

## ASX Announcement

25 July 2025

**Quarterly Activities for Period Ended 30 June 2025****Highlights:**

- **Pilot Phase of U.S. Autism Trial Nears Completion:** At the time of this report, 163 children have fully completed all study procedures in the Pilot Phase of BlinkLab's U.S. autism trial. 55 children were tested at PriMED Clinical Research LLC (Dayton, Ohio) and North Shore Pediatric Therapy (Chicago, Illinois). A further 108 US-based children were enrolled via decentralised recruitment campaign. The pilot trial is on-track to complete recruitment in August 2025 with data locking and unblinding to follow. Results are expected to be released in Q3 2025.
- **Clinical Sites Update - Pilot and Main Phase Progress:** To date Blinklab has two clinical sites actively recruiting in the Pilot Phase and two clinical sites onboarded for the Main Phase of the study. Up to eight additional clinical sites are expected within three months, selected to ensure geographic and socioeconomic diversity.
- **ADHD Trial Expanded in Europe - Larger Dataset in Progress:** 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.
- **U.S. IRB Approval Secured for Main Phase of FDA Study:** Last month Blinklab obtained U.S. Institutional Review Board (IRB) approval to initiate the Main Phase of its FDA-regulated study. This represents a key regulatory milestone in the 510(k) pathway. The company expects to commence Main Phase enrolment by the end of the current quarter.

**BlinkLab Limited (ASX:BB1) ("BlinkLab" or the "Company")**, a leading digital healthcare company focused on AI-powered diagnostics for neurodevelopmental conditions, is pleased to provide its activity report for the April–June 2025 quarter, along with a financial and corporate update for the period. During the quarter, the Company achieved key operational and strategic milestones, primarily related to its FDA 510(k) regulatory trial. While the clinical program to date has focused on the early detection of autism using BlinkLab Dx 1, this work has now progressed to include the significant expansion of a second clinical trial targeting the detection of ADHD using the Company's enhanced ADHD Dx 2 model.

**Commenting on the activities for the Quarter, Co-founder and CEO of BlinkLab, Dr Henk-Jan Boele, stated:** *“During the June quarter, BlinkLab made significant progress across both its FDA clinical trial program and broader corporate objectives. Key regulatory milestones were achieved, IRB approvals secured, and the network of participating clinical sites expanded. We strengthened our financial position with a successful \$7.66M capital raise, enabling the launch of a parallel regulatory trial focused on both autism and ADHD diagnostics.*

*The decision to pursue clinical trials for both autism and ADHD reflects BlinkLab’s commitment to tackling the two most prevalent neurodevelopmental conditions in children. Importantly, BlinkLab is currently the only company developing a unified digital diagnostic platform that addresses both conditions, using the same core technology, same mobile app, and same clinician portal, with distinct diagnostic pathways. This single-platform approach offers unmatched scalability and efficiency for healthcare providers.*

*While most competitors in the digital diagnostic space focus exclusively on autism and primarily on the U.S. market, BlinkLab has adopted a broader vision targeting both the U.S. and European healthcare markets and expanding the clinical utility of our platform to include ADHD.*

*I truly appreciate the dedication of our team, the support of our board, and the confidence of our investors.”*

**Chairman of BlinkLab, Mr Brian Leedman, also commented:** *“The BlinkLab team is proud of the progress made this quarter, especially the strong investor response to our \$7.66M capital raise, onboarding of top U.S. clinical sites, and steady advancement toward FDA approval next year.*

*In a rapidly evolving digital healthcare landscape, staying at the forefront requires both innovation and exceptional execution. We’re fortunate to have secured top-tier talent across clinical, regulatory, and technical domains positioning BlinkLab to lead in this next generation of digital diagnostics.*

*The ongoing support from investors and key management underscores confidence in our approach to closing critical diagnostic gaps. We believe this work holds significant promise not just for the field, but for families seeking earlier and more accessible intervention for neurodevelopmental conditions.”*

