

Biotech Daily

Friday July 17, 2020

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: CYNATA UP 16%; KAZIA DOWN 6%
- * DR BOREHAM'S CRUCIBLE: HYDRIX
- * FEDERAL \$32.5b TAKES MRFF TO \$20b TARGET; AAMRI RESPONSE
- * RUSSIA, ISRAEL APPROVE REDHILL OPAGANIB COVID-19 TRIAL
- * ALCIDION: ACT HEALTH \$1.3m 2-YEAR CONTRACT EXTENSION
- * CANN GROUP RAISES \$14.3m, PLAN FOR \$10m MORE; RECEIPTS UP 17%
- * GENETIC TECHNOLOGIES PLACEMENT FOR \$7.3m
- * PALLA: \$8m UK CONTRACT: NORWAY FACILITY APPLIES FOR APPROVAL
- * THC SHARE PLAN RAISES \$1.5m, TOTAL TO \$8.1m
- * RESPIRI APPOINTS CIPLA AUSTRALIA, NZ WHEEZO DISTRIBUTOR
- * IMUGENE: 2nd PD1-VAXX LUNG CANCER TRIAL APPROVAL
- * AUSCANN UNMARKETABLE PARCEL FACILITY
- * ECOFIBRE: 2 US TRIALS OF CBD FOR NEUROPATHY, AGITATION
- * BOTANIX, FDA AGREE BTX1503 ACNE PHASE III ENDPOINTS
- * INCANNEX IHL-675A REDUCES ARDS SEPSIS, IN MICE
- * RHYTHM REQUESTS 'CAPITAL RAISING' TRADING HALT
- * FACTOR TAKES 'POTENTIAL ACQUISITION' HALT TO SUSPENSION
- * G MEDICAL AGM 57% BLOCK 75m CEO DR YACOV GEVA SHARES
- * HK'S STAR BRIGHT TAKES LOSS TO 12% OF ANTERIS (ADMEDUS)
- * CANN GROUP APPOINTS JENNI PILCHER DIRECTOR
- * BIOTRON APPOINTS DR STEPHEN BECKER CMO
- * BIO-MELBOURNE HOSTS REGENERATIVE MEDICINE WEBINAR

MARKET REPORT

The Australian stock market was up 0.38 percent on Friday July 17, 2020, with the ASX200 up 22.7 points to 6,033.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell and 12 traded unchanged.

Cynata was the best, up 9.5 cents or 15.7 percent to 70 cents, with 855,403 shares traded. Proteomics climbed seven percent; Imugene was up 5.6 percent; Antisense improved 4.8 percent; Pharmaxis was up 3.6 percent; Clinuvel, Nanosonics and Osprey rose more than two percent; Mesoblast, Starpharma and Volpara were up more than one percent; with Cochlear and CSL up by less than one percent.

Kazia led the falls, down 3.25 cents or 6.1 percent to 50 cents, with 94,039 shares traded. Avita and Oncosil fell more than four percent; Genetic Signatures, Medical Developments, Opthea and Resonance were down more than three percent; Alterity, Compumedics, Cyclopharm, Nova (Ellex), Paradigm and Telix shed two percent or more; Dimerix, Impedimed, Next Science and Pro Medicus were down more than one percent; with Resmed down 0.7 percent.

DR BOREHAM'S CRUCIBLE: HYDRIX

By TIM BOREHAM

ASX code: HYD

Share price: 9.5 cents; Market cap: \$7.6 million; Shares on issue: 79,622,263

Financials (March quarter 2020): receipts \$3.5 million, operating cash outflows \$1.16 million, cash balance \$2.12 million, loan facilities \$6.75 million, 1.8 quarters cash

Executive chairman: Gavin Coote

Board: Mr Coote, Julie King, Joanne Bryant, Paul Wright (MEM, ex-UBI)

Identifiable major shareholders: John W King Nominees 21%, Acorn Capital 3.5%, Flet Investments and Associates 3.5%, Peter Russell and Dominique Maurier 2.4%, Beachridge Advisory 2.1%

* All figures are pre this week's \$3 million capital raising.

Hydrix who?

That was your columnist's first reaction on learning about the existence of the medical device development play - and we're sure he's not alone in his bemused response.

