ASX Announcement **5 August 2026**

European ADHD Study Delivers Positive Results, Supporting Expansion of Diagnostic Platform Beyond Autism

Highlights

- **Strong study results:** BlinkLab's European ADHD study achieved sensitivity of 82% and specificity of 83% in children aged 6 through 17 years. The study cohort represents one of the largest case-control datasets reported for ADHD assessment tools.
- **First major step in development of ADHD-focused model:** The findings support development of BlinkLab Dx2, the Company's novel AI model designed to detect ADHD in addition to autism using smartphone tracking of digital neurobehavioural biomarkers.
- **Progression towards regulatory studies:** The Company will commence activities in preparation for a regulatory study program in the US, following a similar development strategy to that established for BlinkLab Dx1 in autism.
- **Capital-efficient development:** The multicentre study was completed in collaboration with Mental Care Group (MCG) in Europe at no cost to BlinkLab, demonstrating the value of the Company's collaborative research model.[1]

BlinkLab Limited (ASX:BB1) ("BlinkLab" or the "Company") is pleased to report results from its European case-control study of smartphone-based digital neurobehavioural biomarkers in children aged 6 through 17 years, both with and without attention-deficit/hyperactivity disorder (ADHD). The study achieved sensitivity of 82% and specificity of 83% (two key statistical measures that are used to evaluate the accuracy of diagnostic tests such as BlinkLab's) relative to its clinical diagnostic reference standard.

Study Procedures & Results

BlinkLab collected neurometric data from children who were recruited across multiple Mental Care Group (MCG)[2] centres in the Netherlands, as well as from the general community. Participants completed brief smartphone-based assessments, which were designed to collect digital neurobehavioural biomarkers that make up BlinkLab's diagnostic platform, including the detection of often subtle and involuntary behaviours from the participant, such as blinking or facial reflexes. For children referred through MCG, the diagnostic reference standard was established through multidisciplinary clinical review, whereas children recruited from the general community formed the "neurotypical" control group for comparison.

[1] ASX Announcement (14 July 2026) – *"Company Update on Clinical Development Programs Beyond Paediatric Autism"*
[2] ASX Announcement (30 July 2024) – *"BlinkLab partners with Mental Care Group in Europe to improve and accelerate the diagnostic evaluation of ADHD"*

Sample derivation

Of the 375 children recruited, those with (co-occurring) neurodevelopmental or psychiatric conditions, and those taking medication, were excluded in order to establish a clearly defined ADHD group and a clean comparison group. Of the resulting 208 children analysed, 117 (56%) had a confirmed clinical diagnosis of ADHD and 91 (44%) had no diagnosis of ADHD or any other neurodevelopmental condition. Both arms exceeded the minimum of 50-per-arm threshold used in published meta-analyses to define studies of robust sample size,[3] and the cohort represents one of the largest case-control datasets reported for ADHD assessment tools.[4]

Our machine learning Dx2 algorithm[5] correctly identified 82% of children in the ADHD group as exhibiting the target neurobehavioural features associated with ADHD (sensitivity), and correctly classified 83% of children in the comparison group (specificity). Importantly, our smartphone-derived objective neurometric markers were positively associated with subjective clinical observations documented in participants' diagnostic reports.[6]

Table 1: Study Cohort Characteristics

	Control Sample (n = 91)	ADHD Sample (n = 117)	Total (n = 208)
Proportion of cohort (%)	44%	56%	100%
Age, years (mean +/- SD)	12.2 (3.1)	10.8 (3.0)	11.4 (3.1)
Age range, years	6–17	6–17	6–17
Male, n (%)	41 (45%)	74 (63%)	115 (55%)
Female, n (%)	50 (55%)	43 (37%)	93 (45%)

Interpreting the Results

The results provide the first evidence that digital neurobehavioural biomarkers can detect differences associated with ADHD. The observed correlation between these biomarkers and clinical observations recorded in ADHD diagnostic reports provides further support that the measures reflect clinically relevant features for the diagnostic process. The findings are an important first step in evaluating how BlinkLab's platform could enhance ADHD assessment pathways and in the development of BlinkLab Dx2, the Company's improved AI model intended to extend BlinkLab's detection capabilities beyond autism to include ADHD. This first exploratory case-control study was not designed to support a regulatory submission. Further prospective clinical validation, model

[3] Gustafsson et al. (2023), *Mental Health Science*

[4] Hult et al. (2015), *J Atten Disord*

[5] 10-fold repeated-stratified cross-validation using a Logistic Regression Classifier

[6] Inattention biomarker: Spearman ρ = 0.37, p < 0.0001, q = 0.0006, Benjamini–Hochberg-corrected across the 123 feature-symptom pairs tested. This is comparable to or greater than the agreement typically observed between parents and teachers rating the same child's ADHD symptoms (r = 0.09–0.39, Narad et al., 2015)[7] indicating that our biomarker **captures clinically meaningful variance** in symptom severity.

improvement and regulatory clearance (FDA/MDR) are required before the technology could be used as an ADHD diagnostic aid.

Addressing a Significant Unmet Medical Need

Reflecting its substantially higher prevalence,[7] ADHD represents a larger addressable clinical opportunity than paediatric autism. ADHD assessment in children and adolescents generally relies on clinical interviews, behavioural observations, questionnaires and input from families and schools. This process is highly subjective and resource-intensive, while limited specialist capacity may result in long waiting times for patients and their families seeking a diagnosis. Digital smartphone-based measures, as part of a scalable and cost-effective technological solution for the diagnostic process, have the potential to complement clinical judgement from medical professionals and specialists, improve workflow efficiency in clinical settings, and help families reach appropriate care sooner.

