Biotech Daily

Tuesday March 18, 2025

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: CLARITY UP 11%; STARPHARMA DOWN 3%**

*** ONEVENTURES: BIVACOR RAISING $94m FOR ARTIFICIAL HEART**

*** SCIENCE ACADEMY URGES AUSTRALIA RESPOND TO TRUMP RED TAPE**

*** CMRI FINDS TELOMERE 'ACTIVE ROLE' IN AVOIDING CANCER**

*** PYC $9m RETAIL RIGHTS; TOTAL $100m; UNDERWRITTEN SHORTFALL**

*** CHIMERIC $3m 2-FOR-5 RIGHTS OFFER**

*** ADHERIUM $2.6m CONVERTIBLE NOTES**

*** TELIX ILLUCIX APPROVED IN BRAZIL; R2 PHARMA BRAZIL J-V**

*** SINGAPORE APPROVES ORTHOCELL STRIATE+**

*** AUSTCO $1m 'LARGEST CONTRACT'**

*** AVITA: US STEDICAL PERMEADERM MANUFACTURE; AMENDS DEAL**

*** DORSAVI 3-D ACL INJURY TEST**

*** CLEO OVARIAN CANCER BLOOD TEST TECHNOLOGY TRANSFER**

*** SYNTARA TO TRIAL SNT-9465 FOR SCARS**

*** CAMBIUM, FDA AGREE ELATE OCULAR TRIAL PROTOCOL**

*** BLUECHIIP VOLUNTARY ADMINISTRATION; SUSPENSION EXTENDED**

*** ROBMAR TAKES 5.6% OF STARPHARMA**

*** CLINUVEL CEO DR PHILIPPE WOLGEN LEAVE; LACHLAN HAY ACTING**

*** SHELLEY STEYN REPLACES ONCOSIL CFO CHRISTIAN DAL CIN**

*** RHYTHM APPOINTS TODD PERKINSON CFO**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Tuesday March 18, 2025, with the ASX200 up 6.3 points to 7,860.4 points.

Twenty-two of the Biotech Daily Top 40 companies were up, 11 fell, five traded unchanged and two were untraded.

The four Big Caps were mixed, with Cochlear up 1.5 percent and CSL, Pro Medicus and Resmed down by less than one percent.

Clarity was the best, up 27 cents or 10.6 percent to $2.81, with five million shares traded.

Prescient climbed 7.3 percent; Actinogen was up 6.25 percent; Atomo, EBR and Orthocell were up more than five percent; Amplia improved 4.2 percent; Avita and Immutep were up more than three percent; Alcidion, Aroa, Dimerix, Nanosonics, Neuren, Proteomics and Syntara rose two percent or more; 4D Medical, Cochlear, Mesoblast, Polynovo and Universal Biosensors were up one percent or more; with Clinuvel and SDI up by less than one percent.

Starpharma led the falls, down 0.3 cents or three percent to 9.7 cents, with 21,243 shares traded.

Impedimed, Nova Eye and Resonance shed two percent or more; Cynata, Genetic Signatures, Micro-X and Paradigm lost one percent or more; with CSL, Cyclopharm, Medical Developments, Pro Medicus, Resmed and Telix down by less than one percent.

ONEVENTURES, BIVACOR

Sydney's Oneventures has confirmed that Bivacor is raising $US60 million ($A94.0 million) to commercialize its total artificial heart.

Last week, Monash University said the first Australian patient to receive Bivacor's total artificial heart had become "the first in the world to be discharged from hospital" following the implant on November 22, 2024 at Sydney's St Vincent's Hospital and the patient later receiving a donor heart transplant" (BD: Mar 12, 2025).

Last year, Oneventures said the Huntington Beach, California and Gold Coast, Queensland-based Bivacor had implanted its first total artificial heart for end-stage heart failure as part of a US Food and Drug Administration feasibility study (BD: Jul 26, 2024).

At that time, Oneventures said the heart was a titanium bi-ventricular rotary blood pump with a single moving part that used magnetic levitation technology.