Small cap investors with a speculative bent might better recall Hydrix's former iteration as Panorama Synergy, which was the best performing stock on the ASX in 2013 after the shares soared from half a cent to 20.5 cents (a 4,000 percent gain).

Panorama Synergy's main game was a promising tech called MEMS, or micro electromagnetic systems (think of those sensors that activate rain-sensitive windscreen wipers). While the company still houses MEMS expertise, Hydrix these days is more about designing and constructing medical devices and equipment.

The quiet achiever was instrumental (excuse the pun) in devising Nanosonics' Trophon sterilizers, Memphasys' Felix sperm separation device, LBT Innovation's culture plate automation devices and Micro-X's portable x-ray device. To date, the work has been done on a contract basis, but now Hydrix wants to make deeper investments in high-potential medical innovation.

"These are all fantastic devices developed in Australia," says executive chairman Gavin Coote. "We played a critical role in developing them, but with no investment exposure to the capital growth and upside."

In March, Hydrix acquired the exclusive Asia Pacific rights to distribute Eatontown, New Jersey Angel Medical's Guardian system, the world's first implantable device to warn the wearer of an imminent cardiac arrest (heart attack).

The rights include Australia, Singapore, Japan, Malaysia and Hong Kong - but more on that later.

Shareholders are now being asked to participate in a \$3 million rights raising (and placement) to pay off debt and bolster the balance sheet.

Hey, sexy lady!

Panorama Synergy emerged as an ASX entity in mid-Noughties to tap the hot MEMS field. The company went by the ASX code PSY and the joke at the time of the stock's 4,000 percent run was that it was a bigger hit than South Korean singer Psy's Gangnam Style (18 million You Tube views and counting).

Inevitably, the story became over-hyped and the MEMS work never evolved from early stage research.

In September 2017, the company acquired the private Hydrix Group, builder of the aforementioned medical devices as well as industrial and defence related systems. The purchase of this "crown jewel" was by way of \$2 million of cash and 50 million Panorama shares.

The company changed its name to Hydrix - and its code from PSY to HYD - in November 2018.

Mr Coote became a director in 2017 and then executive chair in January this year, with CEO Peter Lewis "transitioning" to head of corporate development.

A seasoned corporate wheeler and dealer, Mr Coote spent 12 years in the US where he took a Nasdaq-listed software house, Platinum Technology, from \$US100 million (\$A142 market cap) to \$US1 billion via 45 acquisitions.

A Melbourne lad, Mr Coote eventually moved back to Australia where he became immersed in a family office, performing private equity-style investments in bricks-and-mortar companies. He was also involved in privatizing the Melbourne Rebels rugby team before Rugby Australia bought back the franchise.

Hydrix consists of a team of 65 engineers beavering away in a facility at Mulgrave, in Melbourne's south east.

"We have put together a business with distinct potential as distinct from the past when it hadn't generated a dollar of revenue or product," Mr Coote says.

At the heart of the company ...

While the Hydrix Ventures arm aims to pick winners in medical innovations, Hydrix Medical is focused on cardio-vascular products. One client, Bivacor of Houston, Texas, has been working on an artificial heart that eventually could replace human tickers. Hydrix has been contracted exclusively to develop the control systems in a prototype.

Mr Coote says cardio-vascular disease remains the biggest killer, afflicting 14 percent of the population and accounting for 31 per cent of deaths.

"The heart beats 100,000 times a day, or three billion times a year," Mr Coote says. "It's a busy organ." (It's about 36.5 million a year, actually).

As for the Guardian, the deal with Angel Medical involves Hydrix building the Guardian upgrades under a multi-million-dollar service arrangement. Pace-maker-like, the Guardian detects changes in the heart's electrical conductivity. Hydrix has also invested \$US1 million for a 4.6 percent stake in Angel Medical, payable in a mix of cash and services and the third component is an exclusive distribution rights to eight Asian Pacific countries, including Australia.

Mr Coote says the heart device can detect a pending episode 40 percent better than patient recognized symptoms alone.

Almost half of attacks have no discernable symptoms, such as the one that this month afflicted former TV bigwig (and occasional James Packer sparring partner) David Gyngell.

