Biotech Daily

Monday August 23, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: DIMERIX UP 11.5%; OSPREY DOWN 15%**

*** MACH 7 REVENUE UP 1% TO $19m, PROFIT TO $9m LOSS**

*** CYCLOPHARM H1 REVENUE UP 47% TO $8.5m, LOSS DOWN 31% TO $4m**

*** IDT: VICTORIA BUYS $1m mRNA NANOASSEMBLR; FEDERAL FACILITY**

*** BOD REVENUE UP 25% TO $7.5m, LOSS UP 12% TO $4m**

*** CANN GROUP REVENUE UP 369% TO $4m, LOSS UP 48% TO $25m**

*** BARD1 'OVERSUBSCRIBED' PLAN RAISES $3.4m; TOTAL $18.4m**

*** POLYNOVO STARTS NOVOSORB SYNTREL HERNIA REPAIR TRIAL**

*** IMPEDIMED: FDA SOZO BREAKTHROUGH STATUS FOR KIDNEY FAILURE**

*** TELIX, LIGHTPOINT WORK ON RADIATION-GUIDED SURGERY**

*** ISLAND, GRIFFITH UNI REPURPOSE ANTI-VIRALS**

*** NOXOPHARM: NOX66/IDRONOXIL/VEYONDA BENEFIT FOR COVID-19**

*** LUMOS RELEASES 10m ESCROW SHARES**

*** ACTINOGEN: BRAZIL PATENT COMPLETES XANAMEM PROTECTION**

*** MITSUBISHI TANABE PHARMA KOREA ENDS SUDA ZOLPIMIST LICENCE**

*** VECTUS DOSES 1st VB0004 BLOOD-PRESSURE COHORT**

*** STARPHARMA: 'VIRALEZE KILLS SARS-COV-2 MORE THAN 99.9% IN MICE'**

*** ALTHEA, CANOPY GROWTH MARIJUANA MANUFACTURING DEAL**

*** SUSPENDED TBG SUSPENDED FOR NON-PAYMENT OF LISTING FEES**

*** CO-FOUNDER DR WILLIAM GARNER TAKES 27% OF ISLAND**

*** COTIVITI TALES 11.7% OF MEDADVISOR**

*** PRO MEDICUS APPOINTS ALICE WILLIAMS DIRECTOR**

*** ANTEO LOSES CFO GAIL JUKES; DUNCAN CORNISH INTERIM CFO**

MARKET REPORT

The Australian stock market was up 0.39 percent on Monday August 23, 2021, with the ASX200 up 29.0 points to 7,489.9 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 10 fell, five traded unchanged and one was untraded. All three Big Caps rose.

Dimerix was the best, up 3.5 cents or 11.5 percent to 34 cents, with 4.4 million shares traded. Genetic Signatures and Impedimed climbed more than nine percent; Imugene improved 8.8 percent; Starpharma was up 5.7 percent; Mesoblast, Neuren and Pharmaxis were up more than four percent; Antisense, Avita and Resmed climbed three percent or more; Amplia, Cynata, Oncosil and Opthea rose two percent or more; Clinuvel, Cochlear, Immutep, Nanosonics, Nova Eye, Pro Medicus and Telix climbed one percent or more; with CSL, Cyclopharm, Paradigm, Universal Biosensors and Volpara up by less than one percent.

Osprey led the falls, down 0.2 cents or 15.4 percent to 1.1 cents, with 8.3 million shares traded. Next Science lost 5.1 percent; Polynovo fell 4.5 percent; Uscom was down 3.3 percent; Medical Developments, Patrys and Prescient shed two percent or more; with Compumedics, Kazia and Orthocell down by less than one percent.

MACH 7 TECHNOLOGIES

Mach 7 says revenue for the year to June 30, 2021 was up 0.9 percent to $19,027,093 with a net profit after tax turned to loss of $9,357,196.
Mach 7 said revenue was primarily from sales of imaging equipment for hospitals.
The company said that most of the loss was related to last year's $40,942,776 acquisition of the Waterloo, Ontario-based Client Outlook Inc (BD: Jul 14, 2020).
Mach 7 said Covid-19 travel restrictions impacted the integration of the Client Outlook business and limited time with potential customers, partners and existing customers.
The company said that certain sales orders were subjected to phased roll-outs at the customers' request, which pushed revenue recognition and cash collection into next year.
Mach 7 said that it had recorded "its largest sales order intake in its history and the sales pipeline of opportunities remains strong".
The company said that last year's one cent diluted earnings per share was turned to a four cents diluted loss per share, with net tangible asset backing per share down 63.6 percent to eight cents, and it had cash and cash equivalents of $18,363,398 on June 30, 2021 compared to $48,874,210 on June 30, 2020.
Mach 7 fell 3.5 cents or 3.5 percent to 96 cents.

