Biotech Daily

Wednesday June 5, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYCLOPHARM UP 21%; IMMUTEP DOWN 9%**

*** IMMUTEP PLACEMENT, INSTO RIGHTS RAISE $89.6m; $10.6m TO GO**

*** RESPIRI 'FIRM COMMITMENTS' FOR $1m PLACEMENT**

*** CYCLOPHARM US TECHNEGAS PASS-THROUGH REIMBURSEMENT**

*** BTC TO SELL TEDAN CARDIO-THORACIC SURGICAL PRODUCTS**

*** NANOSONICS 'CORIS BEATS MANUAL ENDOSCOPY CLEANING'**

*** PHARMAUST: 'MONEPANTEL SIGNIFICANTLY EXTENDS MND SURVIVAL'**

*** CHIMERIC DOSES 1st PHASE Ib CHM0201 AML COHORT**

*** BLINKLAB, ERASMUS UNI DEMENTIA TEST TRIAL**

*** AROVELLA SCALES ALA101 MANUFACTURING**

*** FOUNDER ALAN BEASLEY WINS EPSILON DOCA**

*** GENETIC TECHNOLOGIES, STAYHEALTHY TO SELL GENETYPE IN US**

*** PLATINUM DILUTED TO 15% OF ADALTA**

*** GZ FAMILY TAKES $12% OF FIREBRICK**

*** PHILLIP, BIOSCIENCE MANAGERS DETAIL 17% ADHERIUM STAKE**

*** ARGENICA LOSES FOUNDING CHAIR GEOFF POCOCK**

MARKET REPORT

The Australian stock market was up 0.41 percent on Wednesday June 5, 2024, with the ASX200 up 31.90 points to 7,769.0 points. Fourteen of the Biotech Daily Top 40 were up, 16 were down, nine traded unchanged and one was untraded. All three Big Caps were up.

Cyclopharm was the best, up 29.5 cents or 21.1 percent to $1.695, with 2.8 million shares traded. Actinogen improved 7.4 percent; Opthea was up 6.1 percent; Curvebeam climbed 5.7 percent; Compumedics, Nanosonics and Pro Medicus were up more than four percent; Clinuvel, Cochlear and Resmed rose more than two percent; Avita, CSL, Imugene, Neuren, Polynovo and Resonance were up more than one percent; with Telix up by 0.5 percent.

Immutep led the falls, down four cents or 8.9 percent to 41 cents, with 21.6 million shares traded. Atomo and Cynata lost more than six percent; Alcidion, Amplia and Mesoblast were down more than five percent; Micro-X, Orthocell and Syntara fell more than four percent; Clarity, Emvision, Proteomics and SDI were down three percent or more; Percheron shed 2.25 percent; with Dimerix and Medadvisor down one percent or more.

IMMUTEP

Immutep says it has raised $89.6 million at 38 cents a share in a $72 million placement and $17.6 million institutional rights offer, with a $10.6 million retail offer to follow.
On Monday, Immutep said it would raise $100.2 million at 38 cents a share, a 13.3 percent discount to the 30-day volume weighted average price, in a fully-underwritten placement and one-for-16 institutional and retail rights offer (BD: Jun 3, 2024).
Today, the company said the institutional entitlement offer had “a take-up rate from eligible institutional investors of approximately 100 percent”.
Immutep said the offer was underwritten by Bell Potter and joint lead managed by Bell Potter, Canaccord Genuity, Wilsons Corporate and co-managed by CLSA Australia.
The company said following the close of the institutional component of its capital raising it expected the ASX to lift its trading halt and to recommence trading today.
Immutep fell four cents or 8.9 percent to 41 cents with 21.6 million shares traded.

RESPIRI

Respiri says it has “firm commitments” to raise $1 million at 3.0 cents a share in a placement to sophisticated and professional investors.
Respiri said the issue price was a 3.45 percent premium to its last closing price of 2.9 cents on June 4, 2024 and the placement was in addition to the $6.5 million raised in December 2023 and the $1.6 million raised in April 2024, taking the total to $9.1 million.
Respiri said the offer was “unsolicited” but did not disclose the investors.
The company said the funds would be used for contracted clients’ patient profiling, segmentation, targeting and onboarding, to progress its ‘clinic-in-cloud’ remote patient monitoring program, expand its US business and for general working capital.
Respiri fell 0.3 cents or 10.3 percent to 2.6 cents.

