Biotech Daily

Monday September 25, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: DIMERIX UP 13%; NEXT SCIENCE DOWN 7.5%**

*** IMUGENE PLAN RAISES $18.2m; TOTAL $53.2m**

*** POLYNOVO YEAR-TO-AUGUST REVENUE UP 93% TO $15m**

*** AUSTCO BUYS NURSE CALL RESELLER TEKNOCORP FOR $3.85m**

*** INVION PAYS CHO GROUP $900k FOR PHOTOSOFT IN SOUTH KOREA**

*** STARPHARMA RECRUITS UK VIRALEZE COVID-19 STUDY**

*** ADHERIUM: ALLERGY PARTNERS ENROLS FIRST HAILIE PATIENTS**

*** ISLAND TO START ISLA-101 DENGUE FEVER TRIAL IN OCTOBER**

*** DIMERIX: FDA DMX-200 QYTOVRA NAME 'CONDITIONAL APPROVAL'**

*** ADALTA AD-214 'SIMULATIONS' BACK I-V DOSE, SUBCUTANEOUS ROUTE**

*** USCOM CHAIR ROB PHILLIPS 4.8m PERFORMANCE RIGHTS AGM**

*** PROTEOMICS 2nd 'TEST APPROVAL' SUSPENSION EXTENSION REQUEST**

*** BOTANIX REQUESTS 'FDA SOFPIRONIUM BROMIDE' TRADING HALT**

*** ANACACIA TAKES 5% OF COGSTATE**

*** 4D MEDICAL APPOINTS PROF GERALDINE MCGINTY DIRECTOR**

*** TIM LUSCOMBE REPLACES AMPLIA CFO HAMISH GEORGE**

MARKET REPORT

The Australian stock market was up 0.11 percent on Monday September 25, 2023 with the ASX200 up 7.7 points to 7,076.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and four were untraded.

Dimerix was the best, up 0.8 cents or 12.9 percent to seven cents, with 135,526 shares traded. Patrys improved 7.1 percent; Cyclopharm, Imugene and Starpharma climbed six percent or more; Actinogen was up 5.6 percent; Alcidion was up 4.55 percent; Polynovo was up 3.3 percent; Volpara rose 2.1 percent; Avita, Nanosonics, Neuren and Universal Biosensors were up more than one percent; with Cochlear, CSL and Telix up by less than one percent.

Next Science led the falls, down 3.5 cents or 7.45 percent to 43.5 cents, with 357,592 shares traded. Micro-X fell 4.2 percent; Cynata and Resonance lost more than three percent; Impedimed, Mesoblast and Nova Eye shed more than two percent; Clinuvel, Genetic Signatures, Immutep, Medical Developments, Paradigm and SDI were down one percent or more; with Pro Medicus and Resmed down by less than one percent.

IMUGENE

Imugene says it has raised $18.2 million of a hoped-for $30 million in a share purchase plan at 5.6 cents a share, taking the total raised with the placement to $53.2 million.
Last month, Imugene said that it had “firm commitments” for a $35 million placement at 8.4 cents a share and hoped to raise a further $30 million through a share purchase plan at the lower of 8.4 cents or a 2.5 percent discount to the five-day volume weighted average price to the closing data of September 21 (BD: Aug 18, 2023).
At that time, the company said the funds would be used for its acquisition of the licencing rights to the Durham, North Carolina-based Precision Bioscience’s azer-cell CD19 Car T-cell therapy for blood cancers and the associated trial costs (BD: Aug 16, 2023).
Today, Imugene said that subject to shareholder approval eligible shareholders would also receive one option for each share bought, exercisable at 11.8 cents each by August 31, 2026.
Imugene was up 0.3 cents or six percent to 5.3 cents with 46.4 million shares traded.

