Biotech Daily

Friday May 16, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYNATA UP 11%; ACTINOGEN DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: NEUROSCIENTIFIC BIOPHARMACEUTICALS**

*** RECCE RIGHTS RAISE $3.4m; $7.4m SHORTFALL; TOTAL SO FAR $8.4m**

*** ANATARA: MORE GARP DATA 'POSITIVE FOR IBS PAIN RELIEF'**

*** CYNATA 'CYP-001 NOT IMPEDED BY FDA RYONCIL EXCLUSIVITY'**

*** IMUGENE 34-TO-1 CONSOLIDATION**

*** TRYPTAMINE RELEASES 228m ESCROW OPTIONS**

*** CHIMERIC REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EBOS DILUTED TO 8.7% OF MEDADVISOR**

*** REGAL BELOW 5% OF CARDIEX**

*** JDB SERVICES, RAC, JD BRICE BELOW 5% OF AUDEARA**

MARKET REPORT

The Australian stock market was up 0.56 percent on Friday May 16, 2025, with the ASX200 up 46.2 points to 8,343.7 points. Fifteen of the Biotech Daily Top 40 companies were up, 17 fell, six traded unchanged and two were untraded. All four Big Caps were up.

Cynata was the best, up two cents or 11.1 percent to 20 cents, with 96,342 shares traded. Syntara climbed 7.25 percent; Dimerix was up 5.3 percent; Nova Eye improved 4.2 percent; Telix was up 3.4 percent; Alcidion and Proteomics rose more than two percent; Botanix, CSL, EBR, Immutep, Medical Developments, Nanosonics, Neuren, Pro Medicus and Resmed were up one percent or more; with Cochlear, Genetic Signatures and Polynovo up by less than one percent.

Actinogen led the falls, down 0.2 cents or 8.3 percent to 2.2 cents, with 14.6 million shares traded. Amplia and Optiscan lost more than seven percent; Medadvisor was down 5.4 percent; Avita and Imugene fell more than four percent; Aroa, Compumedics, Impedimed and Mesoblast were down three percent or more; Curvebeam shed 2.2 percent; Clinuvel, Emvision, Micro-X and Starpharma were down more than one percent; with Clarity and Orthocell down by less than one percent.

DR BOREHAM'S CRUCIBLE: NEUROSCIENTIFIC BIOPHARMACEUTICALS

By TIM BOREHAM

ASX Code: NSB

Share price: 4.8 cents

Shares on issue: 144,604,870 *****

***** Increases to 333,176,299 shares post-Isopogen WA acquisition and placement

Market cap: $6.9 million

Chief executive officer: Dr Anton Uvarov (founder)

Board: Chris Ntoumenopoulos (chair), Dr Tony Keating, Clarke Barlow, Dr Uvarov, Dr Linda Friedland

Financials (March quarter 2025): revenue nil, cash burn $182,000, cash of $4.3 million (ahead of $3.5 million capital raising).

Major identifiable pre-acquisition shareholders: McRae Technology Pty Ltd/McRae Investment (Clough family office) 30-40%, Lehav Pty Ltd (VHL Family Account) 2%, ECU Holdings 1.77%

Investors now have three ASX-listed stem cell therapy companies to choose from – and we can thank sector big daddy Mesoblast for inspiring the third.

Hitherto a developer of peptide-based drugs for neuroscientific conditions, Neuroscientific Biopharmaceuticals is in the process of acquiring Stemsmart, the stem cell portfolio of the public unlisted Western Australia company Isopogen WA Ltd.

In December, Mesoblast won US Food and Drug Administration (FDA) approval for Ryoncil, its stem cell treatment for paediatric graft versus host disease (GvHD).

Neuroscientific describes this approval as "momentous", as it was the first FDA assent for a therapy derived from donor bone marrow.

Both the Ryoncil and Stemsmart therapies are based on mesenchymal stromal cells (MSCs).

