Initiation Research Report
BlinkLab Ltd (ASX:BB1)
ASD & ADHD Diagnostic App

Price: $0.245 | Valuation: $1.30 | Implied Return: 430% | 1 October, 2024

BlinkLab – Smartphone based diagnostic app

BlinkLab are developing a smartphone-based application (app) which makes it easier to diagnose neurodevelopmental conditions such as Autism Spectrum Disorder (ASD) and Attention Deficit Hyperactivity Disorder (ADHD) in children.

ASD is a developmental condition of the brain which affects 1 in 36 children in the USA. Direct and indirect costs of caring for children and adults with ASD in the USA was estimated at US$268bn in 2015. Currently, diagnosis of ASD is often done with a two-part questionnaire which is time consuming, and the first part of the questionnaire has a high number of false positives.

BlinkLab's app simplifies the procedure by generating results in less than 30 minutes. It works by using real-time detection of stimulus-evoked facial expressions while the child is watching a video. The data is captured and analysed for various biomarkers such as eyeblink conditioning and prepulse inhibition of acoustic startle. It is intended that the BB1 app will be used to diagnose children ages 18 months to 72 months.

Key points

The technology has been in development in various stages since the 1990's however the current iteration saw its biggest advances when smartphones became widely adopted. Prior to listing on the ASX BlinkLab conducted several trials to test the app. Initially BB1 will focus on ASD diagnostics.

- BB1 have conducted a large 280-person ASD trial in Morocco which showed sensitivity of 85% and specificity of 84%.
- Closest competitors, Cognoa and EarliTec Diagnostics, have measured lower sensitivity and specificity of 52%/19% and 71%/81%, respectively.
- BlinkLab are beginning enrollment this year of a 500-person trial with expected readout mid-2025 and FDA feedback 1H CY2026.
- Potential first revenue 2H CY2026 with BB1 initially looking to launch the test in two US states, New Jersey and Pennsylvania.
- The ASD diagnostic market is estimated to grow at a CAGR of 8% annually and potentially grow to US$5.4bn by 2036.
- The earlier and faster a child can be diagnosed will lead to better outcomes and it is currently an unmet need.

Valuation

We have valued BB1 at $1.30 using a future and probability-weighted discounted cash flow model. How many diagnostic tests caregivers will be able to perform using BB1's app is difficult to answer and all we can do is make conservative assumptions. The USA had 3.596m births in 2023 and it is recommended to have ASD screening at 18 & 24 months. We assume BB1's app has a better than even chance to be commercialised due to having a predicate device on the market and the data on hand. We further assume a minimal penetration rate in the first few years before rising to 10% of the diagnostic market by 2031 and pricing of US$250/test. Similarly, we assume BB1 will penetrate 10% of the ADHD diagnostic market by 2031. Using a 15% discount rate we find BB1 with a valuation of $1.30/share. This valuation is only based on the US market and has significant upside should we include rest of world.

Company Data

Recommendation: Speculative Buy
Shares on Issue: 99.15m
Market Capitalisation: $24.3m
Enterprise Value: $18m

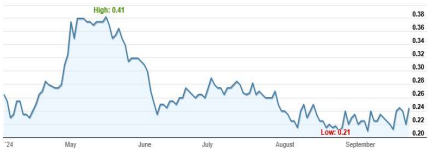
Board Structure

Dr Anton Uvarov: Executive Director
Brian Leedman: Non-Exec Chairman
Dr Richard Hopkins: Non-Exec Director
Jane Morgan: Non-Exec Director

Major Shareholders

Yulia Uvarova: 8.82%
Cason Holding BV: 6.81%
Inacea Holding BV: 5.82%
Bello Holding BV: 5.82%
Total Top 20: 55.83%

Chart



Source: Iress

BB1 is on the verge of commercialising a smartphone app which aids in diagnosing ASD, ADHD, and other neurodevelopmental conditions.

Contents

Executive Summary

Software as a Medical Device (SaMD) has been growing exponentially in recent years, especially since the widespread adoption of smartphones. It is a broad term that also includes wearable devices and telehealth. In 2020 the US digital therapeutics market was worth US$2.3bn and estimated to grow to US$35.78bn by 2030. Not all SaMD's are used as a diagnostic.

BlinkLab is commercializing a smartphone app that is part of this growing market focusing on diagnoses of ASD and ADHD in children. It does so through a neurometric test using real-time detection of facial expressions, including eyes and eyelids, and uses encrypted data transfer and storage to protect patient privacy. BlinkLab are targeting children from 18 months of age to 72 months. The caregiver or health practitioner would use the BlinkLab app to measure stimulus-evoked facial expressions of the child while they are watching a video. Automated facial recognition and image processing techniques analyse the data and test for several biomarkers which give an indication of the child having ASD or ADHD with high sensitivity and specificity.

Autism Spectrum Disorder, ASD, is a neurological and development disorder that affects interaction, communication, learning, and behaviours and affects 1 in 36 children in the USA. Testing for ASD is often a two-stage process which involves an initial questionnaire, called M-Chat, and a follow-up interview usually performed over the phone which is designed to get rid of a high number of false positives. The ASD treatment market was valued at US$29.8bn in 2021 and is estimated to grow at a CAGR of 4.4%. The ASD diagnostic market is estimated to grow at a higher CAGR to US$5.4bn by 2036.

BlinkLab has conducted several trials prior to listing on the ASX in April 2024 including a 280-person trial in Morocco which gave a sensitivity and specificity of 85% and 84%, respectively. BlinkLab will need to conduct another US based trial before receiving FDA approval most likely via the 510(k) pathway. Enrollment of up to 500 participants is scheduled to begin in the current half and readout is expected middle of next year with FDA decision 1st half of 2026. BlinkLab will be seeking approval based on a predicate device already on the market and we do not foresee too much difficulty in receiving FDA approval. Upon FDA clearance we expect commercialisation by 2nd half 2026.

Company History

Blinklab has an exclusive licence from Princeton university

BlinkLab was incorporated in 2021 and has an exclusive license from Princeton University to develop and commercialise a smartphone-based application with an e-platform to test and aid in the diagnosis of ASD, ADHD, schizophrenia and other neurodevelopmental conditions. The main focus is on the ASD and ADHD market.

The BlinkLab technology dates back to the late 1990's and has undergone several developments and iterations but the current commercial application was not able to be fully developed until smartphone technology become more advanced.

