Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SYNTARA UP 18%; NOVA EYE DOWN 8%**

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*** WA GOVERNMENT $500k FOR CURTIN UNI ORGANOIDS**

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*** CONTROL BIONICS FURTHER PLACEMENT RAISES $130k; TOTAL $1.2m**

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*** ALLAN GRAY REDUCES TO 10.6% OF STARPHARMA**

*** CHAIR ALAN TRIBE, AUSTRALIAN LAND TAKE 34% OF PYC**

*** PHARMAUST LOSES SAM WRIGHT, APPOINTS SERGIO DUCHINI CHAIR**

MARKET REPORT

The Australian stock market fell 0.85 percent on Friday May 17, 2024, with the ASX200 down 66.9 points to 7,814.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 23 were down and five traded unchanged. All three Big Caps were down.

Syntara was the best, up 0.3 cents or 17.65 percent to two cents, with 6.2 million shares traded. Dimerix gained 10.3 percent; Clarity and Mesoblast climbed more than five percent; Immutep improved 4.6 percent; with Clinuvel, Genetic Signatures, Impedimed, Imugene, Medadvisor, Orthocell and Percheron up by more than one percent.

Nova Eye led the falls, down two cents or eight percent to 23 cents, with 1.1 million shares traded. Nanosonics, Next Science and Opthea lost six percent or more; Polynovo fell 5.45 percent; Alcidion, Amplia, Avita, Starpharma and Telix were down four percent or more; Actinogen, Atomo, Cyclopharm, Neuren and Paradigm lost more than three percent; 4D Medical, Cochlear, CSL, Curvebeam, Emvision, Prescient, Pro Medicus and SDI shed more than two percent; with Micro-X, Proteomics and Resmed down one percent or more.

DR BOREHAM'S CRUCIBLE: BLINKLAB

By TIM BOREHAM

ASX Code: BB1

Share price: 37.5 cents; **Shares on issue:** 99,150,003*****; **Market cap:** $37.2 million

***** Includes 37.9 million shares escrowed for 14 months and 4.1m shares escrowed for 12 months

Chief executive officer: Dr Hendrikus Johannes Boele (Henk-Jan Boele)

Board: Brian Leedman (chair), Dr Anton Uvarov (executive director), Dr Richard Hopkins, Jane Morgan

Financials (December half 2023): revenue nil, loss of $143,318 ($336,592 deficit previously), cash $1.03 million (pre-IPO).

Major shareholders: Yulia Uvarova 8.57%, Dr Sebastiaan Koekkoek 5.8%, Henk-Jan Boele 6.8% Cornelius Pieter Boele 5.82%.

For a stark insight into the crippling cost of autism, look no further than Australia's National Disability Insurance Scheme (NDIS).

Autism now accounts for 35 percent of the 610,502 active participants in the Federal Government program, with $6.73 billion paid to support autism sufferers in 2022-'23.

That's 28 percent higher than the previous year and a major reason why the cost of the scheme is projected to blow out to $100 billion-plus if no remedial action is taken.

Globally, autism is said to be a $US700 billion ($A1,000 billion) market, with the number of diagnosed cases growing at two to three percent a year.

One reason, of course, is that autism is being diagnosed formally in cases where the children might have been dismissed as being a 'little bit different'.

Boys typically are diagnosed at five to six years old - and older for girls who are better at disguising the symptoms such as social interaction problems.

What if they were to be diagnosed earlier and more accurately? Earlier intervention would result in more effective treatment.

That's the premise of smartphone-based diagnosis Blinklab, which listed on the ASX last month after raising $7 million in an initial public offer.

Specifically, Blinklab claims earlier intervention can result in 40 to 60 percent reduction on costs later in life.

“The autism market is huge and it is growing every year,” says Blinklab CEO Dr Henk-Jan Boele.

“We don’t know exactly why, but certainly the accessibility to healthcare and the increased awareness of autism comes into it.”

