



Biotech Daily

Tuesday November 29, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: PATRYS UP 22%; EMVISION DOWN 6%**
- * **AROA H1 REVENUE UP 63% TO \$26.8m, LOSS TURNED TO \$1.5m PROFIT**
- * **SONIC TO PAY \$17.8m FOR 19.99% OF MICROBA; 5% OPTION**
- * **BOTANIX SHARE PLAN RAISES \$961k; TOTAL \$6m**
- * **4D MEDICAL RECEIVES \$9.4m MRFF XV SCANNER MILESTONE**
- * **MEDADVISOR EXPANDS US 'INMOTION' PLATFORM**
- * **IMMUTEP, MERCK KGaA, PFIZER BLADDER CANCER TRIAL**
- * **AMPLIA RECRUITS 1st AMP945 PANCREATIC CANCER COHORT**
- * **INCANNEX HIRES EUROFINIS FOR MARIJUANA SKIN CREAM**
- * **CRONOS AGM 88% DEFEAT DIRECTOR REMOVALS; VITURA NAME CHANGE**
- * **PARADIGM WITHDRAWS 1.5m DIRECTOR SHARES VOTE**
- * **RHYTHM LOSES DIRECTOR EDUARDO VOM, RESOLUTION 'WITHDRAWN'**
- * **DIMERIX AGM 21% OPPOSITION TO EMPLOYEE EQUITY PLAN**
- * **CYCLOPHARM RECEIVES \$1.6m FEDERAL R&D TAX INCENTIVE**
- * **AROVELLA RECEIVES \$1m FEDERAL R&D TAX INCENTIVE**
- * **PYC TAKES 95% OF VISION PHARMA FOR \$10m**
- * **IMPEDIMED APPOINTS RICHARD VALENCIA M-D, ON \$671k PA**

MARKET REPORT

The Australian stock market was up 0.33 percent on Tuesday November 29, 2022, with the ASX200 up 24.2 points to 7,253.3 points. Eighteen of the Biotech Daily Top 40 stocks were up, 17 fell, three traded unchanged and two were untraded.

Patrys was the best for the second day in a row, up 0.5 cents or 21.7 percent to 2.8 cents, with 13.2 million shares traded. Actinogen, Genetic Signatures and Prescient climbed five percent or more; Immutep, Nanosonics and Pharmaxis improved more than four percent; Dimerix, Micro-X and Starpharma were up more than three percent; Antisense, Imugene and Proteomics rose more than two percent; Amplia, Next Science, Opthea, Polynovo and Resonance were up more than one percent; with CSL up by 0.75 percent.

Emvision led the falls, down 13 cents or 6.1 percent to \$2.01, with 52,783 shares traded. Cyclopharm fell 4.8 percent; Alcidion, Medical Developments and Paradigm were down more than three percent; Clinuvel, Compumedics, Cynata, Impedimed, Neuren and Universal Biosensors shed more than two percent; Atomo, Avita, Kazia, Resmed and Volpara were down more than one percent; with Cochlear, Pro Medicus and Telix down by less than one percent.

AROA BIOSURGERY

Aroa says revenue for the six months to September 30, 2022 was up 63.3 percent to \$NZ28,845,000 (\$A26,760,358) with last year's net loss of \$NZ5,089,000 turned to a net profit after tax of \$NZ1,587,000 (\$A1,472,469).

The company said revenue was primarily from sales of its sheep-stomach based Myriad products for soft tissue repair and Symphony for wound closure, with \$NZ492,000 in revenue from project fees.

Aroa managing-director Brian Ward said the business had "produced a strong result, and with approximately \$NZ50 million in cash, we are poised to enter [2023] with confidence". "As our sales force matures and product portfolio broadens, we expect to see momentum build even further," Mr Ward said.

The company said last years' diluted loss per share of 1.6 NZ cents turned to diluted earnings per share of 0.4 NZ cents, with net tangible assets per security unchanged at 23 NZ cents and it had cash and cash equivalents of \$NZ11,986,000 for the six months to September 30, 2022 compared to \$NZ45,291,000 at September 30, 2021.

Aroa was up two cents or 1.9 percent to \$1.075.

MICROBA LIFE SCIENCES

Microba says Sonic Healthcare will pay \$17.8 million for a 19.99 percent holding, with a further five percent in options, worth \$7.5 million, subject to shareholder approval.

Microba said it had agreed to initial terms with the Sydney-based Sonic for a strategic partnership to deliver its microbiome testing technology to Australia, Germany, the UK, Switzerland, the US, New Zealand and Belgium.

The company said that Sonic had entered into an "equity subscription agreement" to acquire a 19.99 percent stake in Microba, through the issue of shares at 26 cents a share, a 25 percent premium to the five-day volume-weighted average price (VWAP) to November 29, 2022, worth about \$17.8 million.

