Biotech Daily

Friday June 21, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 12.5%; DIMERIX DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: NEUROTECH INTERNATIONAL**

*** VALE DR JOHN CHIPLIN**

*** BOTANIX $70m PLACEMENT**

*** PHARMAUST TO RAISE $10m, $2m SHARE PLAN**

*** WOKE STARTS PHASE IIb WP001 PSILOCYBIN DEPRESSION TRIAL**

*** IMRICOR 2 PARIS MR ATRIAL FLUTTER ABLATIONS**

*** INVEX $1.2m UK R&D TAX REBATE**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 46%**

*** INOVIQ CHAIR DAVID WILLIAMS DILUTED BELOW 5%**

*** GREGORY PLUMMER TRANSFERS 7% OF USCOM FROM JETAN TO NEJA**

*** JASON CARROLL TAKES 19% OF ISLAND**

*** AUDEARA CHAIR DAVID TRIMBOLI TAKES 15%**

MARKET REPORT

The Australian stock market was up 0.34 percent on Friday June 21, 2024, with the ASX200 up 26.6 points to 7,796.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 15 were down and four traded unchanged. All three Big Caps were up.

Yesterday's worst, Cynata, was today's best, up three cents or 12.5 percent to 27 cents, with 458,308 shares traded. Alcidion was up 10.6 percent; Compumedics climbed 9.4 percent; Immutep, Paradigm and SDI improved six percent or more; Amplia was up 4.9 percent; Cochlear and Universal Biosensors were up more than three percent; Avita, Clinuvel and Pro Medicus rose more than two percent; Medical Developments, Percheron, Prescient, Proteomics, Resonance, Starpharma and Telix were up more than one percent; with CSL, Emvision, Nanosonics, Neuren and Resmed up by less than one percent.

Yesterday's best, Dimerix, led the falls, down six cents or 9.8 percent to 55 cents, with 5.6 million shares traded. Impedimed shed 7.8 percent; Atomo lost 6.9 percent; Clarity and Next Science fell more than five percent; Mesoblast and Syntara were down more than three percent; 4D Medical, Curvebeam, Medadvisor and Nova Eye shed more than two percent; Cyclopharm, Opthea and Polynovo were down one percent or more; with Genetic Signatures down by 0.7 percent.

DR BOREHAM'S CRUCIBLE: NEUROTECH INTERNATIONAL

By TIM BOREHAM

ASX code: NTI

Share price: 6.7 cents

Market cap: $68.2 million

Shares on issue: 1,017,388,587

Executive director: Dr Thomas Duthy

Board: Mark Davies (chair), Dr Duthy, Gerald Quigley, Max Johnston

Financials (March quarter 2024): receipts nil, cash outflows $1.74 million, cash balance $4.236 million*****, quarters of available funding 2.4

***** Ahead of a placement that raised $10 million

Identifiable major shareholders: Merchant Funds 7.12%

Is Neurotech the next Neuren Pharmaceuticals, or has the boat sailed in terms of treating children with a suite of rare neurological disorders?

For those living under a rock – or perhaps an internet blind spot – Neuren was last year's superhero stock after gaining US Food and Drug Administration (FDA) approval for its Rett syndrome treatment, Daybue (previously trofinetide).

Firming its status as the 'next most likely', in early May, Neurotech announced highly encouraging phase results for a small study to treat the quixotic disorder, which causes behavioral developmental difficulties in girls.

The results pertained to the company's cannabinoid-based candidate, NTI-164, which has also produced good clinical results for childhood autism and the rare neurological disorder Pandas-Pans.

Neurotech executive director Dr Tom Duthy says the results vindicated the company's September 2022 strategy shift, to focus on paediatric neurological disorders for which NTI-164 has been shown to have an anti-neuroinflammatory effect.

"We have been scouring for paediatric indications where there is a correlation between persistent and progressive neuro-inflammation in children," Dr Duthy says.

"We now have a bona fide clinical development pipeline."

A brief history of Neurotech

Neurotech was incorporated in 2016 to house the acquired Malta-based AAT Research, which developed a home-based device called Mente Autism to relax kids' minds.

AAT Research was founded by neuroscientist Dr Adrian Attard Trevisan.

Neurotech then listed on November 3, 2016, having raised $7 million at 20 cents a pop.