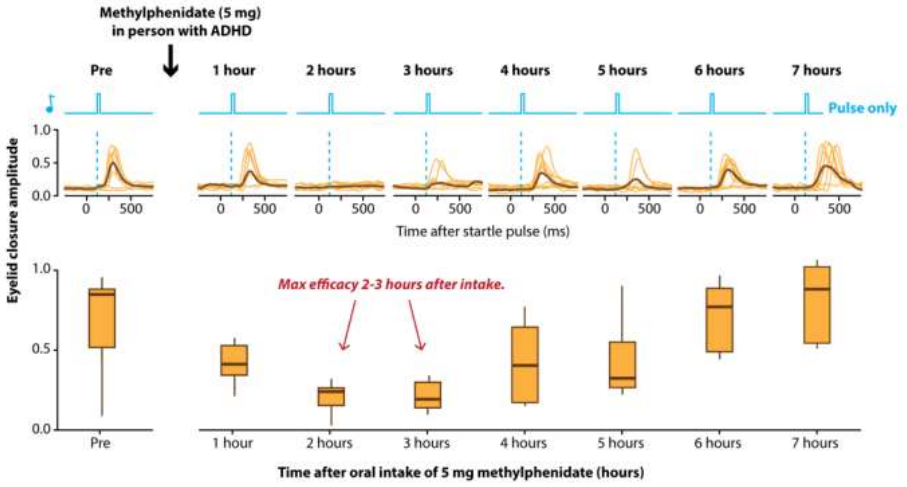
BlinkLab conducted several studies prior to listing

The company used seed raising capital to improve the iOS application and backend system. Further enhancements included a more streamlined user experience, incorporating hearing test and Bluetooth connectivity, and accurate calibration of all stimuli modalities. BlinkLab used funds from the pre-IPO round to conduct multiple trials which are stated below

2020 – A pilot study was completed in 18 healthy volunteers. While a very small test run it did show Eyeblink Conditioning (EBC) and Prepulse Inhibition of Acoustic Startle (PPI) rates superior to conventional methods and showed potential for large scale tests and the possibility for home testing with the aid of a caregiver.

2022 – 58 volunteers were recruited at Princeton University and Erasmus MC in the Netherlands and were tested using an iPhone using three tests which were eyeblink conditioning, prepulse inhibition of acoustic startle response and startle habituation while the participant was watching a video. The different stimuli were measured which the app continually monitored using sophisticated detection algorithms. The data became immediately available to researchers through the BlinkLab analysis portal. Using a smartphone produced less variability in learning curves previously reported and produced strong data to move toward clinical trials. The trial also increased confidence in using smartphones with biomarkers as a measuring tool.

2022 – BlinkLab ran a trial monitoring the effect of Ritalin in patients with ADHD using its proprietary smartphone-based device. The company recruited 20 patients and used the BlinkLab device to monitor the effect of the drug on the patient. At one-hour intervals the BB1 software was able to monitor the effect of methylphenidate in ADHD patients which both shows the sensitivity of the device and that the device can be used as a part-drug device combination.

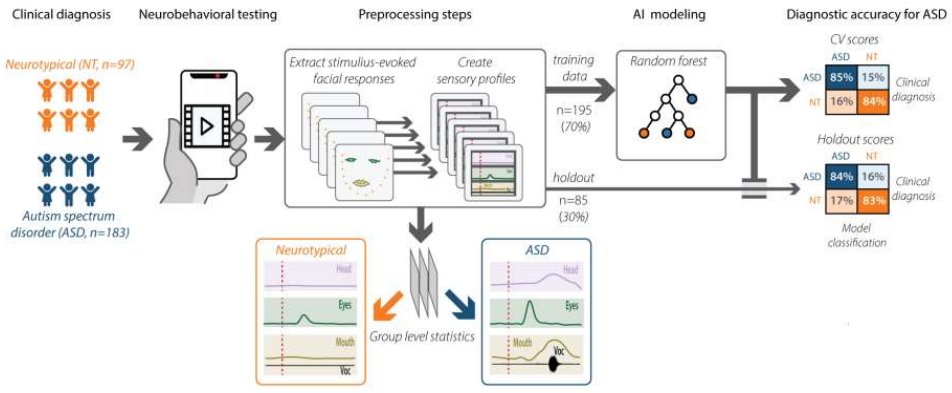


BB1 app tracking ADHD treatment drug. Source: BB1

280-person study in Morocco scored a sensitivity of 85% and a specificity of 84%

2023 – BlinkLab undertook a large study in 2023 recruiting 156 subjects aged 3-12 of which 93 patients with autism and the remaining control subjects. The study demonstrated BlinkLab's ability to differentiate between positive and negative subjects and the data led to a larger study in children previously diagnosed with ASD.

2023 – BlinkLab recruited 280 subjects in a large diagnostic study for Autism. The study was conducted across 8 sites in Morocco. The trial comprised of 100 girls of which 57 were diagnosed with Autism and 180 boys of which 126 diagnosed with autism. The BlinkLab device scored an average sensitivity of 85% in identifying true ASD cases and a specificity of 84% which shows potential to identify true negative. The positive predictive value (PPV) averaged at 92% while the negative predictive value (NPV) was 77% both indicative of the model's precision and reliability in classifying cases. The above scores were only based on BB1 device and did not include additional questionnaires such as M-Chat.

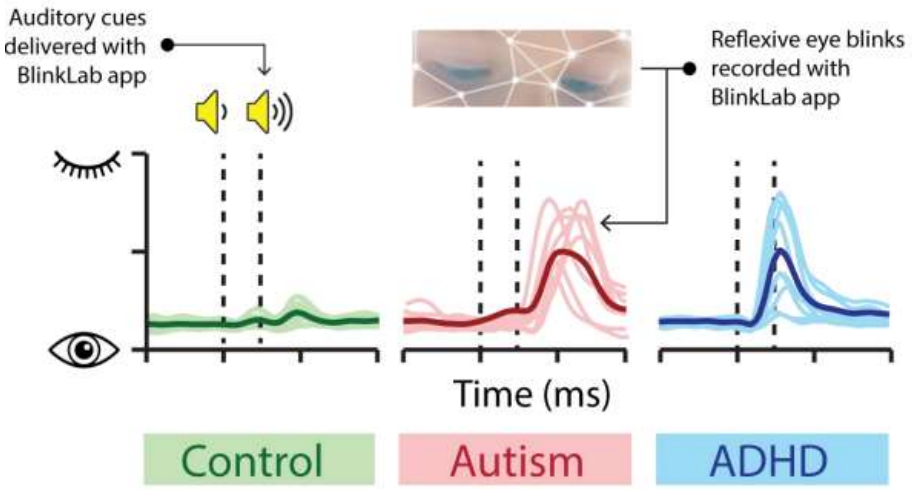


Morocco study infograph. Source: BB1

The BlinkLab Application

Blinklab's device, BlinkLab DX, is an app which performs neurometric tests to aid in the diagnostic of ASD, ADHD, schizophrenia and others. The app can be downloaded from the app store for patients, caregivers and/or parents. The app is not intended to be used as a standalone but as an adjucant to the diagnostic process. It does not depend on any verbal or social interaction hence can be used at a very early age. The data indicates that the BlinkLab App has a much better precision in diagnosing ASD as compared to currently approved FDA medical devices that require significant use of hardware, cannot be used remotely and require clinical visits. The BlinkLab app includes a secure database and CMS system as well as a portal where the caregiver can customize the neurometric tests. BlinkLab are targeting diagnosis in patients 18 months to 72 months of age. Since the device monitors facial expressions as opposed to requiring verbal or social interaction is can be used at an earlier age than current standard tests. The time it takes to administer the test is about 15 to 20 minutes and results are available only a few minutes after. A 280 person test BB1 conducted in 2023 showed a sensitivity of 85% and specificity of 84% which gives the care giver high confidence of the likelihood that the patient does or does not have ASD based on the data collected. Using just a smart phone in testing provides less moving parts and potentially causes participants to perform better under a less stressful testing environment.

BlinkLab DX gives a diagnosis at a much faster rate than peers



BlinkLabs technology. Source: BB1

The device takes the lab setting and questionnaire out of the equiation which can be undesirable and lengthy tests and are currently mainly used to diagnose ASD. It uses real-time detection of facial expressions, including eyes and eyelids, and uses encrypted data transfer and storage to protect patient privacy.