Mr Coote estimates the patient market in the company's distribution zone at 500,000 a year. These patients have had a coronary episode already, or have co-morbidities such as diabetes or dodgy kidneys.

He says undiagnosed secondary heart attacks are likely to increase during the coronavirus epidemic, because patients have been deterred from going to their normal checkups.

Seal of approval

The Guardian device has been approved by the US Food and Drug Administration or, technically, re-approved after Angel Medical installed an improved battery that lasts twice as long. Hydrix also plans to seek approval from the local Therapeutic Goods Administration and Singapore's Health Sciences Authority.

In the US, about 1,000 implants have been done as part of clinical trials, with a further 250 (containing the new batteries) due by the end of 2020.

"The benefit of that is we won't require clinical trials to be approved, so that's a way to fast-track in the Asia-Pacific," Mr Coote says.

In the meantime, early access schemes allow cardiologists to carry out implants ahead of approval. A Singapore heart doctor planned to implant five devices, before Covid-19 intervened. In Australia, the company is working with a cardiology network to initiate implants under an authorized prescriber scheme, which is similar. The implants (and the one-hour surgery) will be reimbursable in the US, but in Australia and Singapore, it will be patient pays, at least for the time being.

Meanwhile ...

Medical devices aside, Hydrix is also expert in other mining and industrial applications, including water and sewerage management.

In the defence sphere, the company provides engineering services for the Joint Terminal Attack Controller training system. Hydrix has also devised an electro-magnetic pulse electronics disabling (jamming) system. For more information, consult your nearest military buff.

"Defence is a smaller piece but we have done some important novel work there in the past," Mr Coote says.

In the medical technology arena, Hydrix is also involved in developing devices for orthopaedics, hip replacements and traumatic brain injury monitoring.

In each case the company will seek an "aligned interest". That could mean services in kind for equity, or a capital investment. Whatever the case, the company will avoid being "all things to all people" and will be pragmatic in what it pursues.

Finances and performance

Having secured \$1 million in a placement, Hydrix is handing out the bowl for \$2 million in a one-for-three, fully-underwritten rights issue (with one attached option for every three shares, exercisable at 12 cents).

The raising is struck at 7.5 cents per share, a hefty 25 percent discount on the immediate closing price of 10 cents a share.

Last year, Hydrix also raised just over \$2.6 million, via a placement and share purchase plan.

Hydrix gleaned \$3.82 million of revenue in the March quarter, up 10 percent, mainly from its service contracts and expects to have turned over \$14.7 million in the financial year to June 2020.

That number is 10 percent higher than previously, but slightly off previous guidance of \$15 million because of a Covid-19 related slowdown in the June quarter.

And earnings? Glad you asked.

Hydrix posted a slim cash operating surplus of \$40,000 in the March quarter and still expects a "cash operating profit" for the full year to June 2020. But the Covid-19 disruptions mean that the current year to June 2021 is likely to be break even only, on lower revenue.

The company derives most of its revenue from the services side of the business, but expects product revenue (from Hydrix Medical) eventually to outstrip services income.

As a guide to the Guardian potential, in the US the devices sell for \$US8,500 to \$10,000 (\$A12,300 to \$A14,500).

Pricing in Australia has not yet been set, but it's likely to be in line with the cost of pacemakers, which sell for between \$US8,500 and \$US12,000. Based on five percent market penetration, the company estimates annual turnover of \$274 million in its Guardian distribution catchments, or \$40 million for the initial geographies of Australia and Singapore.

The company held cash of \$2.1 million as of the end of March but also had \$6.75 million of outstanding debt.

These borrowings are provided by three shareholders: \$1 million from ELG Nominees (Joanne Bryant), \$1.75 million from John W King Nominees (John King, who owns 20 percent of the company) and \$4 million from Pure Asset Management Pty Ltd (\$750,000 of the equity raising proceeds are earmarked to reduce this debt).

Late last year, the company carried out a one-for-10 share consolidation. Accounting for this, Hydrix shares have traded between \$1.30 in January 2018, and nine cents in April 2020.