A Neurotech director and the company's chief scientific officer, Dr Trevisan ceased to be a company employee in April 2016 and resigned as a director in June 2018.

In March 2019, the "disappointed" company confirmed a report in the Times of Malta that Dr Trevisan did not hold a Doctorate of Philosophy in Neuroscience from University College London, as claimed.

His role as an adviser was terminated. Dr Trevisan sold his major holding of 19 million shares in June 2019.

In January 2020, the local Therapeutic Goods Administration (TGA) cancelled Mente Autism registration, citing a lack of clinical evidence to "substantiate compliance with the regulations".

In July 2020, the company turned to pot - so to speak - having acquired the rights to a unique cannabis strain from Dolce Cann Global Pty Ltd.

NTI-164 is a proprietary drug formulation derived from a cannabis strain with low levels of the psychoactive component tetra-hydro-cannabinoid (THC).

To cut a long story short, trials in autism ensued, while a Pandas/Pans study also bought home the bamboo (see below).

Rett syndrome appeared on the company's radar in mid-2023.

Dr Duthy joined as a director and adviser in August 2022.

Dr Duthy has a decades-long involvement in the sector, including as investor relations adviser to Nova Eye, head of corporate development and investor relations at Sirtex Medical and as a director of the ASX-listed Invex Therapeutics.

Rett on trial

Rett syndrome is a rare genetic neurological and developmental disorder that affects the way the brain develops in girls and young women.

Rett symptoms include delayed development milestones, lack of motor skills, seizures, intellectual disabilities, behavioral problems and sleep disturbance.

Conducted locally, an open-label, phase I/II Rett trial enrolled 14 girls aged 8.8 years, on average.

The study compared the endpoints against a baseline score at 12 weeks, with the dose increased in the first week to the maximum tolerance.

The girls showed no serious adverse effects, with some vomiting and no weight loss - although one of them broke out in hives.

The kids were measured by two standard Rett tests, the Clinical Global Impression-Improvement (CGI-I) score and the Rett Syndrome Behavior Questionnaire RSBQ score.

On the CGI measure, the subjects at 12 weeks had improved an average 10 percent from a baseline score.

The trial covered nine “exploratory anchors” but the company focused on the four that rated best: communication skills, mental alertness, social interactions and anxiety levels.

With these, the improvement was 23 percent from baseline at 12 weeks. One patient had “very much’ improved behavior, four were much improved, eight were minimally improved and one had no change.

“In essence, 93 percent of patients improved on the CGI-I score,” Dr Duthy says.

Dr Duthy says typically registrational Rett trials focus on two to three anchors and it would have been an “own goal” for the company to focus on weaker ones such as seizures and sleep patterns.

RSBQ is completed by the care giver who - let’s face it - is best place to discern any improvement.

Used as a secondary endpoint, RSBQ scoring showed an average improvement was minus 13.4 points on the baseline mean of 44.6 points - a 30 percent betterment.

Measurements included mood, facial expressions, body rocking and fear/anxiety.

The trials were overseen by lead investigator, Westmead Children’s Hospital’s Prof Carolyn Ellaway.

Compare the pair

Dr Duthy says: “I’m unashamedly a fan of Neuren and the work they have done to develop their asset.”

That said, Neurotech is not afraid to highlight a few flattering differences between the NTI-164 and Daybue results.

Neuren's registration trial, dubbed Lavender, showed an improvement of 4.9 points on the RSBQ score compared with baseline, equating to an 11 percent improvement versus Neurotech's 30 percent.

(Unlike Neurotech, Lavender had a placebo arm, which showed a four percent improvement).

Crucially, NTI-164's safety profile was superior to Daybue, which has had a high discontinuance rate because of side effects.

"It's clearly an apples-and-oranges comparison, but from a safety perspective [NTI-164] is incredibly clean," Dr Duthy says.

He adds that it's positive for NTI-164's prospects that Daybue is the standard-of-care for Rett syndrome in the US, even with that safety profile.

"They [Neuren and Acadia] have broken the soil for us and there is nothing wrong in being a fast follower.

They set the endpoints which the FDA will accept and how the agency thinks about safety."

Tackling autism

In April this year, the company announced final results from its 54-patient phase II/III autism trial, which showed a statistically significant improvement at eight weeks compared with placebo.

