



Biotech Daily

Wednesday September 18, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: IMUGENE UP 6%; ACTINOGEN DOWN 11%**
- * **EBR \$50m PLACEMENT, RIGHTS OFFER**
- * **ACTINOGEN \$8.1m PLACEMENT; \$3m SHARE PLAN**
- * **ONCOSIL: 'DEVICE SURVIVAL BEATS CHEMO ALONE'**
- * **INVION INV043 'SAFE FOR PROSTATE CANCER, INITIAL EFFICACY'**
- * **BIOXYNE TELLS ASX: 'MONTU \$28m MARIJUANA GUMMIES CUSTOMER'**
- * **TELIX APPOINTS CARDINAL US TLX250-CDX DISTRIBUTOR**
- * **IMUGENE: US FDA CF33-HNIS BILE CANCER ORPHAN DRUG STATUS**
- * **PARADIGM FDA ADVICE 'CLEAR PATHWAY FOR PHASE III PPS OA TRIAL**
- * **CSL CEO DR PAUL MCKENZIE \$11m PERFORMANCE RIGHTS AGM**
- * **MERCHANT FUNDS REDUCES TO 10.5% OF INOVIQ**
- * **BIOTECH CAPITAL TAKES 6.5% OF INOVIQ FOR MERCHANT**
- * **BIOTECH CAPITAL TAKES 10% OF AROVELLA FOR MERCHANT**
- * **MERCHANT FUNDS REDUCES TO 5.75% OF AROVELLA**
- * **BIOTECH CAPITAL TAKES 5% OF NEUROTECH FOR MERCHANT**
- * **MERCHANT FUNDS BELOW 5% OF NEUROTECH**
- * **RADIOPHARM EXECUTIVE CHAIR PAUL HOPPER TAKES 6.9%**
- * **ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 88.8%**
- * **IAN WISENBERG TO REPLACE LBT DIRECTOR BRIAN O'DWYER**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Wednesday September 18, 2024, with the ASX200 up 1.2 points to 8,142.1 points. Twelve of the Biotech Daily Top 40 companies were up, 20 fell, six traded unchanged and two were untraded.

Imugene was the best, up 0.3 cents or 6.25 percent to 5.1 cents, with 139.4 million shares traded. Compumedics climbed 5.2 percent; Opthea improved 4.8 percent; Aroa, Atomo, Avita and Curvebeam rose more than two percent; Clarity, Immutep, Nanosonics, Pro Medicus and Starpharma were up more than one percent; with Cochlear up 0.8 percent.

Actinogen led the falls, down 0.4 cents or 11.4 percent to 3.1 cents, with 25.1 million shares traded. Nova Eye lost 7.7 percent; Dimerix and Syntara shed more than six percent; Paradigm and Proteomics were down more than five percent; Alcidion and Percheron fell more than four percent; Orthocell, Resmed, Resonance and Telix were down three percent or more; 4D Medical, Emvision, Impedimed, Neuren and Prescient shed two percent or more; Clinuvel, Medadvisor and Polynovo were down more than one percent; with CSL and Mesoblast down by less than one percent.

EBR SYSTEMS

EBR says it expects to raise \$50 million in a \$37.4 million placement and a \$12.6 million one-for-20 non-renounceable pro-rata rights offer at 82.0 cents a share.

EBR said the offer was fully-underwritten and the share price was a 14.0 percent discount to the five-day volume weighted average price.

The company said the rights offer would comprise an accelerated institutional offer and a retail offer, with the proceeds to support commercialization, manufacturing scale-up, research and development, general administration and working capital.

EBR said the retail offer had a record date of September 20, would open on September 24 and close on October 9, 2024, with Bell Potter Securities, Morgans Corporate and E&P Capital Pty Ltd joint lead managers and bookrunners, Wilsons Corporate a joint lead manager and Bell Potter the underwriter.

Separately, the company requested a trading halt for the capital raising, until September 20, 2024 or on an earlier announcement.

