



Genetic Signatures

Transforming
Molecular
Diagnostics



Company Presentation – Bell Potter

November 2024

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Commenced as Genetic Signatures CEO 23 September 2024



2002 - 2024



2000 - 2002





Genetic Signatures' 3base® is a unique extraction technology which brings key benefits to molecular diagnostics tests:

- Simplifies the genome of a sample to reduce the impact of mutations in viruses and bacteria
 - As an example, the GSS Covid-19 assay has never had to be modified despite the number of variants during the pandemic
 - The 3base® technology enables targets such as parasites to be analysed
- Enables “**syndromic testing**” – simultaneous screening for the majority of pathogens that could be responsible the same set of symptoms in a patient



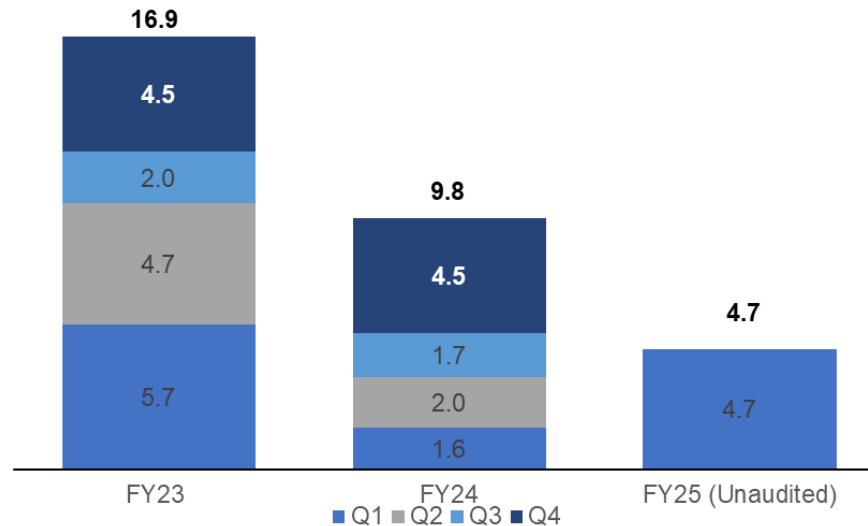
- Quarterly sales revenue of **\$4.7M**, an increase of 294% from Q1 FY24
 - Resumption of sales of *EasyScreen*[™] Respiratory Pathogen Detection Kit to Australian Customers
- Strong pipeline of US commercial opportunities for *EasyScreen*[™] Gastrointestinal Pathogen Detection Kit following **FDA clearance in June 2024**
- Completed **A\$30.0M capital raising** with net proceeds (after costs)
- **Board renewal** announced including:
 - **Retirement** of Chair Nick Samaras and appointment of Ms Caroline Waldron at AGM
 - **Resignation** of Non-Executive Directors Dr Tony Radford and Mr Stephane Chatonsky
 - **Appointment** of Ms Anne Lockwood and Dr Jenny Harry
- Cash receipts from customers in the quarter of **\$7.0M**, cash held at quarter end of **\$41.3M**





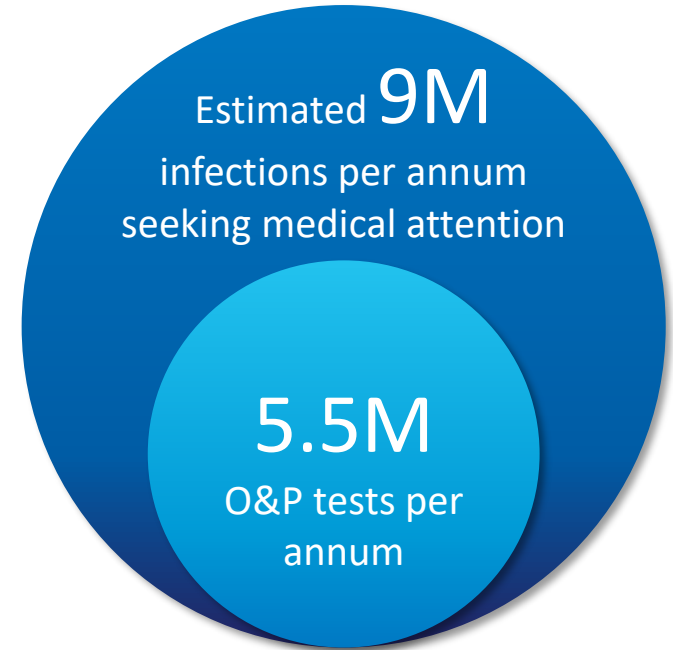
Return to strong quarterly revenue following TGA authorisation for supply of the modified respiratory assay in April 2024

