



# Biotech Daily

Monday November 23, 2020

*Daily news on ASX-listed biotechnology companies*

- \* ASX, BIOTECH UP: IMPEDIMED UP 23%; KAZIA DOWN 10%
- \* IMAGION 'HEAVILY OVERSUBSCRIBED' PLACEMENT RAISES \$6m
- \* CANN GROUP TAKES NAB \$50m MILDURA MARIJUANA LOAN
- \* IMUGENE CLAIMS HER-VAXX CANCER 'STATISTICAL SIGNIFICANCE'
- \* CORRECTION: ACTINOGEN MEDICAL
- \* AZURE \$1.6m TACERA NURSE CALL SALE TO CANADA HOSPITAL
- \* REDHILL BEGINS PHASE III RHB-204 STUDY FOR LUNG DISEASE
- \* REDHILL: SAFETY BOARD BACKS OPAGANIB COVID-19 STUDY
- \* OSTEOPORE APPOINTS MTG GERMANY, AUSTRIA DISTRIBUTOR
- \* NEXT SCIENCE, 3M DROP BLASTX DISTRIBUTION DEAL
- \* RECCE: JAPAN R327, R529 PATENT FOR VIRAL INFECTIONS
- \* BARD1: TEXAS HTERT BLADDER CANCER TEST CUSTOMER
- \* OVENTUS: VGM TO PROMOTE O2VENT
- \* VISIONEERING LAUNCHES SHARED VISION EDUCATION PLATFORM
- \* INCANNEX: 'IHL-675A OUTPERFORMS CBD FOR ARDS, IN MICE'
- \* MEDIBIO: COMPASS LICENCE FOR ILUMEN MENTAL HEALTH PLATFORM
- \* OVENTUS: 10% PLACEMENT FACILITY FALLS ON 35% OPPOSITION
- \* MEDADVISOR 6m CEO, DIRECTOR OPTIONS AGM
- \* ANTISENSE DUAL LISTS ON FRANKFURT EXCHANGE
- \* IQ RESPONDS TO MEDIA REPORTS
- \* MGC COMPLETES \$1.4m MEDICINAL CANNABIS CLINICS ACQUISITION
- \* ELIXINOL DIRECTOR PAUL BENHAIM, RAW WITH LIFE DILUTED TO 12.3%
- \* CHIMERIC APPOINTS JENNIFER CHOW COO, DR SYED RIZVI CMO
- \* ANTERIS DURAVR VALVE WINS 'BEST INNOVATION' GONG

## MARKET REPORT

The Australian stock market was up 0.34 percent on Monday November 23, 2020, with the ASX200 up 22.4 points to 6,561.6 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 15 fell and six traded unchanged.

Impedimed was the best on no news, up 2.5 cents or 22.7 percent to 13.5 cents, with 19.2 million shares traded. Mesoblast climbed a further 17.6 percent to \$4.28 - up 30.9 percent since Friday's Novartis announcement.

Imugene improved 15 percent; Alterity, Compumedics and Resonance were up more than five percent; Immutep and Prescient were up more than three percent; Medical Developments, Neuren, Opthea, Polynovo and Universal Biosensors rose more than two percent; CSL, Cyclopharm, Optiscan, Paradigm, Telix and Volpara were up one percent or more; with Clinuvel and Resmed up by less than one percent.

Kazia led the falls for the second trading day in a row, down 16 cents or 10.2 percent to \$1.41, with 815,467 shares traded.

Next Science lost 9.2 percent; Amplia, was down 6.25 percent; LBT, Orthocell and Osprey fell four percent or more; Avita and Uscom were down more than three percent; Cochlear, Cynata and Starpharma shed more than two percent; Antisense, Dimerix, Pro Medicus and Proteomics were down one percent or more; with Genetic Signatures down 0.3 percent.

## IMAGION BIOSYSTEMS

Imagion says it has raised \$6 million through a "heavily oversubscribed" placement at 8.5 cents a share.

In July, Imagion said it had raised \$5 million in an oversubscribed placement at 4.5 cents share (BD: Jul 29, 2020).