CYCLOPHARM

Cyclopharm says total revenue for the six months to June 30, 2021 was up 47.0 percent to $8,481,555 with net loss after tax down 30.5 percent to $3,928,319.
Cyclopharm said sales of Technegas for lung imaging rose 41.4 percent to $7,935,727, with sales for its Cyclotek Australia collaboration up 161.3 percent to $401,694.
The company said it would pay an unfranked interim dividend of 0.5 cents, for a record date of September 6 and payable on September 13, 2021.
Cyclopharm said net tangible asset backing per share was up 180 percent to 42 cents, diluted loss per share was down 39.3 percent to 4.46 cents and it had cash and cash equivalents of $31,648,411 on June 30, 2021 compared to $8,063,535 in June 30, 2020.
Cyclopharm was up one cent or 0.6 percent to $1.65.

VICTORIA GOVERNMENT, IDT AUSTRALIA, FEDERAL GOVERNMENT

The Victoria Government says a $1 million Nanoassemblr has been shipped to Melbourne's IDT Australia to manufacture the final product for mRNA vaccines.

IDT Australia chief executive officer Dr David Sparling told Biotech Daily that the

A Victoria Government spokesperson told Biotech Daily that the State-funded mRNA Victoria paid for the Nanoassemblr (BD: Apr 21, Jun 21, 22, 2021).

Nanoassemblr was manufactured by the Vancouver, British Columbia-based Precision Nanosystems Inc.

The State Government said the Nanoassemblr was "a key piece of equipment … to enable the critical manufacturing capability of mRNA vaccines to commence".

A media release from the Minister for Innovation and Medical Research Jaala Pulford said the Nanoassemblr was "the only machine of its kind in Australia and can process nanoparticles into final liquid drug form, sterilize the product and fill vials with mRNA vaccines".

The media release said it could manufacture more than 150 doses for phase I clinical trials of Australia's first locally-developed mRNA coronavirus vaccine, as part of a trial run by the Monash Institute of Pharmaceutical Sciences (MIPS).

The media release said that IDT's mRNA manufacturing capability brought "a level of expertise to Victoria that is currently unavailable anywhere else in Australia".

"The collaboration between MIPS, the Doherty Institute and IDT Australia reinforces the strong mRNA sector in Victoria, our research strength and manufacturing capability," the State Government said.

The media release said that clinical trials were due to start in October 2021, with preliminary results expected by July 2022.

Ms Pulford said the Victoria Government had "acted swiftly to establish mRNA Victoria and committed $50 million to grow mRNA capability here".

Separately, IDT it had a Sterile Readiness Agreement with the Federal Department of Health to recommission its Melbourne based sterile manufacturing facilities for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) vaccines.

IDT said that it had agreed to ensure the production capacity of its sterile facility would be exclusively for the Department of Health or its nominee until the earlier of executing a supply agreement to deliver a vaccine, or four months from completion of the sterile readiness works.

The company said that the remaining activities relating to the sterile facility recommissioning would continue for the next one to two months, and it would maintain the facility in a sterile state, exclusively for the Federal Government.

IDT said that during the exclusivity period, the Federal Government could nominate a vaccine, and IDT and the relevant vaccine company would need to agree on commercial terms for the manufacture of the specific vaccine.

The company said that the Federal Department of Health had been briefed on IDT potentially providing manufacturing support for Australia's first locally developed Sars-Cov-2 mRNA vaccine candidate, developed by the Monash Institute of Pharmaceutical Sciences with the support of the Victoria Government.

"IDT has now formalized its activities with the Australian Government to be ready to potentially assist with the production of a Covid-19 vaccine," Dr Sparling said.

"As we have seen in recent weeks, the environment surrounding COVID-19 is very dynamic," Dr Sparling said.

"IDT is doing what it can to be ready and is standing-by for direction from the Federal Government," Dr Sparling said.

IDT was up 13.5 cents or 24.55 percent to 68.5 cents with 21.9 million shares traded.

BOD AUSTRALIA

Bod says revenue for the year to June 30, 2021 was up 25.4 percent to $7,525,774 with a net loss after tax down 12.3 percent to $4,226,105.
Bod said revenue was primarily from sales of marijuana products.
Bod said that diluted loss per share was down 21.1 percent to 4.26 cents, with net tangible asset backing per share was up 64.8 percent to 7.86 cents, and it had cash and cash equivalents of $8,053,279 on June 30, 2021 compared to $6,385,663 on June 30, 2020.
Bod Australia fell 1.5 cents or five percent to 28.5 cents.