The data is captured using the app and is transferred to a secure online platform where the data is analysed using automated facial recognition and image prcessing techniques.

The app tests several biomarkers including

- Eyeblink conditioning
- Prepulse inhibition of acoustic startle
- Habituation of eyeblnk responses

ASD affects 1 in 36 children in the United States

As previously explained, the biomarkers are collected using a smartphone and the data is sent to the cloud for storage and analysis. During the test the participant is shown a movie or TV show to keep their attention while the device records their responses in real time.

ASD Explained

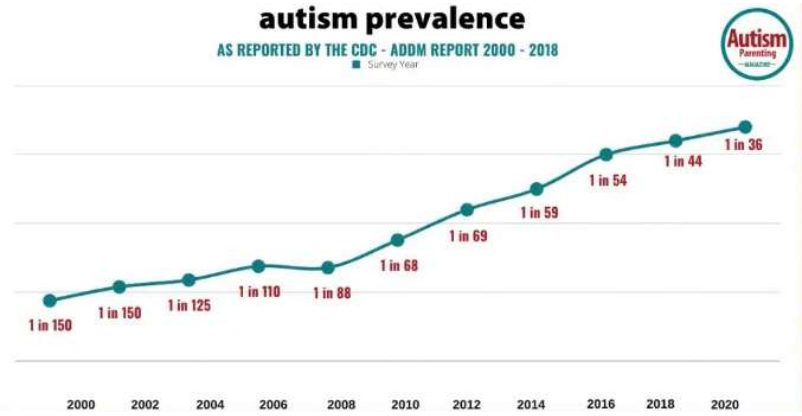
Autism Spectrum Disorder (ASD) is a development condition of the brain that leads to persistent challenges with social communication, restricted interest and repetitive behaviour. The word spectrum is due to autism affecting people in a variety of ways and the severity of symptoms people experience differ greatly and thus there is not one universal treatment for ASD.

There are several signs that a child may exhibit before being diagnosed with autism. Early signs can be detected before a child reaches one year old. Typical diagnosis usually occurs at the age of five however earlier diagnosis usually reduces costs down the line as specific treatments can start earlier. Symptoms may become more pronounced once the child starts school and when among peers. ASD symptoms can range from mild to severe. Children that show signs of ASD may show restricted interest and repetitive behaviour, difficulty tolerating changes in routine and new experiences, sensory hypersensitivity, arranging things, often toys, in a very particular manner, or making little or no eye contact. Back and forth conversations might be difficult.

The primary cause of ASD is not yet known but it is believed to be mainly genetic. ASD affects more than 5 million in the USA alone and about 1 in 36 children. Direct and indirect costs of caring for children and adults with ASD in the USA in 2015 was estimated at US$268bn. Worldwide around 1% of the population has ASD. For this report, we solely focus on the US market.

The rate of autism has been increasing since the early 2000's. However likely this is largely due to an increasing diagnoses rate due to several sociological factors and better understanding of the different conditions people need to be aware of. Another reason is the inclusion of behavioural therapies for autism in non-self-funded private insurance plans. Autism prevalence is more than 300% higher than estimates from 2000.

ASD diagnostic market is estimated to grow to US$5.4bn by 2036



Autism Prevalence since 2000. Source: Autism Parenting Magazine

Due to the increasing prevalence rate both the diagnostic and therapeutic market has grown substantially in recent years. ASD treatment market size was valued at US$29.8bn in 2021 and is estimated to grow to US$45.9bn in 2032 with a CAGR of 4.4%. The ASD diagnostic market size is estimated to be valued at US$5.4bn by 2036 growing at a CAGR of 8% from 2024. This is the market BB1 will be operating in.

The economic burden of dealing with children who have ASD is far greater and is estimated north of US$450bn which is mainly driven by special education needs and loss in parental productivity. This cost can only be reduced through diagnosing ASD at an earlier age so that treatments can start earlier and mitigate the greater cost at an advanced age.

Delayed treatment also has a negative effect on adult life. 70% of adults with ASD are unemployed. Unfortunately, early diagnosis in the USA remains an unmet need. Early intervention can and does influence outcome and ultimately cost. The American Academy of Pediatrics recommends screening for symptoms of ASD through a combination of developmental surveillance at 9, 18, and 30 months of age and standardized autism-specific screening tests at 18 and 24 months of age. However, many children do not receive final diagnosis until they are much older and not every child gets tested. Some parents only get their children tested if they show symptoms. The earlier the diagnosis can be performed the sooner treatment can begin. Since ASD behavioural symptoms can differ greatly between cases so does the type of treatment and behavioral therapies that are most likely to be helpful.

Currently ASD testing is often a two-stage process

Testing is often a two-stage process performed by either a pediatrician or at a specialty center. A team of health care providers who have experience diagnosing ASD will conduct the diagnostic evaluation. This team may include child neurologists, developmental pediatricians, speech-language pathologists, child psychologists and psychiatrists, educational specialists, and occupational therapists.

Diagnosis may range from medical and neurological examinations, assessment of child's cognitive/language abilities, to blood and hearing tests.

One of the more common diagnosis tools is a modified checklist called M-Chat which is a screening questionnaire specific for ASD. It is mainly used at a child's 18- or 24-month well-child exam. It contains 23 questions in a yes/no format and gives an indication of ASD being prevalent. There is also a follow-up interview which is designed to get rid of a high rate of false positives. The follow-up interview is typically a phone interview and children who screen positive on both the questionnaire and phone follow-up will be referred for an ASD diagnostic evaluation. However, even with the follow-up interview the number of false positives remains high.

ASD is more often diagnosed in males than females. The reason for this is not very clear. BlinkLab is attempting to change this and have joined a large consortium of research institutes and industry oranisations which will be researching improvements in the way autism is diagnosed by introducing novel sex-sensitive solutions. The current ratio for ASD in children is 4 in 100 boys and 1 in 100 girls.

Treatment

While FDA-approved medication for treating symptoms related to ASD is limited to risperidone and aripiprazole, caregivers are increasingly turning to complementary and alternative medication

The medications available are to treat specific symptoms, however there are no medications that treat the core symptoms of ASD. People with ASD may suffer from a range of issues and there is no single best treatment. Treatments can also involve referral to health care providers who develop specialized programs which can be highly structured and intensive.

These programs may involve

- Learn social, communication, and language skills
- Reduce any behaviors that interfere with daily functioning
- Increase or build upon strengths
- Learn life skills for living independently

Behavioural approaches are often used and have shown the most positive evidence for treating symptoms of ASD. The goal could be to teach desired behaviour or responses or to improve on pivotal skills. Current treatments aim to improve quality of life and daily interactions with peers. Apart from behavioural therapy multiple treatments can be pooled together such as psychological, pharmacological, developmental, educational and others.

ADHD is estimated to affect 8.4% of children

ADHD Explained

Attention-deficit/hyperactivity disorder (ADHD) is a mental disorder affecting children and is the most common mental disorder. Some of the symptoms are like ASD such as not being able to keep focus, hyperactivity and acting with sudden impulse. People with ADHD can suffer from either being mainly inattentive, hyperactive or both. ADHD is considered a chronic disorder and needs appropriate treatment. It often leads to depression, low self-esteem, anxiety, and potentially substance abuse in later years.

It is estimated ADHD occurs in 8.4% of children and 2.5% of adults and is typically diagnosed by mental health providers or primary care providers.