(The other company is Cynata, also working with mesenchymal stem cells but induced pluripotent ones called IPSCs.)

"Stem cell therapy is a cornerstone of modern medicine," the company says. "Stem cells have the unique ability to develop into different cell types in the body and are often hailed as the body's master cells."

Neuroscientific's initial focus is on the common auto-immune condition Crohn's disease.

That makes sense, given Isopogen underwent a phase II trial for that condition that deemed the therapy to be "potent, efficacious and safe."

About Neuroscientific

To date, the Perth-based Neuroscientific has been developing peptide-based drugs for several neuro-degenerative conditions with high unmet medical demand.

Neuroscientific was founded by former equities analyst Dr Anton Uvarov, on the back of the Emtinb peptide. This asset was developed by the University of Copenhagen and then acquired by the University of Tasmania.

The company listed on July 25, 2018, having raised $6 million at 20 cents apiece.

At the time, Emtinb was most advanced for Alzheimer's disease, but recently the board decided to focus on glaucoma.

Before founding the company, Dr Uvarov had a two-year stint a biotech analyst at Citigroup.

He has also been on the board of several ASX listed biotechnology companies and non-biotechs, including Blinklab, Actinogen, Sun Biomedical (now Dimerix), Acuvax and Imugene.

The company's portfolio includes Emtinb (initially targeting glaucoma) and Emtinac, Emtinan, and Emtinbn "which have demonstrated similar therapeutic potential as Emtinb".

As part of the Stemsmart purchase, current Isopogen directors Robert McKenzie and Paul Fry will join the board.

The force behind Stemsmart, Dr Marian Sturm joins as chief scientific adviser.

An inaugural member of the local Therapeutical Goods Administration (TGA) advisory committee on biologics - among other things - Dr Sturm is a leading expert in cell therapies in Australia (particularly in stem cell therapies).

Peace deal: now for Ukraine and Gaza

Dr Uvarov says he had known about Dr Sturm and her work for some time, given they both hail from Perth medical circles.

In 2021, Perth's East Metropolitan Health Service (EMHS) launched a legal action over ownership of the stem cell intellectual property on which Isopogen was founded.

Dr Sturm was a long-time employee of EMHS's Royal Perth Hospital.

The technology was developed in 2007 and registered in Dr Sturm's and Isopogen's names.

Neuroscientific swooped after Dr Sturm and EMHS last year reached a "mutually acceptable" confidential settlement.

A joint statement said the peace deal provided the basis for an "ongoing relationship" - so let's call it friends with benefits.

Investors had been excited about Isopogen's prospects as a "mini Mesoblast" - and an ASX listing seemed on the cards.

But the prolonged and increasingly complex legal spat put paid to that.

"As soon as it was resolved we jumped on the opportunity," Dr Uvarov says.

About Stemsmart

Neuroscientific describes the Stemsmart cells as having "potent anti-inflammatory and immune-modulatory properties".

This creates a "multifaceted and complex interaction" with the body's immune system, dampening inflammation, moderating immune responses and encouraging tissue repair.

"It's quite an advanced program," Dr Uvarov says. "Overall, more than 200 patients have gone through this therapy, so we know it's quite safe and active."

Derived from adult human donor marrow, mesenchymal stem cells (MSCs) are grown in a culture and then revved up with the patented cell manufacturing process.

To date, patients have received Stemsmart on compassionate grounds for a variety of serious and life-threatening clinical conditions, with "multiple strong positive clinical responses".

Crohn's disease

Isopogen undertook a phase II trial of 18 patients with refractory Crohn's disease.

The results were "promising", with most patients experiencing clinical improvement and even clinical remission.

The company's attention has turned to a small, 12-person, phase I trial for fistulating Crohn's disease under a TGA special access program.

A severe complication of Crohn's disease, fistulas are abnormal tracts connecting the intestine to another organ or to the external surface of the body.

Fistulating Crohn's disease is challenging to treat and sustained healing with standard therapies has been limited.

