



Biotech Daily

Tuesday November 28, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMUGENE UP 10%; NEXT SCIENCE DOWN 8%**
- * **AROA H1 REVENUE UP 8% TO \$28m, PROFIT TO \$6m LOSS**
- * **ACTINOGEN XANAMEM FOR DEPRESSION 50% ENROLLED**
- * **CHINA OKAYS DIMERIX PHASE III DMX-200 FSGS KIDNEY TRIAL**
- * **WEHI SHOWS HOW MUTANT P53 PROTEIN AIDS CANCER**
- * **NOVA EYE US MEDICARE CONTRACTOR DEFERS REBATE CHANGES**
- * **IMUGENE WINS VAXINIA BILE DUCT CANCER FDA FAST TRACK STATUS**
- * **MICROBA, GINKGO SCREEN 182 STRAINS**
- * **AUSTCO COMPLETES TEKNOCORP PURCHASE**
- * **ANTISENSE COMPLETES UNMARKETABLE PARCEL FACILITY**
- * **VITURA 57% REMUNERATION REPORT 1st STRIKE AGM; RESOLUTIONS FAIL**
- * **PHARMAXIS AGM 98% BACK NAME CHANGE TO SYNTARA**
- * **INVEX AGM 16.7% OPPOSE PLACEMENT CAPACITY**
- * **NEUROSCIENTIFIC WITHDRAWS AGM CHAIR PERFORMANCE RIGHTS**
- * **ACTINOGEN RECEIVES \$4.8m FEDERAL R&D TAX INCENTIVE**
- * **PRESCIENT RECEIVES \$2.4m FEDERAL R&D TAX INCENTIVE**
- * **EPSILON 'PAYING OFF' ALPHA \$950k LINE OF CREDIT**
- * **BOD TAKES 'CAPITAL RAISE, FINANCIAL POSITION' HALT TO SUSPENSION**
- * **MERCHANT FUNDS REDUCE, DILUTED TO 7.2% OF BCAL**
- * **JASON PETERSON TAKES 11.7% OF INVEX**
- * **EXOPHARM LOSES DR GREGOR LICHTFUSS, TO LOSE DR IAN DIXON AS CEO**

MARKET REPORT

The Australian stock market was up 0.39 percent on Tuesday November 28, 2023, with the ASX200 up 27.6 points to 7,015.2 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and two were untraded. All three Big Caps rose.

Imugene was the best, up 0.9 cents or 9.9 percent to 10 cents, with 168.4 million shares traded.

Opthea climbed 8.9 percent; Nova Eye was up 7.7 percent; Emvision and Mesoblast were up five percent or more; Cynata and Impedimed improved four percent or more; both 4D Medical and Avita were up 3.95 percent; Clinuvel, Genetic Signatures, Neuren and Telix rose two percent or more; Cochlear, Nanosonics, Paradigm, Resonance and SDI were up one percent or more; with CSL, Cyclopharm, Polynovo, Pro Medicus and Resmed up by less than one percent.

Next Science led the falls, down two cents or eight percent to 23 cents, with 436,296 shares traded. Micro-X lost 7.7 percent; Atomo and Proteomics fell more than four percent; Pharmaxis, Starpharma and Volpara were down more than three percent; Alcidion and Universal Biosensors shed more than two percent; with Antisense and Medical Developments down by more than one percent.

AROA BIOSURGERY

Aroa says revenue for the six months to September 30, 2023 was up 8.1 percent to \$NZ31,186,000 (\$A28,786,683) with last year's \$NZ1,587,000 (\$A1,464,903) profit turned to a net loss after tax of \$NZ6,306,000 (\$A5,820,843).

Aroa said revenue was primarily from sales of its sheep-stomach based Myriad products for soft tissue repair and Symphony for wound closure, with \$NZ685,000 in revenue from project fees.

The company said sales and administration expenses were up due to increased sales team headcount, variable sales compensation and clinical development activities.

Aroa chief executive officer Brian Ward said the company expected revenue to increase by between 30 and 40 percent in the second half of the year and that the revenue uplift would "significantly improve" Aroa's bottom-line.

The company said last years' diluted earnings per share of 0.4 NZ cents was turned to a diluted loss per share of 1.84 NZ cents, net tangible assets per share fell 8.7 percent to 21.0 NZ cents and it had cash and cash equivalents of \$NZ3,955,000 at September 30, 2023 compared to \$NZ11,986,000 at September 30, 2022.

Aroa fell half a cent or 0.7 percent to 71.5 cents.

