Biotech Daily

Monday July 4, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: VOLPARA UP 21%; MICRO-X DOWN 13%**

*** CYCLOPHARM H1 UNAUDITED REVENUE UP 33% TO $11.3m**

*** BUPA UK TO REIMBURSE ONCOSIL DEVICE FOR PANCREATIC CANCER**

*** VOLPARA, RADNET MAMMOGRAPHY ANALYTICS, RISK SOFTWARE DEAL**

*** INVEX PHASE III 'EVOLVE' PRESENDIN TRIAL FOR IIH APPROVED**

*** DIMERIX: DMX-700 REDUCES COPD LUNG INJURY 80%, IN MICE**

*** PATRYS PAT-DX1 LARGE SCALE MANUFACTURE**

*** AUDEARA: AMPLIFON TO BUY 5k A-02 TV BUNDLES**

*** MICROBA, IFF MICROBIOME SAMPLE DATA MILESTONE**

*** ADALTA DELAYS AD-214 PROGRAM TO SAVE CASH**

*** EPSILON, VALENS EXTEND SOUTHPORT MARIJUANA PARTNERSHIP**

*** NEUROTECH REQUESTS 'NTI164 TRIAL RESULTS' TRADING HALT**

*** WALKER, AUCKLAND TRUST INCREASE, DILUTED TO 39% IN NEXT SCIENCE**

*** PLANET INNOVATION TAKES 32.4% OF LUMOS**

*** RPS DIAGNOSTICS REDUCES TO 7% OF LUMOS**

*** RESMED LUCILE BLAISE SLEEP, RESPIRATORY HEAD; ROBERT DOUGLAS**

MARKET REPORT

The Australian stock market was up 1.11 percent on Monday July 4, 2022, with the ASX200 up 72.7 points to 6,612.6 points. Twenty-five of the Biotech Daily Top 40 stocks were up, seven fell, four traded unchanged and four were untraded.

Volpara was the best, for the second trading day in a row, up 10 cents or 21.3 percent to 57 cents, with 929,556 shares traded. Oncosil rose 17.5 percent; Cyclopharm and Dimerix climbed 16 percent or more; Atomo and Patrys were up more than 14 percent; Imugene improved 12.8 percent; Alcidion was up 9.1 percent; Medical Developments rose 8.1 percent; Micro-X improved 7.1 percent; Actinogen and Immutep were up six percent or more; Emvision and Next Science were up more than seven percent; Antisense was up 6.1 percent; Mesoblast improved 5.15 percent; Clinuvel, Cynata and Nanosonics climbed more than four percent; Immutep was up 3.2 percent; Avita, CSL, Polynovo, Resmed and Telix rose more than two percent; Impedimed and Paradigm were up more than one percent; with Pro Medicus and Starpharma up by less than one percent.

Micro-X fell two cents or 13.3 percent to 13 cents, with 86,406 shares traded. Genetic Signatures and Opthea shed more than two percent; Actinogen, Orthocell and Resonance lost more than one percent; with Cochlear and Neuren down less than one percent.

CYCLOPHARM

Cyclopharm says it expects “record” unaudited group sales revenue for the six-months to June 30, 2022, up 32.9 percent to $11.3 million, compared to the prior period.
Cyclopharm said it expected Technegas consumable patient administration sets revenue to increase by about 21 percent compared to the previous period, with Technegas generator sales increasing by about 42 percent.
Cyclopharm managing-director James McBrayer said “today’s numbers reflect our ability to leverage our global sales and service infrastructure off our core Technegas technology that we have built across 63 countries and our ability to successfully sell and service other products though this network”.
Cyclopharm was up 16.5 cents or 16.3 percent to $1.18.

ONCOSIL MEDICAL

Oncosil says that London’s Bupa UK will reimburse its targeted radioactive isotope device for the treatment of locally advanced pancreatic tumors.
The company said Bupa UK would be the first health insurance company to provide reimbursement for its device in the private payer market in the UK to patients with locally advanced pancreatic cancer, in combination with chemotherapy.
Oncosil managing-director Nigel Lange said “with a leading health insurer agreeing to reimburse the Oncosil device, this allows patients with locally advanced pancreatic cancer access to this breakthrough treatment at The London Clinic”.
The company did not disclose the cost of treatment or the value of the reimbursement.
Oncosil was up 0.7 cents or 17.5 percent to 4.7 cents with 8.4 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a 42-month contract with the Los Angeles-based Radnet Management Inc for its mammography analytics and risk pathways software.
Volpara did not disclose the commercial terms of the agreement but said that revenue generated from the agreement was expected to be material.
The company said the contract would see Radnet using its analytics and risk pathways software at its 353 imaging centres in the US, and was expected to begin in 2023.
Volpara chief executive officer Teri Thomas said the company was “pleased to partner with such a large and well-respected organization as Radnet”.
Volpara was up 10 cents or 21.3 percent to 57 cents.