"Nothing disease modifying exists now, so it's a massive market," Dr Uvarov says.

"If we do a phase I trial, the next step would be to move to a phase II/III study as a potential step towards a regulatory trial."

The study will aim for a closure of more than 50 percent of the fistula openings, or a decrease in fistula discharge of more than 50 percent in at least four patients.

Addressable markets

Over the next 24 months, the company envisages expanding its stem cells trial from Crohn's disease, to other inflammatory and immune-based disorders including lung disorders and acute kidney transplant rejection.

Dr Uvarov says Isopogen has 140 doses frozen and ready for use in further clinical studies.

Several patients have received the therapy on compassionate grounds, including both children and adult with graft versus host disease (GvHD).

The company cites a $US13.8 billion addressable market for Crohn's disease and a $US640 million opportunity for GvHD by 2026.

There's a projected $US7.2 billion market for organ transplant immune-suppressants by 2030 - the majority for renal – and a forecast $US33 billion market for lung disorders by 2023.

Legacy program lives on

And let's not forget about Neuroscientific's pre-clinical legacy program.

Emtinb targets Alzheimer's disease and advanced glaucoma.

In 2023, Neuroscientific decided development should focus on the latter as a therapy administered locally, via intravitreal injection.

Dr Uvarov says the company moved to stem cells because the legacy program was not moving as fast as investors would have liked. And an Alzheimer's program would have required a much bigger trial.

In June last year, the company met with the US Food and Drug Administration for a pre-investigational drug approval powwow, with the agency guiding on the pre-clinical studies required to progress Emtinb to a first-in-human trial.

Based on this counsel, the company plans a pharmaco-kinetics rabbit study, by which Emtinb is intravitreally administered.

In parallel, the company plans a 13-week study of “ocular tolerance, systemic toxicity and pharmacokinetic [effects] following repeated intravitreal administration in pigmented rabbits”.

Given there’s shortage of animals for medical research as suppliers withdraw from the market, it’s a case of when the company can obtain the specially bred bunnies.

“It’s harder to do animal studies because of regulatory pressure,” Dr Uvarov says.

“Regulators want to move from pre-clinical animal studies to cell-based research using animal organoids.”

Organoids are three-dimensional structures that mimic the architecture and function of human organs and tissues.

Finances and performance

Neuroscientific must obtain the separate assent from all Isopogen holders, although Dr Sturm is by far the biggest holder.

The company has snared 51.4 percent of Isopogen holders and is confident of the remaining minority holders coming on board.

Under the scrip deal, Isopogen holders receive 85,714,286 shares, deemed to be worth 3.5 cents.

At today’s values the deal is worth $44 million.

Isopogen holders also receive 57,142,857 performance shares convertible to ordinary shares, subject to the aforementioned milestones.

These must be achieved within three years of a shareholder meeting to approve the performance shares, scheduled for mid-June.

All the issued shares will be escrowed for 12 months.

Currently underway, the $3.5 million capital raising is by way of a placement of 100 million shares, at 3.5 cents a share.

Post-raising, the company will have cash of $7.5 million.

Of the funds raised, just over $2 million is expected to be used for Stemsmart-related stuff.

A further $835,000 is earmarked for the Emtinb program.

Over the last 12 months Neuroscientific shares have ranged between 3.3 cents (early January this year) and 5.5 cents (early May 2024).

The stock peaked at 50 cents in mid-September 2021.

The tightly held register is dominated by the Clough family office, of Clough Engineering fame. Clients of Westar Capital account for much of the remainder.

Dr Boreham's diagnosis:

Dr Uvarov says Isopogen's stem cells could be "even more potent" than Mesoblast's cells, although they work more by way of immune modulation rather than regeneration.

"Our cells … have more growth factors they excrete when you culture them," he says.

He says the FDA's approval of Mesoblast's Ryoncil "paves the way for renewed enthusiasm [about] and global investment in clinical research of MSC therapies".

