Mr Bennallack held a Graduate Diploma in Wine Business.

Invion was unchanged at 1.1 cents.

### [BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says it will host a symposium titled 'Covid-19: A Global Progress Update' on November 5, 2020.

The Network said the symposium would provide a progress update on Covid-19 vaccines, diagnostics and treatments and explore other themes including manufacture, regulations, supply and distribution of products.

The Bio-Melbourne Network said speakers would represent the Coalition for Epidemic Preparedness Innovations, World Health Organisation, Janssen Australia and New Zealand, the Commonwealth Scientific and Industrial Research Organisation, Gilead Sciences, the Australian Department of Health, Australian Defence Materials Technology Centre Ltd, Ausindustry and Popper and Co.

The Network said the symposium would be held on November 5, 2020 from 8:45 am to 12:55pm (AEDT) and to register, go to: <https://bit.ly/BioSymp>.