CYCLOPHARM

Cyclopharm says the US Centre for Medicare and Medicaid Services (CMS) has granted pass-through reimbursement for Technegas, from July 1, 2024.
Last month, Cyclopharm said the CMS had approved a unique identifier code for the use of Technegas for diagnosing pulmonary embolism, from July 1, 2024, which would streamline the reimbursement process (BD: May 6, 2024).
Today, the company said the proposed unique identification code for Technegas would replace the need for the miscellaneous code currently being used and the pass-through determination, would “provide clinical sites using Technegas with a more streamlined reimbursement process and an improved financial outcome”.
Cyclopharm said the decision by the CMS, the government authority which sets healthcare reimbursement rates in the US, added a further financial incentive and “would provide full reimbursement for Technegas”.
Cyclopharm managing-director James McBrayer said the company was “delighted” with the earlier than expected positive notification from CMS which was expected to accelerate the rollout for Technegas in the US.”
“The timing of this decision could not have come at a better time,” Mr McBrayer said.
“Later this week, Cyclopharm will have a significant presence at the first major US Society of Nuclear Medicine and Molecular Imaging conference to be held since the company received US [Food and Drug Administration] approval of Technegas in October last year,” Mr McBrayer said.
Cyclopharm was up 29.5 cents or 21.1 percent to $1.695 with 2.8 million shares traded.

BTC HEALTH

BTC says it has the exclusive distribution and sales rights for the Houston, Texas-based Tedan Surgical Innovations' cardio-thoracic surgical instruments in Australia.
BTC said the products were formerly distributed by Melbourne's Advanced Biomedical, were Australian Therapeutic Goods Administration approved and would transfer to its subsidiary BTC Cardio, with immediate effect.
BTC executive chair Dr Richard Treagus said the Tedan range was complementary with "the recently acquired Wexler range and our expanding cardiothoracic product portfolio.
In May, BTC said it would distribute and sell the Houston, Texas-based Wexler Surgical's cardio-thoracic surgical instruments in Australia and New Zealand (BD: May 15, 2024).
BTC was untraded at 5.1 cents.

NANOSONICS

Nanosonics says a study shows that its "Coris technology outperforms manual cleaning in biofilm removal in endoscopes" in air, water and suction, biopsy channels.
Last year, Nanosonics said preliminary study results showed that the Coris flexible endoscope cleaning device was superior to manual cleaning for removing unwanted biofilms from endoscope air and water channels and last month said it had submitted a de novo application to the US Food and Drug Administration (BD: Nov 3, 2023; May 1, 2024).
Today, Nanosonics said "despite current cleaning and disinfection efforts, flexible endoscopes can remain long-term reservoirs for infectious organisms".
The company said studies had shown that flexible endoscopes were linked to more patient infections than any other reusable medical device and biofilm contributed "significantly to bacterial persistence in endoscope channels".
Nanosonics said that biofilm build up could lead to the same strain of bacteria being transmitted to multiple patients from contaminated endoscopes over time.
The company said the study, titled 'Comparison of two endoscope channel cleaning approaches to remove cyclic build-up of biofilm' was published in the Journal of Hospital Infection, with the full article available at: https://bit.ly/4e9OtIB .
Study co-author Dr Michelle Alfa said the results showed biofilm removal with Coris was "significant, given the challenges with biofilm in endoscope reprocessing".
"In particular, the device removed cyclic build-up biofilm from the small diameter channels, while the current manual cleaning approach was not effective," Dr Alfa said.
The article said the study "compared cyclic build-up biofilm removal of an automated endoscope channel cleaner to standard manual cleaning according to instructions-for-use in polytetrafluorethylene channels".
The study said the automated cleaner "significantly outperformed manual cleaning for all markers assessed", including protein, total organic carbon and viable bacteria in both 1.4mm air, water and auxiliary channels as well as 3.7mm suction and biopsy channels.
The article said "manual cleaning failed to remove biofilm from the air, water and auxiliary channels" and according to the instructions-for-use, these channels were not brushed, suggesting that as a potential root cause for some of the endoscopy-associated infections.
The study concluded that an automated endoscope channel cleaner, or the Coris, showed "potential to deliver enhanced cleaning over current practice to all endoscope channels and may thereby address infection risk".
Nanosonics managing-director Michael Kavanagh said Coris was "a significant opportunity to improve patient safety by addressing what is one of the most significant issues in medical device reprocessing today, the reprocessing of flexible endoscopes".
Nanosonics was up 13 cents or 4.7 percent to $2.92 with 989,407 shares traded.

