



# Biotech Daily

Friday May 3, 2024

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.55 percent on Friday May 3, 2024, with the ASX200 up 42.0 points to 7,629.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, nine were down, eight traded unchanged and two were untraded.

Alcidion was the best, up 1.3 cents or 23.2 percent to 6.9 cents, with 11.35 million shares traded. Clarity climbed 11.6 percent; Dimerix was up 7.5 percent; Curvebeam improved 5.7 percent; Compumedics, Medical Developments and Polynovo were up four percent or more; Atomo, Immutep, Next Science, Resonance, Telix and Universal Biosensors improved three percent or more; Cynata, Neuren and Orthocell rose more than two percent; Cochlear, Mesoblast, Pro Medicus and SDI were up more than one percent; with CSL, Opthea and Volpara up by less than one percent.

Actinogen led the falls, down 0.6 cents or 15.8 percent to 3.2 cents, with 9.4 million shares traded. Paradigm lost 10.9 percent; Imugene and Nanosonics were both down 3.5 percent; Avita, Emvision and Micro-X shed more than two percent; Nova Eye and Proteomics were down more than one percent; with Resmed down 0.15 percent.

## [DR BOREHAM'S CRUCIBLE: INVION](#)

**By Tim BOREHAM**

**ASX Code:** IVX

**Share price:** 0.5 cents; **Shares on issue:** 6,424,532,206; **Market cap:** \$32.1 million

**Chief executive officer (and executive chair):** Thian Chew

**Board:** Mr Chew (chair), Alan Yamashita, Rob Merriel, Alistair Bennallack

**Financials (December half 2023):** Revenue (effectively reimbursement from RMW Cho Group) \$2.2 million (up 15%), loss of \$714,000 (previous deficit \$831,000); At March 31, 2024: receipts nil, cash burn \$554,000, cash \$1.4 million, 2.5 quarters of funding

**Identifiable shareholders:** RMW Cho Group/Michael (Honsue) Cho 14.3%, Polar Ventures (Thian Chew) 8.5%, Shengli Wang and associates 6.4%

Invion chief Thian Chew says investors often ask him why the cancer and anti-infectives house has been largely silent about the company's progress.

"Over the last couple of years, we have been doing the essential - but, from the market's view, very uninteresting – pre-clinical work such as safety and toxicology studies," Mr Chew says. "We could have made more announcements for announcements' sake, but what's the point if it's not ... relevant to investors?"

Indeed! Other biotechs could take a leaf out of Invion's minimalist book and refrain from trivial disclosures. They know who they are.

In recent months, however, Invion's news flow has intensified as the company firms up plans to conduct human cancer trials, including for non-melanoma skin cancer and ano-genital cancers (which don't exactly inspire Pink Ribbon Day campaigns).

At the heart of Invion's quest is Photosoft, a novel photodynamic therapy (PDT).

Before PDT was injected into the company in late 2017, Invion had many assets and a history more tortuous than a medieval dungeon

"It's an old company with a new story," Mr Chew says.

### **Shining a new light on an old technique**

By combining oxygen and light, photodynamic therapies are known to kill malignant cells and shut down tumors, with evidence they also stimulate the immune system.

PDT sounds like a new thang, but Danish physiologist Prof Niels Finsen got on to the idea in 1903 and snagged a Nobel Prize for his work.

Since then, at least 500 PDT trials have been carried out, with the Russians proving especially interested. But advancement was hampered by “off target” issues including toxicity and lack of solubility.

Eventually, the US Food and Drug Administration approved a PDT treatment for oesophageal cancer, in 1995. In 2017, Israel’s Steba Biotech won European approval for its PDT prostate cancer treatment, Tookad.

A ‘next-generation’ PDT, Photosoft was developed over a decade ago by the RMW Cho Group, the vehicle of Melbourne businessman Michael Cho.

Photosoft is chlorophyll (plant) based and only accumulates in the cancer cells.

By adding conjugates to enhance selectivity, safety and potency, Invion aims to overcome the shortcomings of the old treatments.

## **About Invion**

Invion started out as Cbio, which listed on the ASX in 2010 with an ultimately unsuccessful rheumatoid arthritis (lupus) program.

The company changed its name to Invion in August 2012 on the back of a smoking cessation aid, but a lack of partner interest stubbed that one out. In 2013, director Dr James Campbell brought in Dr Greg Collier, former head of leukaemia drug developer Chemgenex, as CEO.

In a back-door listing deal in late 2017, Invion entered an exclusive distribution and licence agreement to develop Photosoft.

In 2019, the Hudson Institute said it would partner with Invion to research and develop PDTs, while in the same year Melbourne’s Peter MacCallum Cancer Centre announced a collaboration to research ano-genital cancers.

Dr Collier retired in October 2019 and was replaced by chief operating officer Craig Newton in April 2018 (Mr Newton left in October 2020).