POLYNOVO

Polynovo says its revenue for the year to August 31, 2023 was up 92.7 percent to $14.9 million, compared to $7.7 million in the previous corresponding period.
Polynovo said its US sales for the first two months of 2023-’24 were up 85.3 percent to $10.6 million with total sales up 83.9 percent to $13 million.
The company said its US Biomedical Advanced Research and Development Authority revenue was up 146.9 percent on the previous year’s $600,000 to $1.6 million.
Polynovo chair David Williams said “the increase in sales albeit lumpy and off a low base is at once breathtaking but at the same time more of the same of what we have seen in the last three years”.
“Looking forward the future is bright,” Mr Williams said.
“The more than 150 percent increase in the UK and other significant geographic growth, hides the new hospitals and new staff that commenced recently and are yet to show their full potential,” Mr Williams said.
Polynovo was up four cents or 3.3 percent to $1.26 with 3.9 million shares traded.

AUSTCO HEALTHCARE

Austco says it has acquired Melbourne’s Teknocorp, a reseller of its nurse health call software, for $3,850,000, with completion expected in October 2023.
In May, Austco said it expected to buy Teknocorp for $1,900,000 upfront in cash, $700,000 in shares and a $1,250,000 earn-out (BD: May 29, 2023).
Today, the company said the acquisition was subject to no material adverse events occurring between the parties, entry into executive services agreements with Teknocorp’s employees, assignment of key customer and suppler contracts and regulatory approvals.
Austco said the acquisition would be on a debt-free basis for $1.9 million in upfront cash, $700,000 in shares and an earnout amount of 3.5 times Teknocorp’s annualized earnings before interest, taxation, depreciation and amortization (Ebitda) to December 31, 2024 times less the $2,600,000 in upfront fees and shares.
Austco said it would integrate Teknocorp’s business into its existing operations and retain personnel and expected the acquisition “to provide significant revenue synergies, including the ability to cross-sell products and services and streamline operations”.
Austco said the acquisition fast-tracked its plans to build direct sales in Australia.
Austco was unchanged at 19 cents.

INVION

Invion says it will pay $900,000 for development costs to the RMW Cho Group for exclusive rights to Photosoft light therapy for all cancer types in South Korea.
In 2017, the Hong Kong-based Cho Group took control of Invion providing $5.5 million to develop its Photosoft technology for cancers (BD: Aug 31, 2017).
In 2021, Honsue Cho and Unlimited Innovation Group said they had reduced their holding in Invion to 1,146,031,359 shares (20.70%) following an in-specie distribution of 220,682,156 shares to 49 group members (BD: Dec 4, 2020; Jan 18, 2021).
Earlier this year, Invion said subject to approval it had expanded its agreement with the Cho Group to atherosclerosis and infectious diseases in North America and Hong Kong, providing $2.5 million for prior development costs (BD: Feb 8, 2023).
The company previously said that Photosoft used photo-sensitizers and visible light with oxygen to kill malignant cells, shut down tumors and stimulated the immune system.
Today, Invion said the $900,000 payment to the Cho Group was “a contribution to prior development costs … in relation to cancer indications for the territory of South Korea”.
Invion said half of any up-front fees, milestone payments or royalties it received for sub-licensing the Photosoft technology in South Korea would be shared with the Cho Group.
The company said future non-clinical work for cancer indications in South Korea would be funded 25 percent by Invion and 75 percent by the Cho Group, and that all future clinical work would be funded 75 percent by Invion and 25 percent by the Cho Group.
Invion said the Cho Group may cancel its distribution rights in South Korea subject to paying “fair compensation”, which must be no less than $1.8 million.
Invion said it still had a right to first refusal for the distribution rights of Photosoft for cancer indications in Japan.
The company said the proposed transaction did not trigger ASX listing rule 10.1 and therefore did not require shareholder approval.
Invion fell 0.1 cents or 20 percent to 0.4 cents with 1.8 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it has completed recruitment for its about 200-patient study of its broad-spectrum antiviral barrier nasal spray Viraleze for Covid-19 in the UK.
Last year, Starpharma said it had begun a 160-patient, randomized, double-blinded, post-market UK study to assess the anti-viral performance of its Viraleze nasal spray on Covid-19 (BD: Dec 8, 2022).
Today, the company said the study would assess the Covid-19 viral load in the nasal cavity of patients with the disease while using Viraleze, and that the primary endpoint of the clinical study was the level of viral load over a seven-day treatment period.
Starpharma said the study data would support ongoing marketing and commercial activities and “provide additional clinical safety and efficacy data to satisfy the new European medical device regulations” coming into effect by July, 2024.
The company said it expected to release the results following data and statistical analysis by the end of 2023.
Starpharma chief executive officer Dr Jackie Fairley said the company was “pleased with the high level of interest in the Viraleze post-market clinical study”.
“Many people in the UK and elsewhere are still grappling with Covid-19, as evidenced by the rapid recruitment, and new strains are continuing to emerge,” Dr Fairley said.
“A broad-spectrum antiviral barrier nasal spray, such as Viraleze, has the potential to play an important role globally,” Dr Fairley said.
Starpharma was up one cent or 6.7 percent to 16 cents with 2.7 million shares traded.