INVEX THERAPEUTICS

Invex says its 240-patient, phase III, Australian trial of Presendin for idiopathic intracranial hypertension has been approved.
Invex said the randomized, placebo-controlled, double-blind ‘Evolve’ trial would test the safety and efficacy of Presendin, or exenatide, administered once weekly over 24 weeks, and that the trial had received clinical trial notification scheme clearance by the Australian Therapeutic Goods Administration.
The company said the trial’s primary endpoint was the change in intracranial pressure from baseline, with secondary endpoints related to vision and headache outcomes.
Invex said the approval covered private hospital sites, it would apply for a separate approval for a public hospital, and expected to have 40 sites globally in the trial.
Invex was up one cent or 2.1 percent to 49.5 cents.

DIMERIX

Dimerix says DMX-700 reduces lung injury from with chronic obstructive pulmonary disease by 80 percent, in mice.

Dimerix said that in a mouse model of chronic obstructive pulmonary disease (COPD), DMX-700 showed a “statistically significant” 80 percent reduction in lung injury ($p < 0.01$) when compared to the control group.

The company said that DMX-700 had a “known safety profile in human studies” which meant that, subject to relevant approvals, it could potentially move into clinical studies, expected by July 2023.

Dimerix managing-director Dr Nina Webster said the company had “established that blocking the known targets of COPD with DMX-700 at the same time results in a statistically significant decrease in lung injury that leads to fibrosis, or scarring”.

“These new results confirm the efficacy of DMX-700 in an industry-standard pre-clinical COPD model reducing lung injury by 80 percent,” Dr Webster said.

“This information should provide significant encouragement to clinical investigators and patients in our planned clinical trials of DMX-700 in this devastating disease,” Dr Webster said.

Dimerix was up two cents or 16.0 percent to 14.5 cents with 1.2 million shares traded.

PATRYS

Patrys says it has completed a second engineering run with an updated purification process to produce large scale quantities of clinical grade PAT-DX1.

In January, Patrys said that purification of the fermentation process for PAT-DX1 resulted in less drug product than expected, delaying the first human study by six months to mid-2023 (BD: Jan 24, 2022).

Today, the company said that subject to meeting specification, the PAT-DX1 antibody manufactured from the engineering run would provide it with sufficient quantities to complete its remaining pre-clinical toxicology studies, in preparation for a proposed phase I trial of PAT-DX1 by the end of 2023.

Patrys said the engineering run consisted of two phases; a fermentation phase where cells were grown in culture to produce PAT-DX1, and a purification phase where PAT-DX1 was isolated a purified.

Patrys said that the initial yield from this commercial scale run exceeded what it was expecting based on previous, smaller-scale pilot runs.

The company said the product would be tested to ensure that it met specification in the coming weeks, and if met, it would be able to complete its pre-clinical toxicology studies by July 2023.

Patrys managing-director Dr James Campbell said “the commercial-scale manufacture of antibodies is a complex, multi-dimensional process”.

“The efforts made to understand and remediate the issues with the first engineering run have been both extensive and exhaustive,” Dr Campbell said.

“We are delighted that this has delivered such a successful outcome, both addressing the issue with the original purification process and improving the overall yield,” Dr Campbell said.

“We are now in a position to proceed with our plan to initiate the final … toxicology studies by the end of the year, to support our target of initiating a phase 1 clinical study of PAT-DX1 in [the second half of] 2023,” Dr Campbell said.

Patrys was up 0.3 cents or 14.3 percent to 2.4 cents with 12.0 million shares traded.

AUDEARA

Audeara says the Milan, Italy-based Amplifon will buy a minimum of 5,000 of its A-02 TV bundles “during the second half of … 2022”.
Audeara did not disclose the commercial terms of the agreement and said “due to the uncertainty of timing and market uptake, it [was] not possible to quantify the final economic impact of this agreement”.
The company said that Amplifon was “the largest of the ‘big six’ international audiology retail groups” and serviced 25 countries.
Audeara was up two cents or 21.05 percent to 11.5 cents.

MICROBA LIFE SCIENCES

Microba says it has its first milestone after delivering its first data package to New York’s International Flavors and Fragrances Inc, as part of its research partnership.
Microba said that in November 2021, it began a joint discovery program with International Flavors and Fragrances to identify new allergy treatments by using its databank of more than 15,000 gut microbiome samples and associated health data.
The company said that the data delivery identified multiple microbial therapy leads for asthma and allergic rhinitis and could lead to a longer-term commercial relationship with International Flavors and Fragrances to develop allergy treatments.
Microba chief scientific officer Prof Lutz Krause said that “our human first, data-driven approach has revealed a number of promising leads, and our work in other indications provides us with confidence that the discovery of these leads with [International Flavors and Fragrances] can enable the development of novel microbiome-based therapies”.
Microba was up 1.5 cents or 7.5 percent to 21.5 cents.