A former executive director of the investment bank Goldman Sachs, Mr Chew met Mr Cho by chance and the rest - as they say - is history.

## **Expanding boundaries**

Under the initial 2017 deal, Cho Group agreed to fund all research and Invion was granted exclusive dibs on Australia and New Zealand.

In 2021-'22, the arrangement was tweaked with Invion becoming licensee for Asia Pacific (excluding China) for cancer and inflammatory diseases.

Invion also has rights to infectious diseases in the US, Canada and Hong Kong.

The \$US3 billion South Korean oncology market is of particular interest, given its rising cancer incidence.

In return for contributing \$900,000 to RMW Cho Group for prior development costs, Invion expects half of all upfront fees, milestone payments and royalties from sub-licencing the technology in the 'good' half of the peninsula.

Across the board, Invion will finance 75 percent of future clinical work, with Cho Group bearing the other 25 percent. With non-clinical costs, the burden flips the other way.

Invion's pre-clinical work to date has centred on its Peter MacCallum Cancer Centre and Hudson Institute collaborations.

This included mice study results for triple-negative breast cancer showing no disease recurrence - and some protective immunity.

This was followed up with in-vitro studies to treat atherosclerosis and infectious diseases, including Zika virus, dengue fever, fungi and Sars-Cov-2.

### **In the clinic (skin cancer)**

Invion's first human trial is an open-label study in non-melanoma skin cancer (NMSC), the most prevalent cancer - although not the deadliest. The skin cancer capital of the world, Australia, is an easy patient recruiting ground.

The company expects to enrol between 18 and 174 subjects - probably from one site in Queensland - who will be treated with topical ointment.

There's a twist to the tale, in that there's already an approved PDT NMSC therapy: Galderma's Metvix.

The primary standard of care - surgery or cryosurgery - also works well.

So what problem is Invion seeking to resolve? The answer lies in increased comfort (less pain) and aesthetics (less scarring).

"Metvix has been around for a long time," Mr Chew says. "It doesn't work as well as surgery but has better cosmetic results. Because it's painful, 10 percent of patients can't finish treatment."

Mr Chew says the trial will be open-label and adaptive in terms of dose optimization and the like.

Biotech greybeards will recall that the ASX-listed Peplin was sold to Denmark's Leo Pharma for \$US287 million (\$440 million) in 2009.

Peplin's lead product was a CSIRO-developed, topically-applied liquid skin cancer treatment derived from the milky sap of a common weed.

## **In the clinic (ano-genital cancers)**

The trouble with penile and anal cancers is that sufferers are too embarrassed to see their doctor until it's too late. Former Charlie's Angel Farrah Fawcett became a poster child for the rare disease after succumbing to it in 2007, aged only 62.

In March 2024, the company reported what Peter MacCallum investigator Prof Rob Ramsay dubbed "exceptional" and "consistent" anal squamous cell carcinoma mice trial results. Across the 40 diseased mice, 80 percent of tumors treated with a combined INV043/immune checkpoint inhibitor (ICI) therapy showed tumor control, with 70 percent showing no tumor volume. The more typical response rate for immune checkpoint inhibitor alone is 12 percent.

Furthermore, 10 percent of tumors increased in volume but the culprit was pus rather than cancer.

Two earlier Hudson Institute combination trials for triple negative breast cancer showed a 65 percent improvement in tumor volume versus standalone ICI therapy.

## **Look out for the patent cliff**

Immune checkpoint inhibitors are blockbuster cancer drugs but many are reaching the end of their patent life, some in four short years. For example, Merck derived \$US25 billion of revenue from Keytruda last year - 42 percent of its total sales.

Combining an ICI with a PDT raises the prospect of delaying a nasty fall down a patent cliff, with even a one-month extension adding meaningful value.

Meanwhile Mr Chew notes the versatility of INV043, in that it can be applied topically, intravenously, sublingually or via injection straight to the tumor.

## **Infectious diseases and all the rest**

Invion's interest in infectious diseases centres on microbial resistance - rated by the World Health Organisation as one of the top threats to humanity. Depending on the FDA's requirements, the company's first trial will be periodontal (tooth implant recipients).

About a quarter to half of implant recipients get an infection such as peri-implantitis or mucositis, sometimes so seriously the procedure has to be redone.

The company is also eyeing a program for HPV, the most prevalent sexually transmitted disease in the world despite the good work of Gardasil vaccine co-creator Prof Ian Frazer.

In March 2024, South Korea's Dr I&B Co said it would conduct Photosoft human safety and efficacy tests, including proof-of-concept human trials for HPV. Invion retains all rights to the tech.

Given DR I&B funds the trials, there's little downside for Invion.