Later, in his Millis Oration at the Ausbiotech 2024 conference, Bivacor founding chief technology officer and Bivacor inventor Dr Daniel Timms said that since July, four patients in the US had received a transplant and were able to walk again (BD: Oct 30, 2024).

Yesterday and today, Oneventures confirmed that it and Boston's Cormorant Asset Management were supporting the private capital raise, which was being conducted by Bivacor.

Biotech Daily has attempted to contact Bivacor but without success.

Oneventures said that the funds would "support ongoing clinical trials and regulatory milestones required to bring the Bivacor total artificial heart to market"

Bivacor is a private company.

AUSTRALIAN ACADEMY OF SCIENCE

The Australian Academy of Science says it urges the Australian Government to respond to US Government intervention in Australia-US research collaboration.

A statement from the Australian Academy of Science's president Prof Chennupati Jagadish said the Academy "urges the Australian Government to give serious and urgent attention to recent actions by American authorities".

A document from the US White House Office of Management and Budget (OMB), titled 'Outreach to implementing partners' includes 36 detailed questions over five pages.

The questions include counter-terrorism staff vetting; "patriotic values"; support for US Government policies; free speech (sic); anti-[people]-trafficking policy; not working with communist, socialist or totalitarian parties "or any party that espouses anti-American beliefs"; that the institution "has not received ANY funding from the [People's Republic of China] … Russia, Cuba or Iran" [OMB emphasis]; that there be no diversity, equality and inclusion project or elements; no climate or environmental justice element in the project; does it combat Christian prosecution; and concludes with a Paperwork Reduction Act Statement that "public reporting burden for this collection of information is estimated to average 30 minutes per response" or 18 hours in total.

Prof Jagadish said that "Australian scientists have been surveyed to disclose their institution's compatibility with … US foreign and domestic policy in ways that could have negative repercussions for Australia's strategic capability and advancement, and would contravene Australian laws and international statutes that govern science".

"If responses to the survey lead to reductions or cessation of US-Australian scientific collaborations, it will directly threaten our scientific and technological capability and diminish Australia's strategic capability is areas of national interest such as defence, health, disaster mitigation and response, [artificial intelligence] and quantum technology," Prof Jagadish said.

"Any reasonable assessment of the survey indicates that US government funded research in Australia could be terminated because an Australian institution – not the research project – has links with several named countries, or links with the United Nations and its agencies, or impacts the protection and promotion of specific religions, amongst other factors," Prof Jagadish said.

Prof Jagadish said the US was Australia's largest research partner and in 2024, US government funding involving Australian organizations was $386 million, equivalent to 43 percent of the funding provided through the Australian Research Council.

"Forty percent of Australian publications in the physical sciences involve American collaborators," Prof Jagadish said. "This includes research in strategic areas including quantum science, space science and other sciences that underpin Aukus Pillar II advanced capabilities and Australia's critical technologies list."

Prof Jagadish said 25 percent of Australia's publications in bio-medical and clinical sciences involved US collaborators, and Australian researchers collaborated with the US organizations to develop vaccines and medical products for Australia's heath security.

Prof Jagadish said the Academy "urges the Australian Government to actively and urgently engage with its American counterparts to mitigate risks and minimize the impact on Australian strategic capability".

"A wait-and-see approach could leave us dangerously unprepared," Prof Jagadish said.

Prof Jagadish said Australia had made "significant and commendable efforts to avoid and manage foreign interference in Australian research and technological activities".

"The Australian Government must remain committed to these efforts and resist foreign interference, regardless the actor," Prof Jagadish said. "This requires leadership and direction from the highest level of government."

CHILDREN'S MEDICAL RESEARCH INSTITUTE

CMRI says it has found telomeres play "an active role" in avoiding cancer, which may lead researchers to potentially target telomeres to induce cell death to treat cancer.

The Children's Medical Research Institute (CMRI) said telomeres were "the protective caps at chromosome ends and are involved in aging and cancer".

CMRI said that when people aged telomere length naturally decreased and that over the course of a lifetime, telomere shortening instructs ageing cells to stop dividing and that they normally function "as a critical barrier to stop cancer".