- Revenue of \$4.7M recorded for Q1 FY25:
 - Q1 FY24: \$1.6M impacted by respiratory assay
 - Q1 FY23: \$5.7M which included \$1.6M from stand-alone COVID revenue;
- Revenue from international markets accounted for 7% of sales during the quarter





- Estimated ~**65M** GI parasitic infections per year in US
- In the United States, approximately **9M** of these patients¹ end up actively seeking medical attention
- Approximately **5.5M** manual, microscopy-based O&P (ova & parasite) tests performed each year²
- Genetic Signatures is aiming to replace approximately 40% of the current manual O&P tests with its **EasyScreen™ Gastrointestinal Parasite Detection Kit** within 5 years
- Reduced patient sample burden with molecular test may increase the addressable market over time



¹Estimated GI infections per year in the United States associated with parasites. Schmidt MA, Groom HC, Rawlings AM, Mattison CP, Salas SB, Burke RM, et al. Incidence, Etiology, and Healthcare Utilization for Acute Gastroenteritis in the Community, United States. Emerg Infect Dis. 2022;28(11):2234-2242.

²Based on GSS analysis and external data sources detailed on slide 11.



FDA clearance to market Genetic Signatures' *EasyScreen*TM Gastrointestinal Parasite Detection Kit in the US received in June 2024

The product addresses a well-recognised, poorly-met clinical need

- Broadest molecular syndromic test for eight clinically relevant GI parasites

Product leverages 3base[®] advantages

~5.5M conventional tests conducted in the US each year

- Traditional tests are manual, slow, labour intensive & unreliable
- Current testing is not profitable for pathology laboratories

Molecular reimbursement code already in place

- Estimated TAM of > \$A500M¹ p.a.
- Higher reimbursement rate than traditional microscopic tests
- Targeting 40% market share in US market within 5 years



United States
FDA 510(k) cleared



*EasyScreen*TM Gastrointestinal
Parasite Detection Kit

8 parasites detected



Giardia spp.



Cryptosporidium spp.



Entamoeba histolytica



Cyclospora cayetanensis



Dientamoeba fragilis



Blastocystis hominis



Enterocytozoon bienersi







Encephalitozoon intestinalis

¹Assumes an indicative selling price of US\$60 per test displacing existing Ova & Parasite (O&P) testing estimated at over 5.5 million p.a.

Relevant for all key customer segments



Target segments	GI parasite testing requirements	Potential TAM = 5.5M tests	Share of targeted 2.2M tests by segment
Large commercial reference labs	<p>High volume LabCorp / Quest = >1500 tests / day Others ~100-300 tests / day</p>	<p>1.6 M 30% of TAM</p>	 <p>50%</p>
IDN / core labs (large hospitals)	<p>Low to medium volume, Some sites high volume Average ~50-100 tests / day</p>	<p>3.0 M 55% of TAM</p>	 <p>32%</p>
Specialty reference labs	<p>Medium to high volume Average ~40-100 tests / day</p>	<p>0.3 M 5% of TAM</p>	 <p>12%</p>
Independent hospitals	<p>Low to medium volume, Average ~20-40 tests / day</p>	<p>0.6 M 10% of TAM</p>	 <p>6%</p>

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
- DecBio 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](#)

Commercial sales in the US imminent – Q1 activities



- ✓ Customer experience sites well-advanced in internal review process with several at the final contract stage
- ✓ Established a strong sales pipeline with >60 customer sites at various stages of the evaluation and sales process
- ✓ Engaged with all major commercial reference labs in the US who have expressed strong interest – 50% target market but also requires longer sales cycle
- ✓ Continue to build brand awareness for technology and products with both the **EasyScreen™ Gastrointestinal Parasite Detection Kit** and **3base® platform** through booth-presence at key conferences in the United States
- ✓ Multiple publishing opportunities with Key Opinion Leaders from across US





Genetic Signatures

Transforming Molecular Diagnostics

**Other growth
initiatives and
catalysts**





- **US *EasyScreen*™ Gastrointestinal Parasite Detection Kit sales**
 - Many customer experience at final contract stage
 - Strong pipeline of 60 customers – continuing to build
 - Engaged with all major US reference laboratories – positive interest
- **Building sales and presence in UK and EMEA markets**
 - New contracts in UK
 - Evaluations in progress UK and Germany
 - Dedicated distribution manager and new distributors to accelerate expansion
- **R&D initiatives for new products**
 - Evolution of *EasyScreen*™ detection kits
 - Technology and workflow improvements
 - Development of next generation instrument prototype





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