Diagnosis can be exhaustive including a full psychiatric evaluation which may include getting referred for additional psychological testing. The cause of ADHD may be genetic but is mainly seen as a way in which certain chemical messengers, such as dopamine and norepinephrine, work in the brain.

ADHD is mainly treated with psychostimulants such as amphetamines and methylphenidates. The goal of treatment is to improve symptoms to restore functioning at home and at school. These may also be combined with behavioural-based therapies to help unlearn problem behaviours and ways to cope with stress.

Software as a Medical Device (SaMD)

Software as a Medical Device has grown to become a multi-billion-dollar industry

Software as a medical device (SaMD) has grown significantly in the past 10 years. SaMD officially became a term in 2013 being named as such by the International Medical Device Regulators. While it was once considered a niche market almost all large pharmaceuticals and medical technology companies have sought to contribute to this growing sector. Large pharmaceuticals are keen to invest, acquire companies and collaborate with growing minnows. In 2021 the digital health start-up ecosystem managed to raise USD$5.1 billion.

The diabetes sector has seen the largest inroads of SaMD's and the highest sales channel has been B2C. Applications used on smartphones dominate the digital therapeutics market. This is expected to grow further as an ageing population means an increase in cases of various physiological and neurological diseases and thus further need for digital products and services.

SaMD does not only cover smartphone apps but is a broad term that includes categories such as mobile health, health information technology, wearable devices, telehealth & telemedicine, and personalized medicine. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device, and include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics).

In recent years we have seen AI and computer advances leading to an even larger increase in software based medical devices on the market.

The digital therapeutics market was estimated to be worth US$2.3bn in 2020 growing at a CAGR of 31.4%. It is estimated to be worth US$35.78bn by 2030 due to increasing penetration of smartphones and gadgets such as fitness trackers and increasing investment in the sector.

Blinklab's diagnostic app will likely fall under the SaMD banner and to go commercial will need to satisfy three criteria.

1. Must meet the definition of "Software as a medical device" which states that software is intended to be used for a medical purpose, without being part of a hardware medical device or software that stores or transmits medical information.

2. Must have received marketing clearance or approval by the U.S. Food and Drug Administration (FDA) either through the De Novo premarket process or 510(k) process or pre-market approval.

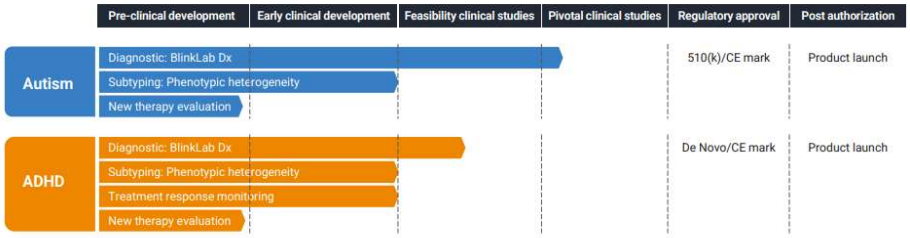
3. Must be prescribed by a healthcare provider.

BlinkLab to begin enrollment for a 500-person study in the coming months

Monetisation

BlinkLab will still have to go through regulatory clinical studies to receive FDA approval and CE Mark. Initially BlinkLab will target rollout in two USA states which are New Jersey and Pennsylvania. Within these two states BlinkLab has good connections to top tier medical research centres that have strong awareness of ASD.

The 280 participant study in Morocco has given BlinkLab a strong indication of where the sensitivity and specificity lies. However to receive FDA approval the company will need to go through the 510(k) regulatory pathway which means a further study needs to be undertaken. BlinkLab is intending to recruit up to 500 participants with enrolment beginning in the current half this year. Completion of the study is anticipated by mid-2025 with FDA approval potentially received by 1st half of 2026. Approval will be sought upon a predicate device already on market, in this case the Cognoa device. By using a device which is already on the market as a predicate the company can demonstrate to the FDA safety and effectiveness. During 1H FY24 BlinkLab have been collecting sensory phenotypes, which are observable characteristics or traits, from up to 200 children. This data will be used to finalise the AI/ML algorithms and models ahead of the upcoming FDA trials.



Stage of progression. Source: BB1

BlinkLab aims to enter into agreements with various Health Care Practicionaires (HCP's) whereby the company will charge them a fee per diagnosis using the BlinkLab device. The actual reimbursement fee per diagnosis will depend on the reimbursement code

There are two codes used for reimbursement. CPT codes and HCPCS codes. They are administered by different entities, CPT by American Medical Association (AMA) and HCPCS codes by Center for Medicare and Medicaid Services. Current Procedural Terminology (CPT) codes offer doctors and health care professionals a common procedure for billing medical services. The codes are meant to streamline reporting, increase accuracy and efficiency. CPT codes fall under 3 categories

Category I: These codes have descriptors that correspond to a procedure or service. Codes range from 00100–99499 and are generally ordered into sub-categories based on procedure/service type and anatomy.

Category II: These alphanumeric tracking codes are supplemental codes used for performance measurement. Using them is optional and not required for correct coding.

Category III: These are temporary alphanumeric codes for new and developing technology, procedures and services. They were created for data collection, assessment and in some instances, payment of new services and procedures that currently don't meet the criteria for a Category I code.

HCPCS code are standardized codes which represent medical procedures, supplies, products and services. The code is used to facilitate the processing of health unsurance claims by Medicare and other insurance. These codes are divided into two subsystems, level I and level II.

Level I comprises CPT code which are used for medical servicea and procedures given by physicians and other health care professionals for which tyey bill public or private health insurance programs.

Level II refers to services which are not included in the CPT codes such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies when used outside a physicians office.

Which code BlinkLab may ultimately receive is not certain. Digital Theraoputics is a growing sector which has received more attention.

The Center for Medicare and Medicaid Services (CMS) issued a first ever digital therapeutics code in 2022 numbered A9291 which allows health care professionals to bill private payers directly for digital therapies which is what they do for any traditional medical device.

However, for the company that received the code, the CMS did not apply a benefits category which means can't be considered for Medicare coverage.

BlinkLab's app is available for download on the Apple store however there is currently no plan for a direct to consumer revenue model. The penetration rate and marketing expenditure would likely not make it worthwhile as well as revenue sharing with the platform host. Parents who show concern for potential ASD in their children prefer to use devices/services which are clinically validated .