Today, the company said the issue price was at a six percent discount to the 30-day volume weighted average price and the funds would be used to accelerate development plans and to begin investing in manufacturing scale-up of its Magsense HER2 breast cancer nanoparticle imaging technology.

Imagion said Evolution Capital Advisors was the lead manager to the placement.

Imagion fell half a cent or four percent to 12 cents with 33.8 million shares traded.

## CANN GROUP

Cann Group says the National Australia Bank has approved a \$50 million secured debt facility to construct the first stage of its Mildura marijuana production facility.

Cann Group did not disclose the interest rate or term of the loan but said it would allow it to recommence construction at the Mildura site, with work expected to be underway by February 2021 and construction of the first stage expected to take nine months.

The company said it expected the first product to be processed and released by March 2022 and to complete the documentation for funding with the bank within the next month.

Cann Group was up four cents or 12.9 percent to 35 cents with 6.3 million shares traded.

## IMUGENE

Imugene says an interim analysis of its 68-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer shows “statistically significant” benefit.

Imugene did not disclose the number of patients in the interim analysis of the trial being conducted in Eastern Europe and India, but said the independent data monitoring committee established a “hazard ratio” of 0.418 meaning that HER-Vaxx reduced the risk of death by 58.2 percent.

The company said that it specified a one-sided false positive probability of 0.10, and the interim analysis resulted in “a statistically significant one-sided p-value of 0.083”.

Imugene said the primary endpoint was overall survival, and the secondary endpoint was progression-free survival, with safety, tolerability and immune response to be measured.

The company said the median overall survival for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months for chemotherapy alone.

Imugene said the phase II trial showed a “proof-of-concept signal for HER-Vaxx when added to chemotherapy ... [indicating] that B-cell activating immunotherapy vaccines can induce clinically active antibody responses”.

The company said that the data monitoring committee confirmed “a favorable survival outcome with no added toxicity for HER-Vaxx combined with [standard-of-care] chemotherapy over chemotherapy alone” and advised the company to lower the number of patients required for study completion.

Imugene said the committee “reported no safety concerns and viewed this preliminary data as strongly in favor of a HER-Vaxx survival effect”, with no difference in safety events between the two treatment arms.

The company said the longest HER-Vaxx treated patient remains on therapy and progression-free 16.3 months after dosing.

Imugene said that historical data from the 2014 Hoffman La Roche ‘Toga’ study of Herceptin, or trastuzumab, with chemotherapy compared to chemotherapy alone in patients with HER2-positive advanced gastric cancer “had an overall survival [hazard ratio] of 0.74 for the intent-to treat analysis of the same patient population as the HER-Vaxx phase II study”.

The company said the data monitoring committee “provided guidance that it is scientifically and ethically appropriate to reduce the overall number of patients required to complete the study given the strong signal observed in the data”.

Imugene chief executive officer Leslie Chong said she was “delighted to report that we have achieved this significant milestone for patients with advanced gastric cancer”.

“I am excited that the interim analysis favored the survival outcome for HER-Vaxx and the [committee] suggested to shorten the study by lowering the number of patients,” Ms Chong said. “This data represents a clinical proof-of-concept for HER-Vaxx and supports our B-cell activating immunotherapy platform.”

Imugene was up 1.5 cents or 15 percent to 11.5 cents with 98.2 million shares traded.

## CORRECTION: ACTINOGEN MEDICAL

Friday’s article on Actinogen included three small errors.

We reported that the Xanamia trial expected data within 12 months, whereas the company says it expects it will require 24 months for the first read-out; in Alzheimer’s disease, beta amyloid is produced in the brain, not as reported; and males are more likely to have Fragile X syndrome than females.

Three small sub-editors have been dismissed.

Actinogen was unchanged at 2.2 cents with 1.3 million shares traded.

## [AZURE HEALTHCARE](#)

Azure says subsidiary Austco Canada has won a \$1.6 million contract to supply its Tacera Nurse Call platform to an undisclosed Canadian hospital.

Azure said the new 27-acre (10.9 hectare), 350-bed hospital was under construction, with completion scheduled for 2023 and the Tacera platform was expected to be delivered during 2022.

The company said all 350 beds would feature its Austco patient station and integrations with Ellis Don's building management system to enhance communication between patients and caregivers.

