



## 1H 24 Market Update

22 February 2024



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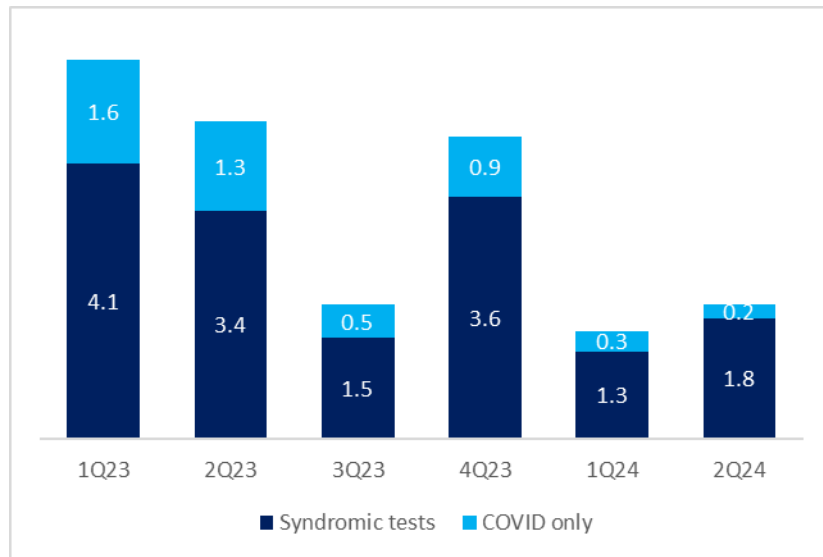
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Sales Revenue (A\$m)



- 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

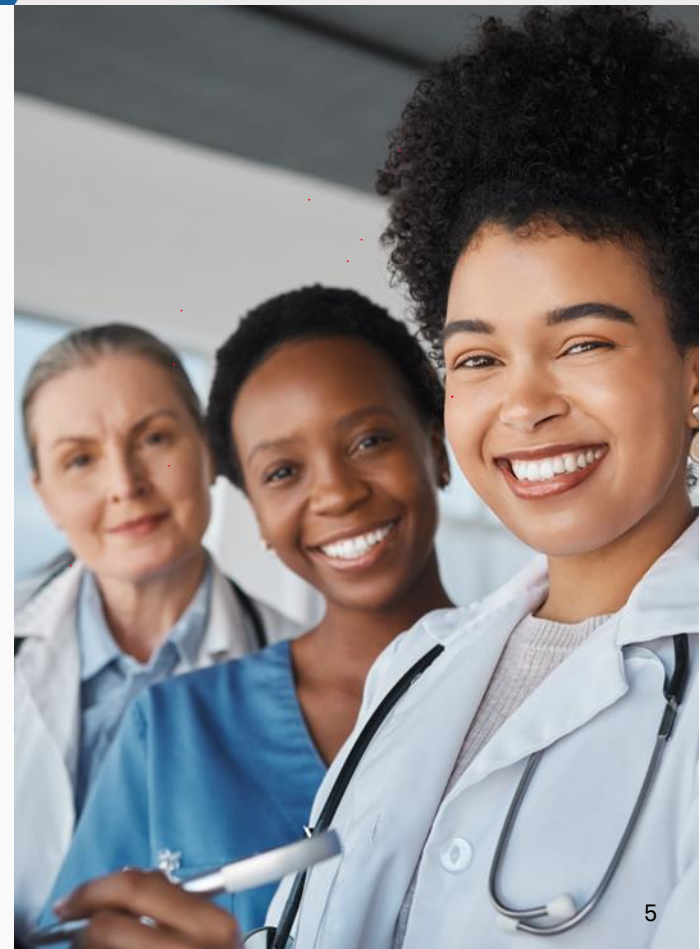


A'000s	1H 24	1H 23
Sales revenue	3,604	10,405
Cost of materials & freight	(2,543)	(4,475)
<b>Gross profit</b>	<b>1,061</b>	<b>5,930</b>
Employee benefits expense	(7,672)	(6,945)
Scientific consumables & clinical trials	(1,734)	(2,097)
Other expenses	(2,975)	(3,058)
<b>EBITDA</b>	<b>(11,320)</b>	<b>(6,170)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