PHARMAUST

Pharmaust says its 10-patient, open-label extension study shows monepantel led to "significantly longer survival of patients with [motor neuron disease]" (p = 0.0022).
Earlier this year, Pharmaust said it had dosed the first of up-to 12 patients in its open-label, phase I, 12-month extension study of monepantel for motor neuron disease (MND), or amyotrophic lateral sclerosis (ALS) (BD: Feb 14, Apr 10, 2024).
Today, the company said it had enrolled 10 of 12 patients eligible for the study, with one deceased patient and one patient unable to participate due to elevated liver enzymes.
Pharmaust said the study results, conducted by its statistical consultant Berry Consultants showed a "statistically significant survival benefit for monepantel compared to untreated matched-controls" from historical data.
The company said the historical data was taken from the pooled resource open-access ALS clinical trials (PRO-ACT) database, which included 16 phase II/III studies and one observational study with eight million data points from more than 8,600 people.
Pharmaust said "treatment with monepantel significantly reduced the risk of death by 91 percent when compared to [historical data]" (p = 0.0154).
The company said patients were treated with monepantel for a median of 16.4 months.
Pharmaust said "updated analysis of the rate of decline in [ALS functional rating score-revised] continued to show monepantel reduces the rate of disease progression".
Pharmaust said that for cohort one and cohort two, when analyzed separately, disease progression was slowed by 23 percent (p = 0.39) and 44 percent (p = 0.21), respectively.
The company said there were "four patients that either had no change or had a slight improvement in ALSFRS-R scope while taking monepantel under compassionate use".
Pharmaust managing-director Dr Michael Thurn said: "I'm very pleased that we have completed enrolment in the [open-label extension] study as this is a significant milestone for Pharmaust."
"The updated survival analysis conducted by Berry Consultants is extremely encouraging, as is the updated efficacy analysis that indicates monepantel continued to slow the rate of disease progression in patients with [motor neuron disease and, or amyotrophic lateral sclerosis]," Dr Thurn said.
"These results provide an exciting backdrop ahead of the anticipated commencement of the pivotal adaptive phase II/III 'Strike' study in [2024]," Dr Thurn said.
Pharmaust was up 3.0 cents or 14.6 percent to 23.5 cents with 5.6 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first cohort of three-patients in its up-to 20-patient, phase Ib trial of CHM0201 NK-cells with standard-of-care for acute myeloid leukaemia (AML).
Earlier this year, Chimeric said it had dosed the first patient in its phase Ib trial of its CHM0201 natural killer (NK)-cells therapy in combination with standard-of-care azacitidine and venetoclax for acute myeloid leukaemia (BD: Feb 8, 2024).
Today, the company said none of the cohort one patients "experienced dose-limiting toxicities" in the 28-day evaluation period, and that the study had advanced to the next planned cohort.
The company said following safety monitoring committee review of the data from the first three patients the trial would advance to the second three-subject cohort, who would receive CHM0201 at dose level two.
Chimeric fell 0.2 cents or 10.5 percent to 1.7 cents with 5.3 million shares traded.

BLINKLAB

Blinklab says Rotterdam's Erasmus University Medical Center will conduct a 250-patient study of its artificial intelligence-based, neurological disease diagnostic.

Blinklab said its smartphone diagnostic would be used in the study which would run for 24 months and recruit 'fronto-temporal' dementia patients from a large dementia risk cohort.

The company said its test would be used as part of the Digital Dementia Lab at-home testing laboratory and aimed to identify, develop and test a variety of digital biomarkers measuring clinically relevant behavior for improving early dementia diagnosis.

Blinklab said its smartphone, remote assessment test included "eyeblink conditioning and pre-pulse inhibition of the acoustic startle reflex".

The company said identifying "sensitive, digital, at-home solutions to detect clinically relevant change in the early stage of the disease will reduce the diagnostic delay and thereby, ultimately, improve the well-being of patients and their families and decrease the burden on healthcare".

Blinklab said the agreement ensured it would have an option to licence or acquire any intellectual property developed as a direct result of the partnership.

The company said the financial details of the deal would "be determined via mutual agreement in the future and in a separate arrangement".

Blinklab chair Brian Leedman said the collaboration further validated the company's "innovative solutions and the power of our smartphone-based technology platform to impact a range of high value therapeutic areas in addition to our core focus of [autism and attention deficit hyperactivity disorder] early diagnosis in children".

