Outstanding USA Pilot results set the path for 2026 FDA Clearance

Healthcare

We update BB1 with a revised Target Share Price of $2.38, **representing a 263% upside potential from the current share price of $0.655 and a 37% increase from our Target Share Price** in our initiation report from February this year. Since February, BB1 has executed on its strategy as it said it would and as we expected, successfully completing a robust USA Pilot Study, focused on autism diagnosis, spanning 485 participants and **achieving strong diagnostic rates of accuracy at levels much higher than what the FDA has advised that BB1 will need to showcase in the upcoming FDA Pivotal Study.** As a result, there is a material risk reduction to BB1's prospects, leading to a justifiable upward valuation rerate. Pilot Study was purposefully designed to stress test BB1's technology under very challenging conditions, and BB1 was more than up to the challenge. Learnings from the Pilot were discussed with the FDA and have led to the FDA approving BB1's proposed study design for the upcoming 2026 FDA study, including a reduction in the study size from 1000 to 528 participants.

BB1 outperforms FDA standards in highly challenging autism Pilot Study

The Pilot's characteristics were designed to be intentionally challenging to create the ultimate stress test for BB1's AI-driven diagnostic tech for autism. The population set contained many diagnostic challenges, such as many children having mild-threshold cases of autism and children who had co-occurring conditions, sometimes overlapping with autism, such as ADHD and other related disorders. Such a population set is exactly the type in which accurately diagnosing autism is the hardest, even for expert clinicians. Despite these challenges that stretched BB1's technology, BB1 did exceptionally well, achieving an 83.7% Sensitivity and 84.7% Specificity, which are both well above the FDA's guided minimum threshold of greater than 65% Sensitivity and Specificity that is needed to meet regulatory clearance. BB1 well exceeded not only that benchmark but also what its two main USA competitors, who already have FDA clearance, achieved in their respective FDA Pivotal studies.

A platform beyond autism – expanding into ADHD, Dementia and beyond

We endorse BB1's management's vision to go beyond just autism and become an innovative platform play that uniquely brings together neuroscience, AI, and smartphone technology to accurately and earlier diagnose a range of neurodevelopmental and neurological conditions that affect millions of children worldwide. BB1 is currently successfully progressing multiple clinical studies with tier 1 partners aimed at expanding its technology's reach beyond paediatric autism into adult autism and conditions such as ADHD (main near-term focus) and subsequently also dementia and Alzheimer's.

Valuation range of A$2.14-$2.62 per share

Our updated valuation justifiably rewards BB1 for its strong USA Pilot Study results that lead us to increase the probability-based expected value of the autism revenue streams that BB1 can capture in the USA due to the now materially lower risk of not achieving FDA clearance. Underpinning our valuation are several other conservative assumptions that add confidence to our bullish investment thesis.

BB1 Valuation (A$m)	Base case	Bull case
Total Equity Value	**340**	**416**
Assumed shares o/s (> basic shares o/s) m	159	159
Implied price (A$)	**2.14**	**2.62**
Current price (A$)	0.655	0.655
Mid-point Target Price (A$)	**2.38**	
Upside (%)	*263%*	

Date	3 Nov 2025
Share Price (A$)	0.655
Target Price (A$)	2.14-2.62
Price / NAV (x)	0.28x
Market Cap (A$m)	82.8
52-week L/H (A$)	0.23/0.78
Free Float (%)	57.9%
Bloomberg	BB1.AU
Reuters	BB1.AX

Price Performance (in A$)

Business description

BlinkLab (ASX: BB1), listed on the ASX in April 2024 founded by Princeton University neuroscientists, has developed a smartphone-based diagnostic platform for neuropsychiatric conditions like autism, ADHD, and dementia. Its flagship product is an AI-driven autism diagnostic test for children aged 2-11 years, enabling earlier and more accurate detection than traditional methods.

Analyst

Rahul Tiwari

rahul.tiwari@sharesinvalue.com.au

Table of Contents

Pilot Study performs strongly as expected, setting the stage for 2026 FDA approval

In announcing the results of its recently completed USA based Autism Spectrum Disorder (ASD) Pilot Study, BB1's Management Team successfully executed on their earlier advice to the market and confirmed our earlier hypothesis, which is that BB1's innovative AI augmented smartphone based diagnostic app (Dx 1) not only works, but works very well to accurately diagnose a challenging neurodevelopmental disorder(ASD) in challenging real world settings. **Consequently, BB1 takes one large stride towards achieving FDA clearance for Dx 1.**

BB1's achieved diagnostic performance metrics easily exceed the FDA's guidance on what BB1 needs to achieve in the upcoming 2026 FDA Pivotal Study in order to qualify for FDA 510(k) clearance (FDA needs > 65% Sensitivity and Specificity).

In around just 7 months since the first child was tested in March of this year, BB1's autism focussed Pilot Study (conducted in collaboration with PriMED Clinical Research and NorthShore Pediatric Therapy -both US-based clinical research and multidisciplinary paediatric therapy and diagnostic centres) tested 485 children (sample size large enough for statistical significance) for autism and achieved strong results. Across the 485 children, the study delivered 83.7 % Sensitivity and 84.7 % Specificity; these performance metrics well exceed the FDA's guidance on what BB1 needs to achieve in the upcoming 2026 FDA Pivotal Study in order to qualify for FDA 510(k) clearance (FDA needs > 65% Sensitivity and Specificity). Additionally, BB1's Pilot Study results again showcase BB1's ability to outperform the existing, already FDA-cleared diagnostic offerings of its two main competitors, Cognoa (reported 59% Sensitivity and 19% Specificity in its FDA Pivotal Trial in overall population) and EarliPoint (achieved 71% Sensitivity and 81% Specificity in its trial).

It is important to note here that autism diagnosis is not a perfectly objective "gold standard." Even among leading clinicians using ADOS, ADI-R, or DSM-5 criteria, **inter-rater agreement typically ranges between 85–90%**. In other words, the ceiling for any diagnostic method, whether human or AI, is inherently defined by the variability of expert judgment itself.

Because autism is behaviourally defined rather than biologically measured, clinical outcomes depend on observation, interpretation, and developmental timing. This variability is especially pronounced in milder or subthreshold cases, where symptoms overlap with other developmental conditions.

Blinklab **U.S. Pilot Study deliberately included this real-world complexity**, enrolling children across the full spectrum, including those receiving a first diagnosis at age 10 or 11, who by definition are not severely affected. Achieving **83.7% sensitivity and 84.7% specificity** in such a heterogeneous population is therefore a **remarkable outcome**, essentially reaching the **upper limit of diagnostic reliability** seen even among experienced clinicians.

In practice, this means Blinklab model is already performing at the ceiling of what is achievable in real-world testing, matching the natural accuracy boundaries of expert consensus itself (see more explanation below).