CANN GROUP

Cann Group says revenue for the year to June 30, 2021 was up 369.05 percent to $4,334,000, with net loss after tax up 48.2 percent to $25,103,000.
Cann Group said revenue was primarily from sales of marijuana products.
Cann Group said net tangible asset backing per share fell 30.4 percent to 32 cents, diluted loss per share was down 18.1 percent to 9.75 cents and it had cash and cash equivalents of $3,105,000 on June 30, 2021 compared to $1,554,000 on June 30, 2020.
Cann Group was unchanged at 29 cents with 1.9 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says its share purchase plan to raise $2 million was “oversubscribed” with applications for $3.4 million in shares, including oversubscriptions.
In July, Bard1 said it raised $15 million in a placement at $1.55 a share (BD: Jul 23, 2021).
Bard1 was up 11 cents or 7.9 percent to $1.495.

POLYNOVO

Polynovo says it has begun a US pig trial of its Novosorb Syntrel hernia repair to show bio-absorption rates, bio-compatibility, toxicology profile and efficacy.
Polynovo said that Syntrel was composed of Novosorb foam “ultrasonically welded to a new Novosorb film” to produce a 100 percent bio-absorbable hernia repair device.
The company said that the film provided strength to the repaired hernia while the foam promoted native tissue regeneration within the foam scaffold.
Polynovo said it was assisted by two external regulatory consultants and advice from the US Food and Drug Administration so that the data generated from the pig study would support product filings using the Novosorb technology.
The company said it expected to file the Syntrel dossier with the FDA as a 510(k) submission about March 2023 with approval expected by August 2023.
The company said that both the Novosorb film and Novosorb foam were designed to be absorbed in the body.
Polynovo company said the Syntrel device would provide reinforcement to the hernia repair site, allowing for optimal tissue regeneration.
Polynovo said the Novosorb film was originally developed to provide sufficient long-term mechanical strength for Syntrel but would also be used “in a portfolio of other hernia repair devices as well as future product applications including breast reconstruction, sports medicine and other clinical applications where mechanical strength is a key requirement”.
The company said that the Syntrel product for the trials and beyond was being manufactured at its Port Melbourne facility.
Polynovo fell 10 cents or 4.5 percent to $2.14 with 2.8 million shares traded.

IMPEDIMED

Impedimed says the US Food and Drug Administration has approved breakthrough device designation for its Sozo device for patients with renal failure.
Impedimed said Sozo was a bioimpedance spectroscopy (BIS) platform to provide an exact measure of fluid volume to remove during a dialysis session.
The company said that the benefits of the breakthrough program included interactive and timely communication with the FDA, efficient and flexible clinical study design, a provision for obtaining a binding agreement on clinical protocols and a priority review.
Impedimed managing-director Richard Carreon said there was “a clear need for an innovative device to help clinicians more effectively manage end-stage renal disease”.
Impedimed was up one cent or 9.1 percent to 12 cents with 4.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has an agreement with Lightpoint Medical to combine TLX599-CDx with Lightpoint’s Sensei for radiation-guided surgery.
Telix said its TLX599-CDx would be evaluated with the Chesham, England-based Lightpoint’s Sensei, the world’s first approved robotic gamma probe.
The company said Sensei was used to detect radiation in patients and guide surgery, controlled by the clinician during the procedure.
Telix said Lightpoint’s device enabled the intra-operative detection of cancer in real time, supporting greater precision in the removal of tumors.
The company said the objective of the collaboration was to obtain marketing approval for use of TLX599-CDx in radio-guided surgery, a new indication for prostate cancer.
Lightpoint chief executive officer Graeme Smith said that surgeons had “no reliable way to detect cancer intra-operatively, relying on sight or touch during an operation”. “As a result, cancer may be left behind or healthy tissue needlessly removed,” Mr Smith said.
Mr Smith said that the combination of Sensei with Telix’s molecularly-targeted imaging had “the potential to create an extremely precise technique to help surgeons detect cancer that might not otherwise be found during surgery, or conversely, confirm the absence of disease to help surgeons retain healthy, functional tissue”.
Telix was up nine cents or 1.3 percent to $6.98 with 678,314 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has a research and development agreement with Griffith University to screen for repurposing small molecules with known histories as anti-viral agents.
Island said the five-year collaboration added to its existing work with Monash University “providing new opportunities to examine anti-viral molecules against emerging viruses with significant unmet medical need”.
The company said that depending on the fee paid by Island in a given project, intellectual property would vest with Island or with Island and Griffith, but Island would have the right of first refusal to develop and commercialize molecules that were identified in the screens under either scenario.
Island said both parties might pursue multiple projects, the scope of which would be determined on a project-by-project basis, although no specific number of projects was required.
The company said that viruses would be screened against small molecule libraries held at the Griffith Institute for Drug Discovery facility, using highly sensitive assays.
Island was unchanged at 36 cents.