Microba said Sonic would acquire unlisted options, subject to approval, exercisable at 33 cents a share, within 18 months of issue and at a 58 percent premium to the five-day VWAP to November 29, for a further five percent of the company.

Microba said the agreement allowed Sonic to "exclusively distribute Microba's microbiome testing products to its customers ... across Germany, Belgium and the United Kingdom for a period of one year commencing on January 31, 2023, with the intention to extend subject to finalization of full licence and distribution agreements".

The company said the agreement provided Sonic with non-exclusive distribution rights for Switzerland, the US, Australia and New Zealand.

Microba said Sonic chief medical officer Dr Stephen Fairy would join its advisory board.

Microba chief executive officer Dr Luke Reid said the company was "excited" to have Sonic become a major strategic shareholder and partner.

"This strategic partnership with Sonic is set to accelerate international distribution of Microba's microbiome testing into primary and specialist healthcare, and move our testing deeper into routine patient management," Dr Reid said.

Sonic chief executive officer Dr Colin Goldschmidt said his company prided itself on accurate, reliable medical diagnostics services using leading laboratory and informatics technologies and the partnership with Microba "exemplifies our commitment to invest in cutting edge developments in laboratory medicine" and microbiome testing would become "a key part of pathology over coming years".

Microba was up 11.5 cents or 52.3 percent to 33.5 cents with 5.2 million shares traded.

Sonic was unchanged at \$31.68.

BOTANIX PHARMACEUTICALS

Botanix says it has raised \$960,504 of a hoped for \$3 million, in a non-underwritten share plan at 6.3 cents a share, taking the total raised to \$5,960,504.

In October, Botanix said Antares Capital committed to a \$5 million placement and it would offer the share plan to raise up-to \$3 million (BD: Oct 31, 2022) (AVW: Nov 4, 2022).

Today, the company said 15,246,240 shares were subscribed for in the share plan but did not mention a shortfall facility.

Botanix fell 0.2 cents or 3.2 percent to 6.1 cents.

4D MEDICAL

4D Medical says it has received a \$9.4 million milestone payment from the Medical Research Future Fund (MRFF), to support development of its XV lung scanner.

Last year, the company said the MRFF Frontier Health and Medical Research Initiative had awarded a \$28.9 million, five-year grant to the Australian Lung Health Initiative (ALHI), a consortium incorporated and led by the company (BD: Mar 4, 2021).

At that time, 4D said the funding was for the development and commercialization of the world's first XVD lung function scanner, now the XV scanner, a progression on the core x-ray velocimetry (XV) in that it was a dedicated system, providing low dose, contrast-free and rapid lung analysis for adults and children.

Today, the company said it had received the milestone payment after "successfully meeting [unspecified] product development milestones".

4D chief executive officer Prof Andreas Fouras said "the XV scanner integrates 4D Medical's core XV technology software into the world's first purpose-built respiratory hardware, enabling scanning in high volume and enhanced commercial returns".

"Receipt of this payment in full reflects the company's ability to deliver as promised," Prof Fouras said.

4D Medical was up two cents or 4.4 percent to 47 cents.

MEDADVISOR

Medadvisor says it is expanding its Inmotion US digital platform for medical information and prescriptions, by increasing "digital access to patients by 50 percent".

Medadvisor said that it had signed an Inmotion agreement with an unnamed pharmacy software group "representing over 10,000 pharmacies in the US, for an initial two-year term" which increased its US network to more than 30,000 pharmacy locations.

The company said it was expected a "larger than usual seasonal increase" in use of Inmotion, due to the influenza season and "the Covid-19 awareness program".

Medadvisor managing-director Rick Ratliff said "Medadvisor is about to see the benefits of its technology platform's ability to scale as we head into the colder months in the US".

"Over the last 12 months we have significantly increased the number of pharmacy locations in the US with access to our digital platform and digital programs, now numbering over 30,000 ... [expanding] our digital reach by 50 percent to 60 million Americans that now have access to digital communications from their local pharmacy."

"In addition, our ongoing Covid-19 vaccination awareness program has produced solid results with click-through rates higher than industry averages," Mr Ratliff said.

"As a result, this program is being extended through to the end of 2022," Mr Ratliff said.

"We expect these factors to drive the company's financial performance in the first half of 2022-'23," Mr Ratliff said.

Medadvisor was up one cent or 5.3 percent to 20 cents.

IMMUTEP

Immutep says it has a second trial collaboration agreement with Merck KGaA and Pfizer for an up-to 30-patient phase I study of urothelial, or bladder, cancer.

