Genetic Signatures

Transforming Molecular Diagnostics

# 1H 24 Market Update

22 February 2024

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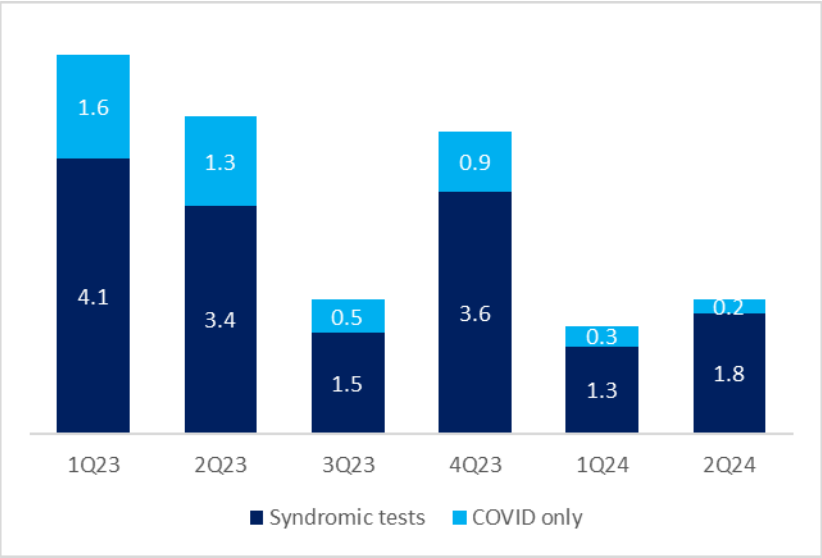
# Revenue dominated by sale of syndromic tests



## Sales Revenue (A$m)




- **Increasing syndromic test focus**
  - Revenue dominated by syndromic tests
  - Growth in enteric syndromic revenue in 1H 24 of 8.8% vs p.c.p.
- **Strong growth drivers to provide long-term, durable growth from syndromic test sales**
  - Multi-pathogen testing for respiratory infections likely to be long-term growth market
  - Syndromic testing increasingly recognised as providing more effective and timely healthcare
  - Unique approach and benefits of **3base®** technology recognised by customers

# Financial Summary – 1H 24 Profit & Loss



| A'000s | 1H 24 | 1H 23 |
|---|---|---|
| Sales revenue | 3,604 | 10,405 |
| Cost of materials & freight | (2,543) | (4,475) |
| **Gross profit** | **1,061** | **5,930** |
| Employee benefits expense | (7,672) | (6,945) |
| Scientific consumables & clinical trials | (1,734) | (2,097) |
| Other expenses | (2,975) | (3,058) |
| **EBITDA** | **(11,320)** | **(6,170)** |
| Depreciation & amortisation | (781) | (702) |
| **EBIT** | **(12,101)** | **(6,872)** |
| Other income | 1,632 | 392 |
| **Profit/(loss) before tax** | **(10,469)** | **(6,480)** |
| Income tax expense | - | - |
| **Net income** | **(10,469)** | **(6,480)** |

- Revenue impacted by reduced respiratory kit sales; – Respiratory revenue expected to be reinstated following TGA registration
- COVID testing representing 14% of revenue (vs 28% p.c.p.)
- Gross margin impacted by additional expenses for provision for stock obsolescence $538k
- Higher employee expenses due to increases in salaries and on-costs as well as restructure costs incurred in the current half
- Ongoing R&D activities and clinical trials for FDA clearance
- $18.1m in cash as at 31 December 2023 with no debt