EBR last traded at 97.5 cents.

ACTINOGEN MEDICAL

Actinogen says it raised \$8.1 million through an institutional placement, at 3.0 cents a share and will offer a \$3 million share purchase plan.

Actinogen said the offer price was an 18.2 percent discount to the five-day volume weighted average price, with three options attached to every four shares subscribed, exercisable at 5.0 cents each by September 30, 2027.

The company said chief executive officer Steven Gourlay had subscribed for \$1 million, with Actinogen directors subscribing for \$130,000, pending shareholder approval.

Actinogen said the funds would be used to accelerate enrolment of 220 patients for its Xanamia phase IIb/III trial for Alzheimer's patients.

The company said the share plan had a record date of September 17, would open on September 24 and close on October 8, 2024, with Bell Potter Securities and Moelis Australia Advisory Pty Ltd joint lead managers for the placement.

Actinogen fell 0.4 cents or 11.4 percent to 3.1 cents with 25.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says that a 104-patient analysis of its brachytherapy device with chemotherapy for pancreatic cancer shows better survival than chemotherapy alone.

Oncosil said the retrospective, investigator-initiated propensity-score analysis of 50 patients receiving its radiotherapy with chemotherapy for locally advanced pancreatic cancer indicated a relative mean survival advantage of 3.7 months, compared to 54 pancreatic cancer patients treated with chemotherapy alone.

The company said there was also a 3.7 months relative mean survival benefit for local progression-free survival and a 2.5 months relative mean survival benefit for distant progression-free survival.

Oncosil said that 31.4 percent Oncosil patients were “down-staged” compared to 13.6 percent for chemotherapy alone, and 28.6 percent underwent surgical resection compared to 12.1 percent receiving chemotherapy alone.

The company said the analysis was the first testing Oncosil with chemotherapy compared to a matched cohort of patients with unresectable locally advanced pancreatic cancer.

Oncosil fell 0.05 cents or 3.6 percent to 1.35 cents with 1.8 million shares traded.

INVION

Invion says its photo-sensitizer INV043 was ‘safe and demonstrated promising efficacy signals’ in a 41-patient, sublingually-administered, phase II trial for prostate cancer.

In 2021, Invion said it selected INV043 for its photo-dynamic light therapy for cancer and work with Melbourne’s Hudson Institute of Medical Research Institute on immune deficient mouse models of T-cell lymphoma, triple negative breast and pancreatic cancers had provided early indications that INV-043 had superior anti-cancer activity and cancer-targeting characteristics than previous compounds (BD: Apr 27, 2021).

Later that year, the company said INV043 Photosoft light therapy killed triple negative breast cancer tumors in mice, with a “protective immunity” suggested, and in 2022 said its third proof-of-concept study with Hudson Institute of Medical Research showed that INV043 reduced tumor size 65 percent, in mice (BD: Oct 28, 2021; May 30, 2022).

Today, Invion said that seven of 16 patients, or 44 percent, in its second dosing cohort showed a “negative result” three months after treatment, while four of 10 evaluable patients in the same cohort showed stable disease, three showed partial regression, and one showed completed regression and no detectable lesions, with two patients showing disease progression.

The company said that of the 31-patients treated in two cohorts with photodynamic therapy, three had biopsy-proven primary prostate cancer and 28 had PSMA-PET or magnetic resonance imaging-diagnosed primary prostate cancer.

Invion said the first cohort of 25 patients were enrolled during the Covid-19 pandemic lockdowns in Melbourne, with 10 dropping out prior to the study so that, for the remaining 15 patients, researchers decided to focus on widely used endpoints for assessment of efficacy and safety only.

The company said a second cohort of 16 patients, aged between 50 to 80 years, were treated after the pandemic, and had a doubled dose of 0.9ml.

Invion said INV043 appeared to be safe and well-tolerated when administered sublingually, or under-the-tongue, in six cycles of treatment, and that there were no serious adverse events, and the only adverse events reported were mild and included fever, fatigue, headache and soreness.