## **Asian cancers pose a medical mystery**

Invion is also interested in lung cancer, especially given the rising incidence of the disease among Asian women who have never smoked. No one knows why. One theory being inhalation of vaporised cooking oil.

Also, 86 percent of the incidence of the back-of-the-nose nasopharyngeal cancer is in Asia, particularly in southern China. Hence the disease is known as 'Cantonese cancer'.

Gastro-oesophageal cancers are highly prevalent in Korea and Japan, possibly because of high consumption of cured meats and pickled vegetables.

These mysteries are being probed by Stanford Medicine's Center for Asian Health Research and Education, which Mr Chew recently joined as an advisory board member.

## **Finances and performance**

With \$1.9 million in the bank as of the end of December, Invion needs to use its funds prudently and seek non-dilutive sources for more of the readyies.

"We are very open to collaborations and licencing," Mr Chew says.

He says there's more shareholder value in advancing multiple trials across more than one cancer, rather than pursuing a single narrow indication all the way to regulatory approval. Meanwhile Cho Group's Invion holding has been reduced from its initial 70 percent, to around 14 percent as a result of share distributions to prior collaborators. Via his Polar Ventures, Mr Chew holds 8.5 percent, while insiders and prior Cho Group collaborators account for about half of the register.

Over the last 12 months Invion shares have traded thinly between 0.4 cents and 0.8 cents. Post the 2017 back-door listing, the shares peaked at 4.0 cents in April 2018.

## **Dr Boreham's diagnosis:**

With the two human cancer trials pending and more in the pipeline, Invion finally looks to be gaining traction. But with a \$38 million market cap, the stock is valued more like a university spin-off than a clinical-stage company.

Previously, Invion in effect was a contract research organisation for Cho Group with rights only to the local and NZ markets. With its turf now covering Asia Pacific and North America, Invion is closer to controlling its own destiny.

Mr Chew admits Invion's corporate structure needs to be further streamlined and liquidity improved, so that investors can focus on the clinical development. "It is complicated, but it can be solved," Mr Chew says.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. It is complicated, but it can be solved.***

## ACTINOGEN MEDICAL

Actinogen says it hopes to raise \$8.9 million at 2.5 cents a share in a \$5.0 million placement and a \$3.9 million, non-underwritten, one-for-15 entitlement offer.

Actinogen said the price was a 21 percent discount to the 30-day volume-weighted average and Biotech Daily calculates it was a 34.2 percent discount to last closing price. The company said the placement had “binding commitments”, with investors to receive one option for every two shares bought, exercisable at 5.0 cents each within three years. Actinogen said the funds would be used to progress its trial of Xanamem in patients with mild-to-moderate Alzheimer’s disease beyond the interim results in the first 100 patients, expected next year, as well as for general working capital.

The company said managing-director Dr Steven Gourlay would take up \$120,000 of the entitlement offer and directors would take up their full entitlements, investing \$67,834.

Actinogen said the entitlement offer had a record date of May 10, would open on May 15 and close on May 29, 2024.

Actinogen said Forrest Capital and McFarlane Cameron were the lead managers.

Actinogen fell 0.6 cents or 15.8 percent to 3.2 cents with 9.4 million shares traded.

## TELIX PHARMACEUTICALS

Telix says it has acquired Qsam Biosciences for \$US33.1 million (\$A50.8 million) in cash and scrip, and up-to \$US90 million (\$A138.0 million) in milestones.

In February, Telix said it would acquire the Texas-based Qsam Biosciences and its Samarium-153-DOTMP “bone-seeking” targeted radio-pharmaceutical for primary and metastatic bone cancer (BD: Feb 8, 2024).

Today, the company said the up-front consideration would be paid through the issue of scrip at \$11.61 a share and in cash, with the final settlement amounts to be determined shortly after closing the agreement.

Telix managing-director Dr Chris Behrenbruch said Qsam’s technology added “a near-term therapeutic asset to the Telix pipeline, which we believe will enable a ‘third-generation’ palliation approach through radiopharmaceuticals”.

“This is needed more than ever, not only because of the change in treatment landscape in prostate and other cancers, but also because of the escalating cost of opioid compliance, particularly in the US,” Dr Behrenbruch said.

“[Samarium-153-DOTMP] is a validated therapeutic candidate, which further enhances and differentiates Telix’s innovation position to provide a continuum of care to patients from diagnosis and staging, through systemic treatment of metastatic disease, to palliative care,” Dr Behrenbruch said.

Telix was up 44 cents or 3.0 percent to \$15.24 with 1.4 million shares traded.

## VOLPARA HEALTH TECHNOLOGIES

Volpara says it will delist from the ASX on May 22, 2024, following New Zealand High Court approval of its acquisition by Seoul, South Korea’s Lunit Inc for \$1.15 a share.