# Upcoming News Flow

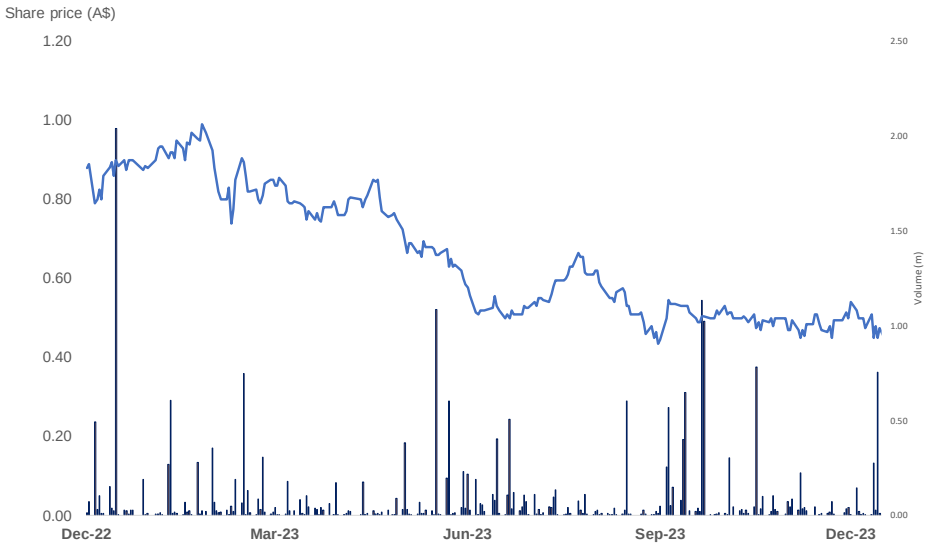


- **Australian sales of the Respiratory Pathogen Detection Kit to major customers expected to return their full volume**
  - Material revenue uplift following TGA approval of Influenza B regulatory submission
- **US *EasyScreen*™ Gastrointestinal Parasite Detection Kit**
  - 510(k) clearance
  - Revenue anticipated to commence in 1H 25
- **Increase sales and presence in UK and EMEA markets**
  - Recently appointed a dedicated distribution manager and secured two new distributors to accelerate expansion
- **R&D initiatives for new products**
  - New *EasyScreen*™ detection kits
  - Technology and workflow improvements
  - Development of Next Generation Instrument prototype

# Company snapshot

## Financial information

| | |
|---|---|
| Share price (21-February-24) | A$0.505 |
| Shares on issue | 186.5m |
| **Market capitalisation** | **A$94.2m** |
| Cash (31-Dec-23) | A$18.1m |
| Debt (31-Dec-23) | Nil |
| **Enterprise value** | **A$76.1m** |




## Top shareholders %

| | |
|---|---|
| Asia Union (Chris Abbott private investment) | 22.8% |
| Perennial Value Management | 12.5% |
| Fidelity International | 9.9% |
| Directors & management | 2.9% |

# Influenza B TGA Regulatory Submission

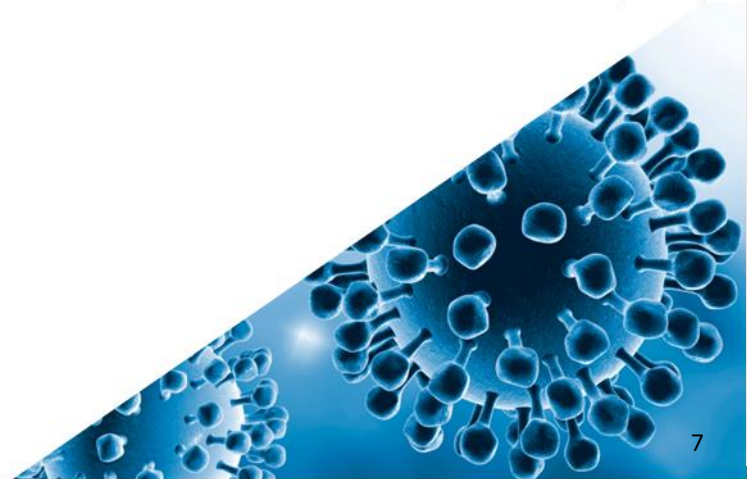


- **The updated *EasyScreen*™ Respiratory Pathogen Detection Kit was submitted to TGA for review in December 2023**

- **Revenue has been impacted with major customers during this time**
  - Expect all respiratory revenue to be reinstated upon approval

- **Minor changes were made in assay design to restore performance in a short timeframe**