Dr Boreham's diagnosis:

Mr Coote says Hydrix's higher purpose is to "enhance the health and wellbeing of a billion lives".

Like Bob Hawke's famed "no child shall live in poverty" pledge, this of course is an aspirational goal.

Hydrix possibly could build and market a device under its own steam, but for the time being securing distribution rights is a de facto way of eking value from the intellectual property.

The company is also open to licencing and royalty fee arrangements.

"We are looking for ways to leverage product development to gain an unfair advantage", Mr Coote says.

"... the research and development capability here (in Mulgrave) could support a \$100 million a year operation. As time goes by and the company gets more scale and cash flow, our ability to leverage that capacity is definitely on our radar."

Unlike South Korea's Psy, Hydrix won't storm to overnight fame but there's a good chance it won't be known as "Hydrix who?" in the not too distant future.

"We are pretty humble but we have an aspiration to build something special, a great Aussie tech company," Mr Coote says.

"We are giving it a red-hot crack."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He also never mastered Gangnam Style on the dance floor.

FEDERAL GOVERNMENT, MEDICAL RESEARCH FUTURE FUND ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

The Federal Government says it will add \$3.2 billion to the Medical Research Future Fund on July 21, 2020 meeting its \$20 billion target ahead of time.

A Department of Health spokesman told Biotech Daily that the credit fulfilled the policy outlined in the 2014-'15 Budget measures.

The Association of Australian Medical Research Institutes welcomed the decision "to not only honor its election promise of meeting the next milestone payment in the Medical Research Future Fund, but increase the initial amount promised from \$2.52 billion to \$3.21 billion".

AAMRI President Prof Jonathan Carapetis said the investment was "excellent news for the medical research sector".

"It shows the clear importance the Government is placing on medical research, now and in the future," Prof Carapetis said.

AAMRI said the Fund provided money for research in a range of priority areas, most recently for a variety of Covid-19 research including vaccines.

The industry organization said that most of the funding for Covid-19 research had come from the MRFF, along with investments in mental health, antivirals, respiratory medicine clinical trials, digital health infrastructure, immunological studies and vaccine development amongst others.

"This is exactly why the MRFF was set up, so Australia could be as responsive as possible to new priority areas," Prof Carapetis said.

REDHILL BIOPHARMA

Redhill says Russia and Israel have approved 270-patient and 50-patient, respectively, phase II/III trials of opaganib for severe Covid-19 and pneumonia.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, the company said the Russian Ministry of Health approved a 270-patient, multicenter, randomized, double-blind, parallel-arm, placebo-controlled phase II/III trial of opaganib, formerly Yeliva or ABC294640, with the primary endpoint of evaluating the proportion of patients requiring intubation and mechanical ventilation by day-14 of treatment.

Redhill said the Israeli approval was for a similar 50-patient study of opaganib for severe Covid-19 and pneumonia, following the approval for the compassionate use of opaganib in April (BD: Apr 7, 2020).

The company said the trials would run concurrently with studies which had been approved in the US and the UK (BD: Apr 21, Jun 30, 2020).

Redhill said the US randomized, double-blind, placebo-controlled phase IIa clinical study of opaganib was currently enrolling up to 40 patients.

Redhill chief operating officer Gilead Raday said that the company was "rapidly advancing the clinical development program with opaganib for Covid-19 and, if successful, plan to submit an application for emergency use authorization [by the end of] this year".

"The phase II/III study with opaganib in patients with severe Covid-19 has already received regulatory approvals in two countries and we are expanding the study to additional countries," Mr Raday said.

"With planned initiation of the phase II/III study later this month and with over 25 percent enrolment in the US phase IIa study, Redhill is well-positioned at the forefront of the race to bring novel potential beneficial therapies to hospitalized Covid-19 patients," Mr Raday said.

Redhill said that an analysis of treatment outcomes in five patients with severe Covid-19 "showed substantial benefit to patients treated with opaganib under compassionate use in both clinical outcomes and inflammatory markers as compared to a retrospective matched case-control group from the same hospital".

The company said that all patients in the opaganib-treated group were discharged from hospital without requiring mechanical ventilation compared to 33 percent of the matched case-control group required mechanical ventilation.