- 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



- **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





## Financial information

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

## Top shareholders %

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



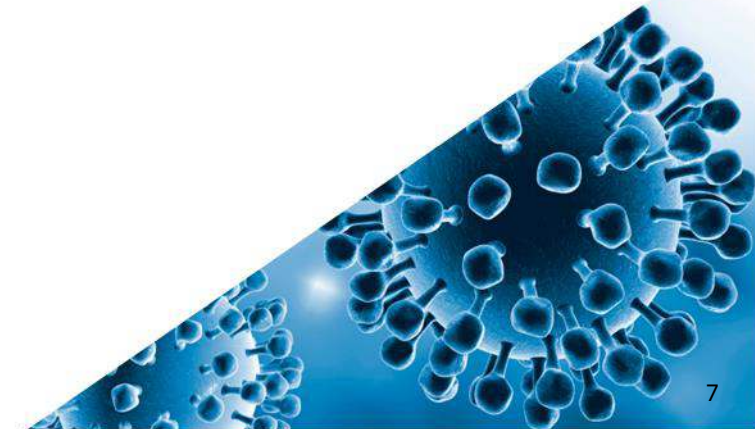


- The updated *EasyScreen*™ Respiratory Pathogen Detection Kit was submitted to TGA for review in December 2023
- Revenue has been impacted with major customers during this time
  - Expect all respiratory revenue to be reinstated upon approval
- Minor changes were made in assay design to restore performance in a short timeframe



Australian Government

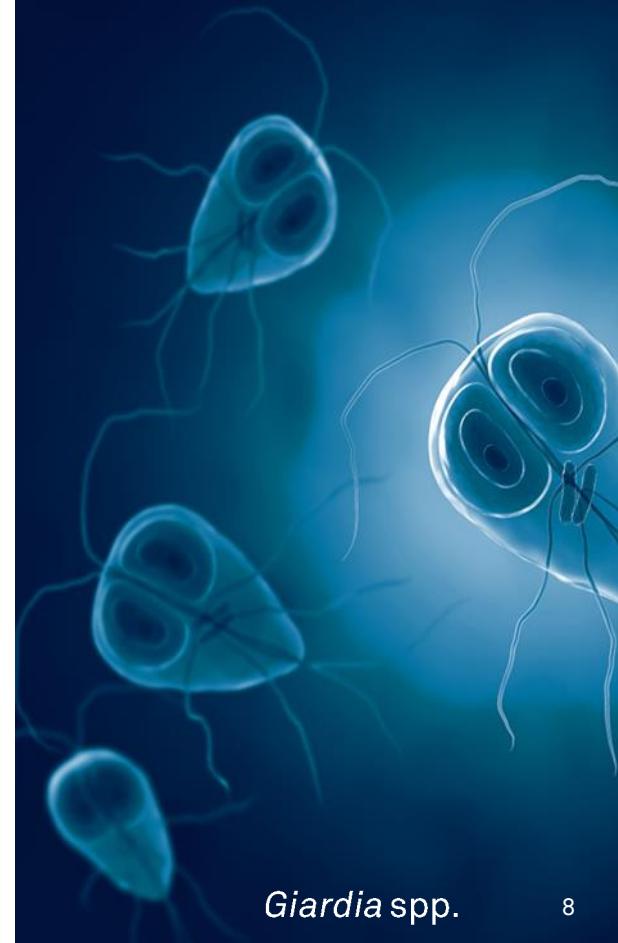
Department of Health  
Therapeutic Goods Administration





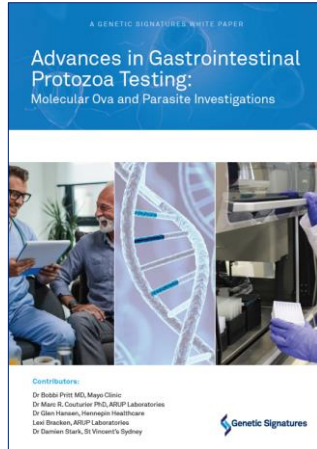


- First product, the *EasyScreen*<sup>TM</sup> Gastrointestinal Parasite Detection Kit submitted to FDA for sales clearance
- The product addresses an unmet need
  - Broadest molecular syndromic test for 8 clinically relevant GI parasites
  - No current stand-alone FDA cleared molecular test detects >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



*Giardia* spp.