It's not just the company that's hyper-enthused: the International Society for Cell and Gene Therapy dubs the Ryoncil approval as "a pivotal moment in the history of medicine shaping the future of therapeutics".

Dr Uvarov adds that after years of being untrendy, stem cells again were the hot topic at JP Morgan's global biotech gabfest in January.

"We are at the beginning of stem cells 2.0," he says.

Given Mesoblast is worth around $2.3 billion and Neuroscientific is valued at not much more than its cash backing, Neuroscientific will be walking in the shadow of a giant.

"When Mesoblast was at a similar stage they had a market cap of several hundred million dollars," Dr Uvarov says.

How soon the company emerges from this penumbra depends on the pace of its trials and - ultimately - its first port of call of initial TGA approval.

"It's complex and tricky so we are taking it slow," Dr Uvarov says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He, too, walks in the shadow of giants and is taking it slow.

RECCE PHARMACEUTICALS

Recce says it has raised $3,436,449 at 28 cents a share of a hoped-for $10,820,208 in a one-for-six, entitlement offer, leaving a $7,383,759 shortfall.
Last month, Recce said it raised $5.0 million at 28.0 cents a share in a placement to an unnamed “Australian-based private investor”, with a one-for-six, pro-rata, non-underwritten rights offer for up-to $10.8 million to follow (BD: Apr 10, 2025).
Today, the company said the funds raised would be used for its Indonesia phase III diabetic foot infection trial and support its phase III trial in acute bacterial skin and skin structure infections in Australia.
Recce said its directors participated in the entitlement offer.
The company said it had the right to place the shortfall within three months.
Recce fell half a cent or 1.7 percent to 29 cents.

ANATARA LIFESCIENCES

Anatara says further analysis of its 78-participant, phase II trial of Garp for irritable bowel syndrome had positive trends for relief of pain and abdominal distension.
Last month, Anatara said its 78-volunteer, phase II trial of gastro-intestinal reprogramming, or ‘Garp’, for irritable bowel syndrome (IBS) showed “the primary endpoint for efficacy … was not met” with no safety concerns (BD: Apr 17, 2025).
At that time, the company said the trial showed a “consistent and sustained improvement” in the irritable bowel syndrome symptom scoring system (IBS-SSS), with a reduction of more than 40 percent, which was not statistically significant when compared to placebo.
Anatara said Garp showed statistically significant improvement in the secondary endpoints of a reduction in anxiety scores and hospital anxiety depression scale scores at eight weeks of treatment ($p = 0.034$ and $p = 0.025$, respectively).
Today, the company said it conducted an internal audit of the study including analyses of the intent-to-treat group, which “confirmed pleasing trends in symptomatic relief of levels experienced in both pain and abdominal distension”.
Anatara said that when the irritable bowel syndrome symptom scoring system (IBS-SSS) was broken down into the five individual scoring sections there was “an apparent trend of pain and distension relief with the more subjective descriptive categories not showing a clear pattern of improvement … [and] despite significant improvements in pain and bowel distention, participants expressed no difference in satisfaction of bowel function or the impact on their life”.
Anatara said patient responses to the IBS-SSS questions ‘how dissatisfied are you with your bowel functioning the past 10 days?’ and ‘how much did abdominal pain or discomfort or altered bowel functioning affect or interfere with your life in general in the past 10 days?’ appeared “to confound the result presumably because the underlying disease is still present with a level of symptomatology”.
The company said the study found no “apparent difference in treatment response” between irritable bowel syndrome diarrhoea-only and mixed-symptom patients.
Anatara said gender “did not appear to alter response” and that trial site performance and efficacy in treatment groups appeared consistent for the duration of the trial.
The company said it was continuing its anti-obesity pre-clinical studies, which were expected to take about six months to complete.
Anatara executive chair Dr David Brookes said the company was “very encouraged by the results of our internal review of the data when looking at subgroups and through the various scoring systems”.
Anatara was unchanged at 0.6 cents with 17.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says Mesoblast's Ryoncil receiving orphan-drug exclusivity would "not impede the potential approval" of its CYP-001 Cymerus mesenchymal stem cells.
Yesterday, Mesoblast said it had an exclusive, seven-year orphan drug approval from the US Food and Drug Administration for Ryoncil for acute graft versus host disease in children following FDA approval last year (BD: Dec 19, 2024; May 15, 2025).
Today, Cynata said its CYP-001 did not contain 'the same drug' as Ryoncil, which consisted of a certain type of bone marrow-derived mesenchymal stromal cells.
The company said it was currently not aware of any other mesenchymal stem cell-based product that contained 'the same drug' as its CYP-001.
Cynata said the active agent in CYP-001 were cells derived from induced pluripotent stem cells using its Cymerus technology, which facilitated scalable production of consistent quality mesenchymal stem cells from a single donor source.
The company said that the indication it was "currently pursuing for CYP-001, newly diagnosed [acute graft versus host disease] in adults, is not the same as the indication that the recently granted [Ryoncil] orphan-drug exclusivity relates to, steroid-refractory [acute graft versus host disease] in paediatric patients".
Cynata was up two cents or 11.1 percent to 20 cents.