Capital-efficient Collaboration with MCG

The European ADHD study with MCG was completed at no cost to BlinkLab. Study procedures, including administration of the smartphone-based assessments and collection and analysis of neurometric data were executed by BlinkLab, while the clinical procedures establishing the diagnostic reference standard were performed by a multidisciplinary clinical team at MCG. MCG contributed clinical expertise, access to participants, and diagnostic review at no cost to the Company. BlinkLab retains ownership of the study data and of all intellectual property generated through the collaboration as part of its agreement with MCG.[8]

Dr Henk-Jan Boele, Managing Director and CEO of BlinkLab, stated: *"Achieving 82% sensitivity and 83% specificity is an exciting result and the first major step in developing BlinkLab Dx2, our improved model designed to detect ADHD in addition to autism. ADHD represents a significant unmet medical need and, in our view, a substantially larger addressable market than paediatric autism.*

These numbers deserve context. There is no blood test or brain scan for ADHD. Diagnosis is a subjective clinical judgement, and two experienced clinicians assessing the same child often disagree. Every objective test is therefore graded against a benchmark that carries its own error. Seen that way, BlinkLab's 82% sensitivity and 83% specificity sit close to the practical ceiling for any test scored against subjective clinical opinion. And that ceiling is precisely the opportunity we intend to break through, by measuring biology directly instead of chasing an imperfect label.

Our new ADHD results give us confidence in the technology and in our decision to progress towards a regulatory study program for Dx2, following the same FDA regulatory pathway and development strategy we established for our autism product.

[7] Yang F, Chen R, Xiong J, et al. Disease burden of autism spectrum disorder and attention-deficit/hyperactivity disorder in the 0–14 age group across 204 countries and regions from 1990 to 2021. Child Psychiatry Hum Dev. 2025. doi:10.1007/s10578-025-01880-w.
[8] ASX Announcement (30 July 2024) – *"BlinkLab partners with Mental Care Group in Europe to improve and accelerate the diagnostic evaluation of ADHD"*

I am incredibly proud of our team for what we anticipate will be the first smartphone-based digital biomarker test for ADHD in the world. I am grateful for the opportunity to work with Mental Care Group and with the children and families whose participation made this study possible.

Beyond diagnosis, we believe we are at the forefront of developing quantitative digital biomarkers capable of measuring ADHD symptom domains (hyperactivity, inattentiveness and impulsivity) and severity and, potentially, tracking treatment response. This matters precisely because it moves us past the subjectivity of the label: if we can measure the underlying neurobiology directly, we are no longer bound by the reliability of clinical opinion. Such biomarkers could support clinicians in optimising diagnosis and personalising therapy, and provide pharmaceutical companies with objective endpoints for clinical trials in children and potentially adults"

Jan Willem van der Windt, CEO of Mental Care Group, commented: *"As one of the largest providers of youth mental health care in Europe, we see every day what long waiting times and resource-intensive assessment pathways mean for children and their families. These BlinkLab results show that a brief smartphone measurement could help our clinicians direct extensive diagnostics to the children who need them most. We eagerly look forward to implementing BlinkLab into our diagnostic workflow. Technology will not replace professional judgement, but it can support it. We thank BlinkLab for making their platform and scientific expertise available to us, and the children, parents and colleagues who made this study possible."*

Next Steps Towards ADHD Regulatory Approval

BlinkLab will use the findings from this European study to further advance the development of BlinkLab Dx2. Consistent with the development pathway successfully established for BlinkLab Dx1, the Company plans to initiate a U.S. pilot study in collaboration with leading ADHD clinical centres, followed by a prospective FDA registrational study, subject to regulatory engagement and successful completion of the pilot.

BlinkLab expects to leverage its existing clinical development and regulatory framework, including engagement with experienced contract research organisations (IQVIA-MCRA) and regulatory advisers. While the initial regulatory focus is expected to be the United States, the Company will also continue to evaluate commercialisation and regulatory opportunities in other jurisdictions, including Europe under the EU Medical Device Regulation (MDR).

Future Opportunities & Outlook

In addition to a diagnostic application in children, BlinkLab intends to investigate **ADHD diagnosis in adults,** whether its smartphone-derived neurobehavioural biomarkers can monitor ADHD symptom progression over time, monitor response to pharmaceutical treatment (supported by preliminary results[9]), and support clinical development of ADHD therapeutics.

[9] BlinkLab Limited, Replacement Prospectus (2 April 2024)

This announcement is intended to lift the Company's Trading Halt, applied for and granted on Monday 3 August 2026.

This announcement has been authorised for release by the Board of BlinkLab Limited.

For further information please contact:

Dr Henk-Jan Boele
Managing Director & CEO
henkjan@blinklab.org
M: +31 (0) 611 132 247

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

About BlinkLab Limited

BlinkLab Limited was founded by neuroscientists at Princeton University and is developing a smartphone-based diagnostic platform for autism. Its most advanced product, BlinkLab Dx1, is an autism diagnostic aid for clinicians that leverages smartphones, artificial intelligence and machine learning to capture objective, reflex-based measures, supporting earlier and more accurate autism identification. This enables timely intervention during critical periods of brain development. BlinkLab is led by an experienced management team and Board with deep expertise in digital healthcare, computer vision and AI, supported by a Scientific Advisory Board of leading experts in autism and brain development.