Figure 1 below shows how BB1's diagnostic accuracy has improved over time across different studies and how its accuracy rates are notably higher than what its 2 key USA-based competitors achieved in their respective FDA Pivotal trials (** Cognoa's device provided indeterminate results in 68% of cases). Although the rates of Sensitivity and Specificity that BB1 achieved in its just concluded USA Pilot study are, in aggregate, slightly lower than what it achieved in an earlier test, as discussed in more detail in a latter section, there were a number of factors leading to the USA Pilot being particularly more challenging **(BB1 still did very well).** For instance, the USA Pilot Study vs the earlier Moroccan studies had more cases of subtle /milder cases of ASD in which a portion of the positive diagnosis itself is subjective and open to clinical debate, in addition to more cases of patients whose symptoms also overlap with other conditions (mild indicators for ASD). If this factor is controlled for, BB1 achieves an 89% (better than what it achieved in the Moroccan study) rate of Specificity across the more pronounced

cases of ASD (level 2 and level 3; level 1 cases are the most benign). **These sequential improvements in results do not surprise us at all. We expect even more improvements to come, because as noted in our Initiating Coverage report, a key outstanding aspect of BB1's AI and data-driven business model is that the more tests that BB1's app does and the more biomarker data it analyses, the better it can fine tune its diagnostic algorithms leading to better and better accuracy over time.**

Figure 1: BB1's diagnostic outperformance

	blinklab				cognoa	ETD
	Original Morroccan Study	**Extended Moroccan Study with Princeton Uni**	**USA Pilot Study***	**USA Pilot (level 2/3 cases)**	**Pivotal Study**	**Pivotal Study**
Sensitivity	85%	**91%**	84%		52%**	71%
Specificity	84%	**85%**	85%	**89%**	19%**	81%

Sources: East Coast Research, Company

Consequently, given these results which are built upon earlier successes across other clinical studies and trials, we are now even more confident that BB1 will receive FDA clearance for its autism focussed diagnostic offering (DX 1), with official clearance expected sometime in the second half of 2026, allowing BB1 to enter into what will likely be a significant revenue ramp in the years 2027 and beyond (as per our prior projections).

Apart from just the valuation uplift to BB1's share price associated with the FDA regulatory clearance risk reduction benefit achieved with the Pilot's results, which allows us to assign a greater probability to the autism associated revenue streams that BB1 can tap into in the US (which are also a function of our conservative USA ASD diagnostics market size and BB1's market share assumptions), there are also other cost and time related benefits associated with BB1's Pilot Study results and recent negotiations with the FDA that investors need to be aware of.

Just prior to the official unblinding of the Pilot Study's results, BB1 held its second formal meeting with the FDA. The meeting was again successful, with the FDA approving BB1's proposition of some changes to the Pivotal 510(k) Study protocol based on learnings from the Pilot Study – these are discussed more in a later section, with the important point to keep in mind that the issue of clinical subjectivity associated with clinician evaluation (a factor present in the Pilot study) will be managed better in the main Pivotal Study which ultimately will only further improve Dx 1's diagnostic accuracy, as explained later. Also, importantly, the FDA approved BB1's revamped recruitment strategy for the main FDA Pivotal Study. Now, children will be recruited for testing from autism specialty centres **and** community-based referral sources, leading to not only a likely benefit to the diagnostic results Dx 1 achieves but also the associated ability to reduce the planned FDA Pivotal Study size from 1,000 to 528 participants (the planned, more balanced clinical population set for the FDA Pivotal study means that a smaller study size would suffice).

Hence, in a nutshell, investors should note that consequent to these Pilot Study results, the factors benefiting BB1 include:

- **a robust intrinsic valuation uplift** ($2.38 from the earlier $1.74) justified due to the now significantly lower risk of not receiving FDA clearance for Dx 1 post the positive results of the Pilot Study
    - **We have assessed this risk as now being only approximately 10%, but have conservatively used a higher 20% risk factor for our updated valuation.**

- lower future expected costs and timeline duration for the upcoming FDA Pivotal study for Dx 1.

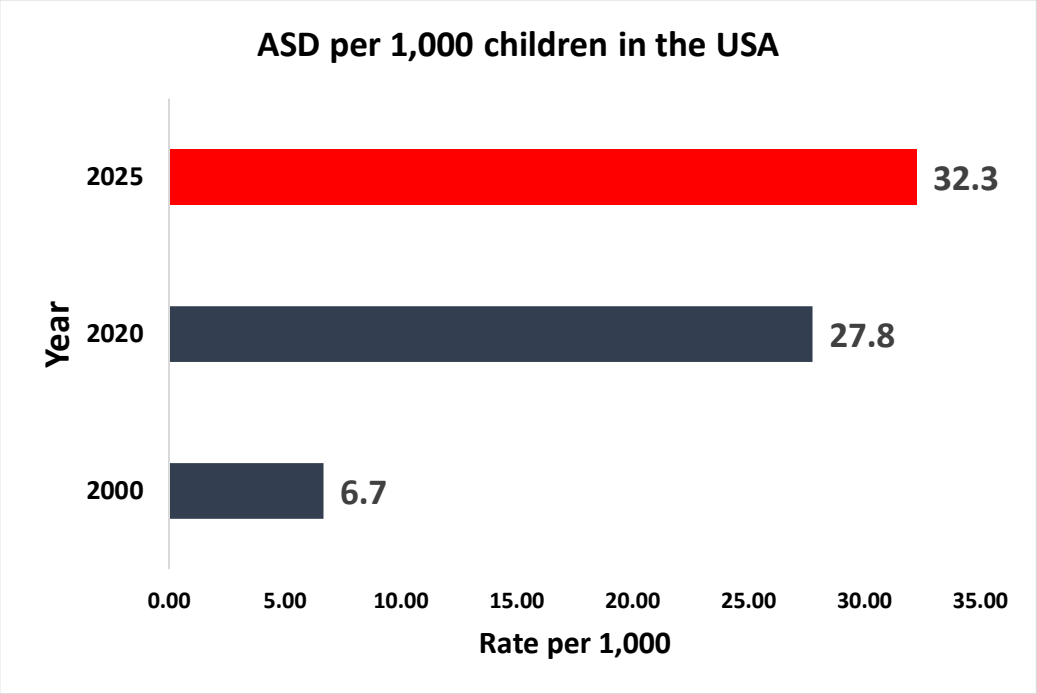
BB1's technology has been proven to help solve a growing healthcare problem.

At the time of our initial valuation and market sizing associated with our Initiating Coverage report from February, CDC estimated the USA's autism burden rate as being 1 in 36; in April of this year this metric was again revised up to 1 in 31 children based on the latest findings.

