



# Genetic Signatures

Transforming  
Molecular  
Diagnostics



## 1H FY23 Market Update

March 2023



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- **Proprietary 3base<sup>®</sup> technology platform** - a revolutionary approach for molecular diagnostics
- **Dramatically simplifies multiple pathogen testing** from a single sample (multiplexing); more informative—simpler with fewer reagents
- **Strong commercial adoption** in AU market – expanding into EU & US
  - 4 Diagnostic Test Kits cleared – 5 new kits completing development
  - Strong underlying growth in core revenue streams – 1H FY23 sales of \$10.4M with 72% from syndromic testing products
- **Multiple drivers for growth** – funded from anticipated future cash flow and existing balance sheet
  - Commercial expansion into large international markets (EU & US)
  - Product expansion - multiple new products completing development or registration
  - Instrument expansion – embed **3base<sup>®</sup>** technology in high-volume customers sites





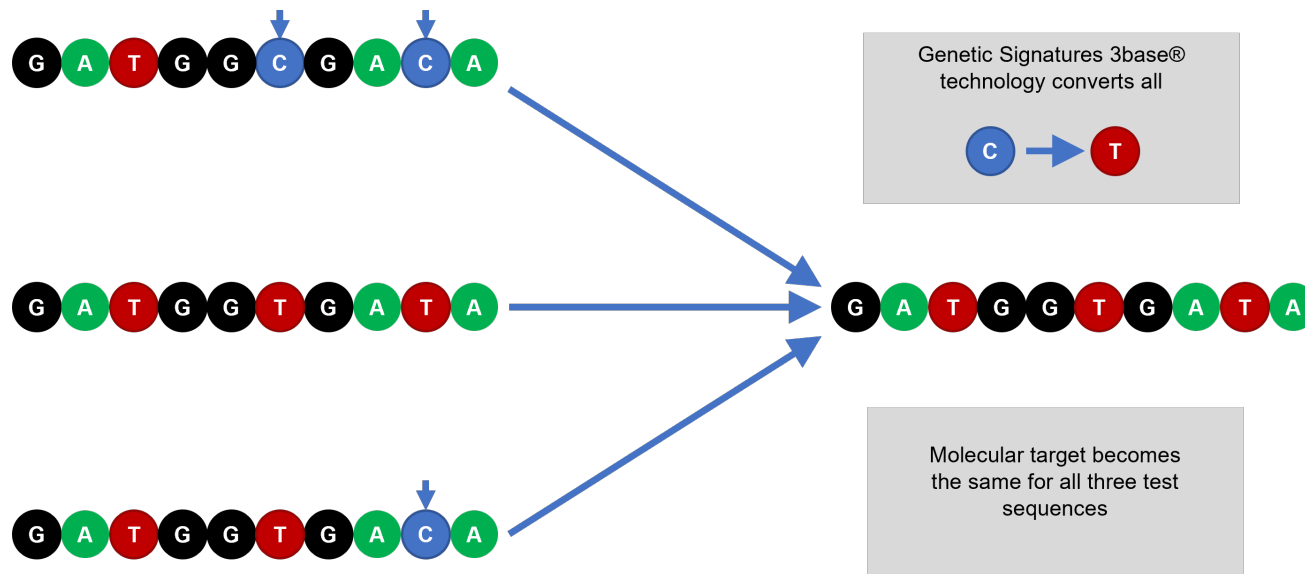
## Financial information

Share price (13-Mar-23)	A\$0.79
Shares on issue	143.4m
<b>Market capitalisation</b>	<b>A\$113.3m</b>
Cash (31-Dec-22)	A\$26.8m
Debt (31-Dec-22)	Nil
<b>Enterprise value</b>	<b>A\$86.5m</b>

## Top shareholders %

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





- **Molecular diagnostic tests are based on DNA/RNA sequences**
  - DNA/RNA is unique to each organism.
- **Genetic Signatures 3base<sup>®</sup> makes multiplex testing easier:**
  - **More informative** – detect related pathogens/genes using fewer tests;
  - **Simpler** – fewer reagents with better matched, reaction conditions.