The enrollees were classed as either level two (requiring substantial support) or level three (very substantial support).

The children were enrolled at the Monash Medical Centre's paediatric neurology unit, overseen by principal investigator Prof Michael Fahey.

The trial kicked off in December 2022.

After eight weeks' treatment, children in the NTI-164 group were reclassified from markedly or severely ill at baseline, to mild-to-moderately ill. This was measured on the CGI-S scale (severity of illness).

"Currently there are no FDA or TGA-approved treatments that show clinically significant improvements in one or more of autism's three core symptom domains: communication, impaired social interaction and restricted behaviors," Prof Fahey says.

The trial followed a phase I/II, non-placebo-controlled effort showing efficacy up to 52 weeks and safety beyond 90 weeks. The patients have now crossed the two-year milestone without any adverse events.

As rare as … pandas

Largely untreatable, paediatric auto-immune neuropsychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuropsychiatric syndrome (Pans) affect about one in 11,000 children in the US and 300 to 500 kids here.

The children go to bed perfectly normal but wake up with uncontrollable tic movements in their hands and legs and become severely obsessive compulsive, with heightened anxiety and depression.

This disorder manifests from streptococcus, or other unknown pathogens which cause an auto-immune response resulting in brain inflammation.

This month, the company said its 15-patient phase I/II trial reached its primary endpoint of a 30 percent reduction in anxiety and depression at 12 weeks, with follow-up results at 52 weeks showing a “highly significant and clinically meaningful” 45 percent improvement.

“It’s a rainbow of colors as to what can happen,” Dr Duthy says. “But we have shown NTI-164 blunts that total misalignment of the inflammatory processes.”

Australia first

The company is channeling the Prime Minister’s ‘Made in Australia’ mantra with an ‘act local, think global’ strategy of approaching the TGA first.

The local autism market is especially attractive given the National Disability Insurance Scheme, which covers 235,000 kids at a cost of $7 billion a year.

As for Rett syndrome, Daybue is not approved here and at a cost of $US1,000 a day per patient it probably would be too expensive to be approved under the Pharmaceutical Benefits Scheme.

“We are taking a bit of time to look at our regulatory strategy and what we can achieve in Australia in terms of smart clinical design for all three of our indications,” Dr Duthy says.

Accelerated approval is possible under the TGA’s provisional registration route, by which the agency will approve a drug for sale but require more safety data later on.

Finances and performance

After the positive autism results, Neurotech raised $10 million in a placement, at 10 cents apiece (a 4.6 percent discount to the prevailing price).

The company now has proforma cash now of around $13.6 million.

“We are well funded to prepare the work for what looks like the next trial, in Pandas-Pans, Rett syndrome and autism,” Dr Duthy says.

Commercialization options include licencing or a Neuren-style partnering.

The company could also be in line for a valuable paediatric review voucher, which the FDA awards to a company with an approved childhood indication.

“We also have provision for one new paediatric study … for a Rett-like disorder with a small number of patients,” Dr Duthy says.

Over their listed life Neurotech shares have traded between 41 cents (late November 2016) and one cent (early April 2020).

Over the last 12 months the shares have ranged between three cents (late June 2023) and 12 cents (late February 2024).

The company’s circa $60 million market cap compares with Neuren’s $2.5 billion valuation.

Dr Boreham’s diagnosis:

For investors, a key focus will be the advice the TGA proffers on a follow-up Rett trial.

There’s also potential news on orphan drug designation for Rett and Pandas in the US and Europe.

Autism approval would require two full-blown trials in the US and Europe - well beyond the company’s resources. But for Rett and Pandas/Pans, one well-designed trial could make the drug “registration worthy”.

NTI-164 potentially could emerge as a combination treatment with Daybue, or a second-line therapy for girls who have gone off the drug because of the side effects.

“While there is a standard of care, we believe there is room in the market for more than one,” Dr Duthy says.

Much more needs to be done before Neurotech becomes the next Neuren, but it’s kicking more goals than your standard ‘pot stock’.

“The company has delivered in spades,” Dr Duthy says. “It’s been a good journey but it’s only just begun.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is approaching 60 but life has only just begun.