The Institute said the study, titled 'A CPC-shelterin-BTR axis regulates mitotic telomere deprotection', was conducted with Japan's University of Kyoto, published in Nature Communications and available at: https://www.nature.com/articles/s41467-025-57456-8.

CMRI genome integrity lead Prof Tony Cesare said "most people think of telomeres as a passive entity that shorten with cell division, this is a passive fail-safe used during ageing".

"Our data shows telomeres are much more active," Prof Cesare said. "They can acutely respond to stress and actively open up to turn on a cellular response that looks like ageing … and do this to avoid cancer."

"This can lead to cell cycle arrest, or death, to prevent these damaged cells with chromosome errors from dividing further," Prof Cesare said. "This suggests telomeres have another anti-cancer mechanism that was previously unknown."

In 2009, the Nobel Prize in Physiology or Medicine was awarded jointly to University of Melbourne graduate Prof Elizabeth Blackburn, with her then graduate student now Prof Carol Greider at the University of California San Franciso and Harvard University's Prof Jack Szostak "for the discovery of how chromosomes are protected by telomeres and the enzyme telomerase".

PYC THERAPEUTICS

PYC says it has raised $9.3 million at $1.25 a share in the retail component of its rights offer, taking the total to $100.3 million and leaving a $46 million underwritten shortfall.

Last month, PYC said it had raised $91 million at $1.25 a share in the institutional component of its up-to $146 million, one-for-four, entitlement offer, with a $55 million retail offer underwritten by existing shareholders to follow (BD: Feb 19, 2025).

Today, PYC said the retail component of the entitlement offer was fully underwritten with the balance to be raised on or before April 7, 2025 by the underwriters.

PYC fell 1.5 cents or 1.3 percent to $1.155.

CHIMERIC THERAPEUTICS

Chimeric says it hopes to raise about $3.2 million at 0.5 cents a share in a two-for-five rights offer, with one attaching option for every share issued.

Chimeric said the price was a 28.6 percent discount to the five-day volume weighted average price, with the options exercisable at 0.8 cents each by December 19, 2025.

Chimeric said the funds would be used for a phase I/II trial of CHM CDH17 chimeric antigen receptor (CAR) T-cells for various cancers, a phase Ib trial of its CHM0201 natural killer-cells therapy and general working capital.

The company said PAC Partners Securities and Taylor Collison were joint lead managers and would receive 25,000,000 adviser options, in total.

Chimeric said the offer had a record date of March 21, would open on March 25 and close on April 8, 2025.

Chimeric fell 0.05 cents or 8.3 percent to 0.55 cents with 1.95 million shares traded.

ADHERIUM

Adherium says it has “firm commitments” to raise $2.6 million in convertible notes, with investors to receive one option for every two shares issued.
Adherium said Bioscience Managers and Trudell Medical International, a company controlled by its director George Baran, each subscribed for $1.2 million under the raise, with Philip Asset Management and K One W One Ltd taking up $825,000 and $200,000, respectively.
The company said the convertible notes had a conversion price of the lower of one cent, the price of shares if it undertakes a placement at the time of the placement, “but in any vent with a floor conversion price of 0.5 cents per note” and if it does not undertake a placement since the issue date, then half a cent.
Adherium said the options were exercisable at the lower of two cents each and if a placement occurs prior to their exercise the lower of a 100 percent premium to the issue price of shares and exercise price of options.
The company said the options were exercisable by February 28, 2028.
Adherium said the funds raised from the notes would be used to support the ongoing roll-out of its Hailie inhaler monitor in the US and for general working capital purposes.
The company said it would seek shareholder approval for the convertible notes at an extraordinary general meeting “to be held as soon as possible”.
Adherium said PAC Partners and Stralis Capital were joint lead managers to the raise.
Adherium was up 0.1 cents or 10 percent to 1.1 cents.

