ASX Announcement

22 October 2025

Pilot Study Confirms High Diagnostic Accuracy and Readiness for FDA Trial

Highlights

- **Pilot Study Completion and Unblinding:** BlinkLab has successfully completed its U.S. Pilot Study of the Dx 1 diagnostic device, involving 485 children. The study was unblinded on 17 October 2025, enabling direct comparison between BlinkLab's smartphone-based test results and independent clinical reference diagnoses provided by PriMED Clinical Research and NorthShore Pediatric Therapy.

- **Strong Diagnostic Performance:** Across a clinically diverse population representing the full spectrum of developmental concerns, BlinkLab Dx 1 achieved 83.7% sensitivity and 84.7% specificity relative to clinical reference diagnosis.

- **Performance Exceeds FDA Benchmark for Registrational Study:** In a formal meeting with the U.S. FDA on 16 October 2025, the agency agreed with BlinkLab's pivotal 510(k) study design and confirmed a minimum performance threshold of >65% sensitivity and >65% specificity for regulatory clearance. Based on FDA feedback, the main study has been refined to enroll approximately 528 participants across leading U.S. autism research centres, streamlining timelines and reducing cost.

BlinkLab Limited (ASX:BB1) ("BlinkLab", or the "Company"), a leading digital healthcare company focused on AI-powered diagnostics, is pleased to announce the successful completion of its United States pilot study (the "Pilot Study") evaluating the Company's smartphone-based digital diagnostic test autism spectrum disorder, BlinkLab Dx 1.

Study Population

The BlinkLab Dx 1 Pilot Study commenced in March 2025[1] targeting children who were either in the process of receiving, or had recently undergone, neurodevelopmental

[1] ASX Announcement (12 March 2025) – *"BlinkLab Commences U.S. Autism Diagnostic Study with First Child Tested"*

assessments at autism centers in the United States, including PriMED Clinical Research, LLC (Ohio) and North Shore Pediatric Therapy, Inc. (Illinois). The goal was to recruit children based on a broad range of developmental and behavioral concerns commonly seen in clinical practice, including, but not limited to, autism spectrum disorder (ASD), attention-deficit/hyperactivity disorder (ADHD), specific learning disorders (including dyslexia and dysgraphia), language and communication impairments, speech delay, global developmental delay, anxiety disorders, developmental coordination disorder, and intellectual disability. The study also included a community sample of children, with whom no developmental concerns have been raised by parents or caregivers, to provide a robust baseline for comparison and enabling the full evaluation of the technology's sensitivity and specificity. This study population closely mirrors the real-world intended-use population for the BlinkLab Dx 1 technology, as well as the study populations for upcoming 510(k) study, following previously FDA-cleared predicate devices.

The Pilot Study enrolled 485 children, aged between 2 and 11 years. The mean age of children with autism was 5.98 years (±2.67 SD), and the mean age of children without autism was 6.64 years (±2.56 SD). In the total sample, 132 children (27%) had a positive autism diagnosis, while 353 children (73%) had a negative diagnosis, which included either a developmental delay other than autism (e.g., ADHD) or no developmental delay. Overall, 42.9% of participants were female and 57.1% were male. Within the autism group, 31.5% were female and 68.5% were male; within the non-autism group, 47.2% were female and 52.8% were male. In terms of race and ethnicity, 5.4% of participants were Asian (2.3% in the autism group vs. 6.5% in the non-autism group), 16.3% were Black (15.2% vs. 16.7%), 60.1% were White (56.8% vs. 61.4%), 14.8% identified with more than one race (21.2% vs. 12.5%), 2.9% identified as Other (3.8% vs. 2.6%), and 0.4% were of unknown race (0.8% vs. 0.3%). Thus, no major differences in terms of sex, age, or racial distribution were observed between the autism and non-autism groups. Overall, the study population represents a balanced and demographically diverse sample of the U.S. pediatric population.

BlinkLab was unblinded on 17 October 2025 to conduct the within-subject comparison analysis, i.e. comparing the BlinkLab Dx 1 device output (index test) with the clinical reference diagnoses (reference test). This comparison produced the true positive, true negative, false positive, and false negative cases, from which the Company calculated the primary study outcomes: sensitivity and specificity of the Dx 1 device.