VALE DR JOHN CHIPLIN (8.11.1958 – 18.6.2024)

It is with great regret that Biotech Daily reports the death of Dr John Chiplin, last Tuesday, in California, from motor neuron disease.

Biotech Daily first met John shortly after our inception in 2005.

Dr Chiplin was the chief executive officer of Peptech and oversaw the merger with Evogenix in 2007 to form Arana of which he was the inaugural chief executive officer.

In 2009, Arana was acquired by Cephalon, which in turn was acquired by Teva Pharmaceuticals (BD: Jun 12, 2009).

John graduated with a Bachelor of Science in Pharmacy and completed a Doctor of Philosophy in Pharmacy and Biochemistry at England's University of Nottingham.

His first job was as a research scientist at Glaxosmithkline before he began a life of entrepreneurship.

John was a director or chief executive officer at Progen, Healthlinx, Calzada (now Polynovo), Cynata, Sienna Diagnostics (now Inoviq), Benitec, Adalta and Regeneus (now Cambium Bio).

He formed Newstar Ventures in La Jolla California in 2000 and continued to lead the company as its managing-director.

According to his colleagues and family, John also spent the last two years raising funds for research into treatments for motor neuron disease, which is also known as amyotrophic lateral sclerosis or Lou Gehrig's disease.

Dr John Chiplin will be dearly missed.

David Langsam
Editor

BOTANIX PHARMACEUTICALS

Botanix says it has "firm commitments" to raise $70 million through an institutional placement at 30.0 cents a share.
Botanix said the issue price was a 2.8 percent premium to the 30-day volume weighted average price and a 10.4 percent discount to the last traded price.
The company said the funds would be used to commercialize Sofdra, of sofpironium bromide gel, for excessive sweating in the US, including sales and marketing costs and support costs, as well as general working capital and the costs of the raise.
Yesterday, Botanix said the US Food and Drug Administration had approved Sofdra for adults and children aged nine years and older (BD: Jun 20, 2024).
Today, the company said Euroz Hartleys and E&P Corporate Advisory were the lead managers to the placement.
Botanix was up 2.5 cents or 7.5 percent to 36 cents with 61.3 million shares traded.

PHARMAUST

Pharmaust says it has “firm commitments” to raise $10 million through an institutional placement at 19.0 cents a share, with a share plan for $2 million more.
Pharmaust said the issue price was an 18.4 percent discount to the 10-day volume weighted average price, a 19.8 percent discount to the five-day volume weighted average price and a 15.6 percent discount to the last closing price.
The company said its directors and management would take-up about $1 million of the placement, subject to shareholder approval.
Pharmaust said the funds would be used for its phase II/III trial of monepantel for motor neuron disease, as well as manufacturing, pre-clinical studies of monepantel in other neuro-degenerative disease, regulatory filings and working capital.
The company said the share plan had a record date of yesterday, June 20, would open on June 28 and close on July 19, 2024.
Pharmaust said that Morgans Corporate was the lead manager to the placement.
Pharmaust fell two cents or 8.9 percent to 20.5 cents with 3.2 million shares traded.

INVEX THERAPEUTICS

Invex says the UK Government has paid it $GBP633,000 ($A1,203,300) in a research and development tax rebate.
Invex said the rebate related to its research and development expenditure in the UK for the year to June 30, 2023.
Invex was up 0.4 cents or 5.7 percent to 7.4 cents.

WOKE PHARMACEUTICALS, MACQUARIE UNIVERSITY

Woke says Macquarie University has begun enrolment of the 266-patient, phase IIb trial of WP001 ‘low-dose’ synthetic psilocybin tablet for moderate depression.
In 2022, Woke told Biotech Daily that the WP001 ‘low-dose’ was 1.0mg of psilocybin, and that it was developing a ‘high-dose’ 25mg WP002 tablet (BD: Mar 3, 2022).
Later, the company said with Macquarie University it would conduct a six-week, placebo-controlled, randomized trial of its WP001 low-dose ‘magic mushroom’ derived psilocybin for moderate depression (BD: Apr 27, 2022).
At that time, Woke said it would provide Macquarie University with doses of WP001 and placebo as well as the required funding, and retained exclusive rights to the study results, which it would use to further development including a phase III trial.
Today, the company said nine patients had been enrolled so far, with a further 16 patients expected to be recruited by January 2025.
Woke said interim data could be available “as soon as” April 2025.
The company said the trial was “Australia’s largest psychedelic clinical trial and is also believed to be the largest psilocybin-based trial focusing on micro-dosing in the world”.
Woke managing-director Matthew Hayne said that “typically, users report experiencing no hallucinatory effects from micro-dosing and psilocybin is known to be a non-addictive substance”.
“We are very excited to see whether Woke’s low-dose formulation of synthetic psilocybin could prove helpful to people suffering from moderate depression,” Mr Hayne said.
“If so, and while there would be many more steps in a process to getting a drug to market, people in the future could potentially have access to a non-addictive mood enhancer to help them get through tough periods in their life,” Mr Hayne said.
Woke is a private company.