NOXOPHARM

Noxopharm says that 37 of 38 Covid-19 patients in a Moldovan study of Veyonda, or NOX66, with dexamethasone and/or prednisone recovered from the infection.
Noxopharm said 41 patients received at least one dose of Veyonda, with 38 patients needing at least 12 days of Veyonda treatment to be included in the analysis.
The company said that 28 of the 38 patients received combined dexamethasone and prednisone for a mean of 6.6 days.
Noxopharm said that 27 of the 38 patients required supplementary oxygen and one patient required mechanical ventilation and eventually died.
The company said that 37 of 38 patients recovered and were discharged.
Noxopharm said that the safety steering committee declared each dose cohort safe, including the highest dose of 1800mg
Monash University and Hudson Institute professor of paediatric immunology Prof Marcel Nold said Veyonda had the “potential to address a gap in our armory” of Covid drugs.
Prof Nold said that patients could “self-administer, allowing its use at home, its mechanism of action may enable treatment of moderately-ill Covid patients and, importantly, it could also be effective against other viruses”.
Noxopharm chief executive officer Dr Graham Kelly told Biotech Daily that Veyonda suppository was approved as an experimental drug for home self-administration.
In the media release, Dr Kelly said the target patients were those with a moderate degree of pneumonia experiencing breathing difficulties.
“Behind this pneumonia is an … excessive inflammatory response to the presence of the virus in the lungs,” Dr Kelly said. “The objective is to use Veyonda to dampen that inflammatory response before it escalates to the point of triggering an even greater inflammatory response that … [could] cause even more widespread tissue damage.”
“The challenge is to dampen down the inflammatory response without compromising the ability of the body to fight the virus,” Dr Kelly said.
Separately, Noxopharm said that in pre-clinical in-vitro studies, Melbourne’s Monash University-based Hudson Institute found that the enzyme TANK-binding kinase 1 (TBK1) was the molecular target of idronoxil, or Veyonda, in terms of its anti-inflammatory properties.
The Hudson’s Prof Michael Gantier said that TBK1 was “a point of convergence of many inflammatory pathways and a target under significant investigation by several big pharmaceutical companies”.
“Our latest findings, which are being prepared for publication, demonstrate that idronoxil may have applications in a range of diseases where TBK1 facilitates aberrant inflammation,” Prof Gantier said.
“Critically, TBK1 also directly controls production of interferon-beta, a cytokine associated with long-Covid symptoms,” Prof Gantier said.
“This suggests that idronoxil may not only be useful to prevent progression of Covid-19 patients from mild to severe disease, but also may decrease the risk of long-lasting post-infectious symptoms, seen in up to half of Covid-19 patients,” Prof Gantier said.
Noxopharm was up 1.5 cents or 2.7 percent to 57 cents with 1.5 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it will release 9,836,317 shares from voluntary escrow on August 30, 2021.
According to the company’s most recent distribution schedule, Lumos had 150,152,413 shares on issue.
Lumos was unchanged at $1.27.

ACTINOGEN MEDICAL

Actinogen says Brazil has granted its application for the Webster 7 family of patents relating to Xanamem and its composition of matter.
Actinogen said Xanamem was patent protected for “all key pharmaceutical markets to cover any use in all diseases, including Alzheimer’s disease and other … diseases”.
The company said the patent provided protection until 2031.
Actinogen was unchanged at 7.8 cents with 4.8 million shares traded.

SUDA PHARMACEUTICALS

Suda says that Mitsubishi Tanabe Pharma Korea has indicated its intention not to proceed with the licence and supply agreement for Zolpimist.
Last year, Suda said that South Korea’s Mitsubishi Tanabe Pharma Korea would pay up-to $US500,000 ($A869,600) plus royalties for a 10-year licence to its Zolpimist oral spray for insomnia (BD Mar 23, 2020)
Earlier this year, the company said Mitsubishi Tanabe Pharma Singapore intended “not to proceed” with the licence and supply agreement for Zolpimist (BD: Jan 27, 2021).
Today, Suda said that Mitsubishi Tanabe Pharma Korea “cited challenges with their regulatory body, the Ministry of Food and Drug Safety.
The company said it agreed to terminate the agreement and there was no immediate financial impact as a result of the termination.
Suda said it would continue to focus on its partnership with Teva and look to secure additional partners.
Suda was unchanged at 4.7 cents with 2.9 million shares traded.