He adds other unknown factors are likely to come into play.

Mr Leedman says many sceptics scoffed at the notion of a “neurotech for smartphone”, but as discuss below, this is not his first rodeo in terms of such ASX ventures.

About Blinklab

Applicable to both autism, attention deficit hyperactivity disorder (ADHD) and possibly other disorders, Blinklab is an algorithm-based tool which carries out neuro-metric evaluations based on miniscule facial reflexes from the kid-in-the-smartphone-camera.

The technology was developed at Princeton University and Erasmus Medical Centre in The Netherlands and then acquired by the newly-incorporated Blinklab in November 2021.

The program was led by Prof Chris de Zeeuw and his PhD student Sebastiaan Koekkoek, who eventually co-founded the company along with Cornelius Pieter Boele (now Blinklab’s chief technology officer).

Commercially, the driving force behind Blinklab is Brian Leedman, a well-known Perth-based biotech entrepreneur.

A University of Western Australia MBA alumnus, Mr Leedman held senior marketing roles at Ernst & Young and Westpac before spending 10 years as a vice president at the ASX and Nasdaq-listed eye disease house Psivida.

He then co-founded Resapp, the first ASX-digital health stock to detect and distinguish respiratory diseases such as asthma, pneumonia and bronchitis, based on the user coughing into a smartphone. The tech was developed by the University of Queensland.

Despite Resapp failing to win FDA approval because of a dud trial, in late 2022 Pfizer acquired the company for $200 million in a cash deal struck at a 130 percent premium. At the time, Pfizer’s interest lay in a test for Sars-Cov-2.

Blinklab listed on April 2, 2024. After listing, the company appointed Dr Boele as CEO. Dr Boele was assistant professor at Erasmus Medical Centre’s neurology department and a visiting researcher at the Princeton Neurology Institute.

Ahead of the IPO, Blinklab had spent $4.4 million developing the device.

The company says that Blinklab has been validated in 6,000 subjects, globally. While not yet approved, the test has been used by more than 30 clinical institutes, special schools and large healthcare providers.

Blink or you will miss it

The device is based on an established neurological test which measures the eyeblink response to “acoustic startles”: in other words, unexpected noises. In short, the kids watch an enjoyable video and every so often they are surprised with a sound.

The child reflexively blinks within milliseconds. The stimulus is then changed to two sounds and the reaction will determine the diagnosis (including whether the condition is autism or ADHD). Neurotypical kids tend not to blink the second time but autistic kids will.

Dr Boele says facial testing is not at all novel, but the smartphone delivery is.

“We are standing on the shoulders of giants in that we didn’t invent the test.”

Mr Leedman adds that there’s no health dangers in using the test: “the only safety risk is if the user drops the phone on their toe.”

Finances and performance

With $7 million in the kitty, Blinklab appears well positioned to fund the cost of the trial and - more importantly - seek approval, reimbursement and the validation of learned peers.

The oversubscribed initial public offer (IPO) was priced at 20 cents per share, with 35 million shares issued. All up the company has 99.1 million on issue, with 42 million shares escrowed (unable to be sold) for 12 or 24 months.

On listing day, Blinklab shares vaulted to a peak of 30 cents - 50 percent higher but by April 9 had slipped to 22 cents.

Mr Leedman says there’s a typical three-week period of softness after a listing, because any positive news has been included in the prospectus.

He’s right, because at last glance the shares changed hands for 38 cents.

The renewed strength suggests existing un-escrowed shareholders who wanted to cash out have done so. These no doubt include happy punters who paid 12 cents apiece in a pre-IPO whip-around to raise $1.4 million in December 2023.

Post IPO, the company has carried out a charm offensive to woo retail shareholders, rather than the big funds.

“There’s a perception that institutional support is the be-all-and-end-all, but retail investors are more powerful in terms of influencing share price movements,” Mr Leedman says.

“I have seen what they can do the share price if they really like a stock.”