- 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







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

# Four distinct customer segments – all targets

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\*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 LabCorp / Quest = >1500 tests / day Others ~100-300 tests / day	1.65 million 30% of TAM	 50%	<ul style="list-style-type: none"> <li>• LabCorp</li> <li>• Quest</li> <li>• Sonic Health</li> <li>• BioReference Laboratories</li> <li>• Clinical Reference Laboratory</li> </ul>
IDN / core labs (large hospitals)	Low to medium volume, Some sites high volume Average ~50-100 tests / day	3.03 million 55% of TAM	 32%	<ul style="list-style-type: none"> <li>• Kaiser Permanente</li> <li>• Baylor Scott and White</li> <li>• Northwell Health</li> <li>• Cleveland Health Clinic</li> <li>• Sutter Health</li> </ul>
Specialty reference labs	Medium to high volume Average ~40-100 tests / day	0.28 million 5% of TAM	 12%	<ul style="list-style-type: none"> <li>• ARUP Laboratories</li> <li>• Mayo Clinic</li> <li>• Wadsworth Center</li> <li>• University of Nebraska</li> <li>• Emory Medical Laboratory</li> </ul>
Independent hospitals	Low to medium volume, Average ~20-40 tests / day	0.55 million 10% of TAM	 6%	<ul style="list-style-type: none"> <li>• Scripps Laboratories</li> <li>• Sharp Laboratories</li> <li>• John Hopkins</li> <li>• Tampa General</li> <li>• Henry Beaumont</li> </ul>

Target size and TAM modelled from various data sources listed here

[Morningstar Credit Ratings, LLC 16<sup>th</sup> 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](#) 10  
[Australian Medicare Benefits Schedule Book \(MBS\). Link](#)



## 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



**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

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

## "Sample-to-result" Instrument

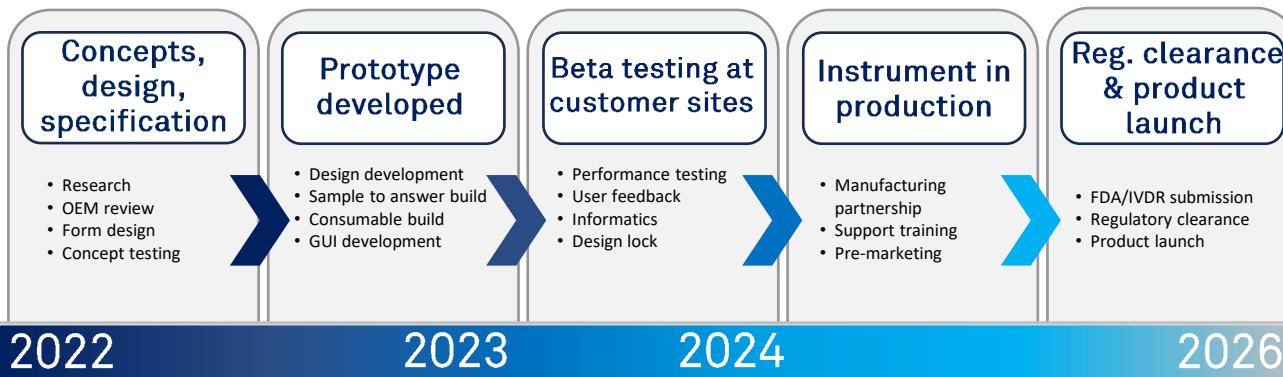
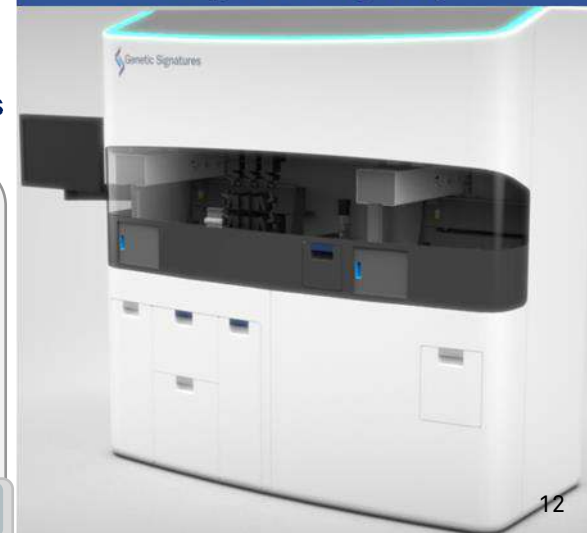
- Highly automated
- High-throughput (~400 samples/shift)
- Can run multiple products and mixed specimen types in a single run
- Embed use of 3base® with customers

## 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





- **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





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