Last year, Immutep said it had a collaboration with the Darmstadt, Germany-based Merck KGaA to evaluate IMP321, or eftilagimod alpha, with M7824 in a phase I/II trial of 12 previously-treated patients, with different solid tumors (BD: Jun 1, 2022).

Today, the company said the trial, titled 'Insight-005', was a Germany-based "investigator-initiated explorative, open-label study evaluating the safety and efficacy of Immutep's lead product candidate, efiti, in combination with avelumab (Bavencio) in up to 30 patients with metastatic urothelial cancer" with first dosing expected by July, 2023 after ethics and regulatory approval.

Immutep did not disclose the commercial terms of the agreement but said that it, with Merck, would jointly fund the trial, to be conducted by Frankfurt's Institute of Clinical Cancer Research.

Immutep chief executive officer Marc Voigt said "we are very pleased to be deepening our collaboration with Merck KGaA, Darmstadt, Germany and Pfizer through this new study in patients with urothelial cancer, the sixth most common cancer in the US, who are in need of treatment options".

"Insight-005 builds on the encouraging clinical efficacy and safety previously reported from the combination of efiti and avelumab in various solid cancers, including deep and durable responses in patients with low or no [programmed death-ligand 1] expression and in indications that typically do not respond to immune checkpoint therapy," Mr Voigt said.

Immutep was up 1.5 cents or 4.3 percent to 36.5 cents with 1.8 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has recruited the first cohort of patients in its phase Ib/IIa, 'Accent' trial of focal adhesion kinase inhibitor AMP945 for advanced pancreatic cancer.

In August, Amplia said it had dosed the first of 12 patients in the open-label trial, studying the pharmaco-kinetics, safety and efficacy of AMP945 in combination with nab-paclitaxel (Abraxane) and gemcitabine for pancreatic cancer (BD: Aug 2, 2022).

At the time, the company said the first stage of the trial was an ascending dose, single-arm, open-label study to select an optimal dose of AMP945, assessing safety, tolerability, pharmaco-kinetics, pharmaco-dynamics and preliminary efficacy of AMP945 in combination with gemcitabine and nab-paclitaxel, in first-line patients with advanced pancreatic cancer.

Today, Amplia said the cohorts of three patients each were given the same dose of AMP945 in addition to standard chemotherapy and that after one month of treatment, the safety committee would review the data and if accepted, authorize dose escalation in a subsequent cohort.

Amplia managing-director Dr John Lambert said "this month, we have opened four additional Accent clinical trial sites, taking our total number of sites to seven".

"There has been a lot of interest in the Accent clinical trial and we expect that recruitment rates will accelerate as the trial builds further momentum," Dr Lambert said.

"We are delighted to have reached today's recruitment milestone and we will make further announcements as we reach future milestones and dose escalate AMP945," Dr Lambert said.

Amplia was up 0.1 cents or one percent to 9.8 cents.

[INCANNEX HEALTHCARE](#)

Incannex says Luxembourg's Eurofins Scientific will manufacture its Renecann marijuana-derived topical cream for a range of dermatological conditions.

Incannex said Renecann combined cannabidiol and cannabigerol "a non-psychoactive cannabinoid with potent anti-inflammatory properties" used for dermatological conditions caused by disorders of the immune system, including vitiligo, psoriasis and eczema.

The company said a previous version of Renecann was used in a six-week, proof of concept study with an undisclosed number of patients, which found that "patients with vitiligo, psoriasis and atopic dermatitis were observed to experience improvements in symptoms of 10 percent, 33 percent and 22 percent, respectively".

Incannex said it would perform clinical trials to confirm the "safety and therapeutic effect of Renecann in vitiligo, psoriasis, and atopic dermatitis" with the data to be used for future regulatory submissions to the US Food and Drug Administration.

Incannex chief scientific officer Dr Mark Bleackley said the Renecann "adds a new route of cannabinoid delivery to the Incannex portfolio, opening the possibility for direct application of cannabinoid medicines to affected areas in dermatological conditions".

Dr Bleakley said Renecann was the company's first product to use the cannabigerol minor cannabinoid and minor cannabinoids provided the opportunity to explore different activity profiles across a range of new therapeutic areas.

Incannex fell half a cent or 2.1 percent to 23.5 cents with 5.9 million shares traded.

[CRONOS AUSTRALIA](#)

Cronos says the board-opposed resolutions to remove directors Rodney Cocks and Guy Headley were defeated with up-to 88 percent opposition.

In September, Cronos said that Matua Hasyo Charlie Jansen called for the removal of directors, chief executive officer Rodney Cocks and chief commercial officer Guy Headley; chief medical officer (BD: Sep 20, Nov 28, 2022).

Today, the company said the removal of Mr Cocks had 413,048,805 votes (87.60%) in opposition and 58,490,295 votes (12.40%) in favor with Mr Headley's removal opposed by 414,971,083 votes (88.0%) with 56,568,017 votes (12.0%) in favor.

