



Biotech Daily

Monday November 20, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PHARMAXIS UP 10%; PATRYS DOWN 11%**
- * **WEHI: SNOW MEDICAL \$100m FOR IMMUNOLOGY CENTRE**
- * **MICROBA RETAIL RIGHTS RAISE \$7.7m; TOTAL \$20m**
- * **LBT PLACES \$420k SHORTFALL; TOTAL RAISED \$4m**
- * **4D MEDICAL CT LVAS WINS FDA CLEARANCE**
- * **CSIRO: A.I.-CHEST XRAY '27% MORE ACCURATE'**
- * **ARTRYA SIGNS NORTHEAST GEORGIA FOR SALIX**
- * **SERVATUS LAUNCHES BIOMIQ ACNE WIPES, SERUM**
- * **CARDIEX EXTENDS LOANS, REDUCES US REPAYMENT**
- * **TRIVARX 15 PHASE II SLEEP DEPRESSION TRIAL SITES OPENED**
- * **AROVELLA RECEIVES \$1.9m FEDERAL R&D TAX INCENTIVE**
- * **PRO MEDICUS 17.6% OPPOSE REMUNERATION REPORT**
- * **ALTERITY REQUESTS 'CAPITAL RAISE' TRADING HALT**
- * **LBT - VIKING TAKES 10.8%; UNICORE 9.5%; M-D BRENT BARNES 6.8%**
- * **STUART MORRIS, SACAVIC TAKE 6.7% OF ADALTA**
- * **NEUREN: 'THE AUSTRALIAN' ARTICLE 'UNFOUNDED SPECULATION'**
- * **IMPEDIMED CEO VALENCIA, CFO CRUIKSHANK OUT; DR BAINS, GRANT IN**
- * **DIMERIX APPOINTS MARK DIAMOND CHAIR**
- * **PARADIGM'S PAUL RENNIE TO M-D, 20% PAY CUT; TO LOSE HELEN FISHER**
- * **LIFE SCIENCES QUEENSLAND \$13k GENE AWARD WINNERS**

MARKET REPORT

The Australian stock market was up 0.13 percent on Monday November 20, 2023, with the ASX200 up 9.0 points to 7,058.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and three were untraded.

Pharmaxis was the best, up 0.3 cents or 10.3 percent to 3.2 cents, with 31,007 shares traded. 4D Medical climbed 8.4 percent; Amplia was up 5.6 percent; Emvision improved four percent; Paradigm rose 2.5 percent; Alcidion, Avita and Polynovo were up more than one percent; with Cochlear, Nanosonics, Neuren and Pro Medicus up by less than one percent.

Patrys led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 3.5 million shares traded. Prescient lost 10.3 percent; Cynata shed 7.4 percent; Starpharma fell 6.7 percent; Dimerix, Impedimed and Orthocell were down more than three percent; Compumedics, Mesoblast, Opthea, Proteomics, Telix, Universal Biosensors and Volpara shed more than two percent; Clinuvel, Genetic Signatures, Medical Developments and Resmed were down one percent or more; with CSL and SDI down by less than one percent.

WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says the Snow Medical Research Foundation will invest \$10 million a year for 10-years to open an immunology research centre with the Royal Melbourne Hospital.

WEHI said the funding would allow researchers to pursue a program “beyond the short-term funding largely available in Australia ... and helped move away from incremental science to solving the grand challenges of immunology”.

The Institute said the partnership would support scientists pursue “high risk, high reward work that is expected to fundamentally change how immunological diseases are treated”.

WEHI said the \$100 million investment more than doubled Snow Medical’s investment in medical research in the four years since 2019 to \$200 million.

The Institute said it would run the Snow Centre for Immune Health, with the Royal Melbourne Hospital and bring researchers to “transform how we research and treat the immune system” and translate laboratory discoveries to benefit patients.

WEHI said the Snow Research Clinics allowed patients to join immune system trials, while still being treated with the and latest research treatments.

Snow Medical founder Terry Snow said “Australia had some of the best researchers in the world ... [and] we want to get them out of short-term funding cycles and give them freedom to experiment and take risks - we’re here to back them”.

WEHI acting director Prof Alan Cowman, said the Snow Centre for Immune Health would “completely change the way we view the immune system, with the ambitious aim of revolutionizing healthcare delivery to be about proactively predicting and preventing, instead of reacting to and treating, immune illness and disorders”.

“The centre will rapidly accelerate this growing field of research and do it at a scale not seen anywhere else in the world,” Prof Cowman said.

