



Genetic Signatures (GSS)

Preparing for potential US launch H2 FY24

Our View

GSS submitted a 510(k) application for US FDA for clearance to market its **EasyScreen Gastrointestinal Parasite** Detection kit, earlier this month.

- The FDA review for 510(k) applications takes between 3 and 9 months, so we expect an FDA decision between December 2023 and June 2024.
- GSS has not disclosed the results of the 1,500 patient US trial, but the significant investment it is making in preparation for a US commercial launch indicates that it is confident in the quality of the data package it has submitted.
- With the kit already approved in Australia, Europe and Canada, we believe that there is a high probability of a positive FDA decision.

We like the fact that molecular testing for gastrointestinal pathogens is already in reimbursed in the US (at **US\$263** vs A\$32.30-36.60 in Australia), and that the kit is replacing low-value, microscopy based testing (reimbursed at US\$9-\$27).

Our base case valuation, which increases slightly to **\$2.19/sh** (vs \$2.09), assumes GSS receives an average of **US\$30 per test** in the US. With reimbursement of US\$263/test already in place, we believe that a price in the US\$60-US\$80 range may be achievable. We note that at **US\$60/test** our valuation would increase to **\$4.20/sh**. We will review our pricing assumption post FDA clearance (if achieved). We highlight a risk that additional funds may be required in FY24 or FY25.

Key Points

Inconsistent Flu B detection will impact Q124 sales

Guidance is for Q1 FY24 sales to be ~\$2m vs \$5.7m in Q1 FY23, due to inconsistent detection of the currently circulating strains of influenza B by the Respiratory Pathogen Detection kit. GSS has resolved the issue and does not expect any impact in subsequent periods. As a result of lower Q1 sales and higher operating expenses in preparation for the anticipated US launch, we have cut our FY24 revenue and EBITDA forecasts by 18% and 13% respectively.

The Gastrointestinal Parasite kit offers unique capabilities

The EasyScreen Gastrointestinal Parasite kit detects 8 pathogenic enteric protozoan parasites, whereas its FDA-cleared competitor, the BD Max Enteric Parasite Panel, detects only 3 of these parasites. KOL commentary underlines the potential for the GSS kit to displace current microscopy based testing, ensuring quicker turnaround and improved accuracy (and increased revenue for labs).

GSS has signed up a number of commercial labs to evaluate the kit under a customer experience program. It expects a number of these sites will become initial customers once the test is cleared for sale by the FDA.

Australian experience underlines potential for strong US uptake

GSS estimates that 5.5m enteric protozoan tests are performed in the US each year. We estimate that if the US matches the per capita uptake achieved in Australia, then sales would reach 2.1m tests per year, or 38% of the addressable market. Our forecasts assume a more modest 20% market penetration by FY28.

Clinical testing of the second product for the US market, the EasyScreen Essentials Respiratory Detection Kit, is 80% complete, and is on track to complete in H1 CY24. This would put it on track for a potential launch in 2025.

Funding and Balance sheet

Cash at end FY23 was \$16.3m. Pro forma cash is ~\$23m, including a pending \$6.9m R&D tax rebate. Cash outflow in FY23 was \$20.5m, including capex of \$8.1m (~\$6.2m for the sample-to-result instrument). Depending on the timing of FDA clearance, additional funds may be required to support the US launch of the Gastrointestinal Parasite kit; we currently model \$5m debt in FY25.

Our conflicts of interests are disclosed on the last page of this report.

12 September 2023

Speculative Investment

Recommendation: Outperform

Summary (AUD)

Market Capitalisation	\$76M
Share price	\$0.53
52 week low	\$0.44
52 week high	\$1.00
Cash as at 30 June 2023	\$16.3m

Share price graph (AUD)



Key Financials (AUD)

	FY23A	FY24E	FY25E
Revenue (\$m)	21.5	23.3	38.3
R&D (\$m)	(5.1)	(4.6)	(4.9)
SG&A (\$m)	(21.5)	(22.2)	(24.2)
EBITDA (\$m)	(13.1)	(10.1)	(2.1)
Reported NPAT (\$m)	(14.1)	(11.7)	(5.0)
NPAT Adj. (\$m)	(14.1)	(11.7)	(5.0)
EPS Adj. (c)	(9.8)	(8.2)	(3.5)
PE ratio (x)	n/a	n/a	n/a
DPS (c)	0.0	0.0	0.0
EV/Sales	1.8	1.7	1.0
EV/EBITDA (x)	n/a	n/a	n/a
EV/EBIT (x)	n/a	n/a	n/a

Genetic Signatures - Summary of Forecasts

GSS \$0.53

PROFIT & LOSS SUMMARY (A\$m)

Year end June	FY22A	FY23A	FY24E	FY25E	FY26E
Sales	35.4	16.9	18.8	38.3	55.9
Other	0.1	4.6	4.5	0.0	0.0
Total Revenue	35.5	21.5	23.3	38.3	55.9
Growth (pcp)	25%	-39%	8.3%	64.3%	46.0%
CoGS	(10.5)	(6.7)	(6.6)	(11.2)	(14.5)
Gross Profit Margin	70%	60%	65%	71%	74%
R&D Expenses	(3.1)	(5.1)	(4.6)	(4.9)	(6.5)
Corporate & other expense:	(15.8)	(21.5)	(22.2)	(24.2)	(26.4)
EBITDA	4.6	(13.1)	(10.1)	(2.1)	8.5
Dep'n/Amort'n	(1.6)	(1.5)	(1.8)	(2.9)	(3.1)
EBIT	3.0	(14.6)	(11.9)	(5.0)	5.4
Net Interest	0.1	0.5	0.2	0.0	0.0
Pre-Tax Profit	3.1	(14.1)	(11.7)	(5.0)	5.5
Tax Expense	0.0	0.0	0.0	0.0	0.0
NPAT Adj.	3.1	(14.1)	(11.7)	(5.0)	5.5
Growth (pcp)	74%	n/a	n/a	n/a	n/a
Adjustments	0.0	0.0	0.0	0.0	0.0
NPAT Reported	3.1	(14.1)	(11.7)	(5.0)	5.5

