

Advancing global neurodiagnostics with strategic partnerships and regulatory milestones on a pathway to commercialisation

Highlights

- FDA registration study on track to commence this calendar year.
- Strategic partnerships signed with leading outpatient mental healthcare providers in Europe, for Autism and ADHD.
- Several clinical studies in Autism, ADHD, Frontotemporal Dementia, Functional Neurological Disorders, Spinocerebellar Ataxia, with top European and US institutions are ongoing and results are expected next calendar year.
- Commenced regulatory work towards obtaining ISO/CE mark certifications in Europe to support future commercial launch.
- As at 30 September 2024, the Company had a cash balance of A\$5.4 million following the \$7 million IPO in April.

BlinkLab Limited (ASX:BB1) (“BlinkLab”, or “the Company”) an innovative digital healthcare company leveraging smartphones, computer vision, AI and machine learning to diagnose neurodevelopmental conditions, is pleased to release its Appendix 4C and Quarterly Activity Report for the period ended 30 September 2024. During the quarter the Company made significant progress towards the launch of its upcoming FDA registration study, which is on-track to commence before the calendar year end.

BlinkLab was also pleased to announce several new strategic partnerships which confirmed the continuing adoption of BlinkLab’s products with world-renowned research institutions. The rapid progress in making the Company’s cutting-edge technology available to healthcare practitioners, families and caregivers is exciting for the BlinkLab team.

Strong progress towards initiation of FDA clinical study later this year for “BlinkLab Dx 1”

We are pleased to report that, after a competitive selection process, BlinkLab are in the final stages of appointing a world-recognised Clinical Research Organisation (“CRO”), with a track record of obtaining regulatory approvals for digital healthcare and medical devices, to co-ordinate our upcoming FDA registration trial.

Throughout the quarter, the Company continued work on finalising the study protocol, engaging with FDA as well as reaching out and interacting with future US based clinical sites that will be conducting the registrational studies. Before the end of CY 2024, we expect to announce the outcomes of this work. We are excited about the progress that our regulatory and development team is making to start the FDA study that we believe will be the largest smartphone based clinical study in the world, in the field of autism diagnostics.

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Strategic Partnerships with large European Mental Healthcare Providers

During the past quarter, we announced two major clinical and future commercialisation partnerships with large European mental healthcare providers. Together with Mental Care Group and INTER-PSY, BlinkLab has launched companion clinical studies in ADHD and autism, evaluating whether the Company's technology can enhance diagnostic accuracy and efficiency in clinical settings, with a future commitment to commercialise our products with these partners in Europe upon successful outcomes. With a national network of over 200 clinical centres serving over 100,000 patients annually, these partnerships are a huge endorsement of the BlinkLab smartphone-based tests and the potential to grow successfully outside the US.

Ongoing Work Towards Obtaining European Certifications of BlinkLab Product

As the Company continues to support the activities for the launch of FDA registrational study, the BlinkLab team has also initiated work towards obtaining applicable regulatory clearances to be able to launch the product outside the US.

Under the EU Medical Device Regulation (MDR) 2017/745, the BlinkLab diagnostic platform is classified as a class IIa medical device and will require CE marking of conformity before the device can be launched on the market. The conformity work will include implementation of quality management systems (ISO13485 certification), usability engineering, labelling, adherence to general data protection regulation (GDPR), developing appropriate post-market surveillance plan and other activities. This work commenced during the prior quarter, and the Company will be providing ongoing updates as it moves forward towards EU certification and future launch in markets outside the US.

Ongoing Clinical Studies in Other Indications with World Leading Research Organisations

Since listing on the Australian Securities Exchange in April this year, BlinkLab has announced multiple clinical research collaborations with several world-renowned research institutions to conduct studies in mental and developmental conditions outside of autism and ADHD.

The data collected from these studies is fundamental to the Company's diagnostic platform and machine learning models, as distinguishing autism and ADHD from other psychiatric disorders in the real world is difficult due to their multidimensional phenotypes and significant overlap of symptoms and characteristics.

At BlinkLab we are trying to fundamentally change the diagnostic approach by collecting digital phenotype data from the broadest possible range of neurodevelopmental and neurodegenerative conditions. By training the model on large data sets from various diseases, we significantly improve future predictive performance of the BlinkLab application in real-world scenarios.

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In partnership with several research institutions, BlinkLab is currently conducting studies in Frontotemporal Dementia, Alzheimer's, Functional Neurological Disorders, Spinocerebellar Ataxia, and potentially other psychiatric conditions in the future. As data from these studies report, we will be adding predictive outcomes to our models, making them more robust and more powerful in the ability to differentiate between multiple conditions based on a single test. We believe this can position BlinkLab as a leader in the field of digital psychiatry applications.

Financial update

Net cash used in operations, for the quarter ended 30 September 2024, was \$0.529 million, which included expenditure on research and development activities of \$0.324 million. Staff costs incurred (not including research and development employees) totalled \$0.057 million and corporate administration outflows totalled \$0.216 million. Payments to related parties were \$0.086 million for the quarter and attributable to the provision of services (salaries and wages/labour).

The Company's cash balance was \$5.414 million as at 30 September 2024.

Use of Funds	Full subscription - \$7,000,000		
	Funds allocated pursuant to Prospectus. (8 Quarters) \$	Actual cash expenditure for the period ended 30 September 2024 (Q2) \$	Balance Remaining \$
Expenses of the Public Offer	\$695,945	\$696,504	(\$559)
Software Improvement and Tech Support	\$1,656,568	\$120,420	\$1,536,148
IP Protection	\$150,000	\$18,551	\$131,449
Research and Business Development	\$1,031,500	\$724,766	\$306,734
Clinical Studies and Regulatory (United States)	\$1,869,609	-	\$1,869,609
Completion of Clinical Study and Regulatory Submission (Europe)	\$480,000	-	\$480,000
General, Admin & Working Capital	\$1,691,114	\$899,971	\$791,143
Ongoing Listing Costs	\$340,000	\$40,143	\$299,857
Total	\$7,914,736	\$2,500,355	\$5,414,381

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).

The level of net cash outflows for the December 2024 quarter is expected to be at similar levels as the current quarter.



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.

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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 September 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(324)	(324)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(46)	(46)
(d) leased assets	-	-
(e) staff costs	(57)	(57)
(f) administration and corporate costs	(216)	(216)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	82	82
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	32
1.9 Net cash from / (used in) operating activities	(529)	(529)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(6)	(6)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	(45)	(45)
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	(51)	(51)

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	(23)	(23)
3.10	Net cash from / (used in) financing activities	(23)	(23)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,017	6,017
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(529)	(529)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(51)	(51)

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(23)	(23)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,414	5,414

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	414	1,017
5.2	Call deposits	5,000	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)	5,414	6,017

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	(86)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

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

7. Financing facilities <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>	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)	(529)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,414
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,414
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	10.23
<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>	

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 October 2024

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.