Biotech Daily

Thursday April 28, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 8%; ACTINOGEN DOWN 8.5%**

*** COCHLEAR TO BUY DENMARK'S OTICON FOR $170m**

*** INCANNEX FREE 'LOYALTY' OPTIONS RAISE $23.6m**

*** ADHERIUM IMPROVES HAILIE MONITOR CONNECTIVITY**

*** FDA GRANTS BOTANIX BTX1801 QIDP FOR GOLDEN STAPH**

*** ANTERIS, YALE STUDY HAEMODYNAMIC FUNCTION**

*** USCOM FILES SPIROSONIC AIR FDA 510(k) APPLICATION**

*** PARADIGM DOSES 1st US PATIENTS IN PPS KNEE PAIN TRIAL**

*** EXOPHARM PLEADS SCHULTZ TO ASX 26% FALL QUERY**

*** JASON CARROLL TAKES 12.2% OF ISLAND**

*** OSTEOPORE APPOINTS CTO DR JING LIM COO**

MARKET REPORT

The Australian stock market recovered 1.32 percent on Thursday April 28, 2022, with the ASX200 up 95.7 points to 7,356.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 24 fell, four traded unchanged and one was untraded.

Uscom was the best, up 0.7 cents or 8.05 percent to 9.4 cents, with 183,338 shares traded. Orthocell climbed 7.6 percent; Dimerix was up 6.9 percent; Prescient improved four percent; Immutep was up 3.2 percent; Emvision, Imugene, Micro-X and Next Science rose more than two percent; CSL was up 1.1 percent; with Clinuvel and Cyclopharm up by less than one percent.

Actinogen led the falls, down 0.8 cents or 8.5 percent to 8.6 cents, with 4.6 million shares traded, followed by Resonance down 8.3 percent to 11 cents, with 30,121 shares traded. Universal Biosensors lost 7.9 percent; Pharmaxis fell five percent; Atomo, Polynovo and Starpharma fell more than four percent; Amplia, Avita and Compumedics were down more than three percent; Alcidion, Medical Developments, Opthea, Paradigm and Telix shed two percent or more; Cynata, Kazia, Nanosonics, Neuren, Nova Eye, Pro Medicus and Proteomics were down one percent or more; with Cochlear, Genetic Signatures, Mesoblast and Resmed down by less than one percent.

COCHLEAR

Cochlear says it will acquire the Smørum, Denmark-based Oticon Medical for DKK850 million ($A170 million), after its parent said it would exit the hearing implant market.
Cochlear said the acquisition from Denmark's Demant AS would be funded through existing cash balances.
The company said that as part of the transaction, it had committed to providing ongoing support for Oticon's base of more than 75,000 hearing implant recipients, but would not assume any liability for issues arising from the voluntary recall Oticon announced in October last year for its Neuro Zti cochlear implant.
Cochlear said that completion of the transaction would be conditional on satisfaction of customary closing conditions and jurisdictional approvals but was expected to be completed by the end of 2022.
The company said as part of these jurisdictional approvals, the transaction would be subject to a mandatory consultation process under French law with Oticon Medical's Nice-based employee works council.
Cochlear chief executive officer Dig Howitt said that the business was currently loss making but was "expected to add $75 to $80 million to annual revenue".
"Our priority post-closing of the transaction will be to determine and implement a plan that returns the business to profitability as quickly as possible," Mr Howitt said.
"Integration costs, which include the development of compatible next generation sound processors, are yet to be determined and could range from $30 million to $60 million," Mr Howitt said. "We continue to target a long-term net profit margin of 18 percent."
"The acquisition of Oticon Medical will provide us with greater scale and will enable us to increase our investments in [research and development] and market growth activities," Mr Howitt said. "While Cochlear is a market leader in implantable hearing, we are a small player in the hearing loss segment where hearing aids remain the primary treatment."
Mr Howitt said Cochlear's goal was to improve the penetration of implantable hearing devices, build customer awareness and confidence and offer more patients products best suited to their needs.
"We will seek to ensure that Oticon Medical's customers continue to be supported with a lifetime of hearing solutions … [and] work closely with Demant to ensure a seamless transition, with continued access to current Oticon Medical technology for customers in the coming years," Mr Howitt said. "We will develop next generation sound processors and services that will enable customers to transition to, and benefit from, Cochlear's technology platform over time."
Cochlear fell $1.28 or 0.55 percent to $229.47 with 141,164 shares traded.

INCANNEX

Incannex says it has raised $23.6 million of a possible $28 million through the exercise of free loyalty options which expired on April 22, 2022.
In March, Incannex said it would offer shareholders one free in-the-money option for every 15 shares they held, plus a second free 'piggyback' option for every two of the first options they exercised (BD: Mar 15, 2022).
Today, the company said a total of 67.3 million new shares and 33.7 million piggy-back options would be issued as a result of the exercise.
Incannex said the piggyback options would be exercisable at $1.00 by April 28, 2023.
The company said the capital raised would be allocated to clinical research and development activities, which it said would ramp up significantly in 2022 and 2023.
Incannex was up half a cent or 1.3 percent to 40 cents with 4.2 million shares traded.