"I look forward to the first patients recruited in this new clinical study in the near term and the commencement of our [US Food and Drug Administration registration study in [autism and attention deficit hyperactivity disorder] in the latter part of this year," Mr Leedman said.

Blinklab fell half a cent or 1.6 percent to 31 cents.

AROVELLA THERAPEUTICS

Arovella says it has developed the manufacturing process for large-scale production of ALA-101 chimeric antigen receptor-positive invariant natural killer T-cells (CAR-iNKT).

Arovella said Melbourne's Cell Therapies Pty Ltd, at the Peter MacCallum Cancer Centre, had developed a modular, semi-automated process for producing high yield CAR-iNKT cells with high purity while "significantly reducing technology transfer risks" and the time required to proceed from proof-of-concept to clinical trials.

Arovella said it could proceed with engineering batches to produce material for phase I clinical trials, and that final product characteristics were consistent with the expectations of regulators such as the US Food and Drug Administration for quality and safety.

The company said achieving this "milestone will facilitate Arovella's pipeline expansion for its CAR-iNKT cell platform" and that the manufacturing process could be applied to all of its future CAR-iNKT cell products.

Arovella managing-director Dr Michael Baker said the manufacturing process had "been a primary focus for Arovella over the past year, and it is incredibly exciting to have completed this step".

"We have been diligent to ensure that our proprietary manufacturing process is robust and delivers high-yield, high purity products," Dr Baker said.

"This enables us to achieve our vision of taking allogeneic CAR-INKT cells into clinical trials and, ultimately, commercial development," Dr Baker said. "We look forward to continuing this momentum as we progress towards our phase I clinical trial for ALA101."

Arovella was up half a cent or 4.35 percent to 12 cents with 3.5 million shares traded.

EPSILON HEALTHCARE (ADMINISTRATORS APPOINTED) (FORMERLY THE HYDROPONICS COMPANY)

Epsilon administrator SV Partners' Ian Purchas says the final creditors meeting resolved to adopt a deed of company arrangement (DOCA) proposed by founder Alan Beasely.

The voluntary administrator told Biotech Daily that the vote was very close with 18 creditors voting, in one of which he acted as a related party and the other for which he held a proxy vote.

Mr Purchas said the vote for DOCA A and DOCA B was then tied at nine votes each.

Mr Purchas said he used his casting vote in favor of DOCA B, and should that be signed and sealed by June 24, the company would then be in the hands of the relevant directors.

Mr Purchas said he considered the various matters relating to the two competing proposals and it was his duty "to use his judgement in deciding in the best interest of the creditors and the company based on the information before him at the time".

Last week, Mr Purchas said that DOCA A was put forward by chair and former chief executive officer Xiao (Josh) Cui, with DOCA B proposed by founder and former deputy chair Alan Beasley, Peter Giannopolos and others (BD: May 28, 2024).

SV Partners said at that time that it was "in the best interests of the creditors and the company to resolve that the company execute a [deed of company arrangement]".

The administrators said that they did not believe it was "in creditors' interests to resolve to wind up the company because it is less likely to provide the opportunity to … preserve shareholder value".

"In our opinion, a resolution that the administration end would not be in the best interests of creditors," SV Partners said.

"The directors placed the company in administration to deal with financial difficulties and we are of the opinion that this position has not been rectified to the extent that would allow the administration to simply end," the administrators said.

Last year, Epsilon deputy chair Alan Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and Xiao (Josh) Cui (BD: Nov 21, 2023).

In the notice of meeting, Mr Beasley said he had "grown increasingly concerned about the governance of the board" and recommended shareholders vote in favor of the resolutions.

Mr Beasley said that he wrote to Mr Cui seeking his resignation, with his letter to Mr Cui and Mr Cui's response posted on-line and later removed.

The following day, Epsilon responded to an ASX query saying that a $388,000 discrepancy between its quarterly reports and its half year report was due to the difference between gross and net payments (BD: Nov 22, 2023).

In a five-page query, the ASX noted multiple financial statements, an auditor's report and loan announcements and then asked 16 questions, including multi-part questions.

In December, Epsilon said that chair Xiao (Josh) Cui has called an extraordinary general meeting to remove founder and deputy chair Mr Beasley (BD: Dec 4, 2023).

Later in December, SV Partners said it has been appointed as Epsilon's administrators following a resolution by the company's directors, to assess its "business operations and financial affairs" (BD: Dec 18, 2023).

