GLIA DIAGNOSTICS

Company and Technology Overview

Making the Invisible Injury Visible

GLIA Diagnostics is an Australian medtech company developing a fingerstick, microRNA (miRNA)-based point-of-care platform intended to support the assessment and monitoring of traumatic brain injury (TBI). The investigational system combines a disposable biosensor cartridge with a handheld electrochemical reader and targets an approximately 20-minute sample-to-result workflow.

7	5	4	~20 min
proprietary candidate miRNA biomarkers	clinical studies	peer-reviewed publications	design target*

CLINICAL NEED

An estimated 69 million people sustain a TBI worldwide each year, and 70-90% of medically treated brain injuries are mild. Assessment still relies heavily on symptoms and hospital-based imaging, which may be normal in mTBI/concussion.

THE PLATFORM

- Fingerstick whole-blood sample at the point of care.
- Seven proprietary candidate miRNA biomarkers linked to brain injury and recovery biology.
- Single-use electrochemical biosensor cartridge plus handheld, battery-powered reader.
- Designed to deliver an objective investigational result in approximately 20 minutes.*

EVIDENCE BASE

- Five clinical studies across acute TBI, mTBI and longitudinal recovery cohorts.
- Four peer-reviewed publications from 2017-2024.
- Biomarker programme assessed at TRL 7; integrated device and cartridge remain in development.
- Earlier electrochemical proof of concept demonstrated correlation with laboratory PCR measurements.

IP AND DEFENSIBILITY

Three-family IP portfolio:

- Exclusive worldwide licence over the foundational miRNA biomarker family.
- GLIA-owned patent family covering point-of-care electrochemical methods and cartridge architecture.
- GLIA-owned patent family covering diagnostic and prognostic methods and reagents.
- Granted and filed protection across major international jurisdictions.

CURRENT DEVELOPMENT STAGE

- Integrated minimum viable product (MVP) development.
- Cartridge manufacturability, assay integration and local supply-chain development.
- Laboratory correlation and analytical validation.
- FDA Pre-Submission preparation to confirm intended use, validation requirements and regulatory pathway.

CURRENT PARTNERSHIP OBJECTIVES

- Clinical and biobank partners for analytical and clinical validation.
- Engineering, manufacturing and supply-chain collaborators.
- Defence and sport organisations for future operational and field studies.
- Investors and strategic industry partners supporting MVP completion and regulatory readiness.

DEVELOPMENT ROADMAP

COMPLETED

01 Biomarker discovery, clinical research & publications
02 Electrochemical proof of concept
03 IP portfolio, regulatory strategy - moat
04 Successful Defence demonstrations

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NOW

01 Integrated MVP development
02 Cartridge manufacturability and assay integration
03 Laboratory correlation and analytical validation
04 Formalise sporting and Defence partnerships

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NEXT

01 FDA Pre-Submission
02 Clinical validation
03 Regulatory submission
04 Scale up manufacturing

Explore partnership, validation or investment opportunities.

www.gliadiagnostics.com

ed@gliadiagnostics.com | +61 450 507 237

*Investigational technology in development. Not approved for commercial clinical use. Approximately 20 minutes is a design target and has not yet been established through completed clinical validation or regulatory review. Key sources: Dewan MC et al. J Neurosurg. 2019;130(4):1080-97; Cassidy JD et al. J Rehabil Med. 2004;(43 Suppl):28-60; Mitra B et al. J Clin Neurosci. 2017, 2022, 2023; MicroRNA. 2024. Full references are available at gliadiagnostics.com.