It's also important to remind ourselves about a key point that we emphasised in our Initiating Coverage note from February of this year, which is that BB1's innovative, AI powered technology using just the features of a modern smartphone and by way of its unmatched diagnostic accuracy (vs competitors and other modes of diagnosis) can help to solve a **leading and growing** healthcare problem associated with the delayed diagnosis and treatment of autism. For example, at the time of our initial valuation and market sizing associated with our Initiating Coverage report from February, CDC estimated the USA's autism burden rate as being 1 in 36 children; in April of this year, this metric was again revised up to 1 in 31 children based on the latest findings.

Figure 2 below shows the increasing progression of ASD diagnosis rates per 1,000 children in the USA. The important takeaway here is that not only is the problem associated with ASD in the USA significant, but that it is **growing in severity and that BB1's innovative technology, which has now across many different clinical trials and studies including a robust and challenging US Pilot proven its abilities to diagnose ASD materially more accurately and at earlier ages vs current conventional clinical practices and competitors via the convenience and speed of just a smartphone application.** Additionally, investors would remember from our earlier Initiating Coverage report that our market sizing and associated market share assumptions for BB1's ASD focussed DX 1 app included a number of layers of conservativeness**. Now, as per the latest CDC figures, our original US-based market sizing estimates in terms of the number of children affected by ASD that provide BB1 its target market size itself are understated by ~16%** (new 1/31 ASD rate vs original 1/36). In line with our overall conservative approach, we have kept the original assumptions and other conservative factors that are outlined again later in the valuation section.

Figure 2: Growing cases of autism disorder in the USA



Sources: East Coast Research, CDC

US Pilot Study was particularly challenging, and even then, BB1's app performed strongly.

BB1 was only listed on the ASX a little over 12 months ago; hence, for it to be able to, in this short time, already come so close to FDA clearance due to the results that its technology achieved in the USA Pilot Study is reflective of a significant corporate achievement.

The USA Pilot Study's design was created to intentionally stress test BB1's technology and BB1 still performed very well and passed.

Making the results more remarkable is the fact that BB1's U.S. Pilot Study was purposefully designed as a "real-world stress test", a rigorous trial structure meant to challenge the Dx 1 diagnostic platform under conditions that not just closely mirror everyday paediatric clinical practice (rather than resembling more controlled lab settings) but **also include other intentional challenges**. Whereas BB1's earlier Moroccan feasibility study (441 children) involved clearer, more profound autism cases (Level 2–3), the U.S. pilot introduced greater diagnostic ambiguity, environmental variability, and sample heterogeneity — all of which made accurate classification far more complex, leading to BB1's Dx 1 achieving slightly lower rates of Sensitivity and Specificity in the Pilot than vs what it achieved in the prior Moroccan study (but still at levels far above its two key competitors who have already received FDA clearance and well above FDA's guidance for what it expects from Dx 1 in the upcoming Pivotal study in order to be granted FDA clearance).

The Pilot's 485 children were composed of children exhibiting a wide clinical spectrum, other than just autism. Participants included children with ADHD, global developmental delay, speech and language disorders, learning disorders (dyslexia, dysgraphia), anxiety, coordination disorders, and intellectual disability. This clinical heterogeneity closely reflects real-world paediatric referrals, where symptoms overlap and boundaries between conditions blur.

Additionally, many participants had mild or threshold autism traits (Level 1), which are the hardest to detect even for expert clinicians. Hence, both these factors – the increased heterogeneity and the presence of milder cases vs the earlier Moroccan study led to predictable slightly lower rates of Sensitivity and Specificity that BB1 achieved in the Pilot vs what was achieved in the earlier Moroccan study.

For instance, more milder cases of autism in the population set will predictably lead to any detection test exhibiting lower Sensitivity rates (more false negatives), whilst related to this phenomenon increased heterogeneity will lead to subtly lower rates of Specificity (more false positives, because BB1's test is classifying children as having autism when they may have quite a mild form of ASD that also coincides with one or more other neurodevelopmental disorders). The actual fall in Specificity rate (Clinicians prioritise Specificity over Sensitivity, whilst Sensitivity is prioritised in broad first point of call mass screening tools) between the extended Moroccan study and the Pilot Study was negligible – only 0.3%. **Blinklab's CEO Henk-Jan Boele explicitly noted that Specificity rose to ~89% in Level 2–3 (more clear-cut) autism cases, indicating that Dx 1's diagnostic model is very accurate in well-defined ASD diagnostic cases.**

Investors should indeed draw assurance from the fact that despite the Pilot's testing conditions being more demanding and hence pushing the limits of BB1's technology more than the earlier feasibility study in Morocco, BB1's Dx1 in the end passed the test and passed it quite comfortably, establishing BB1's technology's resilience, real world feasibility and strong likelihood for eventual at scale consumer use.

Although it can be argued that these are exactly the types of challenging clinical circumstances that BB1 has to eventually perform in, as outlined below, there were other specific factors that reasonably made the Pilot's testing conditions especially more challenging. These include:

- Over 90% of the Pilot's data was collected in home environments rather than in clinical settings. This created multiple operational and technical challenges due to variability in lighting, background noise, and phone position, which affected the video and audio signal quality. Additionally, children's attention, movement, and comfort levels were less controllable. Although possessing the ability to be used in a home environment context is one of the key competitive advantages BB1's technology has, home usage vs usage in supervised clinical settings has its unique challenges that affect the quality of test results. In time, additional guidance will be introduced for home usage that minimises these issues.

- In line with the general USA population, the Pilot Test sample was demographically balanced across sex and race. However, the age range was comprised of kids that are generally older than the range that BB1's technology aims to provide for the earlier detection of autism (2-3 years of age) vs the current norm, where ASD is typically diagnosed at 5 years of age. Children diagnosed at older ages tend to show less severe ASD symptoms, complicating classification and accurate diagnosis by any mode (delayed diagnosis also leads to less favourable treatment outcomes).

However, since there is a clear economic case for autism being diagnosed at earlier ages **(ideally during their recommended "well child" visits (18-24 months)**, so that pre-emptive treatment can minimise future health care costs to the patient, their families and the wider health care system, the eventual practical use of BB1's Dx 1 is likely to occur at earlier ages than the average case of the Pilot Study because this is when ASD cases are better defined, helping to increase Dx 1's diagnostic accuracy.

Consequently, it's no surprise that BB1's competition mostly focuses on very young, more profound cases of ASD. Although that's when ASD diagnosis has the most benefit, BB1 intentionally did not do this in the USA Pilot in order to really stress test its technology. Additionally, as explained in later sections, BB1 is currently actively working towards, via further studies, enhancing its app's already proven abilities to diagnose later-stage ASD, particularly in adults. Complimenting this is the fact that the inherent AI and data-driven learning model that BB1's technology uses only gets better with the more diagnostic challenges that it encounters (and as seen above in **Figure 1**, BB1's sequential performance improvement is supported by the results).