TELIX PHARMACEUTICALS

Telix says it has Brazilian Health Regulatory Agency approval for its Illuccix prostate cancer imaging agent and will establish a manufacturing joint-venture.
Telix said Illucix was the “first and only” prostate-specific membrane antigen positron emission tomography scan (PSMA-PET) to receive full regulatory approval in Brazil.
The company said marketing authorization was granted to its Porto Alegre, Brazil-based partner R2 Pharma, a subsidiary of the Sao Paolo, Brazil-based nuclear medicine distributor GSH Corp Participações SA.
In 2019, Telix said Porto Alegre’s Grupo RPH would distribute its products in Latin America, starting with Illucix for PET prostate cancer imaging (BD: Jul 3, 2019).
Today, the company said it had a ‘Telix Innovations Brazil’ joint-venture with R2 Pharma, which had the exclusive licence to “commercialize and distribute” Illucix and future Telix products in Brazil, but did not disclose the commercial terms.
Telix said that Telix Innovations Brazil would use “the local knowledge and expertise of R2 Pharma to obtain the necessary licenses and governmental authorizations in Brazil”.
Telix fell 21 cents or 0.8 percent to $27.15 with 1.1 million shares traded.

ORTHOCELL

Orthocell says it has Health Sciences Authority approval to market and sell its Striate+ dental-guided, bone regeneration product in Singapore.
Orthocell said the Singapore approval was in addition to existing clearances in the US, Europe, the UK, Australia, New Zealand and Canada and that it was “on-track to receive regulatory clearance in Brazil in three-to-six months”.
The company said Singapore was “a strategic regulatory market and can be used as a stepping stone to approvals in other [Association of South East Asian Nations]”.
Orthocell was up 7.5 cents or 5.5 percent to $1.445 with 2.1 million shares traded.

AUSTCO HEALTHCARE

Austco says it has a $1.02 million contract with Toronto, Ontario's West Park Hospital, the "largest [software and maintenance agreement] contract in company history".
Austco said the five-year deal for its healthcare communication and clinical workflow management solutions would be effective from April 1, 2025.
The company said West Park Hospital was a specialized rehabilitation and complex care hospital dedicated to helping patients recover from serious illnesses and injuries and was one of its largest customers.
Austco managing-director Clayton Astles said the contract renewal showed "the significance of our strategic initiative to boost recurring software revenues".
"It highlights the increasing demand for our solutions and the trust customers have in our ability to deliver mission-critical healthcare communications solutions," Mr Astles said.
Austco was up 1.5 cents or 5.3 percent to 30 cents.

AVITA HEALTH

Avita says it will manufacture Stedical's Permeaderm at its Ventura, California facility and has amended its deal with Stedical Scientific to receive 60 percent of average sales.
Last year, Avita said it would commercialize San Diego's Stedical Scientific's Permeaderm bio-synthetic wound treatment in the US (BD: Jan 21, 2024).
Today, the company said under the original deal each party retained 50 percent of the sales of Permeaderm and that under the revised deal it would receive 60 percent and remit 40 percent to Stedical "after deducting manufacturing costs".
Avita said its Permeaderm manufacturing agreement was effective from yesterday and ensured "the continued availability of this innovative, transparent bio-synthetic wound matrix while optimizing production capabilities to meet growing market demand".
Avita chief executive officer Jim Corbett said the agreements reflected the company's "commitment to driving innovation and expanding market access, while ensuring that patients continue to receive first-in-class care".
Avita was up 10 cents or 3.7 percent to $2.80.

DORSAVI

Dorsavi says it has launched its 3-dimensional (3-D), artificial intelligence (A.I.) knee analysis test for anterior cruciate ligament (ACL) injuries in athletes.
Dorsavi said its US Food and Drug Administration approved test used more than 10,000 proprietary knee assessments with its A.I. program to identify movement patterns linked to ACL injury risk, a "major challenge" for athletes, sports teams and healthcare professionals.
The company said one-dimensional force plates were the industry standard for assessing knee mechanics but were limited to measuring force vertically and unable to capture the "rotational forces that place athletes at risk".
In February, Dorsavi said it would receive $US46,750 ($A73,273) for a US study of its wearable sensors and A.I. algorithms for athlete injury prevention (BD: Feb 3, 2025).
Today, Dorsavi managing-director Dr Andrew Ronchi said the technology was "a paradigm-shift in sports injury prevention".
"Our A.I.-driven 3-D motion analysis offers unprecedented accuracy in assessing knee mechanics in the clinic, something the industry has never had access to outside of bio-mechanics labs," Dr Ronchi said.
Dorsavi was up 0.1 cents or 14.3 percent to 0.8 cents with 7.4 million shares traded.