IMRICOR MEDICAL SYSTEMS

Imricor said the Cardiovascular Institute of South Paris has completed two atrial flutter ablations as part of a 91-patient trial of its catheter and irrigation pump products.
Earlier this year, Imricor said it had approval for a 91-patient trial of its cardiac ablation catheter and irrigation pump products at the Baltimore, Maryland's Johns Hopkins Hospital, Switzerland's Lausanne University Hospital and the Cardiovascular Institute of South Paris (BD: Jan 21, Mar 8, Apr 10, 2024).
Today, the company said the trial was studying the safety and efficacy of type I atrial flutter ablation procedures performed using its Vision-MR (magnetic resonance) ablation catheter and an Osypka HAT 500 RF generator and irrigation pump.
Imricor said the study would support US Food and Drug Administration approval of its Vision-magnetic resonance ablation of atrial flutter (Visabl) system.
The company said complete trial enrolment was expected "before the end of the year" with interim analysis after 76 patients had a seven-day follow-up.
Today, Imricor chief executive officer Steve Wedan said the procedures were "a huge milestone for all of us at Imricor".
"We are on track … to complete enrolment this year, supporting our goal of FDA approval for our platform of technology in the US in 2025," Mr Wedan said.
Imricor was up 3.5 cents or 8.4 percent to 45 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding in Allegra from 52,258,354 shares (43.69%) to 54,888,805 shares (45.89%).
In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and yesterday, filed his bidder's statement (BD: May 27, Jun 20, 2024).
Today, the Bowral, New South Wales-based Dr Hartnell said that with Robinwood and Allegra Innovations he acquired the shares "as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024".
Allegra was in a suspension and last traded at 2.9 cents.

INOVIQ

Inoviq chair David Williams says he and his related parties' 4,999,337 share-holding in the company was diluted below five percent due to a capital raise on June 19, 2024.
Last week, Inoviq said it had raised about $7 million at 50 cents a share in a placement and hoped to raise up-to $2.4 million in a share purchase plan (BD: Jun 12, 2024).
According to its latest filing, Inoviq had 105,518,702 shares on issue, meaning that Mr Williams retained 4.74 percent of the company.
Inoviq was unchanged at 57.5 cents.

USCOM

The Sydney-based Gregory Plummer says he has transferred his 17,633,368 share-holding (7.21%) in Uscom from Jetan Pty Ltd to Neja Pty Ltd.
In two substantial shareholder notices from Jetan and Neja, Mr Plummer, as director of both companies, said Jetan paid $317,401 for the shares, or 1.8 cents a share, in an off-market transfer on June 19, 2024.
Uscom was unchanged at 1.6 cents.

ISLAND PHARMACEUTICALS

Jason Carroll says he has increased his substantial shareholding in Island from 20,000,000 shares (17.58%) to 24,100,000 shares (19.01%).
The Melbourne-based Mr Carroll said that between May 2 and June 19, 2024 he bought and sold shares, with the single largest purchase 4,760,000 shares on June 19 for $285,600, or 6.0 cents a share.
Island was unchanged at 7.8 cents.

AUDEARA

Audeara chair David Trimboli says with his related parties he has increased his shareholding from 17,591,210 shares (12.12%) to 21,591,210 shares (14.87%).
The Perth-based Mr Trimboli said with Audeara Investments and Seefeld Investments he bought 4,000,000 shares on June 19, 2024 for $136,000, or 3.4 cents a share.
Audeara was up 0.9 cents or 26.5 percent to 4.3 cents.