Additionally, in assessing BB1's technology's performance in the Pilot, it is important to note that the reported accuracy rates are relative to the clinical assessment of expert clinical practitioners **(although they are experts, there still exists a subjective human element).** Because many of the children had ambiguous diagnostic profiles, being at the borderline of other disorders and or having mild autism, the actual clinical standard assessment itself is subject to noisy interpretation errors that can lower both Sensitivity and Specificity. For instance, a clinician may assess a borderline/ambiguous child as being autistic, yet the Dx 1 does not detect the symptoms, leading to a false negative (hence a lower rate of Sensitivity) as per the reference to the clinician's interpretation. Similarly, on the flip side, BB1's Dx 1 may assess a borderline/ambiguous child as having ASD, whereas the clinician does not, leading to a false positive and hence a lower rate of Specificity. As a result, whether BB1 was wrong or whether the clinical assessment against which BB1's app is benchmarked is wrong cannot be known for sure in these highly subjective cases. Although Dx 1's performance was still very strong, BB1 has prudently agreed on a new study protocol for its upcoming FDA 510(k) Pivotal Study that will necessitate the presence of a minimum of two clinicians who need to both agree on the final clinical evaluation. This will reduce the issue of subjective clinical judgement in borderline/ambiguous (borderline of multiple disorders with mild indications or a mild form of just ASD) cases, which was present in the Pilot Study (based on the judgement of a single clinician).

The FDA's approval of BB1's updated recruitment strategy for its upcoming main Pivotal Study will also lead to a more balanced sample set of ASD and non ASD cases, because the patients will be sourced from many sites and not just from two as was the case in the Pilot and because the sourcing is planned to be from both autism specialty centers and community-based referral sources which will help in achieving a clinically balanced sample (also a reason for why the FDA agreed to a reduced FDA Pivotal study size).

Why BB1's diagnostic performance will become even better with time

BB1's adaptive data and AI driven business model means that its diagnostic algorithms become even better the more tests that they do.

BB1's learnings and insights from the U.S. Pilot Study have also revealed new digital biomarkers tied to restrictive and repetitive behaviours (RRB), such as recurring movements and vocal patterns—core diagnostic features under the DSM-5 framework. BlinkLab plans to integrate these quantitative RRB markers into an optimised Dx 1 algorithm ahead of its upcoming Pivotal FDA 510(k) study. The company is developing proprietary methods to measure not only frequency but also the similarity and timing of these behaviours over each two 15-minute smartphone session. Management expects the inclusion of these markers to materially enhance diagnostic accuracy, model resilience, and clinical interpretability. **One of these new markers – focusing on vocal responses - has already been incorporated in BB1's Dx 1 model, but more will be released soon to push the accuracy even further. From an investment standpoint, these refinements deepen BlinkLab's data moat and strengthen its differentiation vs its main competitors in the USA.**

Investors should note that the continuous refinement of BB1's diagnostic algorithms is an integral part of BB1's AI and data-driven business model. The more tests that BB1 does for ASD (and also other neurodevelopmental disorders), the more it is able to identify causal, statistically significant biomarker data that later versions of its algorithm then encompass allowing its diagnostic accuracy to become better and better over time– and as shown above in **Figure 1** this can be seen in the BB1's improving chronological diagnostic performance data.

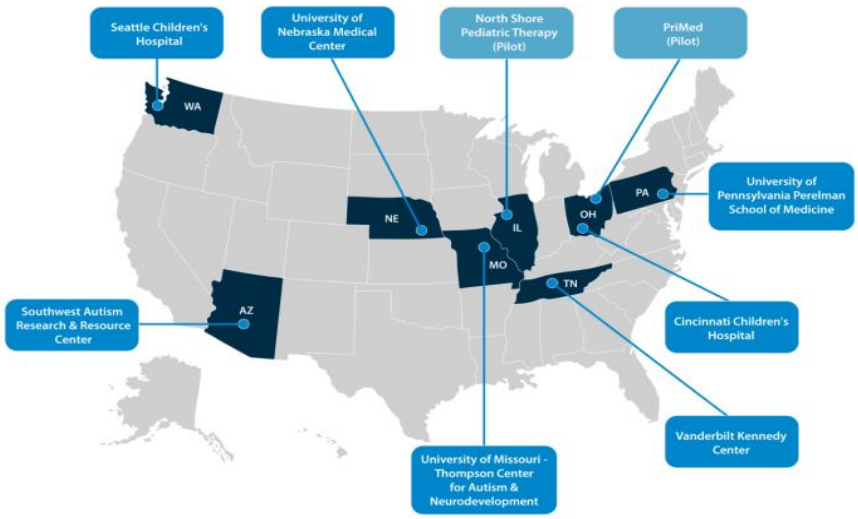
Plans in place for 2026 FDA regulatory approval

Blinklab has already partnered and onboarded 7 other tier 1 reputed clinical centres for the main study Phase of its FDA 510 (k) study, as shown below in **Figure 3**. These institutions are associated with some of the world's most influential key opinion leaders in autism research; hence, partnering with them and receiving their endorsement after what we foresee to be a successful FDA Pivotal Study outcome in 2026, given all the other positive results achieved thus far, will also significantly help BB1's clinical adoption, market penetration strategy and overall commercialisation initiatives.

Furthermore, the onboarding of 7 clinical centres ensures that Blinklab is standardising clinical conditions, because the centres are drawn from both specialty development centres (providing high diagnostic-fidelity ASD cases) and community-based referral sources (reflecting the broader general population). This will likely result in more clinical balance in the Pivotal Study than in the recently concluded Pilot, in which patients were sourced from just 2 centres, in terms of a lesser overrepresentation of either severe or mild ASD cases. Consequently, given this increased balance in the source population for the planned Pivotal Study, BB1's already strong performance in the stress test of the Pilot Study and its plans to further fine tune Dx 1 post the learnings from the Pilot all lead to our conviction that BB1 will successfully achieve FDA regulatory clearance for its autism focussed Dx 1 in 2H 2026 **(FDA Pivotal Study expected to commence in January 2026 and conclude around July 2026).**

BB1's successful May 2025 equity capital raise of $7.66M (before costs) also helps ensure that BB1 is well capitalised for at least the next several months as it commences and then progresses to the final stages of its FDA 510(k) Pivotal Study.

Figure 3: BB1's clinical partnerships for the Pilot and planned Pivotal study



Sources: Company

Management's vision and BB1's adaptive growth-oriented business model

BB1's outperformance in terms of achieving such strong clinical-grade performance from such complex, naturalistic data is a major technological milestone that very few teams globally have achieved across other disease diagnosis.