Cronos said all other resolutions passed easily, including the special resolution to change its name to Vitura Health.

According to its most recent filing, Cronos had 554,813,976 shares on offer, meaning the votes in favor of removing Mr Cocks amounted to 10.5 percent of the company, sufficient to requisition extraordinary meetings.

Cronos fell two cents or 3.1 percent to 62 cents.

[PARADIGM BIOPHARMA](#)

Paradigm says it has withdrawn the annual general meeting resolution to approve an employee share plan, resulting in resolutions to issue shares to directors to be withdrawn.

In October, Paradigm said the meeting would vote to issue 1,500,000 loan shares to directors Dr Donna Skerrett, Helen Fisher and Amos Meltzer (BD: Oct 28, 2022).

Today, the company said that "following discussions with shareholders in relation to the company's employee share plan," it would withdraw resolution three from the meeting.

Paradigm said that as the resolutions to issue employee share plan shares to directors related to resolution three, it would also withdraw those resolutions.

Paradigm fell 4.5 cents or 3.1 percent to \$1.40.

RHYTHM BIOSCIENCES

On the day of its annual general meeting, Rhythm withdrew a resolution to re-elect non-executive director Eduardo Vom, who resigned “prior to the meeting”.

Rhythm posted both the announcement of the departure of Mr Vom and the results of the meeting, including the withdrawn resolution, at the same time.

The company said that all other resolutions passed easily, but the constitutional amendment to allow fully virtual meetings saw 4,655,527 votes (7.85%) in opposition, with 54,624,078 votes (92.15%) in favor.

According to its most recent filing, Rhythm had 217,167,589 shares on issue, meaning that the votes against the amendment to the constitution amounted to 2.1 percent of the company, not sufficient to requisition extraordinary meetings.

Rhythm was up one cent or 0.9 percent to \$1.11.

DIMERIX

Dimerix says its annual general meeting faced 20.89 percent dissent against the renewal of its ‘omnibus equity plan’ to issue employee shares, rights and options.

Dimerix said all other resolutions passed easily but the omnibus equity plan resolution saw 21,634,671 votes against (20.89%) with 81,921,263 votes (79.11%) in favor.

According to its most recent filing, Dimerix had a total of 320,873,666 shares on issue, meaning the votes against the equity plan amount to 6.7 percent of the company, sufficient to requisition extraordinary meetings.

Dimerix was up half a cent or 3.1 percent to 16.5 cents.

CYCLOPHARM

Cyclopharm says it has received \$1,640,212 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cyclopharm said the rebate related to research and development expenditure for the year to December 31, 2022.

Cyclopharm fell 6.5 cents or 4.8 percent to \$1.30.

AROVELLA THERAPEUTICS

Arovella says it has received \$1,048,763 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Arovella said the rebate related to expenditure for the year to June 30, 2022.

Arovella was up 0.1 cents or 4.2 percent to 2.5 cents.

PYC THERAPEUTICS

PYC says it has increased its shareholding in subsidiary Vision Pharm from 93.5 percent to 95.2 percent through a \$10 million re-capitalization.

PYC said Vision Pharma owned the VP-001 program, which would be trialed as a therapeutic candidate for patients with retinitis pigmentosa type 11, and that the \$10 million re-capitalization would allow Vision to begin the trials by July 2023, subject to US Food and Drug Administration investigational new drug application approval.

The company said Vision would conduct in-vivo genotoxicity studies of VP-001 prior to its US FDA submission, expected by March 2023.

PYC was up 0.1 cents or 1.35 percent to 7.5 cents.

IMPEDIMED

Impedimed says Richard Valencia has been appointed managing-director, effective from December 1, 2022, starting on \$US450,000 (\$A671,400) a year.

In July, Impedimed said director David Anderson would be interim chief executive officer until a replacement for 10-year executive officer and managing-director Richard Carreon who had resigned July 26, 2022, was found (BD: Jul 26, 2022).

Today, the company said Mr Anderson would support the company on Mr Valencia's appointment continuing his role as a consultant and executive director.

Impedimed said that Mr Valencia had 30 years' experience in the healthcare and technology sectors, most recently as Waveform Diabetes interim chair and chief executive officer, as well as at Qualcomm Inc as an executive and head of Qualcomm Life, and had been a director of several companies.

Impedimed said Mr Valencia held a Bachelor of Science from California State University in Long Beach.

The company said Mr Valencia would have a fixed remuneration of \$US450,000 a year, with up-to 110 percent of that in short term incentives and, subject to shareholder approval, 10,000,000 options and 20,000,000 'performance' rights.

Impedimed fell 0.2 cents or 2.15 percent to 9.1 cents.