

**Genetic
Signatures**

Transforming
Molecular
Diagnostics



Bell Potter Healthcare Conference

November 2022



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Investment highlights

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- **Proprietary 3base® technology platform** that provides a revolutionary approach for molecular diagnostics
- **Dramatically simplifies multiple pathogen testing** from a single sample (multiplexing)
 - More informative – detect related pathogens/genes using fewer tests;
 - Simpler – fewer reagents with better matched, ideal reaction conditions.
- **Strong commercial adoption** in Australian market – expanding into European and US markets
 - 4 Diagnostic Test Kits cleared in one or more markets – 5 new kits completing development;
 - Strong continued revenue growth – FY22 revenue A\$35.4 million (+25% yoy), cash flow positive (\$6.7M) and profitable (\$3.1M).
- **Multiple drivers for growth** – funded from anticipated future cash flow and existing balance sheet
 - Commercial expansion – into large international markets (Europe and US);
 - Product expansion – multiple new products completing development or registration;
 - Instrument expansion – embed 3base® technology in high-volume customers sites.





Financial information

Share price (4-Nov-22)	A\$0.76
Shares on issue	143.4m

Market capitalisation **A\$108.9m**

Cash (30-Sep-22)	A\$32.4m
Debt (30-Sep-22)	Nil

Enterprise value **A\$76.5m**

Top shareholders %

Asia Union (Chris Abbott private investment)	26.2%
Perennial Value Management	15.0%
Fidelity International	6.9%
Directors & management	3.0%

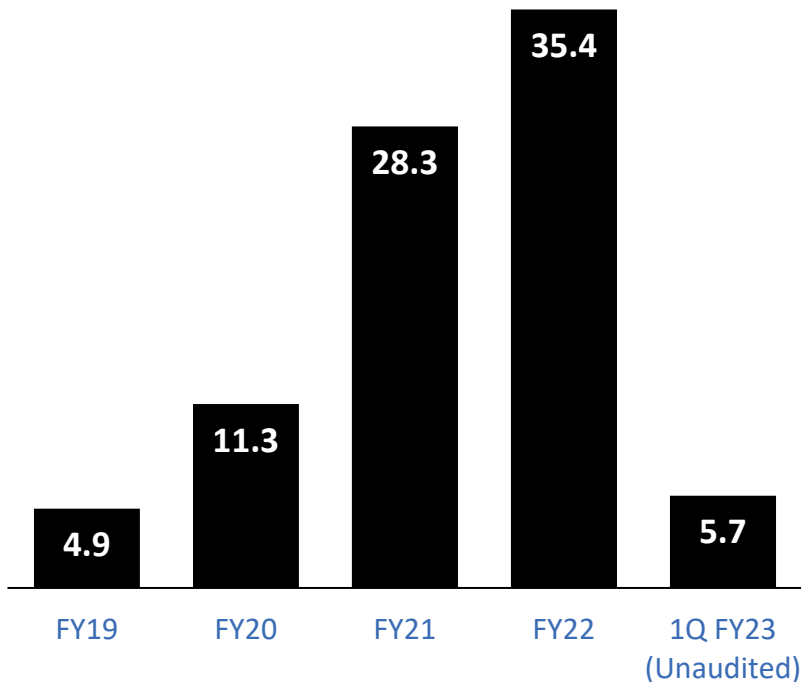


Research reports

	Target price
MST Access (28-Oct-22)	\$1.45
Bell Potter (27-Oct-22)	\$0.90



Sales Revenue (A\$m)



- **Q1 FY23 sales up 16% from preceding quarter**
 - FY22 sales revenue of \$35.4 million (+25% yoy, 89% 4yr CAGR)
- **Growing contribution from international sales**
 - Leveraging experience in Australian market;
 - European orders for non-Covid Syndromic Kits;
 - Significant US contributions to come once FDA clearance secured.
- **Strong demand for SARS-CoV-2 tests during FY21 & FY22**
 - Scale-back of molecular testing programs;
 - Growing contribution from other *EasyScreen*™ Kits;
 - Shifting from COVID only testing to Syndromic Respiratory.
- **Successful strategy of targeting high-volume customer groups**
 - High-throughput labs
 - Multi-hospital groups
 - Private pathology chains
 - Government-led programs



<u>A'000s</u>	<u>1Q FY23</u>
Receipts from customers	7,848
Payments to suppliers and employees	(10,221)
Other	5
Net operating cashflow	(2,368)
Payment for plant & equipment	(840)
Payment for intangibles	(1,246)
Net investing cashflow	(2,086)
Principal elements of lease payments	(32)
Net financing cashflow	(32)
Net increase in cash and cash equivalents	(4,486)
Opening cash and cash equivalents	36,897
Effects of exchange rate changes on cash	8
Closing cash and cash equivalents	32,419

Planned investment in growth opportunities

Funded from existing cash and anticipated future cash flows:

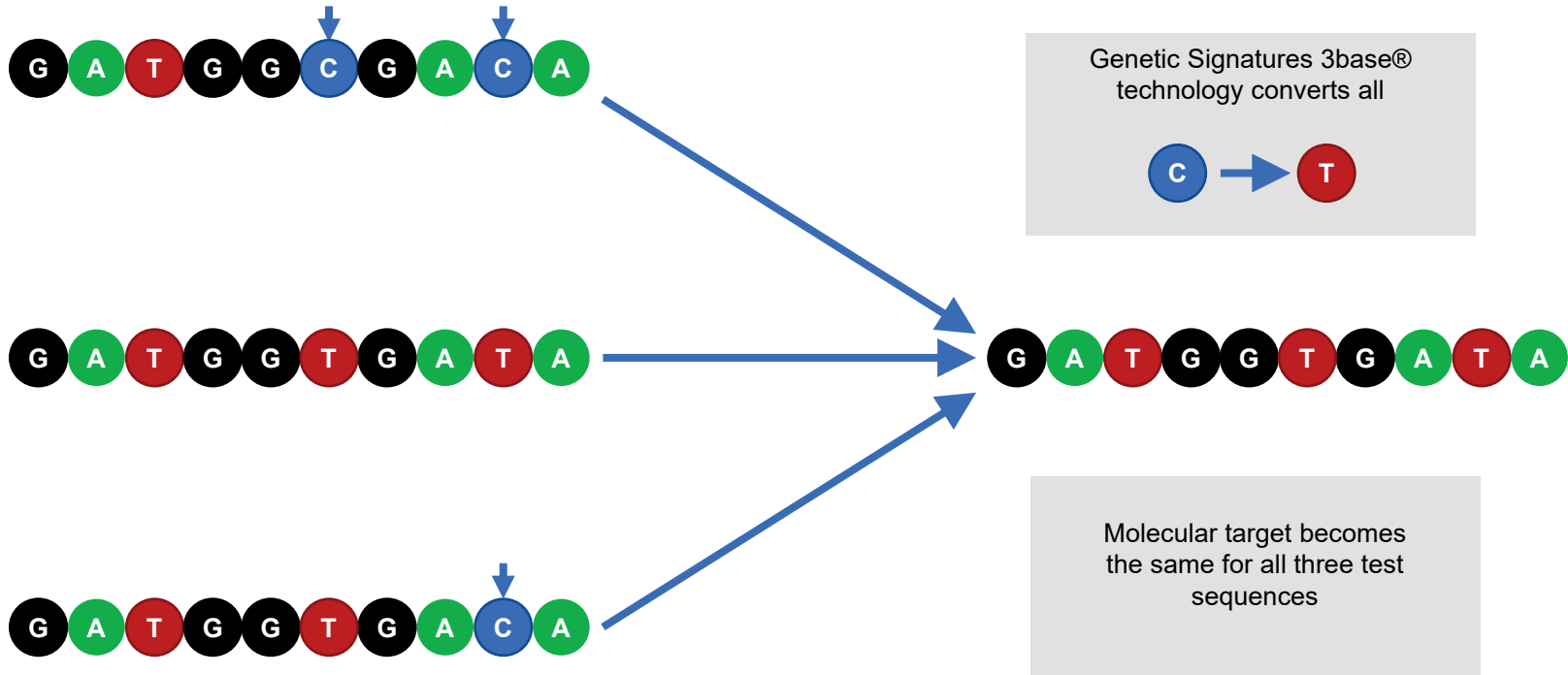
- International markets;
- New products;
- Regulatory clearances;
- Product launches;
- Internal capabilities (clinical, regulatory);
- Technology improvements;
- Sample-to-result instrument



- **Molecular diagnostic tests are based on DNA/RNA sequences**
 - DNA/RNA is unique to each organism.
- **Molecular diagnostic tests are recognised as the ‘gold standard’**
 - Precisely targeted and highly specific – PCR tests;
 - Can be less effective when:
 - Need to detect multiple pathogens or genes;
 - New strains or subtypes of pathogens emerge.
- **Molecular diagnostic tests are often multiplexed**
 - Multiplexing refers to conducting multiple tests simultaneously
- **Genetic Signatures 3base® makes multiplexing easier:**
 - **More informative** – detect related pathogens/genes using fewer tests;
 - **Simpler** – fewer reagents with better matched, reaction conditions.



How 3base[®] simplifies molecular targets



* Human Papilloma virus sequences



Proprietary method - patented until 2031+

1. Extraction and Conversion

- *natural 4 bases to 3base®*



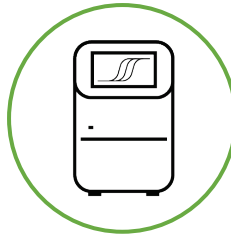
2. DNA Amplification (PCR)

- *uses 3base® DNA*



3. Detection (primers & probes)

- *uses 3base® DNA*



Benefits

- ✓ Rapid
- ✓ High throughput
- ✓ Informative
- ✓ Sensitive
- ✓ Specific
- ✓ Low manual involvement
- ✓ Reduced contamination risk

Equipment

- ✓ Run on standard equipment.
- ✓ Genetic Signatures' instruments further automate the process;
 - increase throughput
 - reduce labour.

