Biotech Daily

Thursday March 25, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ACTINOGEN UP 9%; PATRYS DOWN 6.5%**

*** 4D ACCESS TO US DEFENSE, VETERANS CONTRACTS**

*** TGA OKAYS RESAPP WEARABLE COUGH MONITOR**

*** PALLA RETAIL RIGHTS RAISE $5.8m, TOTAL $18m**

*** RACE, NEWCASTLE UNI STUDY BISANTRENE FOR KIDNEY CANCER**

*** DIMERIX: NASOGASTRIC DMX-200 FOR REMAP-CAP COVID-19 TRIAL**

*** MEDADVISOR $6.2m US VACCINE ADHERENCE CONTRACT EXTENSION**

*** POLYNOVO APPOINTS PREMIER NOVOSORB BTM US DISTRIBUTOR**

*** STARPHARMA APPOINTS LLOYDS UK VIRALEZE DISTRIBUTOR**

*** INCANNEX, FDA MEET ON IHL-675A FOR ARDS, SAARDS**

*** CELLMID RECEIVES $646k FEDERAL R&D TAX INCENTIVE**

*** ELIXINOL HEMP PRODUCTS OK IN UK; TOXICOLOGY STUDY PENDING**

*** JENCAY TAKES 5% OF MEDADVISOR**

*** ELEANORE GOODRIDGE REDUCES TO 5.4% IN NYRADA**

*** RESPIRI APPOINTS DR ANDREW WEEKES, DR MARK LEVY ADVISORS**

MARKET REPORT

The Australian stock market was up 0.17 percent on Thursday March 25, 2021, with the ASX200 up 11.8 points to 6,790.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell and eight traded unchanged.

Actinogen was the best, up 0.3 cents or 8.6 percent to 3.8 cents, with 8.7 million shares traded. Uscom climbed 6.1 percent; Polynovo and Prescient improved more than four percent; Neuren and Nova Eye were up more than three percent; Clinuvel, Compumedics, Cyclopharm and Starpharma rose more than two percent; CSL was up 1.4 percent; with Cochlear and Pro Medicus up by less than one percent.

Yesterday's 6.9 percent best, Patrys, led the falls, down 0.2 cents or 6.45 percent to 2.9 cents, with 11.1 million shares traded. Alterity and Amplia lost more than five percent; Medical Developments fell 4.2 percent; Proteomics was down 3.35 percent; Avita, Immutep, Kazia, Mesoblast, Opthea, Optiscan, Osprey, Resmed and Resonance shed more than two percent; LBT, Nanosonics, Next Science, Orthocell and Paradigm were down more than one percent; with Cynata, Telix and Volpara down less than one percent.

4D MEDICAL

4D says acceptance to NASA's 'Solutions for Enterprise-Wide Procurement' program will expedite US government contracts for its x-ray lung ventilation diagnostic software.

4D said the "streamlined process" for contact with the US Department of Defense (DoD) and Veterans Affairs (VA) was granted by the US National Aeronautics and Space Administration (NASA)'s Procurement program, allowing Defense and Veterans Affairs associated healthcare facilities to integrate its x-ray velocimetry lung ventilation analysis software (XV LVAS) at an undisclosed fixed price without requiring separate reimbursement.

4D chief executive officer Prof Andreas Fouras said that "the access granted adds another important layer to our foundation of securing market share by streamlining the way 4D Medical deals with DoD and VA healthcare facilities".

"Unlike other healthcare systems in the US, the DOD and VA healthcare system do not require separate reimbursement for medical services allowing us to gain traction whilst we progress alternative healthcare reimbursement and billing channels for XV LVAS in both the US and Australia," Prof Fouras said.

4D was up 11 cents or seven percent to $1.69 with one million shares traded.

RESAPP HEALTH

Resapp says it has Australian Therapeutic Goods Administration clearance for its wearable device for patient monitoring using cough audio.

Resapp said the wearable device was listed on the Australian Register of Therapeutic Goods as a Class 1 medical device.

Earlier this month, the company said that it had received Conformité Européenne (CE) mark approval for the wearable device (BD: Mar 2, 2021).

Resapp managing-director Dr Tony Keating said the TGA clearance allowed the company "to market and sell the product in Australia".

"Since we secured CE mark certification for the wearable earlier this month and announced our recent deal with Astrazeneca Japan, we have witnessed increased interest in our cough counting technology," Dr Keating said (BD: Mar 12, 2021).