As shown above in **Figure 1**, BB1's ASD diagnostic outperformance is clearly ahead of its two main USA-based rivals, Cognoa and EarliPoint, who both already possess FDA clearance. However, as we explained in our Initiating Coverage note, BB1's offering is placed in a competitively stronger position that adds to its relatively higher chance of being subject to a rapid market adoption scale-up than vs either Cognoa or EarliPoint. BB1's tool is associated with the convenience of being able to be used quickly (two 15-minute tests) via the convenience of just a smartphone and with the ability to be used outside of clinical settings. Whereas EarliPoint's offering requires the use of a few pieces of cumbersome hardware and, hence, necessitates visiting a specialist clinic. Cognoa's offering, although also utilising a smartphone, is afflicted with overall low detection rates due to its ability to deliver results in only 32% of cases tested.

Furthermore, BB1 also strongly outperforms one of the current main screening tools for autism used in the USA, the M-CHAT/F. M-CHAT/F screening is afflicted with a very high rate of false negatives, with a sensitivity rate of only around 39%, meaning that most children diagnosed with autism in their later years initially screened negatively by M-CHAT. The test is also much harder to administer than BB1's test, and furthermore, it's a screening tool and not a highly accurate diagnostic tool, which is what BB1's Dx 1 is.

BB1's algorithm achieves this outperformance by accurately interpreting subtle, dynamic patterns in spontaneous and stimulus-evoked facial responses, vocalisation patterns, and postural responses captured through just an ordinary smartphone camera and microphone. Achieving clinical-grade performance from such complex, naturalistic data is a major technological milestone that very few teams globally have achieved across other disease diagnoses, and not just with ASD diagnosis.

Consequently, it's much more likely that BB1's Dx1 will be subject to a rapid rate of market adoption and eventual steady state market share than its main two competitors, making the assumptions underpinning our valuation of BB1's Dx1 achieving a maximum 15% steady state market share after a 3-year ramp commencing in 2027 to be very reasonable and even conservative. Additionally, as noted before, BB1's AI-based business model means that its diagnostic algorithms improve over time as its proprietary database of biomarker data grows. In this regard, BB1's business model is more adaptive than its main competitors, who have not shown signs of being as responsive, creating the prospects of further performance gaps between BB1 and its US-based competition over time.

BB1's ability to more effectively utilise new biomarker data is seen not only practically in how it has responded to the stress test of the recently concluded Pilot Study to even further strengthen its already high performance, but it is also seen in the impressive, overarching, broader, longer-term vision that BB1's Management Team have for the commercial utility of its technology. **As recently noted by BB1 Chairman, Brian Leedman, BB1 is not just building an ASD focussed diagnostic product, BB1 is building a broader neurodevelopmental and neurological disease diagnosis platform that brings together neuroscience, AI, and smartphone technology to objectively measure behaviour and cognition for not just autism, but also for other conditions such as ADHD, Alzheimer's, Dementia and other disorders with trials ongoing.**

As noted by Brian, behind this vision is BB1's developers writing thousands of lines of code, its engineers refining every camera and signal-processing feature, and a clinical team dedicating months to data collection, annotation, and analysis. BB1's Management Team envisages BB1's offering to extend beyond just a diagnostic app and to become a clinically validated, AI-driven ecosystem ready to transform how the brain and behaviour are assessed.

Consequently, BB1's well-credentialed Management Team wants investors to view BB1 as benefiting from other sources of future revenue streams apart from just autism, meaning that they want the company to be viewed beyond a single product story. Given BB1's past achievements and current in-progress clinical studies and trials conducted in partnership with tier 1 global research partners, we think that this is a strong likelihood outcome for BB1's future revenue streams. This is especially the case for its ADHD offering, whose development, BB1, is currently progressing well, but could also include other neurodevelopmental disorders that BB1 is also currently developing in parallel, by way of currently active clinical studies, such as for developing an Alzheimer's and Dementia diagnostic offering.

As discussed more in the Valuation section, BB1 appears to be ready for a 2028 ADHD launch (Dx 2 platform) in the USA, given its current progress. We have also reflected this into our financial projections for BB1, but have done so conservatively by purposefully limiting the ADHD diagnostic market size in the US to be less than ASD's despite the former being much larger than the latter and, as explained more in our Valuation section, we have also limited BB1's assumed steady state market share, and furthermore have applied a large risk based reduction to forecasted revenues. Investors should note that the 2028 timeline for the USA based ADHD revenue ramp is reasonable based on current progress and is also arguably conservative based on the assumption of BB1 needing to pursue a De Novo FDA clearance for Dx 2; it could well be that Dx 2 is eventually approved under a 510 (k) FDA process which is generally less time and cost intensive.

In terms of EU-based revenues. Both our original financial valuation from the Initiating Coverage note and the updated one in this note deliberately do not take into account the significant market opportunity for both the ASD and ADHD offering that BB1 can readily address in the EU, based on its current commercial progress in the EU market and its strategic partnerships there. For example, in terms of the ASD focussed Dx 1, BB1 is already in mature discussions with the authorities associated with CE Mark certification in the EU, with the plan to use the positive results from BB1's recently concluded US Pilot Study as part of the final approval submission for CE Mark certification in the EU. This is a well-crafted plan because the EU accepts robust clinical study data in the course of its regulatory assessment, irrespective of whether the relevant study occurred in the EU or not. BB1 expects to receive CE Mark Certification sometime in 2H 2026, with a good possibility of BB1 commencing its EU-based revenue ramp for Dx 1 in the EU by the middle of 2027, an upside that we have completely not accounted for in our valuation.

Aside from EU-based revenues for ASD, given BB1's current progress and milestones, there is also the strong likelihood that BB1 actually achieves ADHD revenues first in the EU sometime in 2027, which is earlier than our conservatively defined expectation of the USA-based revenue ramp commencing in 2028 for ADHD focussed Dx 2. In line with its stated strategy, BB1 expanded its ADHD clinical study program in the EU from 1 to 5 clinical sites, with interim results from 300 participants due by the end of the year. Given the clinical studies current underway and the fact that BB1's AUD $7.66 M placement from May this year expressly noted the intended use of funds as including activities associated with product development other than just for Dx1, as shown below, we are confident that BB1's revenue streams will eventually span multiple product categories; May's placement discussed uses of funds that included work for:

- Supporting CE and MDR approval processes for BlinkLab Dx1 in Europe, the Company's diagnostic tool for autism.
- Launching a second clinical programme targeting ADHD using BlinkLab's novel Dx2 platform (ADHD).
- Initiating registrational trial process for FDA approval of BlinkLab Dx2.