Redhill said that average time to stop the use of a high-flow nasal cannula was reduced to 10 days in the opaganib group, compared to 15 days in the control group.

On the Nasdaq, Redhill was up 19 US cents or 2.92 percent to \$US6.70 (\$A9.59) with 432,324 shares traded.

ALCIDION

Alcidion says it has a \$1.3 million two-year extension for its hospital software support contract with Australian Capital Territory Health.

In 2018, Alcidion said that it had a two-year hospital software support contract with Australian Capital Territory (ACT) Health, valued at \$1.27 million (BD: Dec 19, 2018). Today, the company said it would provide technical support services to ACT Health for the integrated patient management system for two years from January 1, 2021.

The company said the contract did not cover technical support for Alcidion's Miya Precision, Patientrack and Smartpage which were covered under a separate arrangement. Alcidion was up half a cent or 3.3 percent to 15.5 cents with 2.4 million shares traded.

CANN GROUP

Cann Group says it hopes to raise \$24.3 million through a placement and share plan at 40 cents a share, with receipts from up 17.4 percent for the year to June 30, 2020.

Cann Group said it had raised \$14.3 million through a placement to sophisticated and institutional investors and hoped to raise an additional \$10 million through a share plan.

The company said the placement was oversubscribed and was a 56 percent discount to the 10-day volume weighted average price.

Cann said the share plan record date was July 16, it would open on July 22 and close on August 12, 2020 and the proceeds would be used to provide working capital.

Separately, in an Appendix 4C quarterly report, Cann said receipts from customers for the year to June 30, 2020 was up 17.4 percent to \$1,721,000.

The company said that it had \$1,639,000 in cash and cash equivalents at June 30, 2020 Cann Group fell 10 cents or 12.2 percent to 72 cents with 4.7 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it expects to raise \$US5.1 million (\$A7.3 million) in a placement of American depository shares (ADS) at \$US5.00 each.

Genetic Technologies said each ADS represented 600 Australia shares at 1.2 cents each. The company said the capital raising was based on conditional agreements with several

institutional investors and was expected to be completed by July 20, 2020. In April, Genetic Technologies said it had raised \$US3.22 million in two separate

placements of ADSs at \$US2.00 and \$US1.75 each (BD: Apr 2, 6, 21, 2020)

In May, the company said it would raise \$US8 million (\$A12.05 million) through the issue of 4,000,000 ADSs at \$US2.00 each (BD: May 27, 2020).

Today, Genetic Technologies said it would use the funds for US product distribution, research and development and reimbursement studies for polygenic risk tests with the Translational Genomics Research Institute in the US, for testing platforms and preparation for its Covid-19 severity risk test, potential acquisitions and working capital.

The company said HC Wainwright and Co was the placement agent for the raising. Genetic Technologies was untraded at 1.15 cents.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRY ENTERPRISES)

Palla Pharma says it has extended its contract with an unnamed UK customer to supply 270 million codeine phosphate tablets for \$8 million.

Palla said it would supply the codeine phosphate between 2020 and 2021 under the contract, which designated a minimum of eight tonnes of supply and represented about four months of its annual finished dose formulation packaging capacity.

The company said each tonne of codeine phosphate tableted would generate revenue in excess of \$1 million, compared to \$500,000 as an active pharmaceutical ingredient. Palla said its Norway production facility had begun the process to list as an approved manufacturing site for its recently acquired marketing authorizations, with a codeine paracetamol caplet to be the first product manufactured.

The company said it expected stability testing for the codeine paracetamol caplets to start in early August and to make an approval submission to the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in early September.

Palla said generic codeine paracetamol combinations prices had "significantly increased" due a major UK producer losing its MHRA licence and a world shortage of paracetamol. Palla was up 7.5 cents or 9.4 percent to 87.5 cents.

THC GLOBAL GROUP

THC says its share purchase plan has raised \$1,535,000 at 30 cents a share, taking the total amount raised following last month's institutional placement to \$8,136,000.

Last month, THC said it raised \$6.6 million through a placement to institutional and sophisticated investors at 30 cents a share (AVW: Jun 26, 2020).