Invion was up 0.1 cents or 50 percent to 0.3 cents with 57.1 million shares traded.

BIOXYNE

Bioxyne has told the ASX that the unnamed customer buying \$28 million of marijuana gummies is the Melbourne and Berlin-based Montu Group Pty Ltd.

In August, Bioxyne said that its subsidiary Breathe Life Sciences had an agreement with an unnamed “alternative medicine clinic” to supply up-to \$28 million worth of marijuana gummies (BD: Aug 21, 2024).

Last week, the ASX said that it had suspended Bioxyne for failing to provide specific information related to its ‘two-year manufacture and supply agreement’ of marijuana gummies (BD: Sep 13, 2024).

Today, the ASX said that Section 4.15 of Guidance Note 8 on Continuous Disclosure: Listing Rules 3.1 – 3.1B, states: “depending on the circumstances, ASX would generally expect an announcement about the signing of a market sensitive contract with a customer to include information about the name of the customer”.

In its ‘Aware’ query, the ASX said that Bioxyne’s share price increased 240 percent from 0.5 cents prior to the announcement to 1.7 cents after the announcement and asked the company a series of “aware” questions, including the determination of financial information.

Bioxyne said in a ‘Clarifying Statement’ that “the customer provided the company with a non-binding forward forecast for a five-month period to December 2024... [and Bioxyne] calculated the revenue estimate by extrapolating the five-month forecast to a twenty-four-month period”.

Bioxyne said that “since signing the agreement in July, the company received a deposit of more than \$900,000 when the initial order was placed”.

Bioxyne said that the information in the \$28 million marijuana gummies announcement was expected to have a material effect on its share price and answered questions including the name of the customer, the term of the contract and material terms.

The company said that the supply agreement was signed and executed on July 25, 2024 and announced on August 21, 2024, saying that “a number of conditions precedent needed to be met before the supply agreement could proceed” including that Bioxyne needed to be “in a position to meet the forecast demand by the dates required by the customer” with machinery needing to be shipped from China.

Bioxyne said the first orders were received on August 6, the customer requested a visual audit of the production and packing operation, which took place in the week beginning August 12, and a meeting had to be held to agree the terms of any announcement, which took place on August 20, 2024.

The company said it had orders for 1.8 million units a month or \$1.22 million a month with agreed pricing for 24 months.

Bioxyne said it was in compliance with the Listing Rules, and in particular Listing Rule 3.1. In April, the Australian Therapeutic Goods Administration said it had begun proceedings in the Federal Court of Australia “against Montu Group Pty Ltd, its subsidiary Alternaleaf Pty Ltd and their common director Christopher Strauch, for alleged unlawful advertising of medicinal cannabis on websites and social media”.

Biotech Daily contacted the Federal Health Department and TGA media office for further details on that matter but had no response at the time of publication.

Separately, the ASX said that the suspension of trading of Bioxyne securities would be “lifted immediately following the release by [Bioxyne] of a clarification announcement to supplement the information required in relation to [the] announcement on [Bioxyne] Manufactures First Pharmaceuticals Cannabis Gummies’ on August 21, 2024.

Bioxyne fell 0.2 cents or 15.4 percent to 1.1 cents.

TELEX PHARMACEUTICALS

Telix says Cardinal Health will supply finished unit doses of Zircaix, or TLX250-CDx, for kidney cancer imaging in the US, subject to regulatory approval.

In an email announcement not released on the ASX, Telix said the Dublin, Ohio-based Cardinal would supply Zircaix in a “wide range” of US locations.

Telix head of precision medicine Kevin Richardson said the company was “pleased to build on our existing relationship with Cardinal Health to maximize patient access to this breakthrough product for non-invasive kidney cancer diagnosis”.

