



# Genetic Signatures

Transforming  
Molecular  
Diagnostics



## Investor Presentation

October 2022



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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.





- **US FDA clinical trial recruitment completed**
  - Targeting 4Q CY2022 application for clearance
- **3base<sup>®</sup> kit for antimicrobial resistance shows high detection rate**
  - Independent study<sup>1</sup> 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 pa<sup>2</sup>
- **GSS commences commercial sales in Western Australia**
  - Two new sites trialling respiratory & gastrointestinal targets; first sales into WA
- **EasyScreen<sup>™</sup> Enteric Protozoan Detection Kit - application lodged with Health Canada**
  - Canadian market ~2.5% of world IVD market
  - Will be 3<sup>rd</sup> EasyScreen<sup>™</sup> Detection Kit registered



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

<sup>2</sup> 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)



## Financial information

Share price (11-Oct-22)	A\$0.85
Shares on issue	143.4m
<b>Market capitalisation</b>	<b>A\$121.9m</b>
Cash (30-Jun-22)	A\$36.9m
Debt (30-Jun-22)	Nil
<b>Enterprise value</b>	<b>A\$85.0m</b>

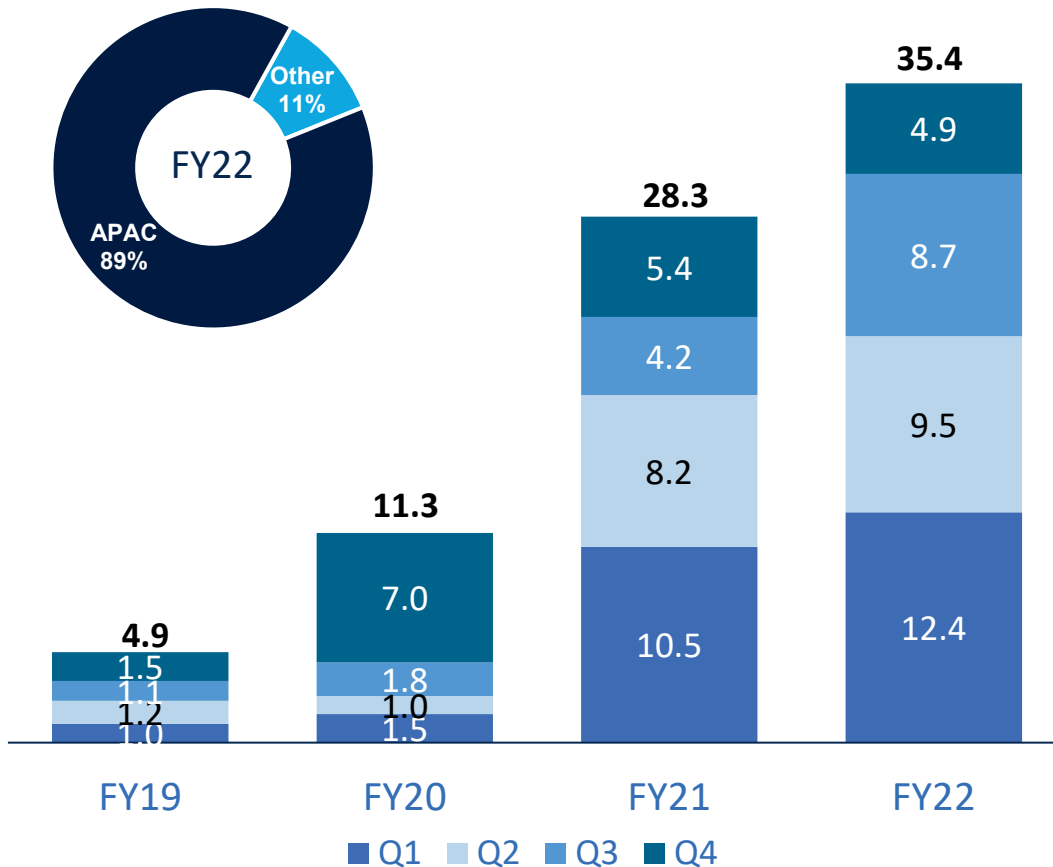
## Top shareholders %

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





## Sales Revenue (A\$m)



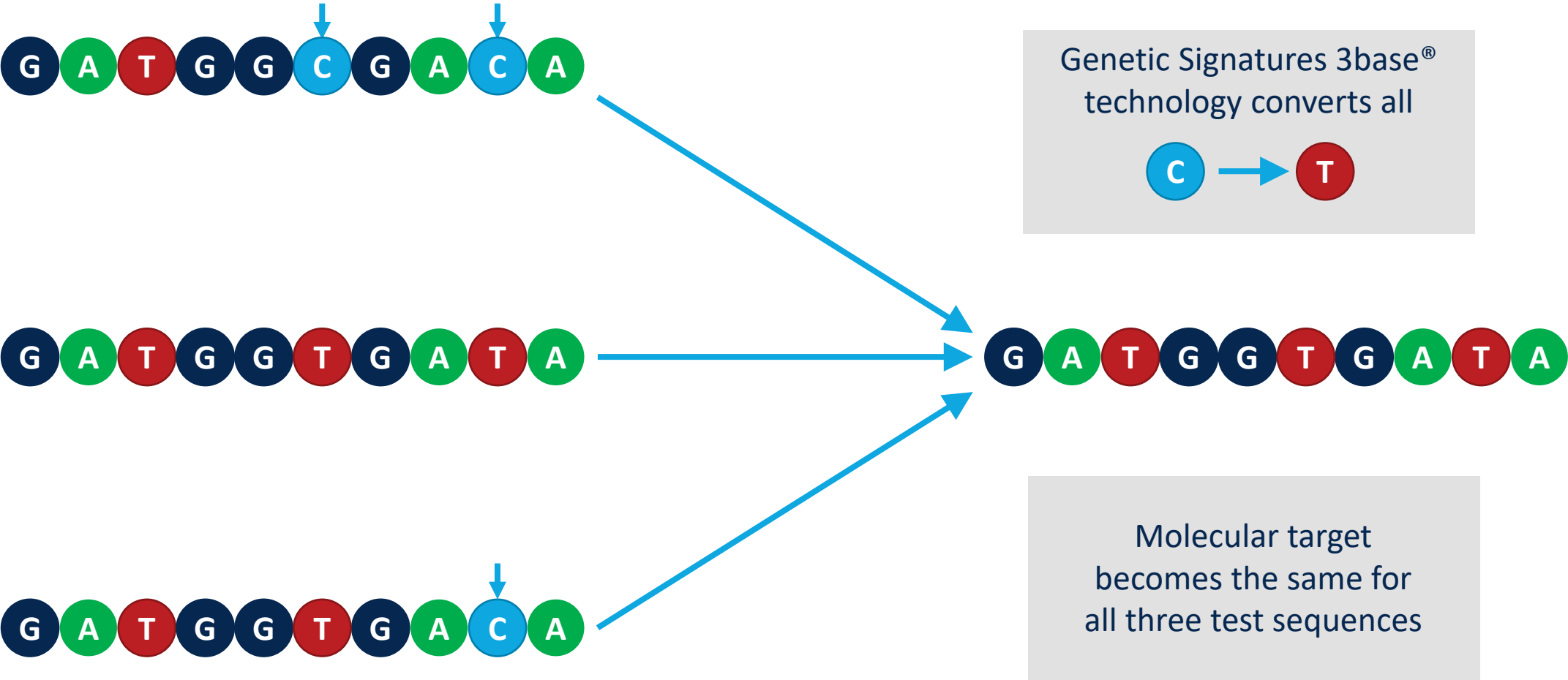
- **FY22 sales revenue of \$35.4 million (+25% yoy, 89% 4yr CAGR)**
- **Growing contribution from international sales**