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## Operational Update

### **U.S. Autism Study Progress and Recruitment Update**

As of this announcement 163 children have been successfully enrolled in the Pilot Phase of BlinkLab’s U.S. autism study. Of these 55 children were recruited through partnering autism centres - PriMED Clinical Research LLC (Dayton, Ohio) and North Shore Pediatric Therapy

(Chicago, Illinois). Clinical evaluations at both sites are currently ongoing. Data unblinding is expected next month, with preliminary results to follow shortly thereafter. BlinkLab also established a parallel remote recruitment cohort which proved highly effective in accelerating participant accrual. Since April 108 children were enrolled through this decentralised approach demonstrating the scalability of the BlinkLab platform. All of the participants have completed diagnostic evaluations for autism or other neurodevelopmental conditions.

### **Dx 1 Autism Model: Training and Validation**

The Dx 1 autism model will ultimately be trained on data from over 1,500 children aged 2–11 years, representing diverse backgrounds and nationalities. Following data unblinding, the model will undergo final validation. A sufficiently powered and diverse training dataset is essential for optimizing classifier performance, minimizing overfitting, and ensuring the model’s generalizability across varied developmental profiles. Given the high phenotypic heterogeneity in autism, capturing a broad range of behavioural and neurocognitive patterns during the Pilot Phase is crucial for improving both sensitivity and specificity of the diagnostic model.

### **At-Home Testing: Strong Parental Support and Operational Insights**

The Pilot Phase has significantly reinforced BlinkLab’s confidence in at-home testing. Feedback from participating families has been overwhelmingly positive, with many parents valuing the comfort and predictability of the home environment for their children. Only 3% of children were unable to continue testing due to non-compliance or technical issues during the screening session. For the upcoming FDA study, participants who fail to pass this screening step will be excluded from the study. This screening process plays a key role in ensuring data quality and protocol compliance.

### **Operational Enhancements and SOP Development**

The Pilot Phase has also led to refinements in clinician’s Standard Operating Procedures (SOPs) to improve model training and implementation. These improvements contribute to the development of robust and generalizable digital biomarkers for autism diagnosis. Insights from the Pilot Phase dataset will help define critical parameters for the Main Phase of the study, including diagnostic classification thresholds, sensitivity and specificity benchmarks, and stratification strategies for subpopulations. This foundational work significantly de-risks the transition into the Main Phase of the 510(k) regulatory study.

### **CEO of BlinkLab Dr Henk-Jan Boele commented:**

*“Running a Pilot Phase of the U.S. study has proven to be a valuable decision, allowing our team to continuously learn and de-risk the Main Phase of the program. This process helps us refine our SOPs for both clinicians and participating families, while we finalize clinical trial agreements with leading U.S. hospitals and research institutions. I want to reemphasize that a bring-your-own-device study like the BlinkLab trial presents unique challenges, and our goal is to address them thoroughly before initiating the Main Phase.”*

### **Building Confidence Through Pilot Phase Insights**

The design of the Pilot Phase of the study closely mirrors that of the main regulatory trial, and the results will serve as a critical predictor of success. By incorporating learnings from the

Pilot Phase, BlinkLab is positioning itself to deliver the highest level of confidence to its stakeholders and investors as it advances toward full-scale execution of the Main Phase of its FDA 510(k) trial.

### **European ADHD Program Expands to Strengthen Diagnostic Dx 2 ADHD Model**

During the quarter, Mental Care Group and the BlinkLab team extended the ADHD clinical trial to include four additional clinical sites. These new sites have been recently onboarded and will actively participate in the study enrolment. The expansion is projected to increase the number of children tested by 400%, with an anticipated recruitment of 50 children per month. Based on current enrolment projections, the clinical team anticipates that data from approximately 300 subjects, including those in the initial cohort, will be available for analysis by year-end.

The ADHD clinical trial was initially designed as a prospective, single-centre, within-subject comparison study. However, to better capture the clinical heterogeneity of ADHD and ensure broader generalizability, the trial was expanded to a prospective, multi-centre design. This shift was also critical for training and validating BlinkLab's machine-learning model to robustly differentiate between autism and ADHD.

To maintain statistical integrity and optimize the performance of machine-learning classifiers, the Company has decided not to conduct interim data analysis from the initial single-site cohort and will continue uninterrupted enrolment across the full multicentre study. This approach will facilitate the aggregation of a significantly larger and more heterogeneous dataset, which is crucial for improving the Dx 2 model's generalizability and, importantly, more accurately identifying ADHD subtypes (inattentive, hyperactive, or combined). The resulting dataset will form a critical part of BlinkLab's clinical evidence package under the European regulatory framework, supporting both technical and clinical performance claims in preparation for CE marking under EU MDR.

### **Expanded Network of Clinical Sites Participating in FDA Autism Study**

As of the time of this report, BlinkLab has two clinical sites actively recruiting participants in the Pilot Phase: PriMED Clinical Research LLC (Dayton, Ohio) and North Shore Pediatric Therapy (Chicago, Illinois). Additionally, two more sites are fully onboarded for the Main Phase of the study: the University of Nebraska Medical Center (Omaha, Nebraska) and the Southwest Autism Research & Resource Center (Phoenix, Arizona). Over the next three months, BlinkLab anticipates announcing up to eight additional sites. Sites participating in BlinkLab's FDA 510(k) trial were chosen based on their prior experience conducting regulatory trials in autism. To ensure broad representation across clinical populations, site selection emphasized geographic and socioeconomic diversity. This multicentre design is intended to enhance recruitment efficiency and support high-quality, generalizable data collection across diverse populations.

### **IRB Approval Secured**

Last month, Blinklab obtained U.S. Institutional Review Board (IRB) approval to initiate the Main Phase of its FDA study, a key regulatory milestone in the 510(k) pathway. IRB approval is a critical prerequisite in the clinical trial process, involving an independent ethics review of

the study protocol, informed consent documents, risk/benefit profile, and participant protections. This ensures that the study meets ethical standards and complies with FDA regulations. For most participating sites, IRB approval was required before proceeding with Clinical Trial Agreement (CTA) execution, site activation, and participant recruitment. For the majority of remaining sites, Blinklab is already engaged in the final stages of CTA negotiation and budget finalization. Once these agreements are complete, additional sites will be formally announced and activated. The company expects to commence enrolment into the Main Phase of the FDA 510(k) study by the end of the current quarter, supported by an expanding site network.

### **Optimization of FDA Regulatory Trial to Save Time and Money**

During the quarter, the Company implemented a strategic change to the recruitment approach for its FDA 510(k) clinical trial to improve efficiency, reduce costs, and accelerate timelines. Initially, recruitment for the Dx 1 trial was limited to autism specialty centres, targeting children already on diagnostic waitlists. However, during the site onboarding process, the Company identified a key limitation: these waitlists were disproportionately composed of children highly likely to receive an autism diagnosis, with autism-positive rates ranging from 70% to 90%, depending on the site.

This imbalance would have resulted in a heavily autism-enriched sample, requiring substantial over-recruitment to achieve the balanced comparison group necessary for the study. Internal projections indicated that up to 1,000 participants would have been needed to reach the target of 260 children with and 260 without an autism diagnosis. To address this, the Company expanded its recruitment strategy beyond diagnostic waitlists. Participants will now also be enrolled through general paediatric offices, psychological practices, local daycare centres and schools, as well as self-referrals from families.

As a result of this shift, the Main Phase of the study is expected to require a significantly smaller sample size than originally projected, ultimately reducing both study costs and the timeline to completion. Importantly, this revised strategy better reflects the real-world use of the BlinkLab Dx 1 device as a diagnostic tool applicable across both primary care and specialist settings. By broadening its recruitment model, BlinkLab is accelerating study completion while creating a more efficient path toward commercialization. The study updates have been fully discussed with the CRO, the protocol has been amended accordingly, and the FDA has been informed.

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## **Corporate Activity**

### **Financial Update**

Net cash used in operating activities for the quarter ended 30 June 2025 was **A\$1.35 million**, with the majority (**A\$0.966 million**) allocated to research and development. This includes ongoing expenditure related to the Pilot Phase of the U.S. clinical study, the ADHD clinical program, and the regulatory work associated with CE marking under the EU MDR. Staff costs (excluding R&D personnel) totalled **A\$0.117 million**, while corporate administration outflows amounted to **A\$0.4 million**, reflecting an increase due to the timing of annual insurance

premium payments. Payments to related parties for the quarter were **A\$0.173 million**, relating to salaries and the provision of professional services.

As of 30 June 2025, the Company's cash balance was **A\$8.711 million**, providing a strong financial foundation to support ongoing clinical and regulatory initiatives.

Use of Funds	Full Subscription - \$7,000,000 AUD		
	Funds allocated pursuant to Prospectus (8 Quarters)	Actual cash expenditure for the quarter ended 30 June 2025 (Q6)	Balance remaining
Expenses of the Public Offer	\$695,945	\$696,504	-\$559
Software Improvement and Tech Support	\$1,656,568	\$178,820	\$1,477,748
IP Protection	\$150,000	\$21,345	\$128,655
Research and Business Development	\$1,031,500	\$2,360,870	-\$1,329,370
Clinical Studies and Regulatory (United States)	\$1,869,609	\$867,621	\$1,001,988
Completion of Clinical Study and Regulatory Submission (Europe)	\$480,000	\$77,058	\$402,942
General, Admin & Working Capital	\$1,691,114	\$2,015,967	-\$324,853
Ongoing Listing Costs	\$340,000	\$139,616	\$200,384
<b>Total</b>	<b>\$7,914,736</b>	<b>\$6,357,802</b>	<b>\$1,556,934</b>

*Note: The Company's first quarter represented 4 months and 9 days (from the Prospectus date (21 February 2024) until 30 June 2024). Accordingly, quarter 8 will be shortened by the same amount (1 month and 9 days).*

**This announcement has been approved by the Board of Directors.**

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**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, ADHD, schizophrenia, and other neurodevelopmental conditions. Our most advanced product is an autism diagnostic test that leverages the power of smartphones, AI and machine learning to deliver screening tests specifically designed for children as young as 18 months old. This marks a significant advancement, considering traditional diagnoses typically occur around five years of age, often missing the crucial early window for effective intervention. 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.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

BlinkLab Limited

**ABN**

53 652 901 703

**Quarter ended ("current quarter")**

30 June 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(966)	(2,857)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(56)	(220)
(d) leased assets	-	-
(e) staff costs	(117)	(312)
(f) administration and corporate costs	(400)	(1,075)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	17	168
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	172	172
1.8 Other (provide details if material)	-	32
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,350)</b>	<b>(4,092)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(16)	(51)
(d) investments	-	-
(e) intellectual property	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
	(f) other non-current assets	(11)	(114)
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(27)</b>	<b>(165)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,450	7,450
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	47	103
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(530)	(530)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Payment of lease liability	(13)	(72)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>6,954</b>	<b>6,951</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	3,134	6,017
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,350)	(4,092)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(27)	(165)

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<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,954	6,951
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>8,711</b>	<b>8,711</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,711	1,134
5.2	Call deposits	7,000	2,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>8,711</b>	<b>3,134</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(173)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

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7. <b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>		
7.5 <b>Unused financing facilities available at quarter end</b>		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,350)
8.2 Cash and cash equivalents at quarter end (item 4.6)	8,711
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	8,711
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>6.45</b>
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

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### Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 25 July 2025

Authorised by: The Board of BlinkLab Limited  
(Name of body or officer authorising release – see note 4)

### Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.