On the same day, the ASX suspended Epsilon from quotation under Listing Rule 17.3, or an unwillingness to comply with, or breaking, a Listing Rule.

In 2017, the then The Hydroponics Company (THC), raised $8,000,000 at 20 cents a share and listed up 65 percent, on May 4, 2017 "to be a leading, global cannabis business, a leader in the development and delivery of medicinal cannabis, worldwide manufacturer and distributor of hydroponics equipment, materials and nutrients, and large-scale hydroponic greenhouse design and construction" (BD: May 22, 2017).

Epsilon was in a suspension and last traded at 2.4 cents a share.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype multi-risk test will be distributed by Los Angeles' Stayhealthy Inc in North America.

Genetic Technologies said Stayhealthy opened "an online discount pharmacy with 1.5 million users and a level five cafeteria workers insurance plan covering over 100,000 employees … [and with] a database of over 200 million US email address, Stayhealthy is well-positioned to promote this new offering".

The company said Genetype would distribute the multi-risk test via Stayhealthyrx, "enhancing the reach of its portfolio of personalized health risk assessments across North America".

Genetic Technologies said the collaboration would provide users with comprehensive insights into their health risks and actionable steps to mitigate them".

Genetic Technologies chief executive officer Simon Morriss said the partnership would "bring the innovative multi-risk test to [Stayhealthy] … customers, this test will help individuals make informed health decisions and improve their quality of life".

Genetic Technologies was up 2.5 cents or 25 percent to 12.5 cents.

ADALTA

Sydney's Platinum Investment Management says its 87,863,759 share-holding in Adalta has been diluted from 16.43 percent to 14.75 percent.

Earlier this year, Adalta said it hoped to raise up-to $3,000,000 in a draw-down equity facility with New York's Bergen-managed New Life Sciences Capital LLC and up-to $700,000 from existing shareholder the Meurs Group (BD: Apr 29, 2024).

On Monday, the company said it had raised $1,877,109 million through the exercise of 62,570,306 options at 3.0 cents each, issued under last year's placement and rights offer (BD: Jun 3, 2024).

Adalta was unchanged at 2.7 cents.

FIREBRICK PHARMA

GZ Family Holdings Ptd Ltd says it has increased its substantial shareholding in Firebrick from 9,045,766 shares (5.06%) to 24,600,000 shares (12.60%).

In a substantial shareholder notice signed by director Qixin Gao, the Oakville, New South Wales-based GZ said it bought 15,200,000 shares in a private placement on May 31, 2024, for $760,000, or five cents a share.

Last month, Firebrick said it had "binding commitments" to raise $800,000 at five cents a share, or a 24 percent discount to the 15-day volume weighted average price, in a placement to GZ and four GZ Family related parties (BD: May 17, 2024).

Firebrick was unchanged at six cents.

ADHERIUM

Phillip Asset Management Ltd says that on May 27, 2024, it bought 50,000,000 shares in an entitlement offer for $1,000,000, or 2.0 cents a share.

Yesterday, Phillip as trustee for Bioscience Managers said it had increased its substantial holding in Adherium and been diluted to 123,733,827 shares (16.95%) but did not disclose the price or date of the acquisition (BD: Jun 4, 2024).

In May, Adherium said it raised $8.4 million at 2.0 cents a share (BD: May 23, 2024).

Adherium was up 0.2 cents or 12.5 percent to 1.8 cents.

ARGENICA THERAPEUTICS

Argenica says founder and former chair Geoff Pocock has resigned as a non-executive director, effective immediately.

Last year, Argenica said Dianne Angus would replace Mr Pocock as non-executive chair, effective from December 1, 2023 (BD: Nov 30, 2023).

Today, the company said Mr Pocock was appointed chair of the company from its incorporation in November 2019 and during its listing on the ASX in June 2021.

Argenica said it was "currently actively reviewing its requirements to ensure the company has the appropriate breadth of capabilities to continue to support business growth".

Ms Angus said "Mr Pocock was instrumental in spinning out the underlying neuroprotective peptide technology from the University of Western Australia and the Perron Institute for Neurological and Translational Science to establish Argenica".

"The company is extremely grateful for Mr Pocock's dedication, stewardship and contributions over the years, and for his time over the past six months with the company assisting with the transition following my appointment," Ms Angus said.

"As Argenica continues its transitions into a clinical stage neurology pharmaceutical development company, we will continue to recruit strong industry-based expertise into the company," Ms Angus said.

Argenica fell one cent or 1.4 percent to 72 cents.