IMUGENE

Imugene says it will seek shareholder approval for a 34-to-one share consolidation at an upcoming extraordinary general meeting, expected to be held in June 2025.
Imugene said it had about 7,467,020,803 shares on issue, and if the consolidation was approved it would have about 219,618,259 shares on issue.
The company said all options would be consolidated at the same rate as shares, with the consolidation expected to increase the market price per share "to reflect the reduced number of shares on issue".
Biotech Daily calculates that the share price would increase from today's 2.2 cents a share to 74.8 cents a share.
Imugene fell 0.1 cents or 4.35 percent to 2.2 cents with 34.4 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it released 227,786,158 options from escrow on May 1, 2025, with 49,873,318 shares and 204,251,170 options remaining in escrow.
Tryptamine said the largest group of options released from escrow were 191,735,780 options, exercisable at 2.7 cents each by May 29, 2027, with others ranging in exercise price from 3.38 cents to 21.25 cents each.
According to its most recent notice, the company had 1,226,548,588 shares on issue, on the ASX, not including the currently shares in escrow.
Tryptamine fell 0.2 cents or 5.3 percent to 3.6 cents with 2.45 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric has requested a trading halt "pending an announcement in relation to a capital raising".
Trading will resume on May 20, 2025, or on an earlier announcement.
Chimeric last traded at 0.8 cents.

MEDADVISOR

Melbourne's Ebos Group says its substantial 53,986,463 share-holding in Medadvisor has been diluted from 9.81 percent to 8.65 percent.
Yesterday, Medadvisor said it raised $2,668,000 in a share plan at 10 cents a share, taking the total with its recent $5 million placement to $7.7 million (BD: May 15, 2025).
Medadvisor fell half a cent or 5.4 percent to 8.7 cents with 3.9 million shares traded.

CARDIEX

Sydney's Regal Funds Management Pty Ltd says it has ceased its substantial shareholding in Cardiex.
Regal said it bought and sold shares between January 15 and May 13, 2025, with the single largest sale 2,764,349 shares on January 24 for $359,365, or 13 cents a share.
Cardiex was up 0.2 cents or 3.9 percent to 5.3 cents.

AUDEARA

Brisbane's JDB Services Pty Ltd and RAC & JD Brice Invest say they have been diluted below the five percent substantial shareholder threshold in Audeara.
JDB and RAC said they were diluted in a placement on February 12, 2025 and sold shares between February 5 and May 15, 2025, but did not disclose the number of shares sold nor the consideration as required under the Corporations Act (2001).
Last year, Audeara said it had commitments to raise $1.35 million at four cents a share, with one attaching option for every three shares issued (BD: Dec 5, 2024).
Audeara fell 0.3 cents or 9.4 percent to 2.9 cents.