CLEO DIAGNOSTICS

Cleo says it has begun transferring technology related to its ovarian cancer blood test to the Minneapolis, Minnesota-based Bio-Techne Corporation for development.
Last year, Cleo said it had recruited the first of “a minimum of 500 patients” in a US trial of its ovarian cancer blood test, with eight medical institutions in six US states recruiting patients, and the data to underpin a US Food and Drug Administration submission for the approval of its blood test in clinical use (BD: Sep 6, 2024).
Today, Cleo managing-director Dr Richard Allman said the technology transfer was “a pivotal milestone in Cleo's strategic pathway toward commercialization”.
Cleo was unchanged at 45.5 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it will begin a 42-patient, phase Ia/b trial of its topical SNT-9465 for hypertrophic skin scarring by July 2025, with results expected by July 2026.
Syntara said it had developed SNT-9456 following a trial of SNT-6302 and hoped to achieve anti-scarring efficacy with an “improved tolerability profile suitable for daily use”.
In 2023, the then Pharmaxis said a phase I trial showed the then PXS-6302 topical cream reduced collagen in scars by 30 percent but not appearance at three months, which pointed to the need for a long study in established scars (BD: May 24, 2023).
Last month, the company said a 14-patient subset of its 42-patient, phase I trial of SNT-6302 showed “significant improvements” in scar vascularization and extra-cellular matrix remodeling (BD: Feb 18, 2025).
At that time, Syntara said SNT-6302 was developed as a topical treatment to modify scar composition and reduce fibrosis by inhibiting the enzyme lysyl oxidase (LOX).
Today, the company said a phase Ia dose escalation study in healthy volunteers would determine optimal dosage in three, eight-patient cohorts, with patients randomly assigned a single dose of the active drug or placebo.
Syntara said the phase Ia trial would be followed by an open-label, phase Ib extension study to assess improvements in appearance and composition of hypertrophic scares less than 25 months old after three months of daily treatment.
The company said patients in the phase Ib trial would include a cohort with six dosed patients for 28 days and two placebo patients followed by a second cohort of 10 patients dosed with SNT-9465 for 90 days.
Syntara said “following extensive discussions with clinicians worldwide regarding the unmet needs in scar treatment, it is evident that a significant commercial opportunity exists in modifying hypertrophic scars”.
The company said the current standard-of-care included “costly laser therapy or painful steroid injections” and required multiple treatments to produce small improvements.
Syntara said a daily topical treatment with SNT-9465 could provide patient benefits that may be effective “without the need for repeat clinical visits”.
The company said that due to recruitment challenges, its ongoing study led by the University of Western Australia on burn injury scars would be discontinued “allowing greater focus on keloid research”.
Syntara managing-director Gary Phillips said “the knowledge gained from our existing topical skin-scarring compound, in addition to our in-house drug discovery capability, has enabled the rapid refinement of this program and transition to the optimized SNT-9465”.
“We aim to deliver an [investigational new drug] ready program with evidence supporting safety and efficacy in 2026,” Mr Phillips said.
Syntara was up 0.2 cents or 2.5 percent to 8.1 cents with 6.05 million shares traded.

CAMBIUM BIO

Cambium says it has met with the US Food and Drug Administration and agreed on the path forward for its Elate Ocular cell-based assay for severe dry eye disease.
Cambium said at a type D meeting the FDA agreed its assay was suitable as a “lot release potency assay” to support phase III trials and a biologics license application.
The company said the FDA agreed with its approach for clinical trials and confirmed its phase I/II and phase III trial protocols were “suitable”.
Cambium said the “positive outcomes from the FDA meeting” allowed it to finalize the validation of the potency assay with its contract development and manufacturing organization ahead of the phase III trial “planned to commence in mid-2025”.
Cambium chief executive officer Karolis Rosickas said the FDA's agreement was “a significant regulatory milestone for Cambium Bio as we prepare to advance Elate Ocular into pivotal phase III clinical trials for moderate to severe dry eye disease”.
“This positive outcome underscores the robustness of our [chemistry, manufacturing and controls] and analytical development approach and keeps us on track to initiate our registration-enabling phase III program mid-year,” Mr Rosickas said.
Cambium was unchanged at 35 cents.