Strong Strategic Pipeline

Product	Associated with an ongoing clinical study	Strategic Rationale /Commentary on progress
Dx 2 / ADHD	European ADHD Study	Extends BB1's platform beyond autism into a second, very large neuro-dx market (ADHD), creating a multi-asset pipeline and a second regulatory path (Dx2) that can diversify revenue and de-risk the company's autism focus. Positions BB1 for EU CE/MDR workstreams in parallel to FDA, leveraging Europe-based partners and studies. European clinical footing: earlier EU clinical collaboration (Netherlands) with Mental Care Group (>120 clinics in Europe) to run a prospective study assessing BlinkLab tests for neurodevelopmental conditions, including ADHD, gave BB1 EU clinical infrastructure for ADHD work. ADHD Trial expanded in Europe- larger data set collection in progress. The ADHD clinical program has expanded from one to five European clinical sites. Including the initial cohort, the study is estimated to report data from approximately 300 participants by the end of the year. The full dataset will support planned European regulatory submission in time for a potential 2027 EU Dx2 product launch.
Autism	Adult autism study with the University of Amsterdam	Opens an adult market segment (distinct clinical, regulatory, and payer paths vs. paediatrics), broadening BB1's total addressable market and supporting multi-population validation of BlinkLab's approach. BB1 announced a collaboration for adult autism diagnostics with VU Amsterdam and NAR. The study: up to 200 participants (50% adults with autism, 50% neurotypical), IRB approved, start of data collection commenced in April 2025.
Alzheimer's and Dementia	Alzheimer's and Dementia Study with Erasmus University	Extends BlinkLab's AI-smartphone paradigm from neurodevelopmental to neurodegenerative disease—a large, global burden and an area with urgent need for early, scalable biomarkers; also creates optionality beyond just paediatric markets. BB1 and Erasmus collaboration to evaluate AI-powered tools for early diagnosis of FTD and Alzheimer's, with BB1's tests integrated into Erasmus MC's Digital Dementia Lab (at-home testing). The study involves participants from a large FTD Risk Cohort ("FTD-RisC") of ~250 individuals (first-degree relatives of mutation carriers) plus participants with a clinical diagnosis of FTD or AD via the Erasmus memory clinic. Importantly, this study comes at no cost to BB1, with BB1 providing Erasmus access to its technology/data to facilitate use of its platform whilst retaining the rights to the anonymised raw biomarker data from the study. BB1 can then use this for its own analysis, algorithm training and related product development.
Autism/ADHD	MAGNET study with Monash University	MAGNET is a large family-based cohort that will use deep phenotyping to identify data-driven subtypes of autism and ADHD that further enhance BB1's proprietary algorithms in their abilities to accurately detect ASD/ADHD, including additional subtypes. The collaboration commenced on 12 November 2024, targeting ~1,000 families (children 4–18 years) with only autism, only ADHD, or both; family-based design (parents + siblings). Interim results will be out early next year, in 2026, and importantly, key learnings from this study will help to further fine-tune BB1's diagnostic model prior to mandatory regulatory. FDA Pivotal trials for both ASD and ADHD.

Financial Performance and Updated Valuation

We have maintained the same conservative approach in this revision as we did in the earlier initial note. For instance, we have purposefully limited the ASD diagnostic market size in the USA, limited BB1's associated market share despite its technology's strong relative diagnostic outperformance as well as intentionally including other downside factors even in the upside valuation case such as assuming a lower ASP than BB1's planned pricing strategy.

Since the time of our Initiating Coverage note in February of this year, BB1 reported its financial performance for the FY ending June 30 2025, with key financial performance measures matching our earlier forecasts. For example, BB1 reported actual operating cash outflows of -$4.09m, whereas our equivalent like-for-like forecasts had estimated these to be -$3.982m. Given our original forecasts then increase this deficit by a significant 3.32 times to -$13.23m (despite a now reduction in the size of the planned FDA Pivotal Study) for FY 26 in addition to including a range of other conservative considerations across the forecast horizon from 2026 and beyond, as explained in our earlier note, we are confident that the underpinning factors supporting our original valuation hold well.

However since then in terms of changes in key assumptions impactful to the valuation, BB1's risk of not achieving FDA 510 (k) clearance has gone down materially due to the strong performance results that BB1 achieved in its recently concluded US Pilot Study – both in terms of absolute diagnostic performance and also relative performance in terms of performing well above what the FDA has advised BB1 that Dx 1 needs to achieve in terms of rates Sensitivity and Specificity and also being well above what either Cognoa or EarliPoint achieved in their Pivotal FDA trials.

Underpinning our $1.74 mid-point target share price from February were baked-in probabilities of BB1 not achieving FDA clearance for its autism offering of 30% and not achieving clearance for its ADHD offering of 67%. These were both conservatively defined, given BB1's achievements across clinical studies and commercialisation efforts. The very low implied rate of probability for ADHD's success is more of a reflection of the earlier commercialisation stage of Dx 2, rather than a truly low intrinsic chance of Dx 2 being able to perform at and above the required diagnostic benchmarks.

Now, given BB1's Pilot Study results, the true likelihood of BB1's probability of success for its autism offering likely exceeds 90%. Despite this, we have changed our model's assumptions to reflect a revised probability of success of only 80%. Additionally, given that certain R&D, technology, and related commercialisation factors overlap between the autism focussed Dx 1 and the ADHD focussed Dx 2, the actual true probability of FDA approval success for Dx 2, is now likely > 50%; however, we have conservatively considered this to be now only 40%.

Despite autism and ADHD both being neuro-developmental and behavioural disorders, they present different diagnostic and regulatory risks, and their underlying biomarker-driven diagnostic algorithms differ. That being said, given BB1's progress thus far across undertaking multiple ADHD focussed studies and given that the methodology to ascertain causality between stimulus and biomarkers itself is similar for both ADHD and ASD, consequently synergistic factors such as learnings from clinical site experience, data-monitoring, statistical analysis plan, and FDA interactions work in effect to lower Dx 2's risk of not achieving timely FDA clearance, resulting in confidence given to our assumptions.

Investors should note that there exist a few recent examples of companies achieving FDA clearance on a first AI algorithm-driven diagnostic product, to then subsequently also receive clearance for a subsequent product that targets a separate but related disorder using the same underlying AI-driven platform, e.g. Eko Health.

Consequent to the above, as seen below in Figure 4 we arrive at an updated intrinsic valuation of $2.14 in the Base Case, whilst in the Upside Case, we arrive at $2.62. The resultant mid-point valuation of $2.38 represents the prospect of a 263% upside potential from the current share price of $0.655. Our revised mid-point price target represents a reasonable 37% increase from our mid-point valuation in our Initiating Coverage of $1.74. Given BB1's impressive execution since then, this is a reasonable uplift.