The ensuing liquidity paves the way for big funders to avoid the Hotel California syndrome: they can check in and check out any time.

Sizing the rivals

With at least two approved autism diagnosis devices on the market – one of them also smart phone based – what is the point of Blinklab? Greater efficacy, says the company.

The private Cognoa has a smartphone-based video-based tool called Canvas Dx, approved by the FDA in June 2021 as a de-novo (novel) device.

The tool involves carers completing an online questionnaire about the child's behavior, with an accompanying video.

Erlitec Diagnostics (ETD) has a non-smartphone device, Erlipoint which the FDA approved in June 2022 under the equivalent device (510k) route. Erlipoint is based on tracking the eye movements of kids with a special camera, as they view 'age appropriate' videos and images. Bluey included, surely.

Based on about 270 samples, Blinklab claims a sensitivity (ability to detect positive cases) of 85 percent, compared to Cognoa's 52 percent and ETD's 71 percent.

Blinklab's 84 percent specificity (ability to detected false negatives) compares with Cognoa's 19 percent and ETD's 71 percent.

Given the Canvas Dx accuracy - or lack thereof - Mr Leedman says he was "absolutely incredulous" that Cognoa got to market.

"Cognoa's sensitivity is a toss of a coin, but they still managed to get de novo approval," he says. "We just need to do better than Cognoa, which is easy."

Ouch!

On a more offbeat note, Linus Bio has an assay called Strand Dx, which tests chemical levels in a child's hair for "cumulative environmental exposures" that may have a bearing on the disease.

Strand Dx is also Conformité Européenne (CE) mark-approved and has FDA breakthrough device designation.

On trial

Blinklab's accuracy claims are based on 300 to 500 tests - big enough to train an algorithm but not enough to convince clinicians.

Hence, the company is in the process of recruiting up to 500 patients for a US-based registration study, in partnership with "some very prestigious institutions."

Costed at $US1 million, the study is pitched at FDA approval under the 510k route. Expected in mid-2025, the results are also aimed at supporting European CE Mark approval as a class one device.

As a preliminary algo-training exercise, the company this month signed up with the Illinois-based Turning Pointe Autism Foundation to carry out a 200-patient trial.

Dr Boreham's diagnosis:

Blinklab says autism is growing at a rate of two to four percent and depending on the geography affects 70 to 400 children per 10,000.

Autism is highly prevalent in Australia, Japan and the US and the least common in Denmark, the UK and France.

Blinklab says the cost of diagnosis in the US is $US1,000 to $US5,000, with the cost of the ongoing treatment (care and support) around $US1 million per person.

The company says the US diagnosis market is worth around $US2 billion a year, growing to $US5.4 billion by 2036.

In addition, Blinklab is eyeing the bigger market of checking whether an autism drug is working. Central nervous system stimulants such as Ritalin and Concerta are prescribed for ADHD and to reduce hyperactivity in some autistic children.

"We have the first test to show efficacy of a drug in the course of treatment with a blink of the eye," Mr Leedman says.

Naturally, attention will focus on whether Mr Leedman can do 'another Resapp' and attract a buyer in pre-revenue stage.

Mr Leedman says large pharmaceutical companies have made it clear they are in the hunt to expand their digital healthcare assets.

"The idea your company can be taken over before it makes a dollar was fanciful," he says. "But I did it with Resapp and that gives me a claim to be able to make that call."

Relative to Resapp, Mr Leedman says the market opportunity for Blinklab is "far larger".

But investors will be conscious that smartphone health diagnosis tools don't have a long track record and that - as discussed - there are other autism and ADHD diagnosis tools are out there.

In the meantime, investors will be hearing more about Blinklab - much more.

"Never stop being proactive in getting your story out and I take advantage of every opportunity," Mr Leedman says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But that won't stop him from proactively getting his story out there.