Australian Government
Department of Health
Therapeutic Goods Administration



# Compelling opportunity in the US

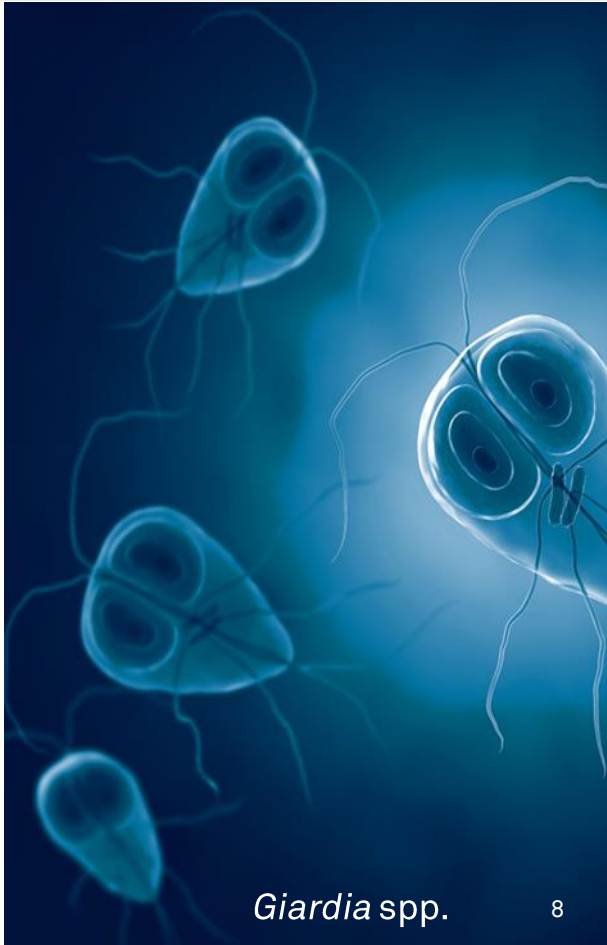


- **First product, the *EasyScreen*™ Gastrointestinal Parasite Detection Kit submitted to FDA for sales clearance**

- **The product addresses an unmet need**
  - Broadest molecular syndromic test for 8 clinically relevant GI parasites
  - No current stand-alone FDA cleared molecular test detects >3 parasites

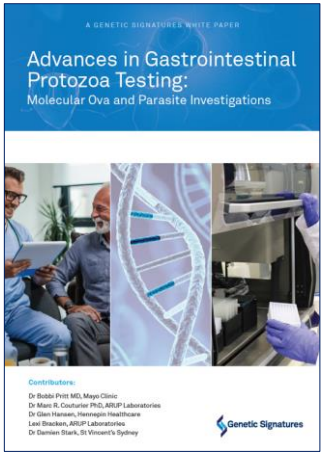
- **~5.5 million traditional tests conducted in the US / year**
  - Traditional tests are manual, slow, labour intensive & unreliable
  - Current testing is not profitable for pathology laboratories

- **Molecular reimbursement code already in place**
  - Higher reimbursement rate than traditional microscopic tests



# Significant investments undertaken to support US launch







US team representation at ASM Microbe 2023 conference in Houston, Texas.

- Clinical trial commenced in 2020 in 3 US sites forming part of the FDA application
- A select, limited number, of pre-qualified customer experience sites in the US are currently evaluating the *EasyScreen*™ Gastrointestinal Parasite Detection Kit
- 6 sites have been trained and performing evaluations. A further 3 sites to be trained in Q3 FY24
- One of these sites has written a scientific paper on the benefits of the *EasyScreen*™ Gastrointestinal Parasite Detection Kit
- Highly experienced sales team in place in preparation for commercial launch
- Distribution, warehouse and laboratory facilities in place
- Engagement with key opinion leaders to understand product appeal and positioning
- Attendance at conferences and delivery of white papers and webinars to increase brand awareness in preparation for launch

# Four distinct customer segments – all targets



*EP005 = *EasyScreen*™ Gastrointestinal Parasite Detection Kit

| Target segments | GI parasite testing requirements | Potential TAM = 5.5 m tests | Share of targeted 2.2m EP005* tests by segment | Potential customers |
|---|---|---|---|---|
| Large commercial reference labs | High volume<br>LabCorp / Quest = >1500 tests / day<br>Others ~100-300 tests / day | 1.65 million<br>30% of TAM | 50% | • LabCorp<br>• Quest<br>• Sonic Health<br>• BioReference Laboratories<br>• Clinical Reference Laboratory |
| IDN / core labs (large hospitals) | Low to medium volume,<br>Some sites high volume<br>Average ~50-100 tests / day | 3.03 million<br>55% of TAM | 32% | • Kaiser Permanente<br>• Baylor Scott and White<br>• Northwell Health<br>• Cleveland Health Clinic<br>• Sutter Health |
| Specialty reference labs | Medium to high volume<br>Average ~40-100 tests / day | 0.28 million<br>5% of TAM | 12% | • ARUP Laboratories<br>• Mayo Clinic<br>• Wadsworth Center<br>• University of Nebraska<br>• Emory Medical Laboratory |
| Independent hospitals | Low to medium volume,<br>Average ~20-40 tests / day | 0.55 million<br>10% of TAM | 6% | • Scripps Laboratories<br>• Sharp Laboratories<br>• John Hopkins<br>• Tampa General<br>• Henry Beaumont |

Target size and TAM modelled from various data sources listed here


- Morningstar Credit Ratings, LLC 16th October 2018. Credit Comparison: LabCorp (BBB+, stable) vs. Quest (BBB+, stable). Link
- Laboratory Economics, Volume 18, No. 3. March 2023. Jondavid Klipp. Link
- Genetic Signatures Market Survey Insights. March 2023
- DeciBio ID DX-Book 2022
- Definitive Healthcare, Healthcare Insights, How many IDNs are in the U.S.?, 21/4/23. Link
- American Hospital Association, Fast Facts. U.S. Health Systems. 2023. Link
- Lab Florida. Types of Labs in U.S. Medical Diagnostics. Accessed on 13/9/23. Link
- Australian Medicare Benefits Schedule Book (MBS). Link