Many peers are private companies who have required far more funding to get to a commercial stage than BlinkLab will need

Competition

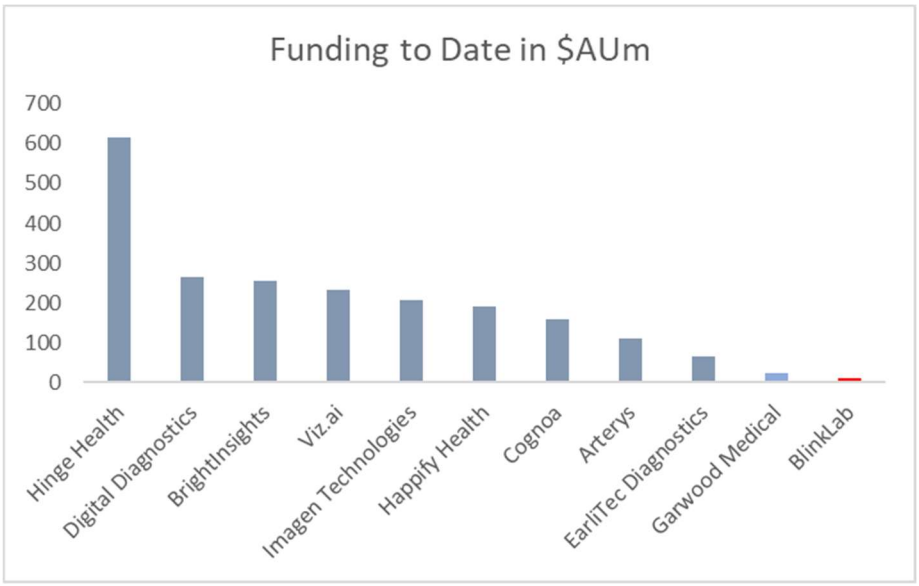
The digital diagnostics space has been growing steadily in recent years as smartphones have become an increasingly part of our lives. The number of companies that offer a diagnostic tool has grown significantly, however a vast majority are private. However, large pharmaceuticals have become much more active in this space and are keen to invest, acquire companies and collaborate with the growing number of minnows. Looking at the competitor market there are two which are direct peers and a vast number which are merely in digital diagnostics. We cover both peer groups separately.

On the list below, Cognoa and EarliTec Diagnostics can be classified as direct peers. The remaining are within the digital medical health sector and are worthwhile comps to gage the amount of funding the other companies have attracted, and the size of the companies compared to BlinkLab. We do not foresee BB1 to need much more funding before first revenue if any. The advantage of BlinkLab being an app available to download on the app store as opposed to needing additional devices can't be understated.

Company	Revenue	Employee size	Total Funding ($AUm)	Description
Hinge Health	>$200m	1001-5000	615.4	Digital Health for joint and muscle care
Digital Diagnostics	>$30m	51-100	266.2	Retina scan for diabetic retinopathy
BrightInsights	>$30m	201-500	255.4	IoT platform for digital health solutions for diabetes, mental health, oncology, respiratory diseases
Viz.ai	>$50m	201-500	233.8	AI diagnostic tool analyzing medical imaging for stroke and hypertrophic cardiomyopathy
Imagen Technologies	>$50m	51-200	207.7	Faster imaging exams for various imaging exams such as mammography, fundoscopy and x-ray
Happify Health	<$10m	120	189.2	Software-based coach that aids people with chronic conditions
Cognoa	<$15m	51-200	158.5	Autism diagnostic tool, software based
Arterys	>$30m	51-200	110.8	Cardiac MRI using AI
EarliTec Diagnostics	<$10m	25-30	64.6	Medical device to diagnose ASD, not software based
Garwood Medical	Pre	20+	21.5	A minimal invasive device that uses electrodes to prevent biofilm infections on prosthetic knee implants
BlinkLab	Pre	<10	11.4	ASD and ADHD diagnostic tool, software based

Peer table. Source: Lodge Partners

BlinkLab has utilized far less funding than peers and has one more pivotal phase trial to go before potential revenue in the 2nd half of 2026. Since BlinkLab DX is a downloadable app we do not expect much more capital to be needed before commercialization except for upcoming ADHD trials and initial marketing.



Out of these companies Cognoa and EarliTec Diagnostics are the closest peers to BlinkLab.

Cognoa has an app called Canvas DX which is used as a diagnostic tool for ASD. Canvas Dx includes three inputs: a questionnaire for the parent or caregiver that asks about the child's behavior, two videos of the child at home that are recorded by the caregiver through the app and a questionnaire for the physician. The caregivers use an app for their part, while the clinicians do their part online. Once all the information has been collected, the Health Care Professional will be able to review the result on the HCP portal wihin 1-3 business days.

EarliTec Diagnostics's flagship product is called EarliPoint and is used to diagnose and assess autism in children ages 16-30 months old. It uses a special device which children use to watch a video while the device tracks the child's eye movements. According toe EarliTec, children with autism won't focus on the video the same way that kids without autism will. Compared to BlinkLab, EarliPoint is not smartphone based and focuses heavily on social-visual engagement and also does not use multiple data points.

Both Cognoa and EarliTec have FDA approval. Cognoa received DeNovo classification in 2021 and EarliTec 510(k) approval using Cognoa as predicate device. Is is important to note that BlinkLab scored a higher sensitivity and specificity rating from their 280 person trial in Morocco than either company managed in their trials prior to FDA approval.

	blinklab	cognoa	ETD
Sensitivity	**85%**	52%	71%
Specificity	**84%**	19%	81%
Smartphone-based	Yes	Yes	No
FDA approval	Not yet	De novo	510(k)

Comparison to Cognoa and ETD. Source: BB1

Valuation

BB1 is aiming to launch its app in 2026 should the upcoming trial yield solid results and be granted FDA clearance. Initially BB1 is looking to launch in two US states, New Jersey and Pennsylvania. This will be a very small test market before a nationwide rollout which we anticipate occurring in 2027.

Our valuation of BlinkLab lands at $1.30/share

In valuing BB1 the question to be answered is how many ASD tests will the company be able to achieve post rollout. To answer this question, we need to make some conservative assumptions. BB1 are targeting children from the age of 18 months to 72 months and the American Academy of Pediatrics recommends screening for ASD at 9, 18 and 24 months of age and standardized autism-specific screening tests at 18 and 24 months. Autism diagnoses are reliable by age 2, hence for the sake of modelling we use 24 months of age as our benchmark and conservatively assume only one test per undiagnosed child and for ASD sufferers a continuous annual assessment.

According to the US Centers for Disease Control and Prevention (CDC) there were 3.596m births in 2023, a decline of 2% from the previous year however it has been steady in the past few years. It is recommended all of them get tested by 24 months. Not all of them will but this is BB1's target market.

As an addition children that have been diagnosed with ASD usually do an assessment once a year to see if the treatment is working which we anticipate being from year 2 to 7. In the USA the diagnosis rate for ASD in children is currently 1 in 36. This gives us our second target market, albeit a much smaller one.

BB1 is also aiming to target the ADHD diagnostic market. The Data Resource Center for Child and Adolescent Health shows that 10.5% of children between the age of 3-17 currently have this condition which gives us a target market of approximately 6.465m. We estimate it will still be a few years of tests until BB1 can enter the ADHD diagnostic market and thus do not foresee any revenue until at least 2028.

We have combined the potential revenue from ASD and ADHD diagnostic tests to derive at a valuation of $1.30 by using the following estimates:

For simplicity we only model success in the US market. BB1 has further ambition to obtain CE Mark and TGA approval to bring the diagnostic app to Europe and Australia. BB1 have partnered with European INTER-PSY who will use and evaluate the BlinkLab app in the diagnosis of autism in children between 2-6 years of age. The INTER-PSY study will mirror the upcoming FDA regulatory trial.

We currently attribute an 80% chance that BB1 will be commercial which might seem high however having a predicate device already on the market and being a non-invasive software based diagnostic tool we believe the risk of not receiving FDA approval is low. We anticipate first revenue in 1st half of FY27, shortly after potential FDA approval which is anticipated mid-2026.