ADHERIUM

Adherium says the first patients have been enrolled in the Hailie asthma sensor trial with the Asheville, North Carolina-based Allergy Partners.
Adherium said the initial patient group receiving services was an “implementation milestone … [and was] an important step forward in transforming asthma care for more than 300,000 patients under the management of Allergy Partners”.
Adherium said the asthma management program would be rolled-out in two more states, with training continuing this month and more markets to follow.
Adherium was untraded at 0.4 cents.

ISLAND PHARMACEUTICALS

Island says it will begin its single-ascending dose study of ISLA-101 for dengue fever in October, complete dosing this year, with a “data read out expected in early 2024”.
In February, Island said the US Food and Drug Administration had place a “clinical hold” on its investigational new drug application for ISLA-101 and required a further “small” trial and protocol amendments, and in April filed a response (BD: Feb 1, Apr 17, 2023).
In May, the company said it had FDA approval for the ISLA-101 dengue fever and other mosquito borne diseases trial (BD: May 16, 2023).
Today, Island said four cohorts of healthy subjects would receive escalating doses of ISLA-101, to assess blood concentrations predicted to be effective against the virus.
Island said subjects were expected to receive increasing doses of ISLA-101 under fasted conditions, with the cohort receiving the highest safe dose repeating the dosing under fed conditions, and that after each cohort a safety review committee would review the data.
The company said the study would be at Sydney’s Scientia Clinical Research site and it had appointed Brisbane’s Beyond Drug Development as a contract research organization.
Island said the study would “form the basis for rapidly transitioning” to its phase IIa dengue challenge trial.
Island managing director Dr David Foster said the company had “been focused on moving the single-ascending dose study along as quickly as possible and are very pleased to be nearing the commencement point”.
Island was untraded at 7.6 cents.

DIMERIX

Dimerix says the US Food and Drug Administration has granted conditional approval of the commercial name Qytovra for DMX-200 for focal segmental glomerulo-sclerosis.
Dimerix said the FDA would grant final approval for the name following a successful new drug application.
The company said the trademarked name Qytovra for DMX-200 had also been accepted and registered in Europe, the UK, Australia, China, Japan and South Korea with applications pending in Canada.
Dimerix said it the US Adopted Names Council had separately granted Qytovra “a designation for repagermanium” meaning it would appear on the US Pharmacopeial Convention Inc’s list of international drug names.
Dimerix chief executive officer Dr Nina Webster said as DMX-200 moved closer to market “the name DMX-200 for [focal segmental glomerulosclerosis] had been replaced by the intended commercial brand name Qytovra”.
Dimerix was up 0.8 cents or 12.9 percent to seven cents.

