blinklab

30 January 2025

Quarterly Activities Report and Appendix 4C for the Period Ended 31 December 2024

Highlights

- **BlinkLab initiated its FDA registrational study, which aims to revolutionise the diagnostics and care for autism, making it more accessible and reliable.**
  - **The initial phase will recruit up to 100 participants (children aged between 2-11 years old), with the main study recruiting up to 1,000 subjects.**
  - **Four clinical sites have been selected, with six additional sites to be added; the sites are spread across the US to ensure diversity of the population.**
  - **Final results are expected by the end of CY 2025 and will be used for the 510(k) Food and Drug Administration ("FDA") approval.**

- **BlinkLab received positive feedback from a Pre-Submission meeting with the US Federal Drug Administration ("FDA") regarding the regulatory pathway for BlinkLab Dx 1 diagnostic app.**

- **Final results from the pivotal autism study (announced in November of 2024) bolster confidence that BlinkLab Dx 1 will surpass the accuracy parameters that are required for regulatory approval in the upcoming FDA registration trial.**

- **BlinkLab and Monash University have partnered on the large-scale Monash Autism-ADHD Genetics and Neurodevelopment ("MAGNET") study, which aims to conduct deep phenotyping in children on the autism spectrum, with ADHD, or both. The study will also work towards further improvements to BlinkLab's Machine Learning ("ML") algorithm to better distinguish between autism- and ADHD-specific clinical features.**

- **As at 31 December 2024, the Company had a cash balance of A$4.4 million.**

BlinkLab Limited (**ASX:BB1**) (**"BlinkLab"**, or **"the Company"**) an innovative digital healthcare company leveraging smartphones, computer vision, Artificial Intelligence ("AI"), and Machine Learning ("ML") to diagnose neurodevelopmental conditions such as autism and ADHD, is pleased to release its Appendix 4C and Quarterly Activity Report for the period ended 31 December 2024 (the "Quarter").

Following the positive outcome from the recent FDA pre-submission meeting, as well as positive final data from the pivotal preliminary study (ASX Announcement 19 November 2024), BlinkLab is confident in the success of its registrational study, as well as the subsequent 510(k) regulatory approval for our first diagnostic tool for autism, called "Blinklab Dx 1".

US FDA Registrational Study in Autism Now Underway

The FDA registrational study program will consist of a pilot study, followed by the primary study. The pilot study will recruit up to 100 participants (children aged between 2-11 years) and will continue into a registrational study, which will be conducted with up to 1,000 subjects across ten clinical sites in the US. The pilot study will be used to train the investigators and personnel at clinical sites, as well as to test the procedures of subject screening and data collection. These steps are part of BlinkLab's considered strategy for mitigating risk leading up to the main FDA study and are aimed at ensuring the highest quality of data and diagnostic accuracy of the BlinkLab tests.

For the 510(k) study, BB1 has completed the following key steps during the quarter:

1. **Submission of Study Protocol & Pre-Submission to FDA**
   In consultation with the Contract Research Organisation ("CRO"), the BlinkLab team submitted the Study Protocol and presubmission to the FDA, during the quarter, in order to discuss and align on the study endpoints prior to the start of the study.

2. **Pre-Submission meeting with the FDA**
   BlinkLab has received positive feedback from the United States FDA on the final clinical study design and data requirements in order to achieve FDA 510(k) clearance. BlinkLab's decision to schedule a Pre-Submission meeting with the FDA stems from the numerous advantages it offers, including **derisking the path to FDA clearance**. The meeting facilitates early feedback on crucial aspects like study design, endpoints, and data requirements, ensuring alignment with FDA expectations and reducing the risk of regulatory setbacks. Additionally, the Pre-Submission meeting helps clarify the regulatory pathway and classification required, confirming the appropriateness of the 510(k) route for the product and identifying potential predicate device comparisons. This proactive approach allows the FDA to flag regulatory challenges early, mitigating risks before a formal submission. For AI-driven technologies like BlinkLab Dx 1, the meeting is particularly crucial for discussing algorithm validation, dataset diversity, and real-world performance expectations, in order to ensure compliance with FDA standards. By addressing key concerns upfront and prior to conducting any primary studies, a Pre-Submission meeting can streamline the review process, potentially shorten approval timelines, and build a collaborative relationship with FDA reviewers, therefore enhancing transparency and engagement.

