



Biotech Daily

Tuesday April 23, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: AVITA UP 10%; ORTHOCELL DOWN 15%**
- * **ADMEDUS CORIDON SALE FAIL; ASX QUERY; FUNDING SUSPENSION**
- * **RESAPP CLAIMS 86% ADULT RESPIRATORY DIAGNOSTIC ACCURACY**
- * **ALCIDION Q3 RECEIPTS UP 50% TO \$6.2m**
- * **COGSTATE: 'ALZHEIMER'S TRIALS HIT Q3 REVENUE', DOWN 28% TO \$8.5m**
- * **ELIXINOL Q1 RECEIPTS UP 37% TO \$8m**
- * **CHINA APPROVES CARDIEX OSCAR 2 WITH SPHYGMOCOR**
- * **AIRXPANDERS FILES \$21m US SEC REGISTRATION FORM**
- * **POLYNOVO: 'POSTER BACKS NOVOSORB BTM FOR LEG ULCERS'**
- * **TOTAL BRAIN OFFERS FREE TRIAL TO MENTAL HEALTH AMERICA**
- * **FIL TAKES 6% OF ACTINOGEN**
- * **BLACKCRANE, DANIEL KIM TAKE 6% OF AVITA**
- * **FOUNDER DR MATTHEW MYNTTI TAKES 11.5% OF NEXT SCIENCE**
- * **G MEDICAL TO RELEASE 234m SHARES, 20m OPTIONS FROM ESCROW**
- * **IMUGENE: DR LESLEY RUSSELL DIRECTOR; 75m DIRECTOR OPTIONS**
- * **ELLUME APPOINTS DAVID GREEN CFO, CO SEC; MARK BOYLE CBO**
- * **NOXOPHARM DR GRAHAM KELLY CHAIR, DR GREG VAN WYK CEO**
- * **AUSBIOTECH MEDICAL TECHNOLOGIES MAY MELBOURNE CONFERENCE**

MARKET REPORT

The Australian stock market was up 0.95 percent on Tuesday April 23, 2019, with the ASX200 up 59.6 points to 6,319.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and two were untraded.

Avita was the best, up 3.5 cents or 9.9 percent to 39 cents, with 12.1 million shares traded. Compumedics and Optiscan climbed more than eight percent; Imugene and Pro Medicus were up more than five percent; Ellex improved 4.2 percent; Immutep, Polynovo and Resmed were up more than three percent; Alterity (Prana), Clinuvel, Cyclopharm, Nanosonics and Paradigm rose two percent or more; with Cochlear, Neuren and Opthea up by less than one percent.

Orthocell led the falls, down two cents or 15.4 percent to 11 cents, with 231,270 shares traded. Patrys, Prescient and Starpharma fell more than four percent; Benitec, Dimerix, Osprey, Proteomics and Telix lost more than three percent; Antisense shed 2.1 percent; with Oncosil and Volpara down more than one percent.

ADMEDUS

Admedus says its sale of Admedus Vaccines, formerly Coridon, has been terminated, the ASX has queried its announcements and it remains suspended for funding.

Last year, Admedus said the Hong Kong-based Star Bright Holding intended to take 60 percent of Admedus Vaccines for \$18 million, with Admedus to retain 29.1 percent of the vaccines business and chief executive officer Wayne Paterson would be chairman of the venture for five years (BD: Apr 27, Jun 27, 2018; Apr 10, 2019).

At that time, Admedus said Admedus Vaccines was developing DNA vaccines for the prevention and treatment of infectious diseases and cancers, including Epstein-Barr virus, or glandular fever, with research led by Gardasil inventor and head of the Brisbane-based Translational Research Institute Prof Ian Frazer.

On April 10, 2019, Admedus said Admedus Investments had a March 22 agreement for Constellation Therapeutics to acquire Admedus Vaccines, subject to conditions.

Today, Admedus said that Constellation Therapeutics had terminated the deal, but “expressed an intention to renegotiate the terms”.

Admedus said the Vaccines board had appointed Peter Anthony Lucas of P A Lucas & Co Pty Ltd as voluntary administrator and said it “previously gave notice that it had stopped funding Admedus Vaccines” (BD: Oct 30, Nov 2, 2017).

The company said that the annual general meeting resolution for approval of the transaction had been withdrawn.

An ASX query, dated April 17, 2019, before the Easter break on April 19, asked Admedus whether news of the Immunotherapies transaction was information that a reasonable person would expect to have a material effect on the price or value of its securities and if so why it was not released to the market prior to April 10, 2019?

Admedus said the information was material “in relation to the Immunotherapies transaction as a whole” but prior to April 10, 2019 the terms of the agreement had informally been agreed but “as the parties were executing the document in counterpart, the company was not aware that all parties had completed their internal processes to approve, execute and exchange the document until April 10, 2019”.