BLUECHIIP

Bluechiip says it has appointed Romanis Cant’s Manuel Hanna as its voluntary administrator, effective from March 17, 2025.
Bluechiip said Mr Hanna was “undertaking an assessment of the company’s business operations and financial affairs”.
Separately, the ASX said “having regard to the announcement of the appointment of voluntary administrators … ASX has determined that Bluechiip’s financial condition is not adequate to warrant the continued quotation of its securities and therefore Bluechiip is in breach of Listing Rule 12.2”.
The ASX said Bluechiip would remain suspended from quotation until it was satisfied that the company complied with the Listing Rules.
Last year, the ASX said it had suspended Bluechiip under Listing Rule 17.5 for “not lodging the relevant period report by the due date” (BD: Oct 1, 2024).
At the time, Bluechiip said it was “currently engaged in discussions with a number of international companies” and that it would not lodge its audited financial statements for the year ended June 30, 2024 until the strategic review and associated capital raising were substantially completed.
Bluechiip last traded at 0.3 cents.

STARPHARMA HOLDINGS

Sydney’s Robmar Investments Pty Ltd says it has become a substantial shareholder in Starpharma with 23,308,980 shares, or 5.57 percent.
A substantial shareholder notice signed by Robmar director Robert Pittorino said that between January 8 and March 6, 2025 it bought 3,218,399 shares in 10 separate transactions for a total $349,526, or an average 11.2 cents a share.
Starpharma fell 0.3 cents or three percent to 9.7 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says chief operations officer Lachlan Hay has been appointed acting chief executive officer while Dr Philippe Wolgen takes leave for medical treatment.
Clinuvel said its existing executive team would assume Dr Wolgen's day-to-day responsibilities for up to three months, while Dr Wolgen took "temporary leave from his full duties to seek treatment for an acute medical condition".
Dr Wolgen said: "While I remain active in the business and its direction, I have advised the board that the temporary reduction of my operational involvement will result in the fastest path to full health".
"I have complete faith in our executive team to be able to continue to deliver and expect no disruption to the business while I receive medical care," Dr Wolgen said.
Clinuvel chair Prof Jeffrey Rosenfeld said the board supported "Dr Wolgen in his decision to reduce his considerable workload and focus on his health and wish him a speedy recovery".
"We continue to work closely with the executive team as we execute on the company's objectives," Prof Rosenfeld said.
Clinuvel was up four cents or 0.35 percent to $11.61 with 233,847 shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Shelley Steyn to replace chief financial officer Christian Dal Cin, effective from May 5, 2025.
Oncosil said Ms Steyn had more than 17 years of experience and had worked for Flynn Global Australia New Zealand, Sirtex, Deloitte Touche Tohmatsu and Grant Thornton.
According to her Linkedin page, Ms Steyn held a Bachelor of Commerce from South Africa's University of Johannesburg.
The company said the CFO Solution's Mr Dal Cin had resigned as company secretary and chief financial officer, effective from March 31, 2025.
Oncosil was unchanged at 0.5 cents.

RHYTHM BIOSCIENCES

Rhythm says that it has appointed Todd Perkinson as its chief financial officer, effective from today.
Rhythm said Mr Perkinson had worked at Adneo, Emerge Aotearoa, Nimble Money and Royal District Nursing and had helped facilitate the $100 million sale of Vault Intelligence to Damstra Holdings.
The company said Mr Perkinson held a Bachelor of Commerce and Administration from New Zealand's Victoria University of Wellington.
In 2023, Rhythm said that chief financial officer and joint company secretary Paul Smith had "resigned for personal reasons, by mutual agreement" with financial controller Guy Carisbrooke assuming financial duties (BD: Nov 16, 2023).
Rhythm was up 0.4 cents or 4.7 percent to 8.9 cents.