This week, the company said the funds would go towards working capital, as well as expanding its finished goods capabilities into additional medicine forms and developing new information technology infrastructure for doctors and pharmacies supplying medicinal marijuana products from its Canndeo and Tetra Health brands.

THC was unchanged at 27.5 cents.

RESPIRI

Respiri says it has appointed the Melbourne-based Cipla Australia to market and distribute its Wheezo asthma monitor in Australia and New Zealand for five years.

Respiri said that Cipla Australia, a subsidiary of the Mumbai, India-based Cipla, supplied more than 15,000 general practitioners and 4,000 pharmacies in Australia.

The company said that Cipla Australia had made an initial minimum order of 2,000 Wheezo units, with the first delivery expected in October 2020.

Respiri chief executive officer Marjam Mikel said that "respiratory disease monitoring and management has never been more important with the Covid-19 pandemic posing an increased risk for asthmatic patients within Australia and globally".

"We anticipate revenues under this partnership to commence [by the end of] 2020, with Respiri receiving a fixed supply price per Wheezo, while also retaining the full annuity revenue stream associated with the monthly per patient subscription fee of approximately \$8." Mr Mikel said.

The company did not specify the Wheezo fixed price.

Respiri was up 3.5 cents or 31.8 percent to 14.5 cents with 18.8 million shares traded.

IMUGENE

Imugene says Sydney;s Macquarie University Hospital has approved its 32-patient, phase I, multi-centre, dose escalation trial of PD1-Vaxx for non-small cell lung cancer.

Earlier this week, Imugene said the Chris O'Brien Lifehouse had approved the trial and expected to begin patient screening in August (BD: Jul 14, 2020).

Today, the company said the primary aim of the trial was to determine safety and optimal biological dose, but efficacy, tolerability and immune response would also be measured. Imagene said additional clinical sites would be opened in Australia and in the US following US Food and Drug Administration investigational new drug approval.

Imagene was up 0.2 cents or 5.6 percent to 3.8 cents with 75.0 million shares traded.

AUSCANN

Auscann says it has a share sale facility for holders of unmarketable parcels of shares, worth less than \$500, based on 15.0 cents a share on the record date of July 16, 2020. Auscann said that 14,622 of its 23,079 shareholders would be eligible for the facility. The company said the facility would allow shareholders to sell shares without brokerage or handling costs and allow the company to reduce administrative costs.

Auscann said the closing date for the facility would be September 4, 2020.

Auscann was unchanged at 15 cents.

ECOFIBRE

Ecofibre says it will conduct two US phase II trials of its cannabidiol for agitation and chemotherapy-induced neuropathy.

Earlier this month, Ecofibre said it had begun a 100-patient, phase II trial of its Ananda Health cannabidiol (CBD) for chemotherapy-induced peripheral neuropathy (CIPN) at Philadelphia's Lankenau Institute for Medical Research (AVW: Jul 3, 2020).

This week, the company responded to an ASX request and said the trial, titled 'Coala-T-CBD', would assess the severity and duration of CIPN for non-metastatic breast, colorectal and ovarian cancer patients over 21 years of age.

Ecofibre said the trial would administer three daily doses of CBD for 12 weeks or a placebo to patients.

The company said the primary endpoints included change in touch sensation, pain sensation, vibration sensation, quality of life, CIPN symptom severity, pain severity and sleep quality.

Ecofibre said the trial was expected to be completed by April 1, 2022.

The company said the second study would be a 40-patient, phase II, randomized, double-blind trial of cannabidiol oil for agitation, sleep and mood in Alzheimer's disease patients. Ecofibre said the trial would administer 15mg of CBD oil twice a day for six weeks or a placebo to patients between 50 and 90 years of age.

The company said the primary endpoints included change in agitation and aggression, caregiver burden, patient quality of life and caregiver quality of life.

Ecofibre said the trial, held at the Norfolk, Virginia-based Eastern Virginia Medical School, was expected to begin this month and be completed in December 2021.