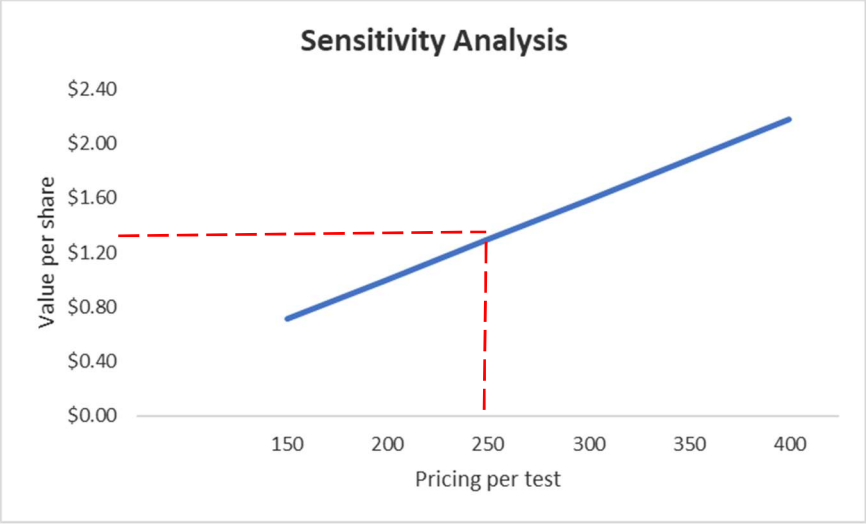
We have modelled a very low percentage of penetration for number of children tested in the first few years, especially the first year due to the likelihood of only being on the market for 6 months and in two states. We anticipate gradual national rollout in CY27. We assume a steady scaling up to eventually capturing 10% of the target market by 2031. We assume a cost per test of US$250. It is not entirely certain which Medicaid/Medicare code BB1's diagnostic test would fall under and how much they would be able to charge but US$250/test gives us a good conservative number. A low cost and faster test give us comfort in quicker adoption rate and penetration. Currently, the cost of developmental screening for autism is at a median price of US$165.95.

However, test results are not immediate and there are problems with false positives. Faster test results and a high sensitivity/specificity would arguably warrant slightly higher prices. It is also worth noting that the current pricing varies by state.

Our assumptions are similar for ADHD however we assume first revenue to begin FY28 on a small scale and increasing to capturing 10% of the diagnostic market by 2031. We also use a lower probability for success for ADHD as BB1 has less test data compared to ASD. Using a discount rate of 15% and using the above methodology we derive a valuation of $1.30. We have accounted for company expenses and taxes. We anticipate BB1's diagnostic app to have a part to play in a growing software as a medical service market. To place a value on BB1 we have focused on the potential of BlinkLab DX within the whole diagnostic market. While we have used a few assumptions we have mitigated the risks by using a probability weighting and discounted model to determine how much of the ASD & ADHD diagnostic test market BB1 may be able to capture.

The pricing per test is currently unknown. For the valuation methodology, we adopted a price of US$250/test. The actual price may be different but likely not too much variation. We have shown the potential value per share using different pricings per test below. Sensitivity Analysis shows how different pricing levels affect the share price.

Year	2026	2027	2028	2029	2030	2031
Discount factor	0.756	0.658	0.572	0.497	0.432	0.376
Discounted cash flow	-$4,244,035	-$733,509	$12,075,056	$25,957,788	$38,901,014	$56,543,247
Total NPV (millions)				$128,499,557		
Shares (millions)				99,150,003		
Value/share				**$1.30**		



BlinkLab Limited (ASX:BB1)

Autism and ADHD Diagnostic App ready to launch

Year ending June	2024A	2025E	2026E	2027E	2028E
NPAT	(1.8)	(1.8)	(5.6)	(1.1)	21.1
EPS_{adj} (¢)	**(0.0)**	**(0.0)**	**(0.1)**	**(0.0)**	**0.21**
EPS growth		**0.0%**	**0.0%**	**0.0%**	**1995%**
P/E ratio	**N/A**	**N/A**	**N/A**	**N/A**	**1.1 x**
Enterprise Value (m)	21	23	22	23	(6.9)
EV/Sales (x)	562.19 x	0.00 x	0.00 x	0.00 x	-0.18 x
EV / EBIT (x)	-11.9 x	-12.7 x	-3.9 x	-20.7 x	-0.2 x
EV / EBITDA (x)	-11.9 x	-12.7 x	-3.9 x	-20.7 x	-0.2 x
DPS ($)	0.00	0.00	0.00	0.00	0.00
Dividend Yield	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Payout Ratio	0.0%	0.0%	0.0%	0.0%	0.0%
Franking	N/A	N/A	N/A	N/A	N/A
FCFPS (¢)	(0.02)	(0.02)	(0.06)	(0.01)	0.21
P/FCFPS	(13.28)	(13.29)	(4.24)	(21.35)	1.13

Cashflow (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Receipts	0.00	0.00	0.65	6.45	39.19
Payment to suppliers	(1.79)	(1.79)	(3.26)	(4.57)	(6.05)
Interest on lease	0.00	0.00	0.00	0.00	0.00
Interest received	0.04	0.04	0.04	0.04	0.04
R&D	0.00	(3.00)	(3.00)	(3.00)	(3.00)
Income Tax	0.00	0.00	0.00	0.00	0.00
Operating cashflow	**(1.75)**	**(4.75)**	**(5.58)**	**(1.08)**	**30.17**
Investing cashflows					
Purchase of intangibles	(0.11)	(0.11)	(0.11)	(0.11)	(0.11)
Purchase of PPE	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
Financing activities					
Proceeds of shares	8.40	0.00	7.00	0.00	0.00
Share issue costs	(0.50)	(0.40)	(0.40)	0.00	0.00
Net cashflow	**5.97**	**(4.93)**	**0.84**	**(1.26)**	**29.99**
Cash at beginning year	0.05	6.02	1.09	1.94	0.68
Cash at 30/06	**6.02**	**1.09**	**1.94**	**0.68**	**30.66**

Revenue Split (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Sales Revenue	0.04	-	0.65	6.45	39.22
Other	-	-	-	-	-
Group Revenue	**0.04**	**-**	**0.65**	**6.45**	**39.22**

Profit and loss (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Operating revenue	0.0	0.0	0.6	6.5	39.2
EBITDA	(1.8)	(1.8)	(5.6)	(1.1)	30.2
D&A	0.0	0.0	0.0	0.0	0.0
EBIT	**(1.8)**	**(1.8)**	**(5.6)**	**(1.1)**	**30.2**
Net interest income	0.0	0.0	0.0	0.0	0.0
NPBT	(1.8)	(1.8)	(5.6)	(1.1)	30.2
Tax Expense (benefit)	0.0	0.0	0.0	0.0	(9.1)
NPAT	**(1.8)**	**(1.8)**	**(5.6)**	**(1.1)**	**21.1**
Significant Items	0.0	0.0	0.0	0.0	0.0
NPAT	**(1.8)**	**(1.8)**	**(5.6)**	**(1.1)**	**21.1**
EBITDA Margin	N/A	N/A	N/A	N/A	76.9%
EBIT Margin	N/A	N/A	N/A	N/A	76.9%
NPAT Margin	N/A	N/A	N/A	N/A	53.8%