"We are particularly excited about the level of enquiry shown by large pharmaceutical and biotech companies that recognize the strong value proposition that our offering provides," Dr Keating said.

Resapp was up 0.2 cents or 2.9 percent to 7.2 cents with 1.75 million shares traded.

PALLA PHARMA

Palla says its fully underwritten, two-for-nine, retail rights offer at 50 cents a share has raised about $5.8 million, taking the total raised to $18 million.

Earlier this month, Palla said it raised about $4.0 million in a placement and about $8.2 million in an institutional rights offer at 50 cents a share (BD: Mar 2, 2021).

Today, the company said the participation rate in the retail rights offer was about 53.8 percent, with 5,358,765 shares worth $2,679,383 allocated to the sub-underwriters to raise the full amount.

Palla said the sub-underwriters included "a combination of new and existing institutional and high-net-worth sophisticated investors".

The company said that Morgans Corporate was the lead manager and underwriter to the capital raising.

Palla was unchanged at 49 cents.

RACE ONCOLOGY

Race says it will collaborate with the New South Wales University of Newcastle for an in-vitro study of Bisantrene for clear cell renal cell carcinoma.

Race said the research project, led by Prof Nikki Verrills, would use cellular models to investigate Bisantrene for clear cell renal cell carcinoma (ccRCC), a form of kidney cancer which had a five-year survival rate "as low as 12 percent".

The company said Bisantrene had been identified as an inhibitor of the fat mass and obesity associated protein (FTO), essential to the clear cell renal cell carcinoma growth.

Race said previous studies has shown that "the inhibition of FTO can directly kill more than 90 percent of ccRCCs".

The company said that the results of the study would inform phase II human trials of Bisantrene in clear cell renal cell carcinoma, expected to begin in early 2022.

Race chief scientific officer Dr Daniel Tillett said the research would "further our knowledge of Bisantrene and it adds to the FTO-directed preclinical work we have just initiated in melanoma".

Earlier this week, Race said it will collaborate with the University of Newcastle to study the use of Bisantrene as a combination drug for melanoma using cellular and mouse models (BD: Mar 19, 2021).

Race fell 13 cents or 3.3 percent to $3.82 with 371,754 shares traded.

DIMERIX

Dimerix says that Covid-19 patients with pneumonia in the Remap-Cap study that cannot swallow a capsule of DMX-200 will be able to receive a nasogastric delivery of the drug.

Last year, Dimerix said DMX-200 for kidney disease would be included the protocol of the pan-European and UK 'randomized, embedded, multifactorial adaptive platform trial for community-acquired pneumonia' (Remap-Cap) phase III study (BD: Jun 4, 2020).

Today, the company said it had completed a study to confirm the viability of nasogastric delivery, or administration through a nasal feeding tube, for patients with Covid-19-related pneumonia admitted to intensive care units who could not swallow capsules.

Dimerix said the Remap-Cap study had "recruited almost 6,000 patients with suspected or proven Covid-19", and was recruiting about 100 patients a week.

The company said DMX-200 was one of more than 20 active treatments in the trial and was part of the "ACE2-RAS domain", which studied interventions aimed at the renin-angiotensin system to improve outcomes for patients with Covid-19.

Dimerix was unchanged at 26.5 cents with 1.8 million shares traded.

MEDADVISOR

Medadvisor says it has a three-month extension to its US vaccine safety adherence contract with an existing unnamed client, worth $US4.7 million ($A6.2 million).

Last year, Medadvisor said that through its US subsidiary Adheris it had a $US3.4 million ($A4.7 million) five-month vaccine contract to inform Adheris' 180 million patient network of the correct and safe adherence to vaccines (BD: Dec 17, 2020).

Today, Medadvisor chief executive officer Robert Read that the company was "delighted to have another health program extended in the US market".

"These health programs deliver tailored content specifically to the right patients based on advanced algorithms and are designed to ensure they are aware of the benefits of certain medications or vaccines," Mr Read said.

Medadvisor was up two cents or 6.15 percent to 34.5 cents.