Ecofibre fell six cents or 2.6 percent to \$2.25.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has agreed on primary endpoints in a phase III trial of its synthetic cannabinoid BTX1503 for moderate to severe acne. Last year, Botanix said its 368-patient, phase II trial of BTX1503 for acne did not meet its primary endpoint for reduction of inflammatory lesions at 12 weeks (BD: Oct 23, 2019). In April, the company said it would suspend its dermatology program and focus on antimicrobial targets following the failure of both BTX1204 for eczema and BTX1503 for acne to meet their primary endpoints (BD: Oct 23, 2019; Mar 25, Apr 16, 2020) Today, Botanix said the FDA meeting was a "major milestone" and the FDA had provided confirmation on the drug development plan for BTX1503.

The company said the co-primary endpoints for the phase III trial would be to demonstrate an absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesions at week-12 and a proportion of patients with an investigators global assessment (IGA) of 'clear' or 'almost clear' and at least a two-grade improvement in IGA from baseline at week-12.

Botanix executive chairman Vince Ippolito said the company now had "clarification on the development program to support a new drug application for BTX1503".

The company said that planning for the phase III trial of BTX1503 would progress following the completion of an ongoing phase II trial of BTX1703 for rosacea, a chronic inflammatory skin condition, which had been halted by Covid-19 related restrictions. Botanix said the BTX1703 rosacea trial was "likely to provide supporting information for BTX 1503 acne program", but given limitations relating to Covid-19, it did not expect to be able to begin a multi-site, international phase III trial until next year.

Botanix fell 0.3 cents or 5.6 percent to 5.1 cents with 57.5 million shares traded.

INCANNEX HEALTHCARE (FORMERLY IMPRESSION HEALTHCARE)

Incannex says IHL-675A for sepsis associated acute respiratory distress syndrome reduces inflammatory cytokine levels in mice 19 to 44 percent more than the vehicle. Incannex said the trial of its marijuana-based IHL-675A dosed cohorts of mice with IHL-675A, hydroxychloroquine or a control, followed by the introduction of an inflammatory agent to induce sepsis, with had blood sampled after two hours.

The company said the trial tested five of the most vital cytokines linked to inflammation. Incannex said that compared to mice that received the vehicle, IHL-675A reduced the production of cytokine levels by a maximum of 19 to 44 percent, while hydroxychloroquine reduced cytokine levels by 18 to 35 percent.

The company said that compared to baseline mice IHL-675A reduced the five key inflammatory cytokine levels by 31 to 90 percent compared to vehicle, whilst hydroxychloroquine reduced the levels by 39 to 88 percent compared to vehicle. Incannex chief executive officer Joel Latham said that the "results confirm our strategy to pursue cannabinoid-based clinical assets relevant to major markets in indications with unmet need and no registered pharmacotherapeutic options".

The company said that it would proceed to an in-vitro study of IHL-675A which, if successful, would be followed by animal testing and later human tests if the drug candidate received an emergency use authorization, which could expedite a US Food and Drug Administration investigational new drug pathway.

Incannex was up 0.1 cents or 1.45 percent to seven cents with 39.2 million shares traded.

RHYTHM BIOSCIENCES

Rhythm has requested a trading halt pending an announcement "in connection with considering, planning and executing a material capital raising".

Trading will resume on July 23, 2020 or on an earlier announcement.

Rhythm last traded at 10.5 cents.

FACTOR THERAPEUTICS

Factor has requested a voluntary suspension to follow the trading halt requested earlier this week "regarding a potential acquisition" (BD: Jul 15, 2020).

The suspension will remain in place until Factor releases an announcement in relation to the outcome of the proposed acquisition.

Factor last traded at 0.5 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says its annual general meeting has blocked the issue of 10,000,000 shares and 65,000,004 performance rights to chief executive officer Dr Yacov Geva.

G Medical said the "incentive securities" to founder Dr Geva were opposed by 92,407,075 votes (57.1%), with 69,300,638 votes (42.9%) in favor.

The company said 20 of its 21 resolutions were passed, including the issue of shares and performance rights to directors Dr Brendan de Kauwe, Dr Kenneth Melani, Dr Shuki Gleitman, Urs Wettstein and Prof Zeev Rotstein, which faced about 20 percent opposition. G Medical's most recent Appendix 2A new issue notice said it had 663,786,555 shares on issue, meaning that the votes against Dr Geva's shares and performance rights amounted to 13.9 percent of the company, sufficient to requisition extraordinary general meetings. G Medical fell 1.2 cents or 18.75 percent to 5.2 cents with six million shares traded.