Balance sheet (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Bank Balance	3.0	1.1	1.9	0.7	30.7
Receivables	0.3	0.3	0.3	0.3	0.3
Inventories	0.0	0.0	0.0	0.0	0.0
Other	3.00	3.00	3.00	3.00	3.00
Current assets	6.31	4.39	5.23	3.97	33.96
Net PPE	0.0	0.0	0.0	0.0	0.0
Intangibles	0.35	0.35	0.35	0.35	0.35
Right of use assets	0.16	0.16	0.16	0.16	0.16
Non-current assets	**0.56**	**0.56**	**0.56**	**0.56**	**0.56**
Total assets	**6.87**	**4.94**	**5.79**	**4.53**	**34.51**
Payables	0.21	0.21	0.21	0.21	0.21
Lease liabilities	0.17	0.17	0.17	0.17	0.17
Employee benefits	0.00	0.00	0.00	0.00	0.00
Total liabilities	**0.38**	**0.38**	**0.38**	**0.38**	**0.38**
NET ASSETS	**6.49**	**4.56**	**5.40**	**4.14**	**34.13**

Balance Sheet Ratios

Year ending June	2024A	2025E	2026E	2027E	2028E
Net Debt	(3)	(1)	(2)	(1)	(30)
NTA	6.49	4.56	5.40	4.14	34.13
Price / NTA (x)	0.037 x	0.053 x	0.044 x	0.058 x	0.007 x
Return on assets	-26.1%	-36.2%	-97.0%	-24.6%	61.2%
Return on equity	-27.6%	-39.3%	-103.9%	-26.9%	61.9%

Valuation

Year ending June			
Discounted Cash Flow	WACC		15.00%
	Discount Period		6 years
	Price Target	**$**	**1.30**

Investment Risks

Funding risks The Company currently has no operating revenue and it is unlikely that the Company will generate any revenue until the BlinkLab Device is registered with the regulator (respective to the jurisdiction) and commercialised. Depending on the Company's ability to maintain its funds and/or generate revenue from its operations, the Company may require further capital in the future.

Licensing Risk. BB1 has an exclusive worldwide license from Princeton University. Princeton University may terminate the Princeton Licence Agreement if the Company commits a material breach and that breach is not remedied within 30 days after notice to do so is given. If the Princeton Licence Agreement is terminated this would have a significantly adverse effect on the Company and its ability to further develop the product and maintain a listing on the ASX. Refer to Section 9.6 for further details regarding the Princeton Licence Agreement.

Clinical Risks. There is the risk of misdiagnosis and/or a delayed diagnosis of ASD with the BlinkLab Device. Such a misdiagnosis or delayed diagnosis of ASD could occur as a result of a false positive result, a false negative result or in a circumstance where no result is generated. Both a misdiagnosis and delayed diagnosis can result in delayed treatment of ASD, or in the case of a misdiagnosis, the delivery of treatment that is not appropriate for ASD.

Competition. The Company operates in a competitive landscape in the medical diagnostic industry. Such competition may include well-funded and well-established corporations in Australia and worldwide, that have significantly greater resources and capital than the Company. Further, competitors of the Company may use factors such as pricing, quality and innovation to set themselves apart and ahead of the Company.

Regulatory approvals. The Company's business involves product development and commercialisation, which requires regulatory approvals from external bodies in the relevant jurisdictions. These regulatory approvals often involve a length evaluation process and there is no guarantee that the Company will meet the requirements of each regulator. If the Company is unable to meet the requirements of a regulator, the Company may be required to undertake further research, which would result in additional cost and delay to the Company.

Reliance on key personnel. The Company's operations and success will depend to a large extent on the continuing efforts and expertise of its senior and key personnel. The loss of a senior or key member of the Company, may adversely affect the Company and its operations. Further, should the Company be unable to retain and attract highly skilled and appropriately qualified personnel, this may impede the Company's business and the Company achieving its objectives.

Board of Directors

Dr Anton Uvarov – Executive Director

Dr Uvarov has significant experience in the healthcare industry with a particular focus on neuroscience. Dr Uvarov started his career in biotechnology investments as equities analyst with Citigroup. He is a co-founding director of several publicly listed companies in Australia including clinical stage companies such as Dimerix Limited (ASX:DXB), Actinogen Medical Limited (ASX:ACW) and Neuroscientific Biopharmaceuticals Ltd (ASX:NSB). He was previously on the board of Imugene Limited (ASX:IMU), a late-stage clinical oncology company. Dr Uvarov is currently a Non-Executive Director at Neuroscientific Biopharmaceuticals Ltd (ASX:NSB), a clinical stage biotechnology company developing new treatments for neurodegenerative diseases and diseases caused by degeneration of the optic nerve. Dr Uvarov holds a Doctor of Philosophy in Biochemistry and Medical Genetics from the University of Manitoba and a Master of Business Administration in Finance from the University of Calgary, Canada.

Brian Leedman – Non-Executive Director

Mr Brian Leedman is an experienced biotechnology entrepreneur with over 15 years' experience in the biotechnology industry. Mr Leedman is the founder of ResApp Diagnostics Pty Ltd which was acquired by Narhex Life Sciences Limited to then form ResApp Health Limited where Mr Leedman was the Executive Director of corporate affairs. ResApp Health Limited was acquired by Pfizer (Aust) Limited in 2022. Mr Leedman is an experienced public company Director having formerly been the chairman of Neurotech International Ltd, Nutritional Growth Solutions Ltd, Neuroscientific Biopharmaceuticals Ltd and was a Director of Alcidion Corporation Ltd, Oncosil Medical Ltd and Respiri Ltd. Prior to ResApp, Mr Leedman co-founded OncoSil Medical Ltd and Biolife Science (QLD) Limited (to be later renamed to Imugene Limited). Mr Leedman previously served for ten years as vice president, investor relations for pSivida Corp. (PVA), which was listed on the ASX, Frankfurt and NASDAQ. Mr Leedman was formerly the WA chairman of AusBiotech, the association of biotechnology companies in Australia. Mr Leedman holds a Bachelor of Economics and a Master of Business Administration from the University of Western Australia.

Dr. Richard Hopkins – Non-Executive Director

Dr Richard Hopkins is an experienced bio-pharmaceutical executive with over 20 years in corporate leadership roles with public biotechnology companies. He has an established track record in drug development of novel therapies with a particular focus in oncology and medicinal cannabis, corporate strategy and financing, business development and intellectual property. Dr Hopkins recently served as the Managing Director for Zelira Therapeutics Limited (ASX: ZLD), a leading global company focused on clinical validation of medical cannabis. Prior to this, Dr Hopkins served as chief executive officer at PharmAust Limited (ASX: PAA) where he oversaw clinical development of a novel cancer therapy for dogs and humans. He was also co-founder and managing director at Phylogica Limited (ASX: PYC), where, in addition to the Chief Executive Officer role, he served in a variate of positions, including Chief Scientific Officer and Chief Operating Officer where he led a team of over 25 scientists.
During his career, Dr Hopkins has managed and overseen strategic alliances and licensing deals with multiple global pharmaceutical partners including J&J, Pfizer, Roche, Genetech, AstraZeneca/Medimmune, generating significant revenue as well as building and launching strong proprietary pipelines. Dr Hopkins currently serves as Executive Chairman of Supertrans Medical Limited and as Non-Executive Director of Rex Ortho Pty Ltd, a medical device company developing a novel screw for surgical fixation. Dr Hopkins is an author of over 30 peer-reviewed publications and is an investor on 15 patents and patent applications.