ACTINOGEN MEDICAL

Actinogen says its 160-patient, phase IIa trial of Xanamem for persistent major depression disorder has enrolled more than 50 percent, or 80 patients.

In 2022, Actinogen said it was planning the phase II, placebo-controlled study of 10mg Xanamem daily, with anti-depressant therapy, to test the effects on both depression and cognition, with results expected in late 2023 or in early 2024 (BD: Jun 14, Dec 8, 2022).

Today, the company said results remained "on track" by July, 2024.

Actinogen was unchanged at 2.3 cents.

DIMERIX

Dimerix says China has approved recruitment for its 286-patient, phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) kidney disease.

Dimerix said the Chinese National Medical Productions Administration center approved its investigational new drug application for the trial.

The company said it expected its part one analysis “on or around” March 15, 2024.

Dimerix said that 144-patients enrolled in countries including mainland China would be incorporated in an “interim analysis” towards accelerated and conditional marketing approval in regions where early access to medicines was possible.

The company said the approval confirmed that “no further manufacturing, non-clinical or clinical [bridging] studies” were required before recruitment of Chinese patients.

In 2022, the company said it had recruited the first of 286 patients in its phase III trial of DMX-200 for FSGS kidney disease (BD: May 31, 2022).

Today, Dimerix chief medical officer Dr David Fuller said the approval was “a milestone”. Dimerix was unchanged at 14 cents with 13.0 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says discovering the traits of the mutant p53 protein are critical for driving cancer growth and will help develop p53 cancers treatment.

WEHI said mutations of the p53 protein were “the biggest driver of cancer development ... found in half of all human cancers around the globe” and the p53 protein was a tumor suppressor that played “a crucial role in preventing the formation of cancerous cells, but when it mutates and becomes defective in cells, the protein can significantly boost a person’s risk of cancer development”.

WEHI said the protein was “a powerful defence mechanism against cancer development by ensuring that cells with compromised DNA either [were] repaired or removed” and mutations could be triggered by environmental factors, including exposure to ultra-violet light radiation, and if the division process went awry, or if they were genetically inherited. WEHI said that its researchers with staff from Italy’s Treto University had shown which function helped mutant p53 fuel tumor growth.

The research study, titled ‘Loss-of-function but not gain-of-function properties of mutant TP53 are critical for the proliferation, survival and metastasis of a broad range of cancer cells’, was published in Cancer Discovery, with an abstract available at:

<https://pubmed.ncbi.nlm.nih.gov/37877779/>.

WEHI’s Prof Gemma Kelly and co-author of the paper said that understanding how the mutations contributed to cancer was “critical to understanding how to treat patients bearing cancers with the dysfunctional proteins”.

“Our study has provided the first evidence to show that it is actually the loss-of-function that impacts cancer growth,” Prof Kelly said.

“We found no evidence of gain-of-function contributing to cancer growth,” Prof Kelly said.

“This is significant because ... there was not much evidence available to properly show whether it is the protein’s loss or gain-of-function that spurs cancer growth,” she said.

“If you look at all cancers of humanity, about 50 percent of them have a mutation in p53 ... [and] specific cancers like those of the pancreas, lung and breast, commonly have defects in these proteins,” Prof Kelly said.

“Our findings have transformed our understanding of these mutations, which help rethink how they can be targeted in the development of new cancer treatments,” Prof Kelly said.

WEHI’s Prof Andreas Strasser, said the findings could prevent hundreds of millions of dollars being wasted on developing ineffective drugs.

NOVA EYE MEDICAL

Nova Eye says one-of-five US Medicare administrative contractors proposing changes to glaucoma surgery reimbursement has deferred the decision until March 23, 2024. Last month, Nova Eye said the Wisconsin Physician Service Insurance Corp proposed to limit or deny coverage for several minimally invasive glaucoma surgery procedures, effective from December 24, 2023; and earlier this month, said the reimbursement changes had been proposed by four more contractors (BD: Oct 31, Nov 14, 2023). Today, the company said the National Government Services (NGS) Medicare administrative contractor, responsible for reimbursement in New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine, Minnesota, Illinois, and Wisconsin, had deferred implementation of the final draft by three months, which was a benefit to the company.

Nova Eye said the deferral by was “a positive outcome for the near-term sales of the company’s Itrack portfolio of canaloplasty devices, which have been performing strongly since the US launch of the generation Itrack Advance in May 2023”.

The company said reimbursement coverage of canaloplasty surgeries by National Government Services beyond March 23, 2024, would depend on whether the proposed local coverage determination was implemented.