\* Human Papilloma virus sequences

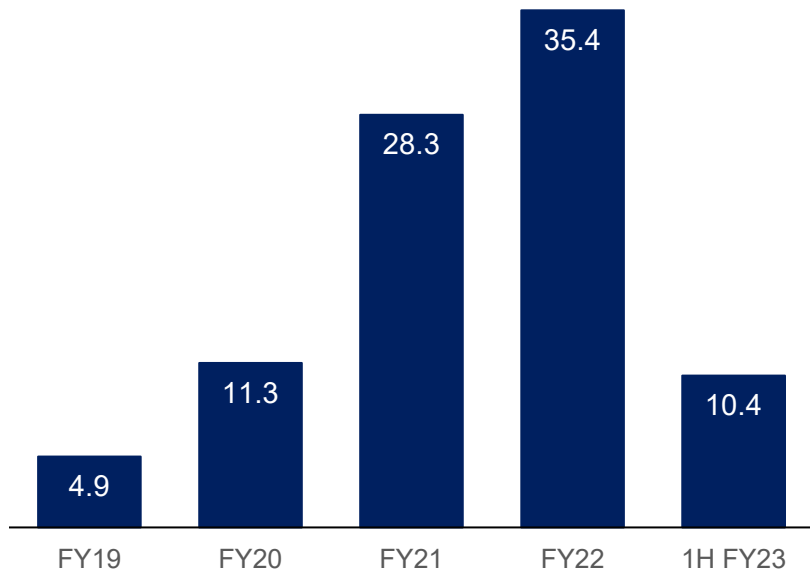


- **Syndromic testing:** simultaneously test for multiple pathogens that all can cause the same signs and symptoms
  - **Respiratory infections:** cough, runny nose, sore throat, headache
  - **Gastrointestinal infections:** nausea, diarrhea, vomiting, cramps, fever
- **Syndromic testing**
  - Allows 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





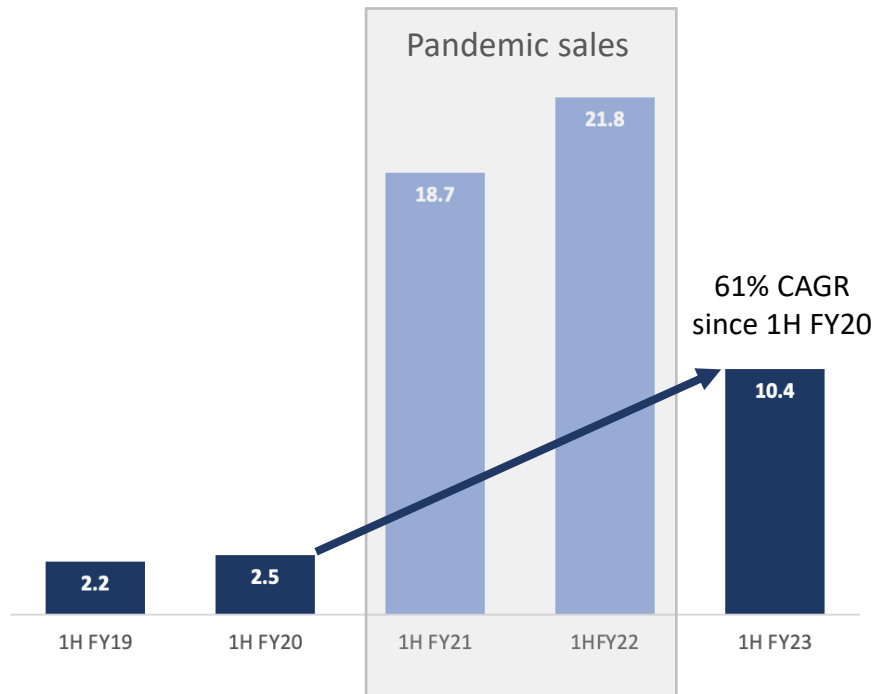
## Sales Revenue (A\$m)



- **1H FY23 sales \$10.4 million**
  - Anticipated material decline in pathogen-specific molecular testing for SARS-CoV-2 experienced across the industry
  - Replaced with growing syndromic respiratory sales— long-term, durable market
  - Several Covid customers currently trialing or commenced purchase of *EasyScreen™* kits for other indications
  - Non-Covid only sales up 49% pcp and account for 72% of sales in 1H FY23
  - 9% sales to international customers—set to grow with increased EU presence and as products cleared in US
- **Maintain successful strategy of targeting focus towards high-volume customer groups**
  - High-throughput labs
  - Multi-hospital groups
  - Private pathology chains
  - Government-led programs



## Sales Revenue (A\$m)



### ● Covid “sugar hit”

- Revenues in FY21 & FY22 were significantly boosted by Covid molecular test sales during pandemic
- Inevitable decline in sales of Covid molecular tests as pandemic management practices evolved

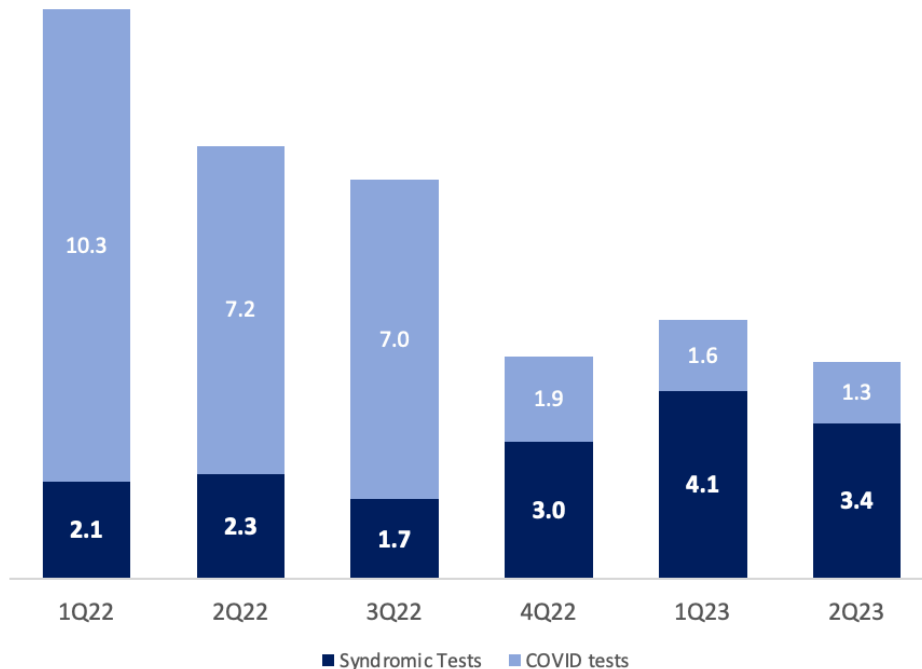
### ● Provided opportunity for GSS to establish strong foundation for long-term growth