MICROBA LIFE SCIENCES

Microba says its retail rights offer raised \$999,635, leaving an underwritten \$6,723,832 shortfall, taking the total raised with the institutional offer to \$20 million.

Last month, Microba said it would buy the Gloucestershire, England-based Invivo Clinical, a microbiome testing business for \$12.5 million and up-to \$8.7 million in earn-out, with a \$20 million rights offer at 23 cents a share to fund it; and later, said it raised about \$12.3 million in the institutional component of the offer (BD: Oct 19, 23, 2023).

Today, Microba said the underwriters were Bell Potter Securities and Morgans Corporate. Microba fell half a cent or 2.2 percent to 22.5 cents.

LBT INNOVATIONS

LBT says it has placed the \$420,000 shortfall from its underwritten, renounceable pro-rata entitlement offer, at 0.5 cents a share, taking the total to \$4,000,000.

Last month, LBT said it hoped to raise \$4.5 million in a four-for-one rights offer, with Candour Advisory Pty Ltd the underwriter (BD: Oct 13, 2023).

Last week, the company said it had raised \$1,030,228 from shareholders and \$2,549,772 from the underwriter, leaving a \$920,000 shortfall (BD: Nov 15, 2023).

Today, LBT said the remaining \$500,000 shortfall was available to be placed within three months, if required, and the raise completed its financial restructure to support the commercialization of its automated plate assessment system (APAS) Pharma QC.

LBT managing-director Brent Barnes said the capital restructure to launch APAS into the pharmaceutical market was “an important reset” to fund the company.

LBT was unchanged at 0.5 cents.

4D MEDICAL

4D Medical says the US Food and Drug Administration has cleared its computed tomography lung ventilation analysis software (CT Lvas).

Last year, 4D Medical said it had released its CT Lvas which provided an “almost identical report” to its XV Lvas but used computed tomography (CT) imaging rather than x-ray equipment (BD: Oct 25, 2022).

Today, the company said FDA clearance followed the commercialization of CT Lvas in Australia.

4D said the US had 43 CT scanners per one million people and its CT Lvas would “broaden the accessibility of functional lung imaging for people ... with lung disease”.

The company said it would apply to the American Medical Association to establish a distinct, category III current procedural terminology (CPT) code to identify the use of CT Lvas among healthcare providers and payers, and then seek reimbursement.

4D Medical managing-director Prof Andreas Fouras said “the clearance for CT Lvas offers further validation of our development and represents significant progress towards commercial release of our CT [ventilation and perfusion] technology.”

4D Medical was up 5.5 cents or 8.4 percent to 71 cents with 3.2 million shares traded.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

CSIRO says an artificial intelligence x-ray model is 26.9 percent more accurate than human radiologists for reporting “some” heart and lung conditions.

CSIRO said research from its Australian Electronic Health Research Centre compared different artificial intelligence models “to better understand and identify improvements in the diagnostic accuracy of automated chest x-ray interpretation reporting”.

The Organisation said current methods of artificial intelligence-based x-ray reporting used an ‘encoder’ to read the chest x-ray images, and ‘decoder’ to produce a report, but that there had been no research into which encoder and decoder was most efficient.

CSIRO said researchers also studied the effectiveness of different tasks for ‘warm starting’ the artificial intelligence chest x-ray report generation task.

The Organisation said ‘warm starting’ an artificial intelligence model was the transfer of knowledge learned from one task, such as classifying natural images or generating Wikipedia articles, to improve the task at hand.

CSIRO said researchers tested different encoders and decoders and found the optimal combination of encoder and decoder, together with the use of the warm starting method.

The Organisation said the research found an optimal artificial intelligence model produced a 26.9 percent relative improvement on the accuracy of automated image reporting compared with human radiologist reports.

Monash Medicine radiologist Dr Doug Anderson said clinician burn-out was “a risk factor for mental illness and particularly prevalent in radiologists due to large workloads and demanding clinical documentation.”

“The increasing clinical reliance on imaging for diagnosis combined with a relative shortage of radiologists is creating unsustainable workloads and a search for workload management solutions,” Dr Anderson said.

“While the model identifies some pathologies consistently, for example pleural effusion, it does not yet accurately identify others, for example lung lesion,” Dr Anderson said.

CSIRO research scientist Dr Aaron Nicolson said a better understanding of models would lead to greater accuracy using artificial intelligence to diagnose x-ray images.

“Automated report generation for x-rays could reduce clinician burnout and create space for them to provide more robust patient care,” Dr Nicholson said.

[ARTRYA](#)

Artrya says Braselton's Northeast Georgia Health Ventures will use its Salix coronary anatomy software in its healthcare system and workflow in five hospitals.