“Through their extensive nuclear pharmacy network, which enables broad geographic reach and flexible scheduling, Cardinal Health has been central to the commercial success of Illuccix [prostate cancer] imaging and we look forward to adding Zircaix to their US roster,” Mr Richardson said.

Telix did not disclose the commercial terms.

Telix fell 65 cents or 3.5 percent to \$17.85 with 760,786 shares traded.

IMUGENE

Imugene says the US Food and Drug Administration has granted oncolytic virotherapy CF33-hNIS, or Vaxinia, orphan drug designation for cholangio-carcinoma.

Imugene said cholangio-carcinoma was “a rare and aggressive form of bile tract cancer”.

The company said orphan drug status promoted development of drugs for rare diseases that affect fewer than 200,000 people in the US and provided incentives, including tax credits, potential grant funding, waiver of certain fees, and seven years of exclusivity.

Imugene said its application was supported by pre-clinical and clinical data from its ongoing phase I metastatic advanced solid tumors (Mast) trial.

Imugene managing-director Leslie Chong said orphan drug designation was “a major milestone for us”.

“It reflects the potential of Vaxinia to address the urgent need for new treatments for cholangio-carcinoma, a disease with limited therapeutic options,” Ms Chong said.

Imugene was up 0.3 cents or 6.25 percent to 5.1 cents with 139.4 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the US Food and Drug Administration has provided it a “clear pathway” for a phase III trial of its polysulfate sodium treatment for osteo-arthritis.

Paradigm said the FDA confirmed its phase II data supported the safety and tolerability of the twice weekly 2.0mg/Kg dose and clinical monitoring for adrenal effects would continue. In 2022, the company said it had dosed the first of 930 patients in its randomized, double-blind, placebo-controlled phase III trial of zilosul, or injectable pentosan polysulfate sodium (PPS) for knee osteo-arthritis (BD: Jan 16, 2022).

Today, Paradigm said the FDA had provided detailed guidance for its 2.0mg/kg PPS twice-weekly dosing regimen.

The company said the FDA also provided feedback on amendments to the monitoring and mitigation plan and statistical guidance, with these changes to the monitoring and mitigation “supported by clinical and non-clinical data” from its clinical development, and intended to implement these changes and submit the updated protocol under the investigational new drug application currently in place with the FDA.

Paradigm said it expected a 30-day review period before proceeding with enrolment for the trial, with preparations underway at sites in the US and Australia.

Paradigm fell 1.5 cents or 5.8 percent to 24.5 cents with 4.4 million shares traded.

[CSL](#)

CSL says shareholders will vote to grant chief executive officer Dr Paul McKenzie performance shares valued at \$US7,967,237 (\$A11,775,239) at its annual meeting.

CSL said investors would vote to grant Dr McKenzie 38,065 shares, equivalent to 425 percent of his \$US1,874,644 annual salary, pending financial hurdles.

Last year, CSL said 24.95 percent of investor votes opposed Dr McKenzie's performance shares and it narrowly avoided a remuneration report first strike (BD: Oct 11, 2023).

Today, CSL said shareholders would vote to approve a 12.5 percent increase in the non-executive directors' fee pool from \$A4,000,000 to \$4,500,000, re-elect directors Dr Brian McNamee, Prof Andrew Cuthbertson, Alison Watkins, Samantha Lewis and Elaine Sorg, adopt the remuneration report, re-insert proportional takeover approval provisions and approve potential leaving entitlements for directors of CSL subsidiary entities.

The meeting will be held online and at the RACV City Club, 501 Bourke St, Melbourne on October 29, 2024 at 10am (AEDT).

CSL fell 60 cents or 0.2 percent to \$295.40 with 518,174 shares traded.

[INOVIQ](#)

The Perth-based Merchant Funds Management says it has reduced its substantial shareholding in Inoviq from 13,082,057 (14.22%) to 11,666,332 shares (10.46%).

Merchant Funds said between November 2022 and September 2024 it bought and sold shares, with the largest sale in June 2023 of 270,000 shares for \$140,400 or 52.0 cents a share, and in September 2024 it assigned 3,139,333 shares to Biotech Capital.