The company said that in its response to the ASX 109.3 percent price query on April 10, 2019, it announced the signing of the transaction on April 10, 2019 following feedback from ASX on the company’s draft notice of annual general meeting.

“The company did not consider the signing of the share sale agreement itself to be price sensitive” given that the key terms had been disclosed and it was subject to conditions outside the control of the company, Admedus said.

“Once the company was aware that the ASX had a different view to the company, the company requested a trading halt and then released the information to the market,” Admedus said.

On April 10, the ASX said the Admedus share price rose 109.3 percent from 4.3 cents on March 29 to 9.0 cents and noted a “significant increase” in the trading volume.

Admedus told the ASX that it did not consider the sale of its vaccines business on March 22, 2019 to be price sensitive, as it had been previously foreshadowed and was subject to conditions (BD: Apr 10, 2019).

Today, the company requested an extension to last week’s voluntary suspension to follow the April 15 trading halt “pending the release of an announcement regarding the immunotherapies transaction” saying the extension was “necessary ... to finalize the next phase of the company’s recapitalization plan” and expected the suspension to last until May 7, 2019 or the release of an announcement. (BD: Apr 15, 17, 2019).

Admedus last traded at six cents.

RESAPP HEALTH

Resapp says a 979-patient study shows its cough diagnostic has more than 86 percent agreement with clinical diagnoses for lower respiratory tract disease and pneumonia. Resapp said the study showed that its smartphone-based algorithms “accurately identified acute exacerbations in patients with chronic obstructive pulmonary disease or asthma” and were able to accurately screen for chronic obstructive pulmonary disease in a broad general population.

The company said that the top-line results from its Australian Breathe Easy adult prospective, double-blind clinical study found its diagnostic could diagnose all respiratory diseases included in the study: lower respiratory tract disease, pneumonia, asthma exacerbations, chronic obstructive pulmonary disease (COPD) and COPD exacerbations. Resapp chief executive officer Dr Tony Keating said “the breadth of these results is exciting”.

“Not only do we have outstanding results for the diagnosis of acute respiratory disease in adults, we also have compelling data on the identification of exacerbations in patients with asthma and COPD, as well as the ability to screen for COPD in the general population,” Dr Keating said.

“These results underpin the commercialization of a range of smartphone-based acute diagnostic and chronic disease management tools and we intend to use this data to support [Conformité Européenne (CE) mark] and [Australian Therapeutic Goods Administration] regulatory submissions,” Dr Keating said.

Resapp said the study compared its smartphone cough-based algorithms to a diagnosis reached by clinicians with full examination and results of investigations including, microbiology, chest x-ray, computed tomography, spirometry and bronchodilator testing. The company said that for identification of lower respiratory tract disease, the diagnostic achieved a positive percent agreement, or sensitivity, of 88 percent and a negative percent agreement, or specificity, of 89 percent when compared to a clinical diagnosis. Resapp said that similar levels of accuracy were demonstrated for pneumonia, with an 86 percent sensitivity and an 87 percent specificity compared to a clinical diagnosis, along with 86 percent sensitivity for COPD and 85 percent specificity, compared to a clinical diagnosis confirmed by lung function testing.

The company said that in patients with a history of COPD, its algorithms were able to identify COPD exacerbations with an 83% positive percent agreement and a 91 percent negative percent agreement compared with a clinical diagnosis.

Principal investigator and Resapp advisor Dr Scott Claxton said that asthma and COPD exacerbations had “a major impact on patient quality of life and the ability to identify exacerbations early will help patients and their doctors better manage their disease”.

“COPD screening in primary care has the potential to reduce the significant number of people who have undiagnosed, untreated COPD and provide them with treatment that can help improve their quality of life and reduce their risk of death,” Dr Claxton said.

Resapp was up 4.5 cents or 36.0 percent to 17 cents with 15.2 million shares traded.

ALCIDION

Alcidion says it has received \$6,182,000 in receipts from customers for the three months to March 31, 2019, up 49.6 percent compared to the previous quarter.

Alcidion’s revenue is not comparable with the previous corresponding period’s \$519,000 as the company subsequently acquired two businesses MKM Health and Patienttrack Holdings (BD: Apr 24, Jul 6, 2018).

Alcidion was up one cent or 16.95 percent to 6.9 cents with 10.3 million shares traded.

COGSTATE

Cogstate says that Alzheimer disease trials have impacted revenue for the three months to March 31, 2019, down 28.3 percent to \$US6.04 million (\$A8.48 million).

Cogstate said that sales “underperformed compared to both current year budget and prior corresponding period”.

The company said that sales in the third quarter was “consistent with sales results from the first two quarters and reflects the way in which the recent failure of Alzheimer’s disease clinical trials has negatively impacted the clinical trials services industry, including but not limited to, Cogstate”.

Cogstate was unchanged at 21.5 cents.