Nova Eye said that, to date, there had been no announcements by the other four Medicare administrative contractors concerning deferrals, all of which had December 23, 2023, implementation dates.

Nova Eye was up one cent or 7.7 percent to 14 cents.

IMUGENE

Imugene says the US Food and Drug Administration has granted Vaxinia (CF33-Hnis) fast track status for bile duct cancer, facilitating its development and review.

Imugene said the fast-track designation increased the frequency of meetings with the Food and Drug Administration (FDA), made it eligible for accelerated approval and priority review and regular dialogue with the FDA, or “rolling reviews”, in support of a new drug application or biological licence application.

In March, the company said it had US approval for a phase I, dose-escalation trial of Vaxinia or CF33-human sodium iodine symporter (hNIS) for metastatic or advanced solid tumors in up to 10 patients (BD: Mar 23, 2022).

Imugene was up 0.9 cents or 9.9 percent to 10 cents with 168.4 million shares traded.

MICROBA LIFE SCIENCES

Microba says it has completed screening 182 probiotic strains with its partner Ginkgo Bioworks, with 36 strains progressing to the second stage of functional screening.

Last year, Microba said it had sent its first bio-bank samples to Boston’s Ginkgo Bioworks to develop microbiome-based therapies for autoimmune diseases, with Ginkgo to identify microbiome-based treatments for three autoimmune diseases including lupus, psoriatic arthritis and certain liver diseases (BD: Jun 8, 2022).

Today, the company said it expected to complete the second stage of screening by about June 30, 2024.

Microba fell half a cent or 2.2 percent to 22 cents.

AUSTCO HEALTHCARE

Austco says it has completed the acquisition of Teknocorp for \$1,900,000 upfront in cash and the issuance of 3,888,889 shares at 18.0 cents a share or \$700,000.

In May, Austco said it expected to buy Melbourne's Teknocorp, a reseller of its nurse health call software, for \$1,900,000 upfront in cash, \$700,000 in shares and a \$1,250,000 earn-out (BD: May 29, 2023).

Today, the company said it had entered into a three-year debt facility and would comprise \$2,000,000 bank bill business loan and a \$1,000,000 overdraft facility, which would be used to fund the Teknocorp acquisition and provide working capital.

Austco was unchanged at 19.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it has completed its unmarketable parcel facility for shareholders with less than \$500 worth of shares, with 632 shareholders selling 2,238,910 shares.

Last month, Antisense said it had an unmarketable parcels facility for holders of shares worth less than \$500 at the record date of October 6 (BD: Oct 9, 2023).

Today, the company said it had received interest from institutional investors for the shares and would seek to sell the shares "directly to those investors where possible".

Antisense said the average sale price would be determined once all the shares were sold and expected to complete the payments by December 31, 2023.

Antisense fell 0.1 cents or 1.6 percent to six cents.

VITURA HEALTH

Vitura says investors delivered a 57.1 percent remuneration report first strike, defeated three board resolutions and prevented the election of three board-opposed directors.

Vitura said that 155,978,675 votes (42.91%) supported the remuneration report, with 207,541,551 votes (57.09%) against.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election within 90 days.

The company said that performance rights for managing-director Rodney Cocks passed with 264,111,525 votes (54.67%) in favor, with 219,011,873 votes (45.33%) against, but the rights resolution for director Guy Headley was defeated by 56.05 percent, with the special resolution for the constitutional amendment and ordinary resolution for the equity incentive plan defeated by 31.18 percent and 60.16 percent respectively.

Vitura said that the election of three board-opposed directors were not carried with 57.18 percent to 60.14 percent opposition.

In September, the company said it received a notice from Elizabeth Sarah Jansen as trustee for the Stanford Investment Trust, under section 249N of the Corporations Act 2001, to appoint Mr Tanner, Nathan Hight and Mr Jansen as directors (BD: Oct 6, 2023).

Today, Vitura said the issue of shares to Regal Nominees under its Doctors on Demand acquisition passed with 57.17 percent of votes in favor.

According to its most recent notice, Vitura had 575,873,788 shares on issue, meaning that the 219,011,873 votes against Mr Cocks' performance rights amounted to 38.0 percent of the company, sufficient to requisition extraordinary general meetings.

Vitura was up half a cent or 1.6 percent to 31 cents with 1.7 million shares traded.

PHARMAXIS

Pharmaxis says its annual general meeting voted 98.32 percent in favor of its name change to Syntara.

Last month, Pharmaxis said the meeting would vote to change its name to 'Syntara', and that the change was due to its current name's association with the branding of the mannitol products to be transferred to Arna Pharma, so it was an "opportunity to rebrand the company" (BD: Oct 27, 2023).