  - Leveraging experience in Australian market;
  - European orders for non-Covid Syndromic Kits;
  - Significant US contributions to come once FDA clearance secured.
- **Strong demand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



- **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<sup>®</sup> makes multiplexing easier:**
  - **More informative** – detect related pathogens/genes using fewer tests;
  - **Simpler** – fewer reagents with better matched, reaction conditions.



# How 3base<sup>®</sup> simplifies molecular targets



\* Human Papilloma virus sequences





## Proprietary method - patented until 2031+

### 1. Extraction and Conversion

- *natural 4 bases to 3base<sup>®</sup>*



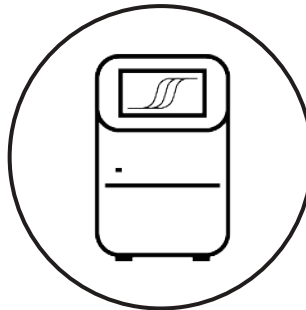
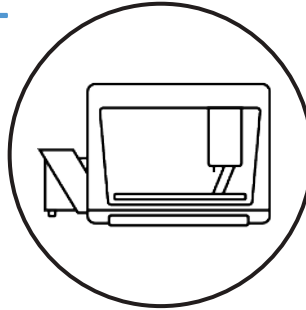
### 2. DNA Amplification (PCR)

- *uses 3base<sup>®</sup> DNA*



### 3. Detection (primers & probes)

- *uses 3base<sup>®</sup> 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.



- **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





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





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

- **Enteric Protozoan Screening Kit**
  - Completed recruitment for 1,500 subject clinical trial;
  - Targeting 510(k) submission in Q4 CY2022;
  - First *EasyScreen*™ product for US
- **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.
- **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.



- **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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