ADALTA

Adalta says simulations of AD-214 for fibrotic disease “supports the potential efficacy of target intravenous doses [and]… subcutaneous administration”.
Last month, Adalta said it had dosed the first of up-to eight patients in a phase I extension study of AD-214 for idiopathic pulmonary fibrosis and other diseases (BD: Aug 4, 2023).
At that time, the company said the trial would give six participants four times 10mg/kg doses of AD-214 and two participants placebo, and the data would be used to inform the safety profile and target dosing schedule for future phase II studies of the drug.
Today, Adalta said the simulations showed AD-214 was clinically feasible for an intravenous dosing regimen of 10mg/kg of AD-214 every two weeks.
Adalta said this dose allowed AD-214 to bind to its target receptor CXCR4 and maintain levels of receptor occupancy necessary to materially inhibit a model fibrosis process.
The company said this intravenous regimen was currently being used in the phase I extension trial and would likely be progressed in a phase II clinical trial.
Adalta said the simulation models also showed the potential of AD-214 to be dosed subcutaneously, suggesting that “target levels of receptor occupancy could be achieved at doses of one-to-three mg/kg weekly, and less than 0.1mg/kg daily.
Adalta said subcutaneous administration was more convenient for the patient, as it could be self-administered, and it reduced costs due to the lower amounts of AD-214 required.
The company said further studies were “required to verify these results and develop a suitable formulation for subcutaneous use”.
Adalta chief executive officer and managing director Dr Tim Oldham said “the simulations further strengthen and support the potential efficacy of [the current] … dosing regimen”.
“While it still makes sense to move forward to phase II studies using intravenous AD-214, these subcutaneous results add significant value to our partnering program by pointing the way to a lower cost product in a more convenient format that patients could self-administer at home”.
Adalta fell 0.2 cents or 9.1 percent to two cents.

USCOM

Uscom says its annual general meeting will vote to issue executive chair Prof Rob Phillips 4,756,891 performance rights, in lieu of a higher salary.
Uscom said that Prof Phillips cash salary of $250,755 was “significantly lower than the remuneration payable by a company of the size and nature of Uscom” and the issue of the performance rights was fair and reasonable”.
The company said that shareholders would vote to approve the remuneration report, re-elect director Xianhui Meng and approve the company’s 10 percent placement capacity.
The meeting will be held at Suite 2, Level 8, 66 Clarence Street, Sydney on October 26, 2023 at 11:30am (AEDT).
Uscom was up 0.8 cents or 19.05 percent to five cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has requested a second extension to its suspension pending an announcement regarding “the application for regulatory approval of the Promarkerd test”.
Last week, Proteomics requested an extension to its suspension following a trading halt the previous week (BD: Sep 14, 18, 20, 2023).
Trading will resume on October 2, 2023, or on an earlier announcement.
Proteomics last traded at 90 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has requested a trading halt pending a “US Food and Drug Administration communication in respect of … [its] sofpironium bromide gel” for sweating.
Trading will resume September 27, 2023, or on an earlier announcement.
Botanix last traded at 18 cents.

COGSTATE

Anacacia Pty Ltd says it has become a substantial shareholder in Cogstate with 8,706,164 shares, or 5.0 percent.
The Sydney-based Anacacia said that between August 16 and September 22, 2023 it bought 429,363 shares for $628,355, or $1.46 a share.
Cogstate was unchanged at $1.55.

4D MEDICAL

4D Medical says it has appointed Prof Geraldine McGinty a director of the company, effective from today.
4D Medical said Prof McGinty was currently a radiologist at New York’s Weill Cornell Medical Centre, and was the first woman elected chair of the American College of Radiology’s board of chancellors.
The company said that Prof McGinty was previously a director of Nextgen Healthcare and Ireland’s Industrial Development Authority.
4D Medical said that Prof McGinty held a Bachelor of Medicine from Dublin’s National University of Ireland as well as a Master of Business Administration from New York’s Columbia University.
4D Medical was unchanged at 53 cents.

AMPLIA THERAPEUTICS

Amplia says it has appointed Tim Luscombe as its chief financial officer, replacing Hamish George.
Amplia said Mr Luscombe was a director of Bio101 Financial Advisory and had been working with the company in a senior accounting capacity for the past two years.
The company said Mr Luscombe held a Bachelor of Commerce from the University of Melbourne.
Amplia was untraded at 8.4 cents.