ANTERIS (FORMERLY ADMEDUS)

The Hong Kong-based Star Bright says it has reduced its substantial holding in Anteris from 1,277,155 shares (21.61%) to 730,192 shares (12.35%).

A substantial shareholder notice from Sydney's Gotham Legal Pty Ltd said the Star Bright Group comprised Star Bright Holding, Constellation International, Constellation Immunotherapy, Carron Services and former Admedus director Lishan Zhang.

The notice said the group sold the shares between June 19 and July 14, 2020, with the single largest sale 326,211 shares for \$HK10,000,000 (\$A1,846,350) or \$5.66 a share, transferring the shares to Everbest City Limited, care of CCS Trustees Limited of Tortola, British Virgin Islands.

In February, the then Admedus said it would hold a second consolidation, at 100-to-one, reducing the number of shares on offer from 590,842,817 shares to 5,908,428 shares and increasing the price per share from about seven cents to about \$7.00, but equivalent to an original pre-consolidation share price of about 0.7 cents (BD: Feb 26, 2020).

The first consolidation, at 10-to-one in November 2015, raised the company's then trading price from 6.7 cents to 67 cents (BD: Oct 14, Nov 16, 2015).

In August 2019, Lishan Zhang, Star Bright Holdings and associates said they increased their holding in Admedus in December 2018 to 133,453,435 shares (22.62), having become substantial with 70,556,169, shares or 19.99 percent in September 2017 (BD: Sep 17, 2018; Aug 7, 2019).

The 2019 notice, filed by Melbourne law firm Norton Rose Fulbright, said there was a change of interests following an entitlement offer at eight cents a share, equivalent to a post-consolidation price of \$8.00 a share.

In 2017, the then Admedus said Star Bright Holding intended to take 60 percent of subsidiary Admedus Vaccines Pty Ltd for \$18 million with Admedus chief executive officer Wayne Paterson to be its chairman for five years, but the sale was terminated in in 2019 (BD: Apr 27, 2017; Apr 23, 2019).

In September 2018, Ms Zhang, Star Bright and associates said they bought shares at prices ranging from 10 cents to 30 cents a share, with most of the shares bought at 13.03 cents a share, equivalent to post-consolidation prices of \$10.00, \$30.00 and \$13.03 a share, respectively (BD: Sep 17, 2018).

Anteris fell 49 cents or 10.2 percent to \$4.30.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network says it will host an event series, titled 'Bio-Business Insights: Opportunities in Regenerative Medicine' from July to October.

Bio-Melbourne said the series would be a collaboration with the Monash University-based Centre for the Commercialization of Regenerative Medicine Australia.

The Network said the series of six stand-alone webinars would include presentations from local speakers and guests from Canada, the UK and South Korea.

Bio-Melbourne said that the series aimed to "deliver insights and knowledge on themes that drive business success both locally and globally, uniting the regenerative medicine industry across research, translation and commercialization."

The Network said the Victoria Government was the main sponsor.

Bio-Melbourne said the first session would be held online on July 30, 2020 from 9am to 10am (AEST) and attendees could register for individual sessions or the full event.

To register go to: https://bit.ly/2WqPSEF.

CANN GROUP

Cann Group says it has appointed Jenni Pilcher as a director, pending statutory clearance from the Department of Health's Office of Drug Control.

Cann said Ms Pilcher was the chief financial officer and company secretary of Mach7 Technologies and had previously held executive roles with Alchemia and Mesoblast. The company said Ms Pilcher held a Bachelor of Business Studies from New Zealand's Massey University.

BIOTRON

Biotron says it has appointed Dr Stephen Becker as chief medical officer, based in the US. Biotron said Dr Becker had more than 30 years' experience as a researcher, clinician and product development executive with a focus on HIV and infectious disease therapeutics and immunology.

The company said that Dr Becker previously worked as the Bill and Melinda Gates Foundation HIV deputy director and held a Doctor of Medicine from State University of New York at Buffalo.

Biotron was up half a cent or 5.3 percent to 10 cents with 5.5 million shares traded.