Jane Morgan – Non-Executive Director

Over the past 16 years, Jane has provided investor and media relations, marketing and advisory services to both ASX listed and public unlisted companies across the mining and resources, technology, financial technology, wagering, biotechnology, SaaS, industrial and services industries. Jane has an exceptionally strong network of brokers, investors, high net worths, media contacts and industry professionals, which she leverages to deliver significant value to Jane Morgan Management Pty Ltd ("JMM") clients. She holds a degree in Commerce / Law with a strong interest in financial markets, corporate transactions and investments, and has developed a unique skill set to provide high level investor relations, strategic advice and corporate governance advisory to clients.

Executive Team

Dr Hendrikus Johannes Boele – CEO

Dr. Hendrikus Johannes Boele is an assistant professor at the Department of Neuroscience at Erasmus University Medical Centre, a visiting researcher at Princeton Neuroscience Institute, and the CEO of the Company. Dr Boele obtained his PhD (cum laude) in 2014 at the Department of Neuroscience, Erasmus University Medical Centre. His PhD research was focusing on the neural mechanisms underlying associative and motor learning. After he obtained his Medical Degree at Erasmus Medical Centre in 2018, he started his postdoctoral fellowship at Princeton University in the laboratory of Samuel S.-H. Wang, where he was working on brain development and autism.

Dr Boele has always been pushing scientific and methodological boundaries, which were awarded over the last five years with over US$3.5 million in funding from institutes (Princeton University, Erasmus MC), the Dutch Research Council, the European Research Counsel, the New Jersey Autism Center for Excellence and prestigious Vidi grant (received in May 2023). Together with his colleague S.K.E. Koekkoek, he has drastically improved the experimental procedures for eyeblink conditioning.
In 2018, Dr Boele together with other co-founders of the Company, completed development of the first version of the neurometric testing smart phone-based application. In 2020 the medical application was awarded funding from Princeton Accelerator fund and successfully completed first pilot study in humans. As the initiator and founder of BlinkLab, it is Dr Boele's strong ambition to bridge the gap between fundamental knowledge of neural processes and clinical application, with a utility that could effectively enhance diagnostics in patients with neurodevelopmental and neuropsychiatric disorders.

Cornelis Pieter Boele – CTO

Mr Cornelis Pieter Boele is an alumnus of Leiden University where he received bachelor degrees in both history and philosophy, and a master's degree in history. Mr Boele was also selected to participate in the Honours Class Crayenborgh College in 2009, a lecture series for high-performing students. Mr Boele has over two (2) decades experience in software development. He wrote his first lines of code when he was as young as 16 and started his professional career as a software developer at large organisations like Erasmus University and Leaseweb. In 2017, Mr Boele moved to the start-up scene and served as Chief Technology Officer at two (2) successful tech start-ups, Kaboom Informatics BV and Insocial BV. At the latter, Mr Boele successfully introduced multiple new products, including Natural Language Processing (NLP) as a service and managed chatbots. Under his supervision the development department has grown by 500% within two (2) years.

Dr Sebastiaan K.E. Koekkoek – Chief Scientific Officer

Dr Sebastian (Bas) Koekkoek received his bachelor's degree in medicine at Erasmus MC in Rotterdam. He obtained his PhD at the department of Neuroscience (Erasmus MC) in 2004 with his thesis 'Molecular mechanisms underlying associative learning'. Since then, Dr Koekkoek has been working at the Department of Neuroscience mainly in the role of rapid prototype of new technology and techniques for neuroscience. Many of the neuroscientific technologies currently used at Erasmus MC has sprouted from his work and have been successfully commercialised. For example, ErasmusLadder is a successful product, best described as a fully automated cerebella phenotyper for mice. The first systems were designed, built and coded by Dr Koekkoek and currently systems are marketed, produced and sold under license by an external company.

More than 40 units are operational in laboratories and companies everywhere in the world. Dr Koekkoek previously was a head of product development at Neurasmus BV that was developing, selling and maintaining turn-key eyeblink systems to research and commercial labs in the European Union and United States. Many of the underlying principles and knowledge generated in developing custom eyeblink solutions are now forming the basis of BlinkLab technology. Scientifically the interests of Dr Koekkoek are on the interplay between neuronal pathology and the effects on behaviour. In addition, Dr Koekkoek has a large interest in new technology and how it could be used to measure behaviour.

Christopher Achurch – Company Secretary

Mr Achurch has considerable experience across the exploration, mining, agricultural, accounting and finance sectors. He holds a Bachelor of Commerce in Accounting from the University of Western Australia and is a member of the Institute of Chartered Accountants Australia and New Zealand. Mr Achurch provides company secretarial, corporate advisory and general consulting services to a number of ASX-listed Companies.

Rating

BUY – anticipated stock return is greater than 10%
SELL – anticipated stock return is less than -10%
HOLD - anticipated stock return is between -10% and +10%
SPECULATIVE BUY – high risk stock with price likely to fluctuate by 50% or more and anticipated return is greater than 10%

Disclaimer

In accordance with section 949A of the Corporations Act 2001, any recipient of the information contained in this document should note that information is general advice in respect of a financial product and not personal advice. Accordingly the recipient should note that: (a) the advice has been prepared without taking into account the recipient's objectives, financial situations or needs; and (b) because of that, the recipient should, before acting on the advice consider the appropriateness of the advice, having regard to the recipient's objectives, financial situation and needs.

Although Lodge Partners Pty Ltd ("Lodge") consider the advice and information contained in the document is accurate and reliable, Lodge has not independently verified information contained in the document which is derived from publicly available sources. Lodge assumes no responsibility for updating any advice or recommendation contained in this document or for correcting any error or admission which may become apparent after the document has been issued. Lodge does not give any warranty as to the accuracy, reliability or completeness of advice or information which is contained in this document. Except in so far as liability under any statute cannot be excluded, Lodge, its employees and consultants do not accept any liability (whether arising in contract, in tort or negligence or otherwise) for any error or omission in this document or for any resulting loss or damage (whether direct, indirect, consequential or otherwise) suffered by the recipient of this document or any other person.

General Securities Advice Warning

This report is intended to provide general securities advice. In preparing this advice, Lodge did not take into account the investment objectives, the financial situation and particular needs of any particular person. Before making an investment decision on the basis of this advice, you need to consider, with or without the assistance of a securities adviser, whether the advice is appropriate in light of your particular investment needs, objectives and financial circumstances.

Disclosure of Interests

Lodge directors, consultants and advisers currently hold less than 1% of total shares in the Company and may buy or sell the shares from time to time. Lodge has earned and will continue to earn broking commissions by acting for individual clients that are buying or selling their shares in company.

The Company currently is, or in the past 12 months was, a client of Lodge Partner's affiliated company and authorised representative Lodge Corporate Pty Ltd. During this period, Lodge Corporate provided corporate services to the company. In the past 12 months, Lodge Corporate have received compensation for corporate services from the company. Part of this was commissioned research which includes this research note. Lodge Corporate intends to seek or expect to receive compensation for Investment Banking services from the Company in the next twelve months.

Analyst Verification

I verify that I, Sven Restel, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions.

Contact Lodge Partners

Lodge Partners Pty Ltd
ABN: 25 053 432 769 AFSL: 246271

Melbourne office:
Level 40, 80 Collins Street, Melbourne VIC 3000
T +61 3 9200 7000
lodgepartners.com.au

Sydney office:
Suite 1002, Level 10, 46 Market Street
Sydney, NSW, 2000
T +61 2 9225 4433