Last year, Volpara said Lunit hoped to acquire it for \$1.15 a share, valuing the company at \$295.7 million, and last month said 96.92 percent of its scheme implementation meeting approved the agreement (BD: Dec 14, 2023, Apr 12, 2024).

Today, the company said the last day of trading was today and that the scheme of arrangement had a record date of May 13, its shares would be acquired on May 21 and that it would delist from the ASX on May 22, 2024.

Volpara was up half a cent or 0.4 percent to \$1.145 with 2.6 million shares traded.

### ALCIDION

Alcidion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 28.85 percent from 5.2 cents at the close of trade on May 1, 2024 to 6.7 cents today, but did not note a "significant increase" in the trading volume.

Alcidion was up 1.3 cents or 23.2 percent to 6.9 cents with 11.3 million shares traded.

### NEUROTECH INTERNATIONAL

Neurotech says it has requested a trading halt "pending the release of the full results of the company's phase I/II Rett syndrome clinical trial".

Trading will resume on May 7, 2024, or on an earlier announcement

Neurotech last traded at 9.1 cents a share.

### MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol says investors will vote on a 30-to-one consolidation and to issue 41,500,161 shares, \$12,195,220 in shares and 6,533,495 options to management and 16 companies. At Melodiol's last traded share price of 0.2 cents, the \$12,195,220 worth of shares to be issued was equal to 6,097,610,000 shares.

Earlier this year, Melodiol faced 33.65 percent opposition to a 20-to-one consolidation which reduced the number of shares on issue from 4,728,824,027 shares to 236,441,201 shares (BD: Jan 23, 2024).

The company said the annual general meeting would vote to issue 3,333,333 shares to managing-director William Lay and \$C25,000 (\$A28,000) worth of shares to Impactive managing-director Brett Ayers, as consulting fees (BD: Oct 25, 2021).

Melodiol said the meeting would vote to issue the remaining shares and options to Everblu Capital, formerly chaired by former Creso chair Adam Blumenthal, Noraton Nominees, Azalea Corporate, Advisir, Six Degrees Relations, VBT, Nandil, Corporate Mining, Isidor 14, Steinepreis Paganin, Harmonica, SBC Global Investment Fund, Oakley Capital, 10 Bay Street Capital Investments and LTC Long Short Fund.

The company said if the 30-to-one consolidation was passed, post-consolidation trading would begin on June 4, 2024.

Melodiol said the meeting would vote to adopt the remuneration report, re-elect directors Bruce Linton and Micheline Mackay, appoint the auditor, approve the issue of placement shares to unrelated parties and shares to unrelated lenders and approve its 10 percent placement capacity.

The meeting will be held online on May 31, 2024 at 9.30am (AWST).

Melodiol fell 0.2 cents or 50 percent to 0.2 cents with 83.8 million shares traded.

### AUDEARA

Audeara chair David Trimboli says he has increased his substantial shareholding in the company from 15,940,805 shares (11.12%) to 17,591,210 shares (12.12%).

The Perth-based Mr Trimboli said that with Seefeld Investments Pty Ltd he bought 110,575 shares on September 8, 2023 for \$4,666, or 4.2 cents a share, and was issued 1,539,830 shares in lieu of director's fees on December 7, 2023 and May 2, 2024 for \$72,458, or 4.7 cents a share.

Audeara fell 0.6 cents or 12.8 percent to 4.1 cents.



## EXOPHARM

Former Exopharm managing-director Dr Ian Dixon says his 11,303,451 post-consolidation shares have been diluted below the five percent substantial level.

Dr Dixon said he was diluted through the issue of shares.

Last month, Exopharm said investors approved all resolutions on its merger with the Kelowna, British Columbia-based Tryp Therapeutics for its intra-venous psilocybin, the name-change and 2.5-to-one stock consolidation (BD: Apr 11, 2024).

Exopharm was in a suspension and last traded at a post-consolidation 1.1 cents.

## IMAGION BIOSYSTEMS

Imagion says directors Dianne Angus and Jovanka Naumoska have resigned, effective from today.

Imagion did not disclose whether it would appoint replacement directors.

Imagion chair Bob Proulx said the company thanked Ms Angus and Ms Naumoska “for their year of service and passion ... and wish them well for their future endeavors”.

Imagion was in a suspension and last traded at 7.3 cents.

## IMMURON

Immuron says non-executive director Stephen Anastasiou has resigned, effective from today.

Immuron said Mr Anastasiou had been a director since 2013 and had “provided valued contributions and experienced counsel to the company” during its commercialization of Travelan in North America and its dual listing on the Nasdaq.

Immuron chair Paul Brennan said Mr Anastasiou had “made significant contributions ... with his strength in marketing and clinical applications for our immunotherapy product”.

“We wish Mr Anastasiou all the best in his new ventures,” Mr Brennan said.

Immuron was up 0.1 cents or one percent to 10 cents.