BlinkLab Dx 1 Device Performance

Across all enrolled participants, BlinkLab Dx 1 demonstrated a sensitivity of 83.7% and a specificity of 84.7% relative to gold-standard clinical assessments, including the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2), the Childhood Autism Rating Scale (CARS), and the Social Responsiveness Scale (SRS).

Unlike BlinkLab's earlier feasibility study of 441 participants[2], which was conducted in well-defined cohorts of children with typically more pronounced autism symptoms, the current Pilot Study was intentionally designed to reflect a real-world clinical setting in the United States. The enrolled population was clinically heterogeneous, encompassing children with a broad range of developmental profiles, including those with clear autism presentations to others with mild, overlapping, or subthreshold developmental characteristics.

Despite this clinical heterogeneity, the BlinkLab Dx 1 model demonstrated strong performance, close to the results observed in the earlier feasibility study. This diversity makes the Pilot Study a strong representation of routine clinical practice, where diagnostic uncertainty and variability in presentation are common.

With diagnostic accuracy exceeding that of other FDA-authorized digital diagnostic aids, such as Cognoa (De Novo) and EarliPoint (510(k)), BlinkLab's Dx 1 technology is well-positioned within the emerging landscape of digital phenotyping and AI-driven diagnostics. The Pilot Study shows the consistency and resilience of the Dx 1 model across the full autism spectrum, setting it apart from existing digital tools that have demonstrated lower sensitivity and specificity in clinically uncertain or borderline cases.

FDA meeting: Regulatory and Clinical Pathway

One day prior to unblinding, BlinkLab held a second formal meeting with the U.S. Food and Drug Administration (FDA) regarding the BlinkLab Dx 1 device, continuing the discussions from the Company's initial pre-submission meeting in late 2024. The meeting was deliberately scheduled at the conclusion of the Pilot Study, but prior to initiation of the Main Study phase, to ensure full alignment with the FDA on all study procedures. A key outcome of this meeting was that the FDA endorsed BlinkLab's proposed changes to the Pivotal 510(k) Study protocol, which were informed by procedural learnings from the Pilot Study, particularly related to the recruitment and enrollment of pediatric participants, and by ongoing engagement not only with the current clinical teams at PriMED and NorthShore, but also with the upcoming participating sites that will take part in the Pivotal 510(k) trial.

The FDA confirmed BlinkLab's proposed minimal performance threshold of >65% sensitivity and >65% specificity, consistent with predicate devices. For comparison, Cognoa (Canvas Dx) reported 59% sensitivity and 19% specificity in its pivotal trial (Megerian et al., 2022)[3],

[2] ASX Announcement (19 November 2024) – *"Large-Scale Study Validates and Enhances BlinkLab's Accuracy in Detecting Autism in Children"*

[3] Megerian, J. T., Dey, S., Melmed, R. D., Coury, D. L., Lerner, M., Nicholls, C. J., ... & Taraman, S. (2022). Evaluation of an artificial intelligence-based medical device for diagnosis of autism spectrum disorder. *NPJ Digital Medicine*, *5*(1), 57.

while EarliPoint demonstrated 71% sensitivity and 81% specificity in its trial (Jones et al., JAMA 2023)[4]. This benchmark reflects the FDA's expectations for the real-world diagnostic performance of BlinkLab Dx 1 and is aligned with currently cleared digital diagnostic aids for autism.

In addition, the FDA approved BlinkLab's updated recruitment strategy, which integrates both autism specialty centers and community-based referral sources to achieve a clinically balanced and operationally efficient sample. A key outcome from this streamlined strategy is that the study size has been reduced from 1,000 to 528 participants. This number is considered sufficient to maintain statistical power without compromising data quality, but with the added benefit of significant reductions in costs and study duration.

The FDA review team included representatives from the Neurodiagnostic Devices Branch, among them the Lead Reviewer and General Engineer, Director of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices, Team Lead of the Neurodiagnostic Devices Section, Physician and Clinical Reviewer, Clinical Reviewer (Psychiatry), and Mathematician & Statistical Reviewer.

Exploration of Pilot Study Data Identifies Potential Novel Markers, Augmenting Diagnostic Accuracy

Developing robust machine learning models for neurodevelopmental assessment represents one of the most challenging problems in digital health. Unlike traditional imaging or lab-based diagnostics, BlinkLab's algorithm must interpret subtle, dynamic patterns in spontaneous and stimulus-evoked facial responses, vocalization patterns, and postural responses captured through 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.