Azure said it was chosen for the contract based on Tacera's software interfaces and open protocols.

The company's website said Tacera Nurse Call included pendants, pillow speakers, call points, workflow systems and tools for infection control, fall prevention and reporting.

Azure fell 0.3 cents or 3.2 percent to nine cents with 1.4 million shares traded.

## [REDHILL BIOPHARMA](#)

Redhill says it has begun an up-to 125-patient, phase III study of RHB-204 as a potential stand-alone oral treatment for pulmonary non-tuberculous mycobacteria.

In August, Redhill said the US Food and Drug Administration approved the phase III trial for pulmonary non-tuberculous mycobacteria (NTM), a debilitating lung disease caused by Mycobacterium avium complex bacteria and which could lead to bronchitis, pneumonia and respiratory failure (BD: Aug 3, Oct 15, 2020).

Today, the company said the multi-center, randomized, double-blind, two-part, placebo-controlled, parallel-group safety and efficacy study would be held at up-to 40 US sites.

Redhill said the study endpoints included sputum culture conversion at six months and patient-report outcomes, including physical functioning, respiratory symptoms and fatigue.

The company said that following part one of the study, patients may continue a double-blind treatment for 16 months for part two of the study.

Separately, Redhill said the independent data and safety monitoring board unanimously recommended its phase II/III study of opaganib for Covid-19 pneumonia continue.

Redhill said the recommendation was based on an unblinded analysis of safety data from the first 70 patients treated for 14 days.

Last week, the company said it had completed enrolment of its 40-patient, phase II US study of opaganib, or Yeliva, for Covid-19-related pneumonia (BD: Nov 17, 2020).

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

On the Nasdaq, on Friday, Redhill was up three US cents or 0.33 percent to \$US9.00 (\$A12.31) with 554,567 shares traded.

## [OSTEOPORE](#)

Osteopore says it has a two-year exclusive distribution agreement with MTG Medizintechnik Göhl to promote and sell its products in Germany and Austria.

Osteopore said that under the agreement, MTG would market its bone healing products for craniofacial procedures and patient-specific implants, including its Osteoplug, Osteoplug-C and Osteomesh.

The company said there were no binding minimum sales thresholds, and it would work with MTG to provide training and to support sale representatives.

Osteopore was up two cents or 3.5 percent to 59 cents.

### NEXT SCIENCE

Next Science says it has agreed with Minnesota's 3M Co to not renew the distribution agreement with its Blastx antimicrobial wound gel treatment for chronic wounds.

Next Science said the three-year agreement required the companies to consider their relationship by December 31, 2020, the end of its second year, the companies agreed to not renew, and discussions were ongoing regarding the return of Blastx.

Next Science fell 11.5 cents or 9.2 percent to \$1.13.

### RECCE PHARMACEUTICALS

Recce says the Japan Patent Office has granted it a patent for R327 and R529 (formerly Recce-327 and Recce-529) for viral infections.

Recce said the patent, titled 'Anti-virus Agent and Method for Treatment of Viral Infection', would protect its intellectual property until February 2037.

Recce was up 7.5 cents or 6.9 percent to \$1.16.

### BARD1 LIFE SCIENCES

Bard1 says it has gained an unnamed high-volume Texas-based customer for its Htert adjunct urine cytology test for bladder cancer.

Bard1 said that in partnership with its US distributor Statlab Medical Products, it was changing its US sales and marketing strategy to focus on high-volume customers who performed more than 10,000 urine cytology tests a year.

In July, the company said it had completed the acquisition of Sienna Cancer Diagnostics to merge both companies' cancer tests (BD: Apr 9, Jul 29, 2020).

Bard1 was unchanged at 2.5 cents with 6.2 million shares traded.

### OVENTUS MEDICAL

Oventus says it has an initial one-year marketing agreement with the Waterloo, Iowa-based VGM & Associates to provide its devices to member organizations.

Oventus said VGM was a member service organisation that provided post-acute healthcare, including durable medical equipment, home medical equipment and sleep and respiratory equipment in the US and its member base exceeded 7,000 locations.