- Strong balance to support growth initiatives (product expansion, international markets, new instruments)
- Significantly expanded customer base and awareness of **3base**® technology and benefits
- Material growth in business compared to pre-pandemic trajectory:
  - Half year sales up 416% v 1H FY20 (pre-pandemic)
  - Equates to 61% CAGR over 3 years





## Sales Revenue (A\$m)



- **Sales mix returning to syndromic tests focus**
  - Ensured company continued to build sales of syndromic tests throughout pandemic while benefitting from Covid opportunity
  - Revenue dominated by syndromic tests with sales at significantly higher level than pre-pandemic
  - **3base**<sup>®</sup> technology may provide future opportunities as new strains and variants continue to emerge
- **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**<sup>®</sup> technology recognised by customers



A'000s	1H FY23	1H FY22
Sales revenue	10,405	21,838
Cost of materials	(3,759)	(6,283)
<b>Gross profit</b>	<b>6,646</b>	<b>15,555</b>
Freight	(716)	(607)
Employee benefits expense	(6,945)	(5,673)
Scientific consumables & clinical trials	(2,097)	(1,619)
Other expenses	(3,058)	(2,213)
<b>EBITDA</b>	<b>(6,170)</b>	<b>5,443</b>
Depreciation & amortisation	(702)	(814)
<b>EBIT</b>	<b>(6,872)</b>	<b>4,629</b>
Other income	392	72
<b>Profit/(loss) before tax</b>	<b>(6,480)</b>	<b>4,701</b>
Income tax expense	-	-
<b>Net income</b>	<b>(6,480)</b>	<b>4,701</b>

## Investing in the future

- Peak COVID testing in 1H FY22
- 1H FY23 includes a prov. for stock write down of \$719k
- 71% GM excluding stock provision - in line with pcp
- Additional personnel, particularly overseas
- Ongoing R&D activity, clinical trials for FDA clearance
- Increased travel & marketing

**\$26.8m cash @ 31 Dec, no debt**

# 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**
  - First *EasyScreen*™ product for US
  - Reimbursement code in place (CPT 87506 US\$262.99)
  - 510(k) filing in April 2023
- **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



## ● Final steps underway

- Recruitment for trial involving 1,500 clinical samples was completed in July 2022
- For the several assays in GSS's Enteric Protozoan Kit that were not included in the predicate device (comparator assay), GSS has had to develop validated comparative tests for verification to provide the final data required to file the 510(k) application
- The final external study requires tests to be conducted at three sites by staff who have not used the test previously (multi-site reproducibility study)
- Currently awaiting Institutional Review Board (IRB) approval at the final site—expected in the coming weeks
- Remain on track to file the 510(k) application to the FDA in April 2023





## ● Next product

- Multi-pathogen syndromic test
- Significant benefits from **3base**<sup>®</sup> technology for this application
- Easier trial as all targets are in a predicate device

## ● Trial initiated

- Trial to be conducted at four sites in the US
- First 2 sites have commenced patient recruitment
- Other 2 sites at site-initiation stage
- Targeting 510(k) filing in mid-CY2024



- **Key appointments**
  - Distributor Channel Manager – Europe
  - Regulatory Affairs Associate – Europe
  - Head of Clinical Operations – North America
- **New distributors pending**
  - Israel
  - Middle East
- **Market preparation**
  - KOL focus group meeting in Texas – March 2023
- **Industry meetings**
  - Europe – ECCMID and others
  - USA – ASM and others
- **Customer trials**
  - Sites trialing Enteric & Respiratory kits for adoption





- **Leverage experience in AU market to grow international sales**
  - Europe – drive adoption of other **3base**® products
  - US – build **3base**® franchise once Protozoan Detection Kit is cleared
- **Build & expand portfolio of *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
- **Next-generation, “sample-to-result” instrument**
  - Highly automated, high-throughput
  - Ideally suited for high-volume commercial users
  - Embed use of **3base**® with customers







- **US Enteric Protozoan Kit**
  - 510(k) filing April 2023
  - 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
- **Complete 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





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