POLYNOVO

Polynovo says it will supply its Novosorb biodegradable temporizing matrix wound treatment to the Charlotte, North Carolina-based Premier Inc at “special pricing”.
Polynovo said that under a group purchasing agreement, from April 1, 2021 Premier would supply Novosorb BTM to its network of 4,100 healthcare facilities, which included more than 2,000 acute care hospitals, 100 of which had designated trauma centres, and 63 children’s hospitals.
The company did not disclose the “special pricing and terms” it had negotiated with Premier.
Polynovo managing-director Paul Brennan said that “signing with Premier, the second largest [group purchasing organization] in the US, is a major milestone”.
“[Group purchasing] agreements put our disruptive BTM on a much larger list of hospitals than our sales team can get around in the short term,” Mr Brennan said.
Polynovo was up 14 cents or 4.9 percent to $3.01 with 3.5 million shares traded.

STARPHARMA

Starpharma says it has appointed Lloyds Pharmacy as the UK distributor of its anti-viral Viraleze nasal spray, which contained SPL7013.
Last month, Starpharma said Viraleze had been registered for sale in Europe and the UK and laboratory studies had shown it could “inactivate a broad spectrum of respiratory viruses, including more than 99.9 percent of [severe acute respiratory syndrome coronavirus-2] ... the virus that causes Covid-19” (BD: Feb 23, 2021).
Today, the company said that the Coventry, UK-based Lloyds Pharmacy was one of the largest pharmacy chains in the UK with about 1,400 shops.
Starpharma said Viraleze would be available online “next week” and was expected to be available in shops by May 2021.
Starpharma was up five cents or 2.5 percent to $2.08 with 1.8 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has been granted a pre-investigational new drug meeting with the US Food and Drug Administration for its IHL-675A for respiratory syndromes.
Incannex said its pre-IND submission detailed the use of IHL-675A for preventing acute respiratory distress syndrome (Ards) and sepsis-associated acute respiratory distress syndrome (Saards).
The company said the FDA would provide feedback on its development proposals for IHL-675A by April 21, 2021, but did not cite a date for the FDA meeting.
Incannex managing-director Joel Latham told Biotech Daily the ‘meeting’ would be in the format of a series of written responses. with a goal date of completion by April 21.
Incannex said the responses would provide regulatory guidance and agreement on the most efficient clinical development plan to be included in an application for IHL-675A for the prevention of Ards and Saards.
Mr Latham said that “being granted a pre-IND meeting review with [the] FDA represents an important milestone for our company and a strong foundation for the clinical development of IHL-675A”.
“We anticipate that the work completed on the FDA information package for IHL-675A for Ards and Saards will assist us with hastening submissions to FDA for the other indications being pursued,” Mr Latham said.
Incannex was up 1.5 cents or 7.5 percent to 21.5 cents with 2.4 million shares traded.

CELLMID

Cellmid says it has received $645,748 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cellmid said the rebate related to research and development expenditure for the year to June 30, 2020.
Cellmid was unchanged at 7.6 cents.

ELIXINOL GLOBAL

Elixinol says the UK Food Standards Agency has allowed continued sale of its hemp-based food additives and skincare products, with toxicological studies pending.
Elixinol said that the European Industrial Hemp Association reported that the sale of "both full-spectrum and natural isolate [marijuana] products" of its members could remain on sale in the UK if applications were approved by the UK Food Standards Agency (FSA).
The company said it would receive official validation of its products from the FSA following the results of toxicological studies on both cannabidiol and tetrahydro-cannabinol expected in the coming months.
Elixinol chief executive officer Oliver Horn said that "the FSA's response means we can continue to operate on a business-as-usual basis for now, while the toxicological work is being undertaken".
Elixinol fell half a cent or 2.6 percent to 18.5 cents with 3.5 million shares traded.

MEDADVISOR

The Sydney-based Jencay Capital says it has become a substantial shareholder in Medadvisor with 18,056,967 shares or 5.02 percent of the company.
Jencay said that between December 16, 2020 and March 23, 2021 it acquired 2,434,579 shares for $863,457 or an average of 35.5 cents a share.

NYRADA

Nyrada says Eleanore Goodridge's substantial holding has been reduced from 7,024,832 Chess depository instruments (CDIs) (6.42%) to 5,974,832 CDIs (5.39%).
Nyrada fell half a cent or 1.45 percent to 34 cents.

RESPIRI

Respiri says it has appointed Dr Andrew Weekes and Dr Mark Levy as advisors ahead of the UK launch of its Wheezo asthma diagnostic.
Respiri said that Dr Weekes was Glaxosmithkline Australia's medical director and would advise the commercialization and clinical development of Wheezo.
The company said Dr Levy was an executive director for the Global Initiative for Asthma and would advise the UK Wheezo launch.
Respiri was unchanged at 16 cents with 1.4 million shares traded.