The company said VGM would promote its sleep apnoea treatment platform and laboratory inside a laboratory business model as a preferred supplier of oral appliance therapy to more than 2,500 members of sleep and respiratory services.

Oventus said the agreement would automatically renew each year unless a party elected not to renew, and it expected to begin the launching in January 2021.

Oventus was up two cents or 9.5 percent to 23 cents.

### VISIONEERING TECHNOLOGIES

Visioneering says it has launched an education platform, Shared Vision, to help eye care professionals understand issues related to myopia management.

Visioneering said Shared Vision had 15 opinion leaders discuss myopia in a series of short videos and covered topics including the impact of eye growth disease states, the future prevalence of myopia, contact lenses, safety for children and multifocal design.

Visioneering fell 0.1 cents or 3.1 percent to 3.1 cents.

## INCANNEX HEALTHCARE

Incannex says a mouse model of its IHL-675A cannabidiol and hydroxychloroquine combination outperforms cannabidiol alone in inhibiting inflammatory cytokines.

In August, Incannex said that both components of IHL-675A displayed anti-inflammatory dose response curves for sepsis-related acute respiratory distress syndrome (Ards) in an in-vitro assay (BD: Aug 26, 2020).

Today, the company said the mouse study injected cannabidiol and hydroxychloroquine alone and in combination into mice to assess IHL-675A for each of five cytokines after two hours.

Incannex said it found that IHL-675A components acted together to inhibit the production of inflammatory cytokines and out-performed the predicted cytokine inhibition by 26 to 81 percent after two hours.

The company said the potent anti-inflammatory activity made IHL-675A “an excellent candidate for prevention and treatment of sepsis-associated acute respiratory distress syndrome”, which was caused by a hyper-inflammatory response to infections and was a leading cause of Covid-19 mortality.

Incannex said it had engaged Camargo Pharmaceutical Services to assist in a pre-investigational new drug meeting with the US Food and Drug Administration to seek advice on the most efficient development plan.

Incannex was up 1.5 cents or 13.0 percent to 13 cents with 17.2 million shares traded.

## MEDIBIO

Medibio says it has an initial three-year licence and services agreement with Chertsey, England's Compass Group for its Ilumen mental health assessment platform.

Medibio said it would make Ilumen available to Compass' contract food and support services companies and would give Compass the right to licence Ilumen to its clients.

The company said it would receive annual licence fees, calculated per employee, from each Compass and client company that implemented Ilumen and the licence would be automatically renewed for an additional two years unless terminated.

In April, Medibio said it had completed its fourth and final pilot study of its Ilumen mental health assessment platform with Compass Group, which aimed to identify high risk Compass employees and to send an email recommending that they see a doctor or access other assistance (BD: Apr 9, 2020).

Medibio fell 0.1 cents or 7.1 percent to 1.3 cents with 54.0 million shares traded.

## OVENTUS MEDICAL

Oventus says its 10 percent placement facility special resolution fell on 34.97 percent dissent at its annual general meeting.

Oventus said there were 22,806,027 votes (34.97%) opposed to the placement facility, with 42,413,659 votes (65.03%) in favor.

The company said all other resolutions passed easily.

According to Oventus' most recent Appendix 2A new issue announcement, the company had 158,262,417 shares on issue, meaning the 22,806,027 votes against the placement capacity amounted to 14.4 percent, sufficient to call extraordinary general meetings.

## MEDADVISOR

Medadvisor says its annual general meeting will vote to issue 6,000,000 options to chief executive officer Robert Read and non-executive chairman Christopher Ridd.

Medadvisor said investors would vote to issue 4,500,000 options to Mr Read under its long-term incentive plan, exercisable at 70 cents by October 30, 2029 and subject to performance hurdles.

The company said the meeting would vote to issue 1,500,000 options to Mr Ridd, with half exercisable at 60 cents by October 30, 2023 and the balance exercisable at 67.5 cents by October 30, 2024.

Medadvisor said it would vote to adopt its remuneration report, to re-elect Josh Swinnerton, Jim Xenos and Mr Ridd as directors, approve the 10 percent placement capacity and ratify the prior issue of shares.

The virtual meeting will be held on December 21, 2020 at 9am (AEDT) with registration at” <https://medadvisor.verovoting.com.au/>.