THE ROYAL SOCIETY, THE UNIVERSITY OF QUEENSLAND
THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Royal Society says that five Australians are among the more than 90 Fellows appointed in this year's round, including Prof Barry Dickson and Prof David Komander.
A media release from WEHI said that Prof David Komander had been elected a Fellow of the Royal Society, the UK's national science academy, for his research on ubiquitin, a protein which tells our cells which proteins to break down or recycle.
The University of Queensland said neurobiologist Prof Barry Dickson was elected a Fellow for "key advances in the field of neuroscience".
The University said Prof Dickson was "an outstanding scientist, widely respected for his research on understanding animal instincts.
The Royal Society said the other Australians appointed as Fellows included the Australian National University's Prof Richard Hartley, Monash University's Prof Douglas MacFarlane and the University of Melbourne's Prof Ivan Marusic.

CURTIN UNIVERSITY, WESTERN AUSTRALIAN GOVERNMENT

Curtin University says the Western Australian Government has granted it $500,000 for research into miniature organs, called organoids.
Curtin University said the funds were through the State Government's Future Health Research and Innovation Fund enabling scheme and would be used to open its Western Australian Organoid Innovation Hub.
The University said organoids were "miniature human organs grown in laboratories using a patient's own cells, which allow researchers to learn about diseases and test potential therapies facilitating truly personalized care for patients".
Curtin University said the hub would be based at the Curtin Health Innovation Research Institute, in Perth.
The University said the grant would be used to upgrade equipment which would allow the hub to "capitalise on the growing momentum surrounding organoid research and significantly enhance the current liver cancer organoid program's capabilities".
Curtin University study lead Dr Ben Dwyer said organoids were used "in the context of liver cancer to better understand disease mechanisms to develop new treatments, and also for large scale screening experiments to repurpose approved compounds for use in cancer treatment".
Dr Dwyer said there was a "significant demand to apply this emerging technology and expertise to a broader range of diseases and cancers".

FIREBRICK PHARMA

Firebrick says it has "binding commitments" to raise $800,000 at five cents a share in a placement to GZ Family Holdings Pty Ltd and four GZ Family related parties.
Firebrick said the price was a 24 percent discount to the 15-day volume weighted average to May 15, 2024, and the participants would receive one attaching option for every two shares issued, exercisable at 7.5 cents within two years.
The company said the funds would be used to commercialize Nasodine in the US for the next 12 months as well as ongoing working capital.
Firebrick said GZ Family had been an investor in Firebrick since October 2022 and became substantial in March 2024, and following the placement it would hold about 12 percent of the company.
Firebrick fell half a cent or 7.7 percent to six cents.

CONTROL BIONICS

Control Bionics says it has further commitments to raise $130,000 at 4.3 cents a share, taking the total raised with Wednesday's placement to $1,170,000.
On Wednesday, Control Bionics said it had commitments to raise $1.04 million at 4.3 cents a share, in a placement (BD: May 15, 2024).
Today, the company said Lynx Advisors would receive six percent of the amount raised.
Control Bionics fell 0.2 cents or four percent to 4.8 cents.

PHARMAUST

Pharmaust says the US Food and Drug Administration has granted orphan drug designation to monepantel as a treatment for motor neuron disease (MND).
Pharmaust said its application included results from its 12-patient, phase I study of monepantel and data that showed monepantel could induce autophagy in diseased cells and consideration of the pathology of the disease, including clinical.
Last year, the company said it completed the trial, had applied for orphan drug status and, later, reported the FDA wanted more data due to the absence of pre-clinical or clinical data to establish the potential for the drug's efficacy (BD: Dec 1, 2023; Jan 29, 2024).
Today, Pharmaust said the orphan drug designation provided "incentives including tax credits, grants, waiver of some administrative fees for clinical trials, and seven years of market exclusivity following drug approval".
Pharmaust managing-director John Clark said the approval was "an outstanding milestone for Pharmaust and monepantel, providing an even stronger pathway forward for the drug, particularly in light of recent failures of other [motor neuron disease] treatments".
"We are now increasingly optimistic as we progress to our pivotal registration adaptive phase II/III study which will commence [before 2025]".
Pharmaust was unchanged at 18.5 cents with 22.0 million shares traded.