Also reflective of BB1's enhanced strategic position since February, BB1's underlying share price itself has increased by 144% since February.

Figure 4: BB1's revised valuation results

Valuation (A$m)	Base case	Bull case
Present value of FCF (EV)	333	409
Debt	0.2	0.2
Cash*	7.2	7.2
Equity value (A$)	**340**	**416**
Current Ordinary Shares O/S (m)	125	125
Assumed Dilutive Shares** (m)	34	34
Total Shares O/S (m)	**159**	**159**
Implied price (A$ cents)	**2.14**	**2.62**
Current price (A$)	**0.655**	**0.655**
Upside (%)	*226.4%*	*299.5%*

Sources: East Coast Research

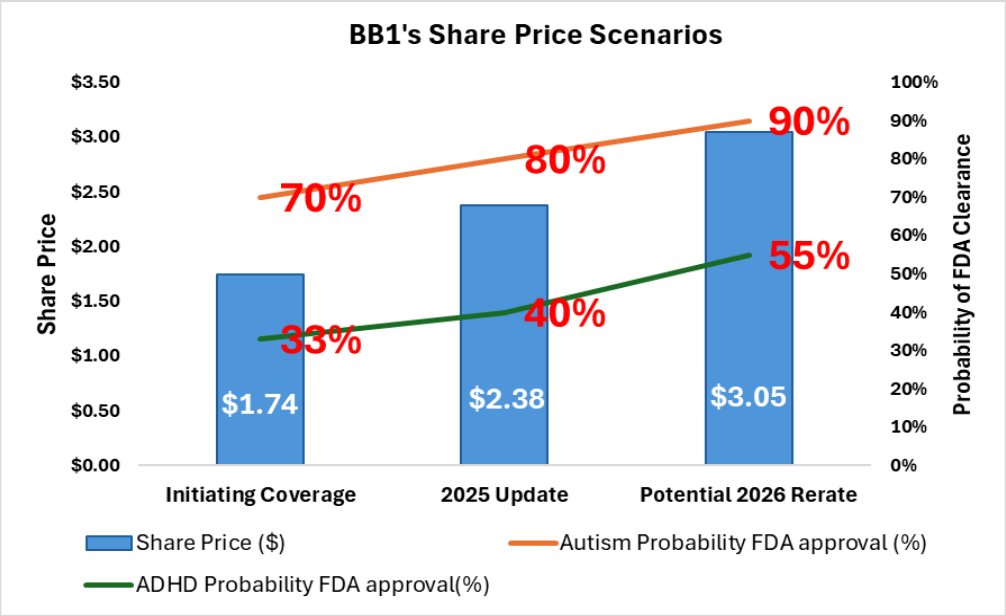
As seen above in **Figure 4**, we have increased the current number of ordinary shares outstanding by ~30% to account for the prospect of future dilution from capital raises, options and performance rights; this adds a good degree of conservativeness to our share price estimation. BB1's cash balance as of the end of the September 2025 quarter was $7.232.

In order to reflect BB1's enhanced prospects post the US Pilot Study, we have conservatively only increased BB1's expected future revenues and have not additionally lowered BB1's WACC.

Figure 5 below showcases how, under our already conservative assumptions, which include, for example, ignoring the significant market opportunity in the EU and limiting BB1's market share in the USA despite material diagnostic outperformance vs competitors, BB1's share price is expected to evolve upwards. Our current 2025 re-rate revises BB1's intrinsic share price to **$2.38** from $1.74. Sometime in 2026 under our assumption that BB1 continues to successfully execute on its then live FDA Pivotal Study and progresses further on its currently live ADHD clinical studies, we expect BB1's share price to be somewhere in $3.00 range, underpinned at that time by a 90% probability of FDA clearance for its autism focussed Dx 1 product and 55% for Dx 2. This itself could be conservative since sometime in the 2H of 2026, BB1 is expected to receive full FDA 510(k) clearance (probability of approval then would effectively be 100% - higher than our 90% assumption that underpins our 2026 potential rerate price).

The factors underpinning a 2026 rerate will be discussed in more detail sometime next year with a new coverage note.

Figure 5: BB1's 2026 share price rerate scenario



Sources: East Coast Research

Re-rating of BlinkLab's stock

Despite BB1's stock price rise since February, BB1's stock still trades well below our midpoint intrinsic valuation. Achieving the following milestones could trigger a further share-price re-rating toward our target revised share price:

- **FDA 510(k) Progress and final clearance (ASD):** Ongoing positive updates from the final U.S. Pivotal Study and eventual FDA clearance (expected 2H 2026).
- **CE Mark Certification:** Receipt of CE Mark approval for its ASD offering (also expected to occur sometime in 2H 2026) would unlock the significant European commercial potential, diversify revenue, and de-risk BB1's business model.
- **ADHD (Dx2) Development:** Advancing its ADHD pipeline—including favourable trial updates and data read-outs from its currently active EU ADHD study and its Australian MAGNET study would add confidence to BB1's prospects of an eventual successful USA FDA clearance for Dx 2 and hence make BB1 into a minimum 2-product business.
- **Other Clinical and Academic Collaborations:** Results from current and future studies focused on other neurodevelopmental disorders, such as dementia and Alzheimer's, would validate BB1's vision to be a platform-based business with multiple revenue streams, supporting a further valuation uplift.
- **Strategic Partnerships and Brand Visibility:** Post-FDA clearance, U.S. market entry will be accelerated by partnerships and KOL engagement—low-cost but high-impact levers for awareness and adoption.
- **Takeover Potential:** BlinkLab's unique IP and data-driven network effects make it an attractive acquisition target for larger digital-health or med-tech companies seeking AI diagnostic capabilities.

Risks

While our investment thesis rests on conservative assumptions, the following remain key risks:

- **Execution / Regulatory Risk:** As a pre-revenue company, BlinkLab's success hinges on effective execution and FDA 510(k) approval; non-approval would materially affect valuation.
- **Princeton Licence Agreement:** Any unremedied material breach could terminate BlinkLab's exclusive licence, severely impacting operations. Routine business expansion beyond ASD/ADHD does not constitute a breach.
- **U.S. Government Interest:** The U.S. retains a non-exclusive licence over Princeton-developed IP under the Bayh-Dole Act, though the probability of intervention is low and not considered a material obstacle.
- **Reimbursement Risk:** Uncertainty around the applicable CPT code and timing of reimbursement approval could affect U.S. commercialisation.
- **Competition Risk:** While BlinkLab's AI-based network effects offer a moat, disruptive new diagnostic technologies could erode its advantage.
- **Intellectual Property Risk:** The company's patents and licensed IP may face infringement or legal challenges from competitors.
- **Funding / Dilution Risk:** With FCF deficits expected to occur through FY 2026, BlinkLab will likely require further equity raises before turning cash-flow positive post-2027.