Medadvisor was up two cents or 5.5 percent to 38.5 cents with 1.7 million shares traded.

## ANTISENSE THERAPEUTICS

Antisense says it has begun its dual listing on the Frankfurt Stock Exchange from today and will trade under the code AWY.

Earlier this month, Antisense said it had begun proceedings for a dual listing on the Frankfurt Stock Exchange to facilitate European investment and the Frankfurt-based Institute for Asset and Equity Allocation and Valuation had been appointed as its European investor and corporate relations advisor (BD: Nov 9, 2020).

Today, the company said the dual listing was possible without primary listing procedures and there was no requirement to issue additional shares as its shares were listed on the ASX, and approved Frankfurt exchange.

Antisense fell 0.1 cents or one percent to 9.9 cents with 11.4 million shares traded.

## IQ3 CORP

There have been media reports relating to IQ Group and a subsidiary called Ethical Bioscience Investments.

The IQ Group told Biotech Daily today that it provided the following responses to the Australian Financial Review, last week.

The IQ Group said that Ethical Bioscience Investments “considers that appropriate disclosure has been made to relevant sophisticated investors eligible to invest in the ... fixed income notes”.

The company said that its group of companies were “in compliance with applicable corporate law and regulations and relevant listing rules”.

The IQ Group said the audited financial statements and disclosures of its companies were “prepared in accordance with applicable Australian accounting standards or US generally accepted accounting principles, as applicable.

The company said that of the total funds its group of companies had raised to date, “the component represented by external bonds amounts to 25 percent”.

IQ Group said that in relation to a further article, it would provide an announcement to the ASX today.

The announcement had not been made at the time of publication.

IQ3 Corp was untraded at 30 cents.

### MGC PHARMACEUTICALS

MGC says it has completed the \$1.4 million acquisition of Cannvalate Pty Ltd subsidiary and telehealth clinic Medicinal Cannabis Clinics Pty Ltd.

In July, MGC said it would pay Cannvalate \$1 million in shares and \$400,000 in cash for its Melbourne subsidiary Medicinal Cannabis Clinics (BD: Jul 20, 2020).

Today, the company said it would pay Cannvalate the shares and cash in the coming days and for the first two years, the clinic would continue to be managed by Cannvalate.

MGC said Medicinal Cannabis Clinics was in the process of obtaining state and federal licences to import and distribute MGC's marijuana products in Australia.

MGC was up 0.1 cents or 4.8 percent to 2.2 cents with 4.5 million shares traded.

### ELIXINOL GLOBAL

Elixinol non-executive director Paul Benhaim and Raw with Life and say their 29,523,008 share-holding has been diluted from 15.31 percent to 12.25 percent.

The Mullumbimby, New South Wales-based Mr Benhaim and Raw with Life said that they were diluted on November 23, 2020 following the \$8.2 million placement at 17 cents a share (BD: Nov 16, 2020).

Elixinol fell half a cent or 2.9 percent to 16.5 cents with 1.2 million shares traded.

### CHIMERIC THERAPEUTICS

Chimeric says it has appointed the US-based Jennifer Chow as chief operating officer and Dr Syed Rizvi as chief medical officer.

Last week, Biotech Daily said it understood that Chimeric was planning a \$30 million ASX initial public offer at 20 cents a share to develop chimeric antigen receptor T-cells (Car-T cells) for glioblastoma (BD: Nov 17, 2020).

Today, the company said Ms Chow was previously Kite Pharmaceuticals head of marketing, analytics and commercial operations and Celgene Corp's cell therapy commercial lead.

Chimeric said Dr Rizvi was previously the Legend Biotech head of clinical development, medical affairs and clinical sciences and Celgene Corp medical affairs head of Car-T program, and previously worked at New York's Saint Vincent's Comprehensive Cancer Center.

Chimeric is a public unlisted company.

### ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says its Duravr single-piece aortic valve has been selected as a "best innovation" at the Paris Course on Revascularization London Valves conference.

Anteris said data from its first-in-human trial would be presented at the virtual conference from November 22 to 24, 2020.

Anteris was up 10 cents or 2.6 percent to \$3.90.