Artrya said the agreement included Northeast validating Salix in its network while it was going through the US Food and Drug Administration 510(k) clearance process.

The company said the deal would develop and expand the specific use cases for Salix at five Northeast hospitals, with clinicians benefiting from early access to its software to validate the detection of coronary disease by showing the presence of critical high-risk plaques, the leading cause of heart attacks.

Artrya said that following FDA pre-market clearances, Northeast would work with it to commercialize and expand its point-of-care Salix system to clinicians and patients across its network of more than 100,000 annual heart disease patients in Georgia.

The company said Northeast would advise Artrya on future priorities and provide technical guidance during the development of its fractional flow reserve, non-invasive blood flow assessment solution product.

Artrya did not state the commercial terms of the agreement.

Artrya chief executive officer Mathew Regan said the agreement allowed the company to "conserve cash and expedite the development-to-commercialization trajectory into the US market with a major player".

"Once our product has been approved for sale [Northeast] will work with us to expand our point-of-care Salix coronary anatomy solution to clinicians and patients across [the] Northeast Georgia health system," Mr Regan said. "And of course, this collaboration opens the door for potential future investments in North America."

Artrya fell one cent or 4.8 percent to 20 cents.

[SERVATUS](#)

Servatus says it has launched its Biomiq acne wipes and Biomiq acne serum for facial acne as the first microbiome-based, over-the-counter product from its skin care range.

Servatus said Biomiq products used "the skin microbiome to address the underlying causes of certain skin conditions, while helping soothe the skin and restore ... balance".

The company said it studied the role of bacteria and microbiome regulation as treatments for certain skin diseases, which allowed it "to apply its scientific knowledge and evidence-based research to the consumer skin care market".

Servatus said its Biomiq skin care range expanded its product portfolio, which included a range of powdered over-the-counter, Australian Therapeutic Goods Administration-approved therapies for indications including constipation and bloating.

Servatus scientist Dr Rebekka Williams said the company's broader work presented "a compelling opportunity to improve skin health".

"Acne is a cluttered, but still under-serviced, market which hasn't welcomed many novel and effective products in over four decades," Dr Williams said.

"As we learn more about the interaction of microbes on the skin, we believe our extensive expertise in the field of the human microbiome has supported us to develop a product that both reduces pathogenic acne forming bacteria, but at the same time, preserve and enhance the healthy ecosystem of the skin's natural microbiome," Dr Williams said.

"This is a significant advancement and can allow us to make an immediate difference in skin health," Dr Williams said.

Servatus is a public unlisted company.

CARDIEX

Cardiex says it has extended two loans with Mitchell Asset Management, and its primary US creditor has reduced its owed fees to \$2.3 million after it withdrew its Nasdaq listing. Last week, Cardiex said it had a \$7.5 million loan from chair Niall Cairns and managing-director Craig Cooper-owned C2 Ventures at 10 percent or 15 percent per annum, pending shareholder approval, to fund operations and pay debts (BD: Nov 9, 2023).

Today, the company said it had agreed to a three-month extension of its \$595,000 loan with Mitchell Asset Management to March 31, 2024, which would allow it to lodge a Federal Research and Development Tax Incentive claim.

Cardiex said it had extended an up-to \$880,000 short-term working capital facility with Mitchell Asset Management to October 31, 2024, providing it “ample time to finalize its [research and development] tax incentive registration and lodgment for ... [2023-'24]”.

The company said the refund for the years to June 30, 2023 and June 30, 2024 were expected to exceed the value of the loan and the facility, which would allow it to repay all of its debts with Mitchell Asset Management within their revised expiry dates.

Last week, Cardiex said it had withdrawn its registration with the US Securities and Exchange Commission and Nasdaq initial public offering (BD: Sep 28, 2023).

Today, the company said it had \$3,515,000 in outstanding fees to its primary creditor to the US listing process Wilson Sonsini Goodrich & Rosati (WSGR).

Cardiex said following negotiations, WSGR had agreed to reduce the outstanding fees to \$2,344,000 with long-dated repayment terms, given it had withdrawn its listing, and that it had repaid these fees with a promissory note equivalent to the principal sum.

The company said the renegotiation allowed it to continue to progress its business and product development plans with reduced impact on its working capital requirements.

Cardiex said the restructure of its debt facilities, together with its C2 Ventures loan, provided a “material step in bolstering the company’s working capital position”.

Cardiex was in a voluntary suspension at 13.5 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has opened its up-to 400-participant phase II trial of its “sleep signal analysis” algorithm for major depressive episodes at three additional sleep centres.