Appendix I: Financial Summary

Profit & Loss (AUD $M)	2024 FY	2025FY	2026e	2027e	2028e	2029e	2030e	2031e
Sales Revenue	**0.0**	**0.4**	**0.0**	**70.2**	**118.1**	**194.6**	**216.2**	**227.0**
Operating expenses	1.5	(6.0)	11.9	56.7	86.4	131.5	146.0	154.1
EBITDA	**(1.5)**	**(5.6)**	**(11.9)**	**13.4**	**31.6**	**63.2**	**70.2**	**72.9**
Depn & Amort	(0.1)	(0.1)	(0.4)	(0.9)	(1.9)	(3.2)	(4.5)	(6.1)
EBIT	**(1.6)**	**(5.7)**	**(12.4)**	**12.5**	**29.7**	**59.9**	**65.7**	**66.8**
Finance Cost	(0.00)	0.01	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)
Profit/(Loss) before tax	**(1.8)**	**(5.7)**	**(12.6)**	**12.2**	**29.3**	**59.5**	**65.2**	**66.3**
Tax expense	0.0	0.0	0.0	(3.1)	(7.3)	(14.9)	(16.3)	(16.6)
NPAT	**(1.8)**	**(5.7)**	**(12.6)**	**9.2**	**22.0**	**44.6**	**48.9**	**49.7**
Cash Flow (AUD'000)	**2024 FY**	**2025e**	**2026e**	**2027e**	**2028e**	**2029e**	**2030e**	**2031e**
Profit after tax	(1.8)	(5.7)	(12.6)	9.2	22.0	44.6	48.9	49.7
Depn & Amort	0.1	0.1	0.4	0.9	1.9	3.2	4.5	6.1
Changes in working capital	(0.4)	0.5	0.2	(10.7)	(12.0)	(19.9)	(7.7)	(2.5)
Other operating activities	0.3	0.9	0.6	10.5	17.7	29.2	32.4	34.1
Operating cashflow	**(1.8)**	**(4.2)**	**(11.3)**	**9.9**	**29.7**	**57.2**	**78.1**	**87.4**
Payments for purchase of plant and eq	(0.0)	(0.2)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Other investing activities	(3.1)	3.0	(1.0)	(2.0)	(3.9)	(5.9)	(7.3)	(9.1)
Investing cashflow	**(3.1)**	**2.8**	**(1.0)**	**(2.0)**	**(4.0)**	**(5.9)**	**(7.4)**	**(9.2)**
Equity raised (repurchased)	8.4	7.0	14.0	0.0	0.0	0.0	0.0	0.0
Net proceeds from borrowings	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)
Other Financing activities	(0.5)	(0.0)	0.0	(3.0)	(15.0)	(35.0)	(50.0)	(55.0)
Financing cashflow	**7.9**	**7.0**	**13.9**	**(3.1)**	**(15.1)**	**(35.2)**	**(50.2)**	**(55.2)**
Net change in cash	**3.0**	**5.6**	**1.6**	**4.8**	**10.6**	**16.1**	**20.5**	**22.9**
Cash at End Period	3.0	8.7	10.3	15.2	25.8	41.8	62.4	85.3
Balance Sheet (AUD'000)	**2024 FY**	**2025e**	**2026e**	**2027e**	**2028e**	**2029e**	**2030e**	**2031e**
Cash	3.0	8.7	10.3	15.2	25.8	41.8	62.4	85.3
Total Assets	6.9	9.4	11.8	29.5	55.4	95.9	127.9	157.1
Total Liabilities	0.4	0.8	1.2	2.2	3.4	5.1	5.8	6.2
Shareholders' Funds	6.5	8.5	10.6	27.3	52.0	90.8	122.1	150.9
Ratios	**2024 FY**	**2025e**	**2026e**	**2027e**	**2028e**	**2029e**	**2030e**	**2031e**
Net debt (cash)/Equity	-40.6%	-92.2%	-85.7%	-47.6%	-43.1%	-40.5%	-46.4%	-52.4%
Total Cash / Total Assets	43.9%	92.9%	87.2%	51.5%	46.5%	43.6%	48.8%	54.3%
Return on Equity (%)	-27.0%	-67.0%	-118.8%	33.6%	42.3%	49.1%	40.0%	33.0%

*** In 2024, $3m of the investing cash outflow relates to payment for term deposit**

Appendix II: Analyst's Qualifications

Rahul Tiwari, the analyst on this report, is an equity research analyst at Shares in Value (East Coast Research).

- Rahul has a bachelor's and master's degree in Applied Finance from Macquarie University, a master's in Accounting from UNSW, and an MBA from Cornell University in the USA.
- Rahul has several years of experience across wealth management and investments, infrastructure project finance, private equity and high tech.

General advice warning, Disclaimer & Disclosures

Terms & Conditions

The information contained herein ("Content") has been prepared by Shares in Value Pty Ltd (East Coast Research). Shares in Value Pty Ltd (ACN: 643 558 436) is a Corporate Authorised Representative of One Mile Investment Group (ACN: 664624846), which holds an Australian Financial Services Licence (AFSL no. 547945). All intellectual property relating to the Content vests with East Coast Research unless otherwise noted.

Disclaimer

The Content is provided on an as is basis, without warranty (express or implied). Whilst the Content has been prepared with all reasonable care from sources we believe to be reliable, no responsibility or liability shall be accepted by East Coast Research for any errors or omissions or misstatements howsoever caused. Any opinions, forecasts or recommendations reflect our judgment and assumptions at the date of publication and may change without notice. East Coast Research will not accept any responsibility for updating any advice, views, opinions or recommendations contained in this document.

No guarantees or warranties regarding accuracy, completeness or fitness for purpose are provided by East Coast Research, and under no circumstances will any of East Coast Research officers, representatives, associates or agents be liable for any loss or damage, whether direct, incidental or consequential, caused by reliance on or use of the Content.

General Advice Warning

The Content has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) personal advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

Disclosures

East Coast Research has been commissioned to prepare the Content. From time to time, East Coast Research representatives or associates may hold interests, transact or hold directorships in, or perform paid services for, companies mentioned herein. East Coast Research and its associates, officers, directors and employees, may, from time to time hold securities in the companies referred to herein and may trade in those securities as principal, and in a manner which may be contrary to recommendations mentioned in this document.

East Coast Research receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where East Coast Research has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.

FINANCIAL SERVICES GUIDE

Shares In Value Pty Ltd (East Coast Research)

ABN: 56 643 558 436

Corporate Authorised Representative (AFSR No: 001283429) of One Mile Investment Group (ACN: 664624846) which holds an Australian Financial Services Licence (AFSL no.: 547945)