During the analysis of the Pilot Study data, the BlinkLab team identified new potential digital markers that are not yet part of the current BlinkLab Dx 1 model, but that are intended to be incorporated into the optimized algorithm prior to the Pivotal 510(k) Study. These include quantitative features capturing restrictive and repetitive behaviors (RRB), such as repetitive movements, vocalization patterns, and other structured response behaviors corresponding to the DSM-5 criterion of "restricted, repetitive patterns of behavior". BlinkLab is currently exploring new ways to objectively measure not only the frequency, but also the similarity

[4] Jones, W., Klaiman, C., Richardson, S., Aoki, C., Smith, C., Minjarez, M., ... & Klin, A. (2023). Eye-tracking–based measurement of social visual engagement compared with expert clinical diagnosis of autism. *JAMA, 330*(9), 854-865.

and temporal consistency of these behaviors over the course of the 15-minute smartphone assessment. Incorporating these RRB-based features is expected to further enhance diagnostic accuracy, robustness, and clinical interpretability of the BlinkLab Dx 1 and will be locked ahead of the 510(k) pivotal study.

Management Commentary

BlinkLab Chairman, Brian Leedman, commented:

"We are thrilled with these results as they validate the strength of our approach and the tremendous progress our team has made. Building a model that can interpret behavior through a smartphone and achieve this level of accuracy in this study population is an extraordinary accomplishment. The learnings from the pilot give us the confidence that our pivotal study is likely to deliver the results needed for FDA clearance. Ultimately, our technology which utilizes neuroscience, AI, and smartphone-tech, will help millions of families access earlier, faster, and more objective diagnosis. We are also encouraged by the FDA's feedback and look forward to commencing the main 510(k) study in partnership with the many prestigious centers of neurological research in North America."

BlinkLab Co-Founder and CEO, Dr. Henk-Jan Boele, commented:

"I would like to express my deepest gratitude to all the families who participated in our study, to the dedicated clinicians at PriMED and NorthShore, to our supportive investors, and to the incredible BlinkLab team for their commitment and collaboration throughout this journey. Patient recruitment efforts were met with overwhelming interest, surpassing the original goal of 100 children and resulting in 485 participants, nearly matching the number needed for BlinkLab's upcoming FDA 510(k) study. Looking ahead, we are excited to continue our mission to transform mental health diagnostics through accessible, objective, and scalable digital tools. This Pilot Study marks just the beginning of a new era in how neuroscience and technology come together to improve patient care."

Statement from BlinkLab's CEO providing guidance on how to interpret these study results

"To fully appreciate these results, it's important to understand how we designed this study. We deliberately created what I call the 'ultimate stress test' for the BlinkLab Dx 1 device. This was not a controlled lab study or a narrowly defined perfect autism cohort. Instead, it was a real-world sample that included children with a broad range of developmental

challenges, overlapping symptoms, and sometimes even diagnostic uncertainty. A substantial number of children had mild or subthreshold presentations, often referred to clinically as Level 1 autism, children who might show very subtle social or sensory features, often with low ADOS, CARS, or SRS scores.

In this kind of population, even the clinical ground truth is inherently subjective and sometimes 'shaky'. The boundary between developmental delay and mild autism is not clear-cut. It's a gray zone, where diagnostic interpretation can vary between specialists, and where outcomes are influenced not only by clinical presentation but also by parental awareness and access to clinical resources. Yet, it's precisely this setting - the chaotic, complex reality of everyday clinical practice - where BlinkLab must ultimately prove its value.

Compared to our earlier feasibility case-control study, which was conducted in specialized autism centers in Morocco, and included fewer children in the diagnostic "gray zone" (focusing primarily on those with a more profound autism presentation), this U.S. Pilot Study truly tested the true limits of our technology. And it passed! The device's performance shows correlations with autism severity, confirming that BlinkLab Dx 1 captures genuine neurobehavioral signatures that scale with clinical presentation. These findings suggest that our Dx 1 device is fully ready for the upcoming FDA 510(k) pivotal study.

