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Daily news on ASX-listed biotechnology companies

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 the facial testing technique 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.