Inoviq fell 0.5 cents or one percent to 49.5 cents.

[INOVIQ](#)

Biotech Capital Management says that as "an investment manager for the Merchant Biotech Fund" it has acquired 7,176,284 shares or 6.435 percent of Inoviq.

The Melbourne-based Biotech Capital said it was assigned Merchant Biotech's investment management agreement effective from September 13, 2024, with the previous manager being Merchant Funds Management Pty Ltd.

[AROVELLA THERAPEUTICS](#)

Biotech Capital Management says that as "an investment manager for the Merchant Biotech Fund" it has acquired 108,836,842 shares or 10.348 percent of Arovella.

The Melbourne-based Biotech Capital said it was assigned Merchant Biotech's investment management agreement effective September 13, 2024, with the previous manager being Merchant Funds Management Pty Ltd.

Arovella fell 0.5 cents or 3.1 percent to 15.5 cents with three million shares traded.

[AROVELLA THERAPEUTICS](#)

The Perth-based Merchant Funds Management says it has reduced its substantial shareholding in Arovella from 86,210,282 (11.36%) to 60,496,667 shares (5.75%).

Merchant Funds said that between May 2023 and September 2024 it bought and sold shares, with the single largest sale in September 2023 of 5,255,000 shares for \$327,466 or 6.2 cents a share, and that in September 2024 it assigned 59,369,000 shares to Biotech Capital Management.

NEUROTECH INTERNATIONAL

Biotech Capital Management says that as “an investment manager for the Merchant Biotech Fund” it has acquired 54,987,203 shares or 5.4 percent of Neurotech. Melbourne’s Biotech Capital said it was assigned Merchant Fund’s investment management effective September 13, 2024. Neurotech fell 0.1 cents or 1.45 percent to 6.8 cents.

NEUROTECH INTERNATIONAL

The Perth-based Merchant Funds Management says it has reduced its substantial shareholding in Neurotech to below the five percent substantial threshold. Merchant Funds said that between March 2024 and September 2024 it bought and sold shares, with the single largest sale in August of 1,810,374 shares for \$130,063 or 7.18 cents a share, and in September it assigned 26,850,255 shares to Biotech Capital.

RADIOPHARM THERANOSTICS

Radiopharm executive chair Paul Hopper says he has become substantial in the company with 149,221,428 shares or 6.9 percent. Mr Hopper said the shares were held with Deboarh Coleman and Kilinwata Investments Pty Ltd and on September 13, 2024 he bought 55,000,000 shares at 4.0 cents a share. Radiopharm was up half a cent or 16.7 percent to 3.5 cents with 7.9 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding from 104,859,604 shares (87.67%) to 106,199,153 shares (88.79%). In May, Allegra said Allegra Innovations, a related party of director Dr Hartnell, would pay 0.4 cents a share in a cash bid, valuing it at \$478,444 (BD: May 27, 2024). Today, Dr Hartnell said he acquired the shares through “acceptances of takeover offers”. Allegra was in a suspension and last traded at 2.9 cents.

LBT INNOVATIONS

LBT says Ian Wisenberg has been appointed a non-executive director from October 1, 2024, replacing Brian O’Dwyer who will retire at the November annual general meeting. LBT said the Park City, Utah-based Mr Wisenberg had worked with life science and pharmaceutical companies, advised on growth strategies and mergers and acquisitions, including the acquisition of Bridgewest Groups from Pfizer Australia, and was the chief executive officer of Biocina Pty Ltd.

According to his LinkedIn page, Mr Wisenberg held a Bachelor of Commerce from South Africa’s University of Cape Town.

The company said Mr O’Dwyer would resign at the annual general meeting due to “increasing executive responsibilities” in his role at Iqvia.

LBT fell 0.1 cents or 7.1 percent to 1.3 cents with 1.7 million shares traded.