This work moves us one step closer to bringing objectivity to a field that has long been constrained by subjectivity. Autism diagnosis today still relies heavily on human interpretation and resource access, leading to delayed or inconsistent identification, particularly for those at the milder end of the spectrum. As global awareness and diagnoses rise, largely driven by less profound autism, the need for accessible, standardized, and objective assessment tools has never been greater.

BlinkLab Dx 1 is built to meet that challenge. It's ambitious, but that's precisely what makes it important: a technology that can make early, accurate diagnosis not only possible in specialist clinics, but scalable across communities and healthcare systems worldwide.

While other devices primarily target social engagement and visual attention, BlinkLab Dx 1 advances the field by validating an innovative focus on sensory sensitivity, a core yet historically under-assessed feature of autism (Narzisi et al. 2025)[5]*. Using BlinkLab's smartphone-based neurometric platform, the device quantifies objective markers of sensory processing and behavioral responsiveness, providing clinicians with actionable, quantitative insights. As a diagnostic aid, BlinkLab Dx 1 is designed not merely to meet regulatory definitions, but to deliver genuine clinical value to support clinicians in identifying and understanding the sensory and neurobehavioral profiles of children with developmental concerns."*

[5] Narzisi, A., Vivanti, G., Berloffa, S., Milone, A., Fantozzi, P., Tancredi, R., ... & Masi, G. (2025). Sensory processing in autism: a call for research and action. *Frontiers in Psychiatry*, *16*, 1584893.

Outlook

With the Pilot Study now complete and optimization underway, BlinkLab is well-positioned to transform early diagnosis of neurodevelopmental conditions by delivering two 15-minute, smartphone-based tests that can bring clinical-grade assessment into homes, clinics, and primary care settings worldwide. The Company remains on track of submitting a 510(k) clearance application to the FDA next year.

This announcement is intended to lift the trading halt applied for and granted on 20 October 2025.

This announcement has been approved by the Board of Directors.

For further information please contact:

Dr Henk-Jan Boele
Chief Executive Officer
henkjan@blinklab.org
+31 (0) 611 132 247

Brian Leedman
Non-Executive Chairman
brian@blinklab.org
+61 (0) 412 281 780

About BlinkLab Limited (ASX:BB1)

BlinkLab Limited, a company founded by neuroscientists at Princeton University, over the past several years has fully developed a smartphone based diagnostic platform for autism and ADHD. Our most advanced product is an autism diagnostic aid for clinicians that leverages the power of smartphones, AI and machine learning, that enables early and accurate detection of autism enabling early intervention during crucial early windows of brain development. BlinkLab is led by an experienced management team and directors with a proven track record in building companies and vast knowledge in digital healthcare, computer vision, AI and machine learning. Our Scientific Advisory Board consists of leading experts in the field of autism and brain development allowing us to bridge most advanced technological innovations with groundbreaking scientific research.

All sites participating in the BlinkLab Dx 1 510(k) study are top-tier academic and clinical centers. These include:

- Cincinnati Children's Hospital[6]
- Seattle Children's Hospital[7]
- University of Pennsylvania[8]
- MU Thompson Center for Autism & Neurodevelopmental Disorders[9]
- Southwest Autism Research & Resource Center[10]
- University of Nebraska Medical Center[11]
- Vanderbilt Kennedy Center[12]

Together, these sites represent a geographically diverse and demographically representative sample of the U.S. population, each with a proven track record in autism research and clinical trial execution.

[6] ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

[7] ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

[8] ASX Announcement (21 August 2025) – "ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

[9] ASX Announcement (17 September 2025) – *"BlinkLab Engages The University of Missouri's Thompson Center for Autism & Neurodevelopment as its sixth Clinical Site for FDA 510(k) Diagnostic Trial"*

[10] ASX Announcement (22 May 2025) – *"BlinkLab Expands U.S. Clinical Trial Network: University of Nebraska Medical Center Engaged as Second Site in Main Phase of FDA 510(k) Study"*

[11] ASX Announcement (8 July 2025) – *"BlinkLab Expands U.S. Clinical Trial Network: University of Nebraska Medical Center Engaged as Second Site in Main Phase of FDA 510(k) Study"*

[12] ASX Announcement (18 September 2025) – *"BlinkLab Onboards 'The Vanderbilt Kennedy Center' as Seventh Clinical Site for FDA 510(k) Autism Trial"*