# Update on 510(k) submission to the FDA

## *EasyScreen*™ Gastrointestinal Parasite Detection Kit

- **The Company received multiple rounds of questions from the FDA since submitting the 510(k) application on 1 September 2023**
  - This process was expected due to the complexity of the submission and the lack of commercial comparators (unmet need)
- **Genetic Signatures is currently preparing responses for the recent round of questions to the FDA**
  - Final response required before 28 April 2024
  - Genetic Signatures has partnered with experts who have experience in similar submissions to expediate this process
- **The Company anticipates that the FDA will review and respond to the information presented soon after receipt**
- **Solid opportunity pipeline developed in readiness for clearance**
  - Expecting to convert pre-qualified customer experience sites to initial customers, post clearance

FDA U.S. FOOD & DRUG ADMINISTRATION

*EasyScreen*™ Gastrointestinal Parasite Detection Kit

**Submitted to US FDA for 510(k) clearance**
Currently investigation use only (IUO) in US

- *Giardia* spp.
- *Cryptosporidium* spp.
- *Entamoeba histolytica*
- *Cyclospora cayetanensis*
- *Dientamoeba fragilis*
- *Blastocystis hominis*
- *Enterocytozoon bieneusi*
- *Encephalitozoon intestinalis*

# Next Generation Instrument development



Design input received by laboratory leaders including Johns Hopkins, Mayo Clinic, Quest Diagnostics, Texas Children's and Baylor Scott & White

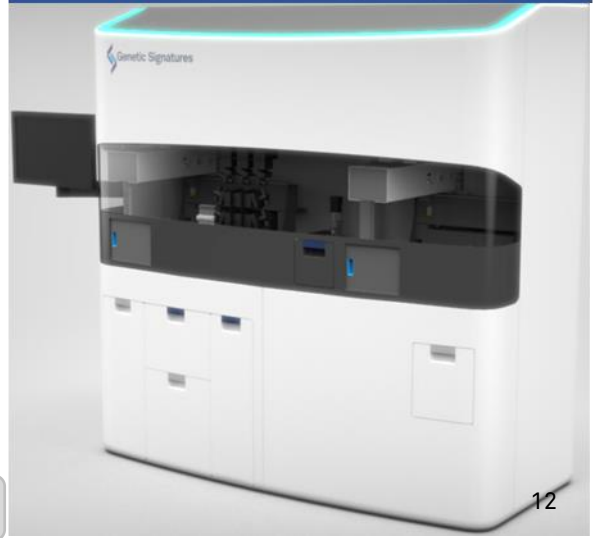
## "Sample-to-result" Instrument

- Highly automated
- High-throughput (~400 samples/shift)
- Can run multiple products and mixed specimen types in a single run
- Embed use of **3base®** with customers

## Value Position

- Address a market gap for automated high-throughput syndromic testing
- Provide operational efficiency in our target market
- Single platform to consolidate multiple tests that are currently conducted on numerous instruments

Images are concepts only




**Concepts, design, specification**
- Research
- OEM review
- Form design
- Concept testing

**Prototype developed**
- Design development
- Sample to answer build
- Consumable build
- GUI development

**Beta testing at customer sites**
- Performance testing
- User feedback
- Informatics
- Design lock

**Instrument in production**
- Manufacturing partnership
- Support training
- Pre-marketing

**Reg. clearance & product launch**
- FDA/IVDR submission
- Regulatory clearance
- Product launch

2022 2023 2024 2026

# EMEA growth initiatives to accelerate revenue



- **Highly experienced direct sales and support team in place**
  - Located in the United Kingdom and Germany
  - Transitioning customer sites to broader syndromic testing
  - Building awareness in the region with a strong pipeline of opportunities forecasted to close in FY24 and beyond
- **Channel partnerships in place in select European markets, and recent contracts executed in Israel and the Middle East**
  - Carefully selected channel partners are deeply experienced and highly connected in their respective markets
  - Operating in markets where language and culture requires local representation or where it isn't economic to operate a direct sales force
- **Distributor Channel Manager in place to support global expansion**
  - Dedicated resource to provide channel partner training and support to build regional brand equity and sales growth

almog diagnostic

integrated gulfbiosystems

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## Contact Us

**Dr John Melki**

Managing Director & Chief Executive Officer

E: john.melki@geneticsignatures.com

P: +61 (0)2 9870 7580

**Karl Pechmann**

Chief Financial & Operating Officer &
Company Secretary

E: karl.pechmann@geneticsignatures.com

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