VECTUS BIOSYSTEMS

Vectus says it dosed the first eight-patient cohort with 2mg VB0004 in the single ascending dose component of its phase I/Ib hypertension trial.
Vectus said VB0004 was administered orally to healthy volunteers and to patients with mild to moderate hypertension with low cardiovascular risk.
The company said the safety committee deemed it safe to proceed with the next dose.
Vectus said that dosing the first cohort was “an important milestone” and VB0004 targeted fibrosis which underpinned a broad spectrum of cardiovascular disease.
Vectus was up one cent or 0.8 percent to $1.24.

STARPHARMA

Starpharma says its Viraleze nasal spray reduces viral load by more than 99.9 percent in mice with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
Last month, Starpharma said that SPL7013, the active ingredient in Viraleze showed a more than 99.9 percent reduction of the virus in-vitro (BD: Jul 27, 2021).
Today, the company said the study, conducted at the San Diego, California-based Scripps Research Institute, showed that Viraleze administered nasally significantly reduced viral load by more than 99.9 percent in the lungs and trachea of mice infected with Sars-Cov-2.
Starpharma chief executive officer Dr Jackie Fairley said the results provided “compelling data supporting the utility of a broad-spectrum nasal spray, like Viraleze, to reduce exposure to virus, and reduced virus in respiratory tract and other organs, and prevention of pro-inflammatory cytokines, which are important to the pathogenesis of Covid-19”.
Starpharma was up seven cents or 5.7 percent to $1.29 with 1.1 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says its Canadian subsidiary Peak Processing Solutions has a marijuana manufacturing agreement with Canopy Growth Corp subsidiary Supreme Cannabis.
Althea said that Peak would “perform hydrocarbon extraction services to create various concentrate products for Supreme using their cannabis inputs”.
The company said that Peak would provide Supreme with additional manufacturing capabilities and the agreement included minimum order quantities of about $C600,000 in the initial one-year term and the agreement had two renewal options of one year each.
Althea was untraded at 28.5 cents.

TBG DIAGNOSTICS

The ASX says that TBG Diagnostics failed to pay the annual listing fees for the year ending June 30, 2022 and has been suspended.
TBG has been in an ASX suspension since last year, relating to claims regarding a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and Covid-19 test and last traded at 27 cents (BD: Mar 19, 2020).

ISLAND PHARMACEUTICALS

Island co-founder Dr William Garner says he has increased his substantial holding from 21,090,605 shares (26.05%) to 21,913,908 shares (27.06%).
The San Juan, Puerta Rico-based Dr Garner said between July 29 and August 19, 2021 he bought 822,493 shares for $265,062 or 32.2 cents a share.
In May, Melbourne’s PAC Partners said that Dr Garner was a co-founder and seed investor in the company (BD: May 1, 2021).

MEDADVISOR

Cotiviti Services says it has become a substantial shareholder in Medadvisor with 43,999,999 shares or 11.66 percent.
The South Jordan, Utah-based Cotiviti said that on August 20, 2021, it bought 43,999,999 shares for $US11,305,140 ($A15,793,252) or 35.9 cents a share.
Medadvisor fell half a cent or 1.4 percent to 35.5 cents.

PRO MEDICUS

Pro Medicus says it has appointed Alice Williams as a non-executive director, effective from September 1, 2021.
Pro Medicus said Ms Williams had been a financial services executive, including at JP Morgan and had worked as a director of aviation strategy and fleet planning.
The company said that Ms Williams was formerly a director of Equity Trustees and Cooper Energy and was currently a director of Djerriwarrh Investments, Defence Health, Mercer Investments (Australia) and Vocus Communications.
Pro Medicus said that Ms Williams had been a member of Government boards, including the Foreign Investment Review Board, Port of Melbourne Corp, Victorian Funds Management Corp and Airservices Australia.
The company said that Ms Williams held a Bachelor of Commerce from the University of Melbourne.
Pro Medicus was up 67 cents or one percent to $66.52 with 316,505 shares traded.

ANTEOTECH

Anteo says that chief financial officer Gail Jukes has resigned, effective from August 31, 2021 for “personal reasons”.

Anteo said that a search for a replacement would begin immediately.

The company said that company secretary and former chief financial officer Duncan Cornish would resume his role on an interim basis from September 1, 2021.

Anteotech was up one cent or 5.7 percent to 18.5 cents with 6.3 million shares traded.