ADALTA

Adalta says it will extend its existing cash runway by deferring its pre-booked AD-214 manufacturing campaigns and toxicology studies by six months.
Adalta said that “to ensure that its manufacturing campaigns and toxicology studies are designed to maximise the development options for, and hence value of, AD-214, the company has negotiated a six-month deferral of AD-214 production and toxicology campaigns to maximise decision-making flexibility and ensure that these significant cash commitments are made with the benefit of the maximum amount of pre-clinical data and confirmed partner indication priorities”.
The company said that clinical timelines were expected to be delayed by “a lesser amount” and that it would not need to commit funds to the next round of manufacturing and toxicology costs until the end of 2022.
Adalta managing-director Dr Tim Oldham said that “by the end of the September quarter 2022 we also anticipate having significant new pre-clinical data in multiple indications and routes of administration for AD-214”.
“While we have been focused on speed to clinical trials, it is now prudent that we make final decisions about incurring the significant costs of manufacturing and toxicology with the fullest possible data and partnering information in hand, and to that end have negotiated a deferral of the commencement of these campaigns with our suppliers,” Dr Oldham said.
In its Appendix 4C quarterly report for the three months to March 31, 2022, Adalta said that it $10,528,000 in cash and equivalents, or 7.9 quarters of cash.
Adalta was up half a cent or 9.1 percent to six cents.

EPSILON HEALTHCARE

Epsilon says it will continue its exclusive partnership with the Valens Company to use its Southport, Queensland marijuana manufacturing plant (BD: Sep 9, 2021).
In March, Epsilon said it had an exclusive partnership with the Kelowna, British Columbia-based Valens for an initial period of three-months and today said it had an informal extension until August 1, 2022 and expected to secure a longer-term relationship.
Epsilon chair Steven Xu said that "working with the Valens Company over the past few months we have been able to continue to ramp up production volumes through the Southport facility".
Epsilon was up 0.1 cents or 3.1 percent to 3.3 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a trading halt pending "the results of its phase I/II clinical study of the NTI164 strain [of marijuana] in paediatric autism spectrum disorder".
Trading will resume on July 6, 2022 or on an earlier announcement.
Neurotech last traded at 7.5 cents.

NEXT SCIENCE

Walker Group and Auckland Trust Co say they have increased and been diluted in Next Science from 76,072,938 shares (39.53%) to 83,547,061 shares (38.90%).
In February and March, Next Science said it raised $14.8 million in a placement and share plan at 90 cents a share (BD: Feb 24, Mar 22, 2022).
Today, the Sydney-based Lang Walker as sole shareholder of Walker Group, and Auckland Trust said that between November 20, 2021 and July 4, 2022 they bought 7,474,123 shares for $7,370,043 or an average of 98.61 cents a share
Next Science was up six cents or 7.6 percent to 85 cents.

LUMOS DIAGNOSTICS

Melbourne's Planet Innovation says it has increased its substantial share-holding in Lumos from 55,860,176 shares (28.99%) to 68,021,060 shares (32.41%).
In June, Lumos said it had raised $11.2 million in a rights offer at 19 cents a share, with Planet Innovation as a sub-underwriter (BD: Jun 28, 2022).
Today, Planet Innovation said it was issued 12,160,884 shares under the entitlement offer.
Lumos was up half a cent or 3.45 percent to 15 cents.

LUMOS DIAGNOSTICS

RPS Diagnostics says it has reduced its substantial holding in Lumos and been diluted from 15,647,189 shares (10.40%) to 14,647,189 shares (6.98%) (see above).
According to its initial public offering prospectus, Lumos merged with the Sarasota, Florida-based RPS in 2019, which was focused on the development and commercialization of the diagnostic test Febridx, and issued it 15,647,189 shares.
The prospectus said that then Lumos chief executive officer Robert Sambursky held shares in RPS "resulting in a potential indirect economic interest in Lumos" of about 3.9 percent on July 5, 2021.
Biotech Daily asked Lumos when RPS reduced its holdings by 1,000,000 shares, but the response did not directly address the date of the sale of shares.

RESMED

Resmed says it has appointed Lucile Blaise as head of its sleep and respiratory care business, with interim head Robert Douglas to resume as chief operating officer.

Resmed said Ms Blaise had 25 years' experience in medical device sales, marketing, finance and business development and had been its head of sleep and respiratory care for Western Europe since 2015.

The company said Ms Blaise had worked for Resmed since 2006 and previously worked for Weinman France, Thuasne, and Tyco Healthcare.

Resmed said that Ms Blaise would receive an annual base salary of $US470,000 ($A690,357) with a target short-term incentive opportunity of 80 percent, an equity award with a target value of $US1,400,000 ($A2,056,382) as well as relocation benefits with her expected move to the US.

Resmed was up 84 cents or 2.75 percent to $31.34 with 1.5 million shares traded.