ADHERIUM

Adherium says it has updated its Hailie respiratory medication monitoring system for better integration with patient management and medical records systems.
Adherium said the updates for its inhaled medication sensors included an application programming interface and a software development kit, which would help achieve greater interoperability with its disease management and clinical trial customers.
The company said the application programming interface and software development kit were “important software milestone achievements”.
Adherium chief executive officer Rick Legleiter said that to drive sales the company needed to be flexible and meet customer needs across different channels and markets.
“This includes strengthening the commercial attractiveness of our respiratory product portfolio with improved, adaptable service offerings,” Mr Legleiter said.
Mr Legleiter said the software as a service platform included integration services, enhanced data security, as well as clinical and provider portals operating with both Apple and Android systems and applications.
Adherium was up 0.1 cents or 10 percent to 1.1 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has granted BTX1801 qualified infectious disease product (QIDP) status for Staphylococcus aureus, or golden staph.
Botanix said the QIDP designation applied to the use of its synthetic cannabidiol BTX1801 antibacterial to potentially “reduce the risk of [Staphylococcus] aureus bloodstream infections in colonized patients dependent on central venous catheters for haemodialysis”.
The company said the QIDP status entitled BTX1801 to receive an additional five years of FDA regulatory exclusivity above that from approval of a new drug application, and provided eligibility for fast-track status and priority review.
Botanix said BTX1801 was previously granted qualified infectious disease product status for the prevention of post-surgical infections (BD: Apr 24, 2020).
The company said the new designation was the first granted for a nasal decolonization agent for haemodialysis patients and it had completed pre-clinical studies to support its planned phase II study, which was on-track to begin in Australia by July 2022.
Botanix executive chair Vince Ippolito said Botanix was “very excited to receive QIDP status from the FDA”.
Mr Ippolito said the designation was supported by studies that highlighted the impact of bloodstream infections in haemodialysis patients using central venous catheters.
Botanix was up 0.35 cents or 4.4 percent to 8.3 cents with 8.1 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says the New Haven, Connecticut-based Yale University will study haemodynamic function in transcatheter aortic valve replacement patients.
Anteris said the aim of the study was to inform future designs of its aortic valve replacements for patients with severe aortic stenosis.
The company said the study would be led by the director of the Yale Cardiovascular Research Group Prof Alexandra Lansky.
Anteris said that Yale University and Yale Cardiovascular Research Group had “decades of experience in pre-clinical and clinical cardiovascular research and have been at the forefront of many therapies and health advances over the years”.
Anteris fell six cents or 0.3 percent to $17.34.

USCOM

Uscom says it has filed a 510(k) application with the US Food and Drug Administration for its Spirosonic Air lung function diagnostic.

Uscom said its Spirosonic devices included digital vocal user guidance, phonic outputs and auto-diagnostic interpretation and had applications for asthma, chronic obstructive pulmonary disease and Covid-19.

The company said it expected to receive a series of responses to the application over the coming 60 days.

Uscom said it had appointed the Hillsborough, North Carolina-based Sovereign Medical to distribute its ultra-sonic cardiac output monitors (Uscom 1A) on the US East Coast, and expected first sales to critical care, respiratory care, emergency medicine, sleep medicine, maternal health and infusion therapy clinics within the next two months.

The company said that Sovereign had agreed to sell 40 Uscom 1 A units over three years, taking its US subsidiary to profitability.

Uscom executive chair Prof Rob Phillips said the FDA clearance for the Spirosonic Air would “allow us to actively sell into the US and, combined with our NMPA in China which is mid review, will enable Uscom Spirosonic devices to establish clinical and commercial leadership in spirometry and lung function monitoring world-wide”.

“Regulatory clearance, particularly with the FDA, is becoming increasingly expensive, costly and complex, and as such is a significant value add once received, and a barrier to entry for competitors,” Prof Phillips said.

“The appointment of Sovereign Medical as specialized East Coast distributors will compliment this clearance and build out our US market access,” he said.

“The agreement adds 12 new sales staff to our growing US footprint as the US rebounds from two years of restrictions due to the Covid pandemic and as FDA clearance is received for the Spirosonic suite of pulmonary products,” Prof Phillips said.

Uscom was up 0.7 cents or 8.05 percent to 9.4 cents.

PARADIGM BIOPHARMA

Paradigm says it has dosed its first US patients in its phase III trial of pentosan polysulphate sodium (PPS or Zilosul) for pain associated with knee osteo-arthritis.

In January, Paradigm said it had dosed the first two of 930 patients in the randomized, double-blind, placebo-controlled trial (BD: Jan 16, 2022).

Today, the company said its first US subject randomization was confirmed at Chicago’s Northwestern University.

Paradigm said the pivotal phase III study was enrolling subjects in eight sites in Australia, and in 21 of the 56 selected sites in the US, with activations continuing throughout 2022.

Paradigm interim chief executive officer Dr Donna Skerrett said the first US subjects randomized in the trial was “an important milestone” in the clinical program.

Paradigm fell 2.5 cents or two percent to $1.205 with 775,567 shares traded.

EXOPHARM

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

The ASX said the company’s share price fell 6.5 cents or 26.0 percent from 25 cents at the close of trade on April 26, to an intra-day low of 18.5 cents on April 27, 2022 and noted a “significant increase” in trading volume.

Exopharm was up half a cent or 2.6 percent to 20 cents.

ISLAND PHARMACEUTICALS

Jason Alan Carroll says he has increased his substantial holding in Island from 9,085,609 shares (11.17%) to 9,900,000 shares (12.18%).
The Melbourne-based Mr Carroll said that between February 23 and April 27, 2022, he bought 814,391 shares for $153,514 or an average of 18.85 cents a share.
Island was up 1.5 cents or 7.9 percent to 20.5 cents.

OSTEOPORE

Osteopore says it has appointed its chief technology officer Dr Jing Lim as its chief operating officer, effective from May 1, 2022, and working in both roles.
Osteopore said Dr Lim held a Doctor of Philosophy from Singapore's Nanyang Technological University, and as a biomaterials researcher had published 14 articles in peer-reviewed journals.
The company said Dr Lim had been with Osteopore since 2014.
Osteopore was up one cent or five percent to 19 cents.