In September, the then Medibio said it had begun its phase II trial of its MEB-001 algorithm at up-to 14 US sleep centres (BD: Sep 4, 2023).

Today, the company said the additional centre followed “considerable in-bound interest from industry partners” since the launch of the phase II trial, including an enquiry from the Texas-based Comprehensive Sleep Medicine Associates (CSMA) adding three sites.

Trivarx said it had enrolled 132 patients in the study so far and was confident that it would complete phase II testing during the six months to June 30, 2024.

Trivarx chair David Trimboli said the phase II trial would provide the company with insight into how its algorithm could be as a diagnostic screening tool.

Trivarx was up 0.2 cents or 5.7 percent to 3.7 cents.

AROVELLA THERAPEUTICS

Arovella says it has received \$1.94 million from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Arovella said the rebate related to expenditure for the year to June 30, 2023.

Arovella fell 0.7 cents or 7.6 percent to 20 cents.

PRO MEDICUS

Pro Medicus says all annual general meeting votes passed but the remuneration report was opposed by 5,869,722 votes (17.62%), with 27,434,970 votes (82.38%) in favor. The company said the resolutions to re-elect directors Deena Schiff, Dr Leigh Farrell and Anthony Hall were passed with more than 96.0 percent support. According to its most recent notice, Pro Medicus had 104,455,279 shares on offer, meaning that the votes against the remuneration report amounted to 5.6 percent of the company, sufficient to requisition extraordinary general meetings. Pro Medicus was up 48 cents or 0.55 percent to \$88.02 with 188,812 shares traded.

ALTERITY THERAPEUTICS

Alterity says it has requested a trading halt “pending an announcement in relation to a capital raise”. Trading will resume November 22, 2023, or on an earlier announcement. Alterity last traded at 0.7 cents.

LBT INNOVATIONS

Brisbane’s Viking BCM Pty Ltd says it has become substantial in LBT with the purchase of 115,576,792 shares, or 10.78 percent. Viking BCM director Dan Hill said that on November 9, 2023, he bought 115,576,792 shares for \$577,884, or 0.5 cents a share (see above).

LBT INNOVATIONS

Adelaide’s Unicore Investments Pty Ltd says it has become substantial in LBT with the purchase of 101,980,000 shares, or 9.51 percent. Unicore director Michael Matarazzo said that on November 9, 2023 he bought 101,980,000 shares for \$509,900, or 0.5 cents a share (see above).

LBT INNOVATIONS

LBT managing-director Brenton Barnes says he has become substantial in the company with 72,121,797 shares, or 6.73 percent. The Sydney-based Mr Barnes said with Hawkeye Self-Managed Superannuation Fund Pty Ltd and Barnes’ Love Work Live Pty Ltd he bought 70,000,000 shares on November 9, 2023 for \$350,000, or 0.5 cents a share (see above).

ADALTA

Stuart Morris as director of Sacavic Pty Ltd and trustee for Morris Super Fund says he has become substantial in Adalta with 33,862,999 shares, or 6.73 percent. The Melbourne-based Mr Morris said that between March 12, 2019 and November 14, 2023 he bought shares on market, in rights issues and placements at prices ranging from 2.0 cents to 24.03 cents, with the single largest purchase 10,000,000 shares in a placement on November 14, 2023 at 2.0 cents a share. Earlier this month, Adalta said it had raised \$1.65 million of a hoped-for \$1.23 million in an “oversubscribed placement” at 2.0 cents a share (BD: Nov 7, 2023). Adalta was up 0.1 cents or 5.6 percent to 1.9 cents.

NEUREN PHARMACEUTICALS

Neuren says that an article published in The Australian newspaper last night is unfounded “media speculation”.

Neuren said the article reported that: “Neuren Pharmaceuticals is understood to have brought in a defence adviser after fielding buyer interest from US-based industry giants.” The company said that it had “appointed a corporate and strategic adviser several months ago”.

“The appointment was a normal step in Neuren’s ongoing growth and development and not in response to any approaches from third parties,” the company said.

“Media speculation to the contrary is unfounded,” Neuren said.

Neuren chief executive officer Jon Pilcher told Biotech Daily that the appointment of New York’s Jeffries Group was not announced at the time because it was not material.

Neuren was up eight cents or 0.5 percent to \$14.76 with one million shares traded.

IMPEDIMED

Impedimed says managing-director Rick Valencia has resigned effective immediately with Dr Parmjot Bains appointed interim managing-director from January 8, 2024.

Impedimed said that chief financial officer Tim Cruickshank has resigned and will be replaced as chief financial officer by chair McGregor Grant.

The company said that Dr Bains would be paid \$450,000 a year, pro rata, including superannuation and as an interim managing-director and chief executive officer for three to six months, would not be eligible for short or long-term incentives.

Impedimed said that Mr Grant would be paid \$430,000 a year, pro rata, including superannuation for the three to six months in the position, would not be entitled to incentives, nor director’s fees.

The company said that when the new board was elected, it announced a review of strategy “to ensure it was maximizing the potential opportunities to transition to a high growth and profitable business” (BD: Sep 28, Oct 3, 2023).

Impedimed said that the review “identified a very capable core management team, a distinctive product portfolio and an undeniable opportunity ... [but] more is needed to deliver robust execution and control costs”.

The company said it was “grateful for Mr Valencia’s contribution over the past year in what has been a challenging time and wishes him all the best for the future” and said he would be paid his entitlements in accordance with his employment contract.

Impedimed said that it acknowledged Mr Cruickshank’s “contribution over the last 15 years ... [in which he had] been instrumental in the company’s transition from the [research and development] phase into its commercialization phase, including moving from a capital equipment model to predominantly a software as a service model”.

The company said that Mr Cruickshank would support the business until a mutually agreed time, after which he would be paid his contracted entitlements.

Impedimed said that Dr Bains had experience in strategy, sales and marketing, commercial execution and change management in the US, Asia, Middle East and Australia.

The company said that Dr Bains had worked for Pfizer and previously was Neuren’s joint chief executive officer and chief operating officer, Perseis Therapeutics chief executive officer, a manager at McKinsey and Co and a medical doctor.

Impedimed said that five-month director Dr Michael Seiden had resigned.

Impedimed fell half a cent or 3.7 percent to 13 cents with 11.6 million shares traded.

[DIMERIX](#)

Dimerix says it has appointed former Antisense managing-director Mark Diamond as its non-executive chair, effective from December 1, 2023.

Dimerix said Mr Diamond retired from Antisense in May 2023, after 22 years as chief executive officer, and had previously worked in product and business development roles at the then Faulding Pharmaceuticals, now Pfizer, in the US and Europe.

The company said Mr Diamond held a Bachelor of Science from Melbourne's Monash University and a Master of Business Administration from Sydney's Macquarie University. Dimerix fell half a cent or 3.6 percent to 13.5 cents with 5.5 million shares traded.

[PARADIGM BIOPHARMACEUTICALS](#)

Paradigm says chair Paul Rennie will take a 20 percent pay cut, step down to managing-director when an independent chair is appointed, with director Helen Fisher to resign.

In an announcement to the ASX titled 'Pre-AGM Update', Paradigm said that Mr Rennie would continue as executive chair until an independent non-executive chair was found.

The company said that resolutions to the November 29, 2023 annual general meeting regarding the issue of 1,200,000 performance rights to Mr Rennie and 1,000,000 performance rights to executive director Dr Donna Skerrett, were conditional on a minimum total shareholder return compounded annual growth rate of 40 percent a year, remaining employed by Paradigm at the vesting date, meeting the clinical primary endpoints in the phase III pentosan poly-sulphate osteoarthritis trial and filing a new drug application to the US Food and Drug Administration (BD: Oct 25, 2023).

Paradigm said its independent directors "consider that, in view of the vesting conditions being directly aligned with shareholder interests, these financial incentives are an appropriate incentive for key management personnel".

The company said that Ms Fisher had "informed the board that due to increased demands on her time, she will resign ... on the appointment of a replacement suitable non-executive director, in order to focus on her other commitments going forward".

Paradigm said that Mr Rennie had "voluntarily agreed to a salary reduction of 20 percent with effect from December 1, 2023 to drive enhanced alignment with shareholders".

Paradigm was up one cent or 2.5 percent to 40.5 cents.

[LIFE SCIENCES QUEENSLAND](#)

Life Science Queensland says six Gene awards, worth \$13,000 were present on Friday November 17, 2023 "in recognition of excellence" in life sciences.

Life Science Queensland said the National Heart Foundation and University of Queensland's Dr Sonia Shah won the \$3,000 Rose-Anne Kelso Commemorative award for "an individual woman's endeavors, passion and dedication" to the sector.

The industry organization said Vaxxas won the \$2,000 prize for company of the year for its work on its needle-free vaccine patch.

Life Science Queensland said the four other awards, worth \$2,000 each, went to Vicebio, the University of Southern Queensland's Prof Gavin Ash, James Cook University's Prof Sabina Knight and Infensa chief executive officer Prof Mark Smythe.