ELIXINOL GLOBAL

Elixinol says that receipts from customers for the three months to March 31, 2019 was up 37.4 percent to \$8,096,000 compared to the previous corresponding period.

Elixinol said that sales revenue was primarily from its hemp-derived food additive and cosmetic products.

Elixinol fell seven cents or 1.4 percent to \$5.06 with 561,868 shares traded.

CARDIEX

Cardiex says the Chinese Food and Drug Administration has approved its Oscar 2 with Sphygmocor inside ambulatory blood pressure monitor.

Cardiex said that the Oscar 2 was a product collaboration between its wholly-owned subsidiary Atcor Medical and the Morrisville, North Carolina-based Suntech Medical Inc and the companies would share sales margins.

The company said that the CFDA approval mean that the Oscar 2 monitor could be used by more than 20,000 physicians, hospitals and clinics throughout China.

Cardiex said that hypertension was a leading cause of more than 12 percent of annual adult deaths worldwide and a growing health disorder in China with over half the adult population currently affected.

The company said that the Oscar 2 with Sphygmocor allowed patients “to monitor blood pressure over a 24-hour period in their own homes and away from physician clinics and hospitals - a need that is specifically important in the Chinese market where the medical infrastructure and overburdened hospital systems often lead to less than optimal treatment and diagnosis”.

Cardiex said the total addressable market opportunity for sales of the Oscar 2 with Sphygmocor in China alone was about \$US50 million and with a combined effort of the Suntech and Atcor China sales divisions “we believe a 10 percent market share is potentially achievable”.

Cardiex chief executive officer Craig Cooper said that CFDA approval for Oscar 2 with Sphygmocor “marks yet another significant milestone for Cardiex and is an excellent example of our global health strategy in action”.

“The Chinese market for hypertension is massive and growing at over six percent per annum and there is an enormous need for effective blood pressure monitoring tools to meet the requirements of physicians, clinics, and patients,” Mr Cooper said.

Cardiex was up 0.1 cents or 2.6 percent to four cents with 9.7 million shares traded.

AIRXPANDERS

Airxpanders says it has filed a Form S-1 registration statement with the US Securities and Exchange Commission to raise up to \$US15,000,000 (\$A21,050,000).

Airxpanders said the filing related to a proposed rights offer and was an interim filing only. The company said that it intended the voluntary suspension would remain in place until at least May 6, 2019 (BD: Apr 2, 2019).

Airxpanders last traded at 3.5 cents.

POLYNOVO

Polynovo says a poster presentation backs its Novosorb biodegradable temporizing matrix (BTM) for diabetic foot and venous leg ulcers.

Polynovo said the study of three patients was conducted at Wake Forest University Hospital in North Carolina and the poster, titled 'Early Experience Using Biodegradable Temporizing Matrix For Reconstruction Of Chronic Wounds', by Dr Lucian Vlad and Dr Joseph Molnar was presented at the Diabetic Limb Salvage conference in Washington DC, April 4 to 6, 2019 and is available at: <http://polynovo.com.au/resources/>.

The poster presentation concluded that "BTM has proven a useful treatment strategy for management of chronic wounds presented".

"There is a need to further explore this option in randomized controlled trials and in other types of chronic wounds," the poster concluded.

The company said the poster reported on three patients where the Novosorb BTM "performed extremely well with final wound closure achieved" without surgery.

Polynovo said the size of the wounds healing without surgery or a skin graft "was a surprise" and demonstrated the high quality of dermis generated in the Novosorb BTM.

The company said that further trials would be required and a multi-centre trial was expected to begin by October 2019.

Polynovo chief executive officer Paul Brennan said the paper was "evidence that Novosorb BTM continues to perform strongly in difficult chronic wound environments".

Polynovo was up three cents or 3.35 percent to 92.5 cents.

TOTAL BRAIN (FORMERLY BRAIN RESOURCE)

Total Brain says it will offer a free trial of its "mental health and fitness platform" to the 7.7 million people who visit the Mental Health America website each year.

Total Brain said that the Alexandria, Virginia-based Mental Health America was a non-profit organization and its "constituents" would have the option to continue using the Total Brain service, post-trial, for a monthly fee.

The company said the free trial started on April 22, 2019 and the platform measured "the 12 brain capacities that define mental health" screened for mental health risks and engaged individuals in mental fitness programs that maximized their mental health.

Total Brain was unchanged at 2.8 cents.

ACTINOGEN MEDICAL

FIL Limited says it has increased its substantial shareholding in Actinogen from 56,375,471 shares (5.04%) to 68,461,972 shares (6.12%).

The Hong Kong-based FIL said it bought the shares between March 13 and April 16, 2019 at pricing ranging from 5.20 cents to 5.65 cents a share.

Actinogen was unchanged at 5.3 cents with 4.3 million shares traded.