Today, the company said all other resolutions were passed overwhelmingly with more than 96.4 percent of votes.

A Pharmaxis spokesperson told Biotech Daily the change would be effective next week. Pharmaxis fell 0.1 cents or 3.2 percent to three cents.

INVEX THERAPEUTICS

Invex says its annual general meeting passed all resolutions but with up-to 16.69 percent of the vote against the approval of its 10 percent placement capacity.

Invex said the placement capacity was opposed by 3,758,015 votes (16.69%), with 18,756,273 votes (83.31%) in favor.

The company said the re-insertion of proportional takeover provisions in the constitution faced 16.25 percent dissent, with the remuneration report and re-election of director Dr Thomas Duthy passing with more than 98.57 percent in favor.

According to its most recent notice, Invex had 75,153,848 shares on issue, meaning that the 3,758,015 votes against the placement capacity amounted to 5.0004 percent of the company, sufficient to requisition extraordinary general meetings.

Invex was unchanged at 23 cents.

NEUROSCIENTIFIC BIORESEARCH

Neuroscientific says it will withdraw resolutions five and six to issue up-to 7,200,000 rights through an incentive plan and 2,000,000 rights to chair Paul Rennie.

In October, Neuroscientific said Mr Rennie's performance rights were for his role as acting interim chief executive officer, on-top of his \$160,000 yearly salary, \$16,800 superannuation and \$440,706 in share-based payments (BD: Oct 24, 2023).

Neuroscientific said the on-line meeting was postponed to November 30, 2023 at 12pm (AWST).

Neuroscientific was untraded at 7.1 cents.

ACTINOGEN MEDICAL

Actinogen says it has received \$4,792,865 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Actinogen said the rebate related to research and development expenditure for the year to June 30, 2023.

PRESCIENT THERAPEUTICS

Prescient says it has received \$2,368,123 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

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

Prescient was unchanged at 7.8 cents with two million shares traded.

[EPSILON HEALTHCARE](#)

Epsilon says its \$950,000 line of credit from the Sydney-based Alpha Securities for working capital was extended and ended November 1, 2023.

Epsilon said the line of credit was executed on December 30, 2022 at 15 percent interest per year, had a \$70,000 facility fee, with a default interest rate of an additional five percent, and it was being repaid in instalments.

Epsilon was untraded at 2.8 cents.

[BOD SCIENCE](#)

Bod has requested a suspension following Friday's trading halt "regarding the outcome of the capital raise and overall financial position of the company" (BD: Nov 24, 2023).

Earlier this month, Bod said it would raise \$2.05 million in a placement at 3.0 cents a share and pay directors shares, in lieu of cash, subject to approval (BD: Nov 8, 2023).

Bod said it expected trading to resume on December 1, 2023, or on an earlier announcement.

Bod was in a suspension and last traded at 2.4 cents.

[BCAL DIAGNOSTICS](#)

Perth's Merchant Funds Management Pty Ltd says it has decreased its shareholding and been diluted in Bcal from 19,597,348 shares (8.28%) to 18,191,663 shares (7.23%).

Merchant said between September 1 and November 27, 2023 it sold 1,405,685 shares for \$144,500, or an average of 10.3 cents a share, and was diluted in a share issue.

In August, Bcal said it had raised \$2.4 million at 10 cents a share; and later said its share plan raised \$615,500 of a hoped-for \$500,000 (BD: Aug 28, Sep 18, 2023).

Bcal was unchanged at 10 cents.

[INVEX THERAPEUTICS](#)

The Perth-based Jason Peterson says he has increased his shareholding in Invex from 7,705,675 shares (10.2532%) to 8,807,500 shares (11.719%).

Mr Peterson said through Celtic Capital Pty Ltd and Sunset Capital Management he bought 1,101,825 shares on "various" dates for \$255,054 or 23.15 cents a share.

[EXOPHARM](#)

Exopharm says head of business services Dr Gregor Lichtfuss has resigned and it expects chief executive officer Dr Ian Dixon to step-down to director in six-months.

Exopharm said the changes were part of its management changes and cost-reductions, with Dr Dixon and Dr Lichtfuss working with directors Mark Davies and Clarke Barlow to reduce operating costs, sell surplus equipment and finalize recent patent activities.

The company said it was working to bring a potential transaction to shareholders.

Last month, Exopharm requested a voluntary suspension in relation to a "material acquisition" to last until its shareholders approve the acquisition (BD: Oct 3, 2023).

Exopharm last traded at 1.1 cents.