3base® simplifies Syndromic Testing – *EasyScreen™* Kits



- **Syndromic testing:** simultaneously test for multiple pathogens that all can cause the same signs and symptoms
 - **Respiratory infections:** cough, runny nose, sore throat, headache, breathlessness;
 - **Gastrointestinal infections:** nausea, diarrhea, vomiting, abdominal cramps, fever.
- **Syndromic testing**
 - allows single test to determine the potential cause of a disorder;
 - avoids having to order separate tests for each possible pathogen.
- **Genetic Signatures' *EasyScreen™* is ideal for Syndromic Testing**
 - Tests for over 100 different types of pathogens;
 - Able to detect variants (i.e. different strains or subtypes);
 - Combine tests to create *EasyScreen™* Syndromic Detection Test Kits;
 - Detect >20 different pathogens from a single sample.



Robust pipeline with multiple products cleared for sale





North America accounts for 40% of the global molecular diagnostics market

- **High need for Enteric Protozoan Kit**
 - 5.5 million tests conducted in the US pa;
 - Primarily culture/microscopy: slow, labour intensive, unreliable;
 - Detects leading protozoan infections;
- **Enteric Protozoan Screening Kit**
 - Completed recruitment for 1,500 subject clinical trial;
 - Targeting 510(k) submission in Q4 CY2022;
 - First *EasyScreen*™ product for US;
 - Reimbursement code in place (CPT 87506 US\$262.99).
- **US Market preparation activities underway**
 - KOL webinars;
 - Sales & marketing presence in US;
 - Warehousing facility in Los Angeles;
 - Initial focus on 30 high-throughput, centralised labs.
- **First 3base® product for the US**
 - Regulatory dossier relevant for other *EasyScreen*™ products.



- **US FDA clinical trial recruitment completed**
 - Targeting 4Q CY2022 application for clearance
- **3base® kit for antimicrobial resistance shows high detection rate**
 - Independent study¹ showed excellent biological performance for the 5 most common carbapenemases
 - WHO has declared AMR as one of the top 10 global public health threats facing humanity > 5m deaths pa²
- **GSS commences commercial sales in Western Australia**
 - Two new sites trialling respiratory & gastrointestinal targets; first sales into WA
- **EasyScreen™ Enteric Protozoan Detection Kit - Health Canada registration**
 - Canadian market ~2.5% of world IVD market
 - 3rd EasyScreen™ Detection Kit registered



¹ Gonzales, C et al, (2022), *Diagnostics* **2022**, 12(9), 2223; <https://doi.org/10.3390/diagnostics12092223>

² Antimicrobial Resistance Collaborators (2022), *The Lancet*: [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)



- **Leverage experience in Australian market to grow international sales**
 - Europe – drive adoption of other 3base® products;
 - US – build 3base® franchise once Protozoan Detection Kit is cleared.
- **Build and expand portfolio of commercially-available *EasyScreen*™ products**
 - Expand menu of 3base® tests;
 - Develop new *EasyScreen*™ Syndromic Test Kits;
 - Secure registration for new *EasyScreen*™ products.
- **Embed 3base® technology in high-value customer's workflow**
 - Increase adoption of *EasyScreen*™ kits for more applications;
 - Broader range of commercial arrangements with customers.





- **Expand available *EasyScreen*™ Syndromic Kits**
 - 3 kits research use only (RUO) – tropical diseases, MMR & meningitis;
 - Other kits in development (tick-borne, skin infections, etc.);
 - Advance additional 3 products through the FDA process
- **Improve and enhance 3base® technology platform**
 - Saliva-based protocol for SARS-CoV-2 cleared by TGA;
 - Process improvements for amplification and time-to-result
- **Next-generation, “sample-to-result” instrument**
 - Highly automated, high-throughput;
 - Ideally suited for high-volume commercial users;
 - Embed use of 3base® with customers;
 - Facilitates different commercial models;

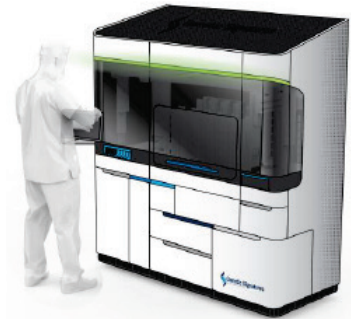


Image is concept only



- **US Enteric Protozoan Kit**
 - File 510(k) application by end of CY2022;
 - Launch product once clearance is granted.
- **Increase sales and presence in UK and European markets**
 - Contracts with new customers;
 - Direct sales force and distributor appointments.
- **Initiation of US clinical trial for next *EasyScreen*™ product**
- **R&D initiatives for new products**
 - New tests and *EasyScreen*™ kits;
 - Technology improvements;
 - Development of Next Generation instrument prototype.
- **Quarterly sales updates and progress reports**





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