Genetic Signatures

Transforming Molecular Diagnostics

Investor Presentation
US Commercial Launch

September 2023

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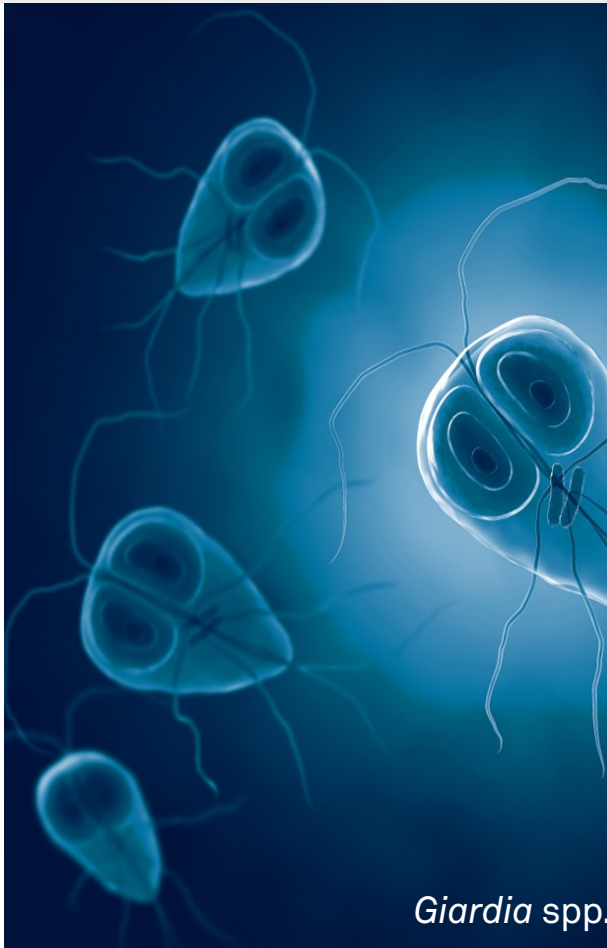
Introduction

- **Proprietary 3base® technology platform**
  - A revolutionary approach to molecular diagnostic assays for infectious diseases
- **Simplifies multiple pathogen testing from** a single sample
  - Multiplexing; more informative and simpler
- **Significant market share achieved in Australia**
  - 11 tests registered with TGA for sale
  - Secured 1 of the 3 major pathology groups
- **EMEA sales and marketing efforts generating traction**
  - Large pipeline of customers/ tenders
  - New channel partners in Europe, Israel and Middle East
- **Strong underlying growth in core revenue streams**
  - FY23 sales of $16.9M; 75% from syndromic testing
  - FDA clearance expected to drive growth in FY24 and beyond

US commercial launch underway

- **First product submitted to FDA for sales clearance**
- The *EasyScreen*™ Gastrointestinal Parasite Detection Kit addresses an **unmet need**
  - **Broadest molecular syndromic test for 8 clinically relevant GI parasites**
  - **No current stand-alone FDA cleared molecular test detects >3 parasites**
- **Estimated 5.5 million traditional tests conducted in the US / year**
  - Traditional tests are manual, slow, labour intensive & unreliable
- **Molecular reimbursement code already in place**
- **Pre-qualified customer experience sites commenced product workflow evaluation**
  - Many of these sites expected to become customers, post clearance



Company snapshot

Financial information

Share price (13-September-23)	A$0.53
Shares on issue	143.4m
Market capitalisation	**A$76.0m**
Cash (30-Jun-23)	A$16.3m
Debt (30-Jun-23)	Nil
Enterprise value	**A$59.7m**

Top shareholders %

Asia Union (Chris Abbott private investment)	26.2%
Perennial Value Management	14.0%
Fidelity International	6.9%
Directors & management	3.0%

Extensive US commercial and regulatory experience

Nick Samaras
Non Executive Chairman

- Significant experience leading international sales teams
- Former Managing Director of Applied Biosystems (Thermo Fisher)
- Senior executive roles at Perkin Elmer and AMRAD Corporation (CSL)

Michael Aicher
Executive Director

- Currently based in the US with significant experience driving US sales
- Founder of National Genetics Institute
- Led Lab-Corp' s esoteric business – generated US$1bn revenue p.a.

John Melki
Managing Director and CEO

- Led global commercialisation efforts of Genetic Signatures since 2011 and product development since 2003
- Successfully commercialised 2 research products globally and 7 diagnostic products in Australia and Europe

Tony Radford
Non Executive Director

- Co-Founder and CEO of Cellestis — acquired by Qiagen for c.US$400m
- Significant diagnostic sales experience
- Proven track record of executing a sales strategy for medical devices into Europe