AVITA MEDICAL

Blackcrane Capital and Daniel Kim say they have acquired the equivalent of 105,443,712 shares of 5.66% of Avita Medical.

The Bellview, Washington-based Blackcrane said that it held 59,445,952 Australia shares and 2,299,888 American depository receipts (ADRs), equivalent to 45,997,760 Australian shares.

The company said that it acquired the shares between Feb 8 and April 9, 2019, with the single largest purchase 975,945 ADRs equivalent to 19,518,900 Australian shares for \$US6,830,709 (AU\$9,589,540) or 49.1 cents a share.

Avita was up 3.5 cents or 9.9 percent to 39 cents with 12.1 million shares traded.

NEXT SCIENCE

Next Science founder and chief technology officer Dr Matthew Myntti says he has become substantial in the company with 20,657,000 shares or 11.53 percent.

Last week, Next Science listed in the ASX to commercial its Xbio anti-bacterial technology (BD Apr. 2019).

The company's directors have published their initial directors interest notices.

Next Science was up 32.5 cents or 24.1 percent to \$1.675 with 4.4 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it will release 233,898,001 shares and 20,315,170 unlisted options from ASX escrow on May 10, 2019

G Medical said the options were exercisable at 30 cents each by May 1, 2020.

The company's most recent Appendix 3B new issue announcement said that it had 129,326,038 shares quoted on the ASX and following the release it would have 363,224,039 shares available for trading with no more shares held in escrow.

G Medical was unchanged at 32.5 cents.

IMUGENE

Imugene says it has appointed pharmaceutical executive Dr Lesley Russell as a non-executive director, effective from April 23, 2019.

Imugene said that Dr Russell had more than 25 years of operational and leadership experience with established and emerging pharmaceutical companies across multiple therapeutic areas including oncology and haematology.

The company said that Dr Russell previously worked for Amgen, Eli Lilly, US Bioscience - Medimmune Oncology, Cephalon, Teva Pharmaceuticals, Tetralogic and Innocoll Holdings and was currently a non-executive director of Amag Pharmaceuticals, Enanta Pharmaceuticals and Sojournix.

Imugene said that subject to shareholder approval, it would issue Dr Russell a total of 25,000,000 unlisted options, comprising 5,000,000 options exercisable at 4.0 cents each, 10,000,000 exercisable at 4.2 cents each and 10,000,000 options exercisable at 4.5 cents each within three years from approval and to be vested over 24 months.

The company said it would issue 25 million unlisted options to non-executive directors, Charles Walker and Dr Axel Hoos on the same terms and conditions.

Imugene was up 0.1 cents or 5.9 percent to 1.8 cents with 2.7 million shares traded.

ELLUME

Ellume says it has appointed David Green as chief financial officer and company secretary and Mark Boyle as chief business officer (BD: Apr 9, 2019).

Ellume said that Mr Green had more than 25 years' experience in finance roles in private and public companies and had been employed by Sigma Pharmaceuticals and Alchemia as their chief financial officer.

The company said that Mr Boyle had more than 20 years' experience in in-vitro diagnostic and biotechnology management and was previously Cellestis Inc's president and more recently was Clinical Genomics head of in-vitro diagnostics.

Ellume is a public unlisted company.

NOXOPHARM

Noxopharm says that founder Dr Graham Kelly has replaced chairman Peter Marks as executive chairman with Dr Greg van Wyk promoted to chief executive officer.

Noxopharm said that Mr Marks continued as a non-executive deputy chairman "prompted by a strategic decision to start the process of raising the company's profile and presence in the US including a listing of its securities on the Nasdaq".

The company said that as chairman Dr Kelly, who was formerly the company's chief executive officer, would "spend a considerable amount of time looking to raise the company's profile in the US capital markets".

Noxopharm said that Dr Beata Niechoda had been appointed as "a special advisor to the board".

The company said that Dr Niechoda had experience as a medical director in pharmaceutical companies.

Noxopharm said Dr Greg van Wyk had been appointed as chief executive officer as well as the previously reported position as chief medical officer (BD: Oct 22, 2018).

The company said that Jeanette Bell had been appointed as chief operating officer and Shawn Van Boheemen as chief financial officer.

Noxopharm fell one cent or 2.1 percent to 47 cents.

AUSBIOTECH

Ausbiotech says its 23019 medical technology industry conference Ausmedtech 2019 will be held in Melbourne on May 14 and 15, 2019.

Ausbiotech said that the twelfth annual conference would bring together more than 300 medical technology developers and professionals to Melbourne for the conference, under the theme 'Bionics and Beyond'.

The industry organization said the conference would be officially opened by Victoria's Minister for Jobs, Innovation and Trade Martin Pakula, with speakers including industry leaders, regulatory experts and researchers.

Details, including the program are at: www.ausmedtech.com.au/.