PER SHARE DATA

Year end June	FY22A	FY23A	FY24E	FY25E	FY26E
EPS (c) - Reported	2.1	(9.8)	(8.2)	(3.5)	3.8
Growth (pcp)	74.1%	n/a	n/a	n/a	n/a
EPS (c) - Adjusted	2.1	(9.8)	(8.2)	(3.5)	3.8
Growth (pcp)	74.1%	n/a	n/a	n/a	n/a
Dividend (c)	0.0	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0	0.0
Gross CF per share (c)	6.9	(8.7)	(4.9)	(0.9)	2.7
NTA per share (c)	37.1	26.1	14.8	11.3	15.5

KEY RATIOS

Year end June	FY22A	FY23A	FY24E	FY25E	FY26E
Net Debt : Equity (%)	-67%	-38%	-4%	13%	10%
Net Debt: EBITDA (x)	(8.1)	1.3	0.1	(1.6)	0.4
Current ratio (x)	10.7	6.0	2.9	2.6	2.7
ROE (%)	6%	-29%	-32%	-17%	19%
ROIC (%)	11%	n/a	n/a	n/a	12%
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Year end June	FY22A	FY23A	FY24E	FY25E	FY26E
PE Ratio (x)	24.8	n/a	n/a	n/a	13.9
Dividend Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales (x)	1.1	1.8	1.7	1.0	0.7
EV/EBITDA (x)	8.6	n/a	n/a	n/a	4.6
EV/EBIT (x)	13.3	n/a	n/a	n/a	7.2

BALANCE SHEET SUMMARY

Year end June	FY23A	FY24E	FY25E	FY26E
Cash	16.3	1.3	1.7	1.9
Receivables	4.4	4.1	6.1	8.9
Inventories	8.8	8.6	11.5	16.2
Other	6.9	4.6	0.0	0.0
Total Current Assets	36.4	18.6	19.3	27.1
Inventories	0.0	0.0	0.0	0.0
Property Plant & Equip	7.2	9.0	9.4	10.5
Intangibles	5.5	10.0	10.0	9.5
Other	0.0	0.0	0.0	0.0
Total Non- Current Assets	12.7	19.0	19.4	19.9
TOTAL ASSETS	49.1	37.7	38.7	47.0
Accounts Payable	4.8	5.1	6.1	8.9
Borrowings	0.0	0.0	0.0	0.0
Provisions	1.3	1.3	1.3	1.3
Other	0.0	0.0	0.0	0.0
Total Current Liab	6.1	6.3	7.4	10.2
Borrowings	0.0	0.0	5.0	5.0
Provisions	0.1	0.1	0.1	0.1
Other	0.0	0.0	0.0	0.0
Total Non- Current Liab	0.1	0.1	5.1	5.1
TOTAL LIABILITIES	6.2	6.4	12.5	15.3
TOTAL EQUITY	42.9	31.2	26.3	31.7

CASH FLOW SUMMARY

Year end June	FY23A	FY24E	FY25E	FY26E
EBIT (excl Abs/Extr)	(14.6)	(11.9)	(5.0)	5.4
Add: Dep'n & Amort'n	1.5	1.8	2.9	3.1
Other non- cash items	(1.1)	2.6	(1.7)	6.1
Less: Tax paid	0.0	0.0	0.0	0.0
Net Interest	0.6	0.2	0.0	0.0
Change in Rec.	(0.3)	0.3	(2.0)	(2.8)
Change in Inv.	1.4	0.1	(2.8)	(4.7)
Gross Cashflows	(12.5)	(7.0)	(1.3)	3.8
Capex	(8.1)	(8.1)	(3.3)	(3.6)
Free Cashflows	(20.5)	(15.1)	(4.6)	0.2
Share Issue Proceeds	0.0	0.0	0.0	0.0
Other, incl. loans	(0.0)	0.0	5.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cashflows	(20.5)	(15.1)	0.4	0.2
FX Effect on Cash	(0.0)	0.0	0.0	0.0

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Analyst: Dr Dennis Hulme

Release Authorised by: Campbell Taylor

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ABN 53008172450 AFSL 247083

Sharebrokers and Investment Advisors

Established 1928

ADELAIDE

Level 16, 211 Victoria Square
Adelaide SA 5000
GPO Box 2046
Adelaide SA 5001
Telephone 08 8217 3900
Facsimile 08 8321 3506
broker@taylorcollison.com.au

SYDNEY

Level 10, 167 Macquarie Street
Sydney NSW 2000
GPO Box 4261
Sydney NSW 2001
Telephone 02 9377 1500
Facsimile 02 9232 1677
sydney1@taylorcollison.com.au

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ABN 53008172450
AFSL 247083