CANN GROUP

Cann says it remains in a suspension, has cut costs, reduced staff by more than 10 percent and will reduce "production of less profitable products".
In a letter to shareholders, Cann chair Dr Julian Chick said the company had undergone an internal restructure and reduced staff and would continue "to find further efficiencies in the production facility, thus reducing the need for casual labor".
The company said a restructure would allow it "to keep control of its operating costs and provide the company with a clear knowledge of its baseline operating costs so that it can target sales to firstly cover these costs and then become profitable".
Cann said it had been "revising its sales strategy" with a focus on production of "high quality … medical cannabis products of various forms to meet market demands".
Cann was in a suspension and last traded at 6.2 cents.

CURVEBEAM AI

Curvebeam says it will release 58,971,104 shares from ASX escrow on May 23, 2024.
According to its most recent notice, Curvebeam had 215,034,998 shares on issue, meaning that following the release it would have 274,006,102 shares on issue.
Curvebeam previously told Biotech Daily it had a total of 320,138,492 shares, including those in ASX escrow.
Curvebeam fell half a cent or 2.9 percent to 17 cents.

AMPLIA THERAPEUTICS

Sydney's Washington H Soul Pattinson says it has become substantial in Amplia through its more than 20 percent holding in Pengana Capital Group.
Yesterday, Sydney's Pengana Capital Group Ltd says it had become a substantial shareholder in Amplia with 15,200,044 shares, or 5.60 percent (BD: May 16, 2024).
Amplia fell 0.25 cents or 4.1 percent to 5.8 cents.

STARPHARMA HOLDINGS

Allan Gray Australia Pty Ltd says it has decreased its substantial shareholding in Starpharma from 47,820,976 shares (11.65%) to 43,591,315 shares (10.58%).
The Sydney-based Allan Gray said that between September 9, 2023 and May 4, 2024 it sold 4,229,661 shares for $552,232, or an average of 13.1 cents a share
Starpharma fell half a cent or 4.35 percent to 11 cents.

PYC THERAPEUTICS

PYC chair Alan Tribe says with Australian Land Pty Ltd he increased his holding from 1,537,267,467 shares (32.95%) to 1,587,267,467 shares (34.02%).
Mr Tribe said that through Locca Pty Ltd, on May 17, 2025, he acquired 50,000,000 shares for $5,250,000 or 10.5 cents a share.
PYC was up 0.3 cents or 3.1 percent to 10 cents with 6.3 million shares traded.

PHARMAUST

Pharmaust says Sam Wright, who has been company secretary since August 2007 and a director since October 2008 has resigned, effective immediately.
Pharmaust interim managing-director John Clark said Mr Wright had "to be commended for his extremely loyal service to Pharmaust over many years, during which time he has gone above and beyond what is expected of someone in a non-executive or company secretary role".
"On behalf of the current team and shareholders, I want to thank Sam and wish him all the best moving forward," Mr Clark said.
Last month, the company said chief operating officer John Clark had been appointed interim chief executive officer following the resignation of nine-month managing-director Dr Michael Thurn (BD: Aug 28, 2023, Apr 23, 2024).
Last week, Pharmaust said chair Dr Roger Aston and directors Robert Bishop and Dr Thomas Duthy had resigned from the company, with Mr Wright promoted to interim chair, effective on that day (BD: May 9, 2024).
On Tuesday, the company said director Neville Bassett had resigned (BD: May 14, 2024).
Today, Pharmaust said it had appointed Sergio Duchini as chair to replace Mr Wright.
The company said Mr Duchini was an Enlitic director and Lymphoma Australia chair and had been an Ausbiotech director and Deloitte Australia director.
Pharmaust said Mr Duchini held a Bachelor of Commerce from the University of Melbourne.