3. **IRB Protocol Submitted**
   The Study Protocol, Informed Consent Forms, and the recruitment materials, have all been reviewed and approved by WCG Clinical in Princeton, New Jersey (https://www.wcgclinical.com/). BlinkLab is pleased to announce that the study has been classified as a "**minimal risk study"** because it streamlines the IRB approval process and reduces regulatory burdens, allowing BlinkLab to move forward more efficiently. This minimal risk designation confirms that the probability and magnitude of harm or discomfort for participants undergoing a BlinkLab smartphone assessment are no greater than those encountered in daily life or simple routine clinical assessments. It also simplifies ethics approval oversight, making it easier to recruit participants and conduct the study without

unnecessary delays. Most importantly, it reassures parents and caregivers that their children's well-being remains BlinkLab's top priority while we gather critical data to advance autism diagnosis using AI-driven, accessible mobile technology.

4. **Onboarding of Clinical and Research Sites**
   Together with our CRO, BlinkLab is currently onboarding leading clinical sites and research centers spanning across the US, ensuring a diverse population of children in terms of race, ethnicity, and gender. Developing ML-based medical devices necessitates training and validating models on diverse populations to ensure accuracy, generalisability, and fairness across varied patient demographics. Sites will be represented by top clinical research institutions. Sites will be announced after they have been activated.

5. **Health Insurance Portability and Accountability Act ("HIPAA") Compliance.**
   In the context of BlinkLab's clinical trials for FDA 510(k) clearance, HIPAA compliance is crucial due to the collection and handling of sensitive patient data during the study. The HIPAA sets standards for protecting patient health information. BlinkLab will ensure that all patient data collected during the trials is handled in accordance with HIPAA regulations, which includes implementing safeguards to protect patient privacy and security. Adhering to HIPAA regulations not only protects patient privacy but also ensures the integrity and trustworthiness of the clinical trial data, which is essential for obtaining FDA clearance.

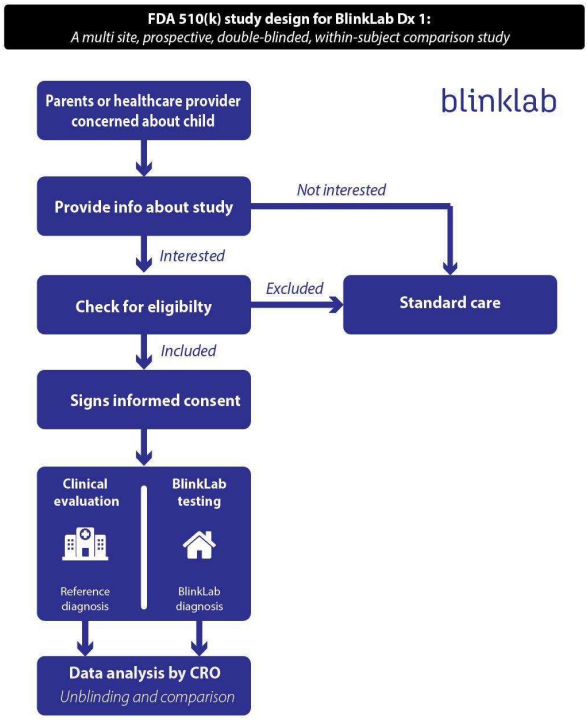

Figure 1 - BlinkLab's 510(k) regulatory study program is a multi-site, prospective, double-blinded within subject comparison study. *IRB approval has been received, and final study results are expected by the end of 2025. These results will be used for the 510(k) FDA approval expected mid-2026.*

Other Key Items

Results from Pivotal Autism Study

The Company announced the final results from a pivotal autism study (N=441), conducted in partnership with the Turning Pointe Autism Foundation in Illinois, Princeton University, and the National Center for the Disabled in Morocco. Results showed a class leading sensitivity of 91% and specificity of 85%. This represented a significant improvement when compared to data generated using older versions of the ML software, which validates our platform development strategy. BlinkLab is confident in the ML model that is used in the current US registration study as it surpasses all competitive products and exceeds the accuracy parameters required for regulatory approval.

Current Research Programs

BlinkLab is making significant strides in clinical research with two key programs launched in 2024. In the Netherlands, BlinkLab is collaborating with Mental Care Group on an ADHD study involving up to 500 children aged 6 to 18. Expected to conclude by the end of 2025, this study will provide essential data to further improve our machine learning model for ADHD diagnosis, which will be used in our planned US ADHD registrational study, anticipated to begin in 2026.

Family-Based Trial

Additionally, our partnership with Monash University in Australia is conducting a clinical study with a novel family-based trial design. This study is expected to enrol up to 1,000 families with children diagnosed with autism and/or ADHD, along with their siblings and parents. Preliminary results are anticipated in late 2025. This research aims to overcome limitations in current diagnostic methods, paving the way for more accurate and less categorical diagnostics, as well as personalised support for children with autism and ADHD. These initiatives highlight the Company's dedication to advancing neurodevelopmental research and transforming mental healthcare and diagnostics globally.

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Financial Update

Net cash used for operations for the Quarter ended 31 December 2024, was A$0.963 million, with the majority of this (A$0.693 million) related to expenditure on research and development activities. Staff costs incurred were A$0.084 million and corporate administration outflows totalled A$0.204 million. Payments to related parties were A$0.107 million for the quarter and attributable to the provision of services (salaries and wages/labour).

The Company's cash balance was A$4.396 million as at 31 December 2024.

	Full subscription - $7,000,000		
Use of Funds	**Funds allocated pursuant to Prospectus. (8 Quarters)**	**Actual cash expenditure for the period ended 31 December 2024 (Q3)**	**Balance Remaining**
Expenses of the Public Offer	$695,945	$696,504	($559)
Software Improvement and Tech Support	$1,656,568	$152,486	$1,504,082
IP Protection	$150,000	$18,551	$131,449
Research and Business Development	$1,031,500	$1,112,224	-$80,724
Clinical Studies and Regulatory (US)	$1,869,609	$305,498	$1,564,111
Completion of Clinical Study and Regulatory Submission (Europe)	$480,000	$0	$480,000
General, Admin & Working Capital	$1,691,114	$1,164,538	$526,576
Ongoing Listing Costs	$340,000	$68,272	$271,728
Total	**$7,914,736**	**$3,518,073**	**$4,396,663**

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).

Director Trading

During December 2024 and January 2025, in accordance with the Company's securities trading policy, Directors demonstrated their support for the Company by purchasing shares on-market. These are reflected in the Change of Directors Interest Notice(s) which have been lodged with the ASX in accordance with the ASX Listing Rules.

The Board of Directors has approved this announcement.

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About BlinkLab Limited

BlinkLab, 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	**Quarter ended ("current quarter")**
53 652 901 703	31 December 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(693)	(1,017)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(27)	(73)
	(d) leased assets	-	-
	(e) staff costs	(84)	(141)
	(f) administration and corporate costs	(204)	(420)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	45	127
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	32
1.9	**Net cash from / (used in) operating activities**	**(963)**	**(1,492)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(5)	(11)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	(32)	(77)
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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(37)**	**(88)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
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	(18)	(41)
3.10	**Net cash from / (used in) financing activities**	**(18)**	**(41)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,414	6,017
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(963)	(1,492)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(37)	(88)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(18)	(41)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,396**	**4,396**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	1,396	414
5.2	Call deposits	3,000	5,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,396**	**5,414**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(107)
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.

7.	**Financing facilities** *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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	-

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.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(963)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,396
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,396
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**4.56**

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.

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

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.

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: 30 January 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.