Biotech Daily

Tuesday December 3, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MICRO-X UP 31.5%; CYNATA DOWN 6.5%**

*** MICRO-X 'AWARE OF ALLEGED $12.75m US DEVELOPMENT CONTRACT'**

*** BLUECHIIP $464k BIOLIFE CELL THERAPY SAMPLE DEAL**

*** FEDERAL R&D REVIEW - PANEL APPOINTED, FINDINGS BY 2025**

*** PROF GUS NOSSAL FAMILY ENDOWS WEHI PROFESSORSHIP**

*** INOVIQ: 'EXO-OC 94% ACCURACY FOR OVARIAN CANCER'**

*** RENERVE APPOINTS ACCESSION NERVALIGN HONG KONG DISTRIBUTOR**

*** INVION DOSES 1st PHASE I/II INV043 SKIN CANCER PATIENT**

*** CYCLOPHARM IMAGES 15 FRENCH TECHNEGAS TRIAL PATIENTS**

*** MESOBLAST: MORE REVASCOR PHASE III HEART DATA**

*** PERCHERON ENDS U.S. ADR FACILITY, 'UPLISTS' TO OTCQB**

*** HEXIMA SCRAPS REAL THING ACQUISITION**

*** ANTERIS SCHEME MEETING 98% APPROVE US REDOMICILE**

*** ISLAND BOARD SPILL EGM**

*** COMPUMEDICS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ACRUX REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** AUDEARA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CAMBIUM REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** RHYTHM CHAIR OTTO BUTTULA, WEBINVEST INCREASE, DILUTED TO 13%**

*** NEUROTECH LOSES CO-CO SEC ERLYN DAWSON**

MARKET REPORT

The Australian stock market was up 0.56 percent on Tuesday December 3, 2024, with the ASX200 up 47.3 points to 8,495.2 points. Twenty-three of the Biotech Daily Top 40 companies were up, 10 fell, six traded unchanged and one was untraded.

Micro-X was the best (see below), up 1.7 cents or 31.5 percent to 7.1 cents, with 6.9 million shares traded. Syntara climbed 15 percent; Dimerix was up nine percent; Prescient rose 7.7 percent; Actinogen was up 6.9 percent; Neuren and Opthea were up five percent or more; Impedimed, Medadvisor, Nova Eye, Pro Medicus and Resonance were up more than three percent; Avita, Mesoblast and Polynovo rose more than two percent; 4D, Aroa, CSL, Cyclopharm, Immutep, Nanosonics and Orthocell were up more than one percent; with Cochlear, Emvision, Genetic Signatures and Telix up by less than one percent.

Cynata led the falls, down 1.5 cents or 6.5 percent to 21.5 cents, with 101,828 shares traded. Amplia fell 4.6 percent; Paradigm lost 3.9 percent; Alcidion, Clarity, EBR and Medical Developments were down more than one percent; with Clinuvel, Proteomics, Resmed and SDI down by less than one percent.

MICRO-X

Micro-X says it is aware that a US Government website reports it has won a $US8,153,718 ($A12,750,000) development contract.

According to a US Government website, the funds were for a project titled 'Platform Accelerating Rural Access to Distributed and Integrated Mobile Care' by the US Department of Health and Human Services' Advanced Research Projects Agency.

Micro-X said it was in the "advanced stages of working with a US Government agency with respect to a development contract … [but] has not received a fully executed contract".

Micro-X was up 1.7 cents or 31.5 percent to 7.1 cents with 6.9 million shares traded.

BLUECHIIP

Bluechiip says it will be paid $US300,000 ($A464,000) to licence its cryogenic sample management technology to Seattle, Washington's Biolife Solutions.

Bluechiip said Biolife Solutions' primary packaging containers would use its wireless sample management technology for the cell and gene therapy market.

The company said the partnership was a "major milestone for Bluechiip, with the potential for ongoing royalties and product sales" and Biolife's products were the "gold standard in maintaining the viability of biologics through manufacturing, storage and distribution".

The company said it would be paid an upfront fee of $US300,000, followed by subsequent quarterly licencing or royalty fees, whichever was greater, on Bluechiip-enabled products.

Bluechiip said the exclusivity did not include its standard products used in "multiple applications or existing Bluechiip products" and it expected the inclusion of its technology into Biolife's range of Cellseal and Cryocase final packaging containers to be valued at about $US750,000, with Biolife to have non-exclusive rights to distribute existing products.

Bluechiip managing-director Andrew McLellan said that the deal was "a transformative step in our strategic vision and provides significant validation for Bluechiip's technology in the rapidly expanding [cell and gene therapy] market".

Bluechiip was in a suspension and last traded at 0.3 cents.

FEDERAL GOVERNMENT

The Federal Government says it has appointed a panel to conduct a review of Australian research and development, with findings expected by the end of 2025.

Earlier this year, the Budget Papers said the Government would "undertake a strategic examination of Australia's research and development system to strengthen its alignment with Australia's priorities and improve innovation and research and development outcomes" (BD: May 15, 2024).

A media release from the Federal Minister for Industry and Science Ed Husic said that it would be "the first time in almost 20 years that this important foundation of our economy will come in for such wide-ranging review".

The Federal Government said it had appointed Tesla chair Robyn Denholm to lead the panel with former chief scientist Prof Ian Chubb, Avita (then Clinical Cell) founder Prof Fiona Wood and Launchvic chief executive officer Dr Kate Cornick as members.

The Government said the strategic review would "assess the benefits to economic growth and productivity from a more purposeful approach to [research and development]".

The Federal Government said that the independent panel would consider opportunities to "maximize the value of existing investments in [research and development], strengthen linkages between research and industry, support the achievement of national priorities, drive greater [research and development] investment [and] uplift Australia's overall [research and development] intensity".

The Government said the panel would make recommendations "to secure Australia's future prosperity by strengthening Australia's research and development system".

The Department of Industry, Science and Resources website said that the review would find ways to optimize an industry supported research and development system that attracted increased investment.

The media release said that the panel would "lead the development of an action plan to strengthen alignment of the research and development system with government priorities and global opportunities to improve innovation and … outcomes".

The Government said it would consult with "industry, universities, peak bodies, government, first nations peoples [and] the public".

The terms of reference for the examination are available at: https://bit.ly/3OG7RkU.

The site did not mention the existing Federal Government's Research and Development Tax Incentive program.

The Minister for Industry and Science Ed Husic said Australia's "ideas and intellectual property are an indicator of future economic success … [and] this review is designed to give us an evidence-based pathway to stronger growth".

"It's been almost 20 years since we asked the hard questions about our [research and development] performance, despite the alarming slide over the last decade," he said.

"We said after the pandemic we would boost our manufacturing self-sufficiency," Mr Husic said. "That is a big challenge, but Australian know-how can help us do things smarter, sharpening our edge against international competition."

"Our $23 billion Future Made in Australia plan is a critical investment in building up our industrial muscle," Mr Husic said. "We've got to back up that investment with a world-class [research and development] system that will deliver more firepower from our boardrooms and labs so we can compete with the best in the world."

The Federal Minister for Education Jason Clare said that research was "critical to Australia's economic growth and productivity".

"It's a vital part of our plan for a Future Made in Australia," Mr Clare said.

"The Universities Accord recommended we improve the ways research is funded to put it on a more predictable footing, and that's what this review will look at," Mr Clare said.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Nossal family has provided funding for the Prof Gustav Nossal Professor of Immunology of Medical Research.

The Walter and Eliza Hall did not state the value of the funding but said it would "fund the salary of the [professorship] in perpetuity" and that WEHI intended to increase the fund to support the laboratory team of the Nossal Professor, also in perpetuity.

The Institute said that an international recruitment search was being led by Marcus Engeman at Alumni Global.

WEHI said that "the exceptional research, discovery and advocacy legacy" of former Institute director and Prof Gustav Nossal would continue through the professorship, which would "lead pivotal research to advance human immunology".

The Institute said that Prof Nossal "spent nearly four decades at WEHI after arriving as a young medical graduate in 1957".

WEHI said that Prof Nossal's immunology research advanced understanding of immune tolerance, how the immune system learnt to distinguish between our own body and foreign 'invaders' and how the failure of this process could lead to rheumatoid arthritis and other immune diseases.

The Institute said that in 1965 he became its fourth director, a position he held until 1996.

"Under his leadership WEHI transformed into a leading research institute with a broadened research scope, enhanced technologies and facilities, and an environment that attracted and nurtured some of the leading scientists of our time," the Institute said.

WEHI director Prof Ken Smith said that the professorship was a fitting recognition for one of Australia's preeminent scientists.

Prof Smith said Prof Nossal's research and leadership legacy was "firmly established, and we are delighted that it will endure through this prestigious, perpetual role".

"This incredible gift provides the opportunity for new immunological discoveries that will help people live healthier and longer lives today, and importantly, well into the future for generations to come," Prof Smith said.

"Early in my career I had the great good fortune to be [Prof Nossal's] last Doctor of Philosophy student, so I'm particularly proud that the professorship will sustain [his] passion for nurturing the next generation of immunologists," Prof Smith said.

Prof Nossal said that he was "very fortunate to be involved with immunology at an early stage of the science, and we have come a long way".

"But there is a lot more work to do before we have a full understanding of the immune system and related diseases," Prof Nossal said.

"With this family donation, our aim is to support an exceptional scientist to help WEHI continue its global leadership in the field," Prof Nossal said.

"It is humbling that WEHI intends to establish this position in perpetuity which will allow my family to remain connected with this wonderful institution into the future, as they have indicated a desire to do," Prof Nossal said.

"We live in an age where good science is particularly important," Prof Nossal said.

"In that regard, I note that WEHI intends to grow this fund further to eventually support the whole lab team of the Nossal Professor in perpetuity," Prof Nossal said.

"We hope that others will follow our lead and donate generously to this fund, or to the support of other scientific research, given how important private support is to Australian medical research," Prof Nossal said.

WEHI said that donations to support the Fund can be made online at www.wehi.edu.au/support-us/nossal-professorship/ or by telephoning the Fundraising and Philanthropy Office on +613 9345 2403 or email: fundraising@wehi.edu.au.

INOVIQ

Inoviq says an independent patient validation study showed its Exo-ovarian cancer (OC) blood test had “outstanding test results with accuracy of over 94 percent”.
Inoviq said that the study isolated exosomes from more than 500 blood samples using its Exo-net fully-automated, high-throughput, robotic platform; and exosome ovarian cancer biomarkers were measured using targeted mass spectrometry.
The company said the study showed “all targeted biomarkers were identified in ovarian cancer samples and their diagnostic performance was confirmed”.
Inoviq said the “Exo-net isolation of exosomes also identified additional cancer biomarkers for use in the future”.
Inoviq said the “outstanding test results” would be used to optimize the blood test on a commercial instrument platform and perform additional clinical validation before delivering the test in a clinical laboratory.
Inoviq chief executive officer Dr Leearne Hinch said that the “biomarker panel showed exceptional performance in detecting early-stage ovarian cancer, where accurate diagnosis is most critical for improving patient outcomes”.
“Early detection enables timely intervention, which is crucial for increasing survival rates and reducing disease progression,” Dr Hinch said.
Inoviq chair David Williams said that the study provided “clinical evidence to pursue a commercial product for early ovarian cancer detection”.
Inoviq was up five cents or 10.75 percent to 51.5 cents.

RENERVE

Renerve says Hong Kong’s Accession Medical Supplies Co will market and sell its Nervalign nerve cuff in Hong Kong and Macau.
Last week, Renerve raised $7 million in initial public offer at 20 cents a share to commercialize its nerve repair products including Nervalign (BD: Nov 26, 2024).
Today, the company said Accession would buy its products as a wholesaler and be supported in its sales and marketing activities.
Renerve said the companies would work together to gain regulatory approval in Hong Kong using Accession’s “existing relationships with local hospitals and day surgeries to drive sales and increase product demand as adoption increases”.
The company said it had filed for regulatory approval in Hong Kong and expected approval “to be granted in mid-2025”.
Renerve did not disclose the commercial terms of the agreement.
Renerve managing-director Dr Julian Chick said that the partnership was “a pivotal step forward in Renerve’s growth strategy”.
“By leveraging Accession's extensive local expertise and established relationships with key hospitals and surgeons in Hong Kong and Macau, we are confident in our ability to successfully introduce and expand the reach of the Nervalign nerve cuff in this dynamic market,” Dr Chick said.
“This collaboration not only accelerates our international expansion but also positions Renerve to tap into the broader Greater Bay Area, unlocking significant opportunities for growth,” Dr Chick said.
“As we continue to advance our innovative solutions for nerve repair, this partnership underscores our commitment to improving patient outcomes and driving sustainable value for our stakeholders,” Dr Chick said.
Renerve fell one cent or 5.3 percent to 18 cents.

INVION

Invion says it has dosed the first of at least 18 patients in its phase I/II trial of topical INV043 for non-melanoma skin cancer at Brisbane's Veracity Clinical Research.

Earlier this year, the company said its photo-sensitizer INV043 was "safe and demonstrated promising efficacy signals" in a 41-patient, sub-lingually administered, phase II trial for prostate cancer (BD: Sep 18, 2024).

Today, Invion said that the open-label trial was "designed to evaluate the safety and efficacy of its lead drug candidate INV043, a novel photo-sensitizer developed in Australia for use in photo-dynamic therapy for the treatment of multiple cancers".

The company said that the first part of the trial aimed to assess the safety of the topical formulation of INV043, followed by dose optimization and identifying efficacy signals.

Invion said part three would expand testing to include superficial basal cell carcinoma.

The company said the design of the trial allowed for modifications of procedures based on interim results, which improved efficiency and effectiveness and that the patient number could "be increased depending on the results".

Invion executive chair Thian Chew said dosing the first patient the trial was "a significant milestone for Invion in demonstrating the potential for the Photosoft technology to address limitations and undesirable side effects of current standard-of-care … including scarring and pain".

"On the back of the recently announced prostate cancer results, this trial can also provide clinical evidence that INV043 can be safely used in more than one formulation to treat multiple cancers," Mr Chew said.

"This can then open up the potential for our next-generation [photo-dynamic therapy] to become an important alternative modality for treating cancers," Mr Chew said.

Invion was up 18 cents or 100 percent to a post-100-to-one-consolidation 36 cents with 995,832 shares traded.

CYCLOPHARM

Cyclopharm says 15 patients in a 665-patient, French clinician-driven trial have been imaged by its Technegas lung ventilation system for pulmonary embolisms.

Cyclopharm said the trial would assess "the potential of nuclear medicine imaging using Technegas to enable improved detection of residual pulmonary vascular obstruction as a predictor of venous thrombo-embolism, which is a critical area currently dominated by incumbent [computed tomography] pulmonary angiogram scanning".

The company said the trial was being conducted at 13 nuclear medicine centres in France and would enrol more than 665 patients diagnosed with pulmonary embolism who had completed three-to-six months of anti-coagulation treatment.

Cyclopharm said it expected the results to "further validate Technegas' clinical and economic value, providing a platform for continued growth and long-term shareholder value creation".

Cyclopharm managing-director James McBrayer said imaging the first patients in the trial was "another milestone in our strategy to expand the use of Technegas".

"This study validates Technegas' capabilities in advanced pulmonary diagnostics and aligns with our commitment to improving global healthcare outcomes," Mr McBrayer said.

"We look forward to sharing the trial results, which we believe will have implications for patient care and our commercial strategy," Mr McBrayer said.

Cyclopharm was up 2.5 cents or 1.5 percent to $1.675.

MESOBLAST

Mesoblast says further phase III data shows Revascor "significantly lowered the risk of cardiovascular death" in 303 reduced ejection fraction patients (p = 0.003).
In 2020, Mesoblast said the trial showed a statistically significant reduction in heart attacks or strokes (p = 0.002) and death from cardiac causes (p = 0.037) but did not meet the primary endpoint of a "reduction in recurrent non-fatal decompensated heart failure events" (BD: Dec 15, 2020).
In 2021, the company said at 30-months a single dose of Revascor mesenchymal precursor cells, or rexlemestrocel-L, led to "substantial and durable reductions in heart attacks, strokes, and cardiac death" in heart failure patients (BD: Jan 17, 2021).
Today, Mesoblast said risks for cardiovascular deaths among control patients at a mean follow-up of 30 months were inflammation and ischemic heart failure reduced ejection fraction, increasing the risk of death by 61 percent and 38 percent, respectively.
The company said Revascor reduced heart attack or stroke by 57 percent (p = 0.016) and cardiovascular death, heart attack or stroke by 35 percent (p = 0.049) in patients with reduced ejection fraction compared to controls.
The company said in the 158 patients with reduced ejection fraction and inflammation Revascor reduced heart attack and stroke by 88 percent (p = 0.005) and cardiovascular death, heart attack and/or stroke by 52 percent (p = 0.018).
Mesoblast managing-director Prof Silviu Itescu said the company had received feedback from the US Food and Drug Administration providing support for an accelerated approval pathway in end-stage ischemic [heart failure with reduced ejection fraction] patients with a left ventricular assist device".
"This new publication identifies the larger ischemic [heart failure with reduced ejection fraction] population which responds to Revascor with mortality benefit," Prof Itescu said.
Mesoblast was up five cents or 2.8 percent to $1.85 with 10.1 million shares traded.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says it has ended its American depository receipt (ADR) facility on the over-the-counter markets and uplisted to the Over-the-Counter Bulletin Board (OTCQB).
Percheron said it had applied to the US Financial Industry Regulatory Authority to change the ticker code from 'ATHJF' to 'PERCF'.
The company said the changes would "substantially improve access to the company's securities for US-based investors, while realizing a substantial cost saving for the company".
Percheron said it expected "to undertake a program of investor relations activity in the US during 2025, with the objective of raising awareness of the company among US investors".
Percheron managing-director Dr James Garner said the "portfolio of securities in the US was not optimized for our present circumstances, with several illiquid securities quoted on the 'pink sheets' tier of the over-the-counter markets".
"We now have a single security quoted on the OTCQB tier, the so-called 'venture market', which we expect to greatly improve access for US-based investors," Dr Garner said.
"In addition, we have discontinued our ADR facility with [Bank of New York] Mellon," Dr Garner said.
"With no ADRs outstanding, this will not have any implications for any shareholder, but it will allow us to reallocate the funds that would otherwise have been spent on fees to promoting the company in the US," Dr Garner said.
Percheron was unchanged at 7.1 cents with 1.7 million shares traded.

HEXIMA

Hexima says it will not proceed with the acquisition of Real Thing Entertainment as it is "unable to have sufficient confidence that the conditions will be able to be satisfied".
Earlier this year, Hexima said it would acquire Real Thing Entertainment Pty Ltd for 789,743,000 shares and 87,215,040 options, raise up-to $7.5 million and hold a 10-to-one consolidation (BD: Jul 24, 2024).
At that time, the company said Real Thing Entertainment had "developed an artificial intelligence platform that allows users to achieve outcomes using simple voice commands through to complex dialogue".
Later, Hexima it had extended the date for satisfaction of conditions for its purchase of Real Thing Entertainment from September 30 to December 16, 2024 (BD: Sep 27, 2024).
Today, the company said the acquisition had been "subject to conditions … including shareholder approvals and raising capital as part of re-compliance with the ASX Listing Rule Chapter 1 and 2 admission requirements".
Hexima said no exit or break fees were payable.
Hexima was in a suspension and last traded at 1.35 cents.

ANTERIS TECHNOLOGIES

Anteris says its scheme meeting voted a 97.66 percent approval of its redomicile to the US and Nasdaq listing.
In August, Anteris said it intended to redomicile to the US, list on the Nasdaq this year, through the Delaware-based ATGC, and remain on the ASX; and later, said it had delayed the scheme (BD: Aug 13, Sep 30, 2024).
Today, the company said the scheme remained subject to the approval of the Supreme Court of Queensland, with a second court hearing on December 4, 2024.
Anteris fell 10 cents or one percent to $9.90.

ISLAND PHARMACEUTICALS

Island says its extraordinary general meeting will vote on a board spill, to be held on January 28, 2025.
Last month, Island said 92.2 percent of its annual general meeting voted a remuneration report second strike with the conditional board spill approved by 98.43 percent of the meeting (BD: Nov 19, 2024).
Today, the company said director nominations would close on December 10, 2024.
The meeting will be held at K&L Gates, 31/1 O'Connell Street, Sydney on January 28, 2025, at 11am (AEDT).
Island fell 1.5 cents or 8.1 percent to 17 cents.

COMPUMEDICS

Compumedics has requested a trading halt "pending an announcement in relation to the proposed capital raising".
Trading will resume on December 5, 2024, or on an earlier announcement.
Compumedics last traded at 27 cents.

ACRUX

Acrux has requested a trading halt pending “an announcement to the market in relation to a proposed capital raising”.
Trading will resume on December 5, 2024, or on an earlier announcement.
Acrux last traded at 4.5 cents.

AUDEARA

Audeara has requested an “immediate trading halt pending an announcement regarding a capital raising”.
Trading will resume on December 5, 2024, or on an earlier announcement.
Audeara last traded at 4.2 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium has requested a trading halt as it “expects to make an announcement to the ASX in connection with a proposed capital raising”.
Earlier this year, the then Regeneus said it had completed its merger with Cambium Medical Technologies for its Elate Ocular for dry eye disease and raised $3.48 million in a placement at 0.6 cents a share to fund clinical trials (BD: Apr 5, 2024).
Trading will resume on December 5, 2024, or on an earlier announcement.
Cambium last traded at 64 cents.

RHYTHM BIOSCIENCES

Rhythm chair Otto Buttula says he has increased his holding in the company and been diluted from 34,961,396 shares (14.21%) to 36,384,575 shares (12.83%).
The Brisbane-based Mr Buttula said that through Newfound Investments Pty Ltd and Webinvest Pty Ltd his holding was diluted in a placement and did not disclose how his holding increased.
Last month, Rhythm said it raised $3.5 million at 10 cents a share in a placement, with investors receiving two options for every three shares purchased (BD: Nov 19, 2024).
Rhythm fell 0.2 cents or 2.3 percent to 8.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says Erlyn Dawson has resigned as joint company secretary, effective from today, with Alessandra Gauvin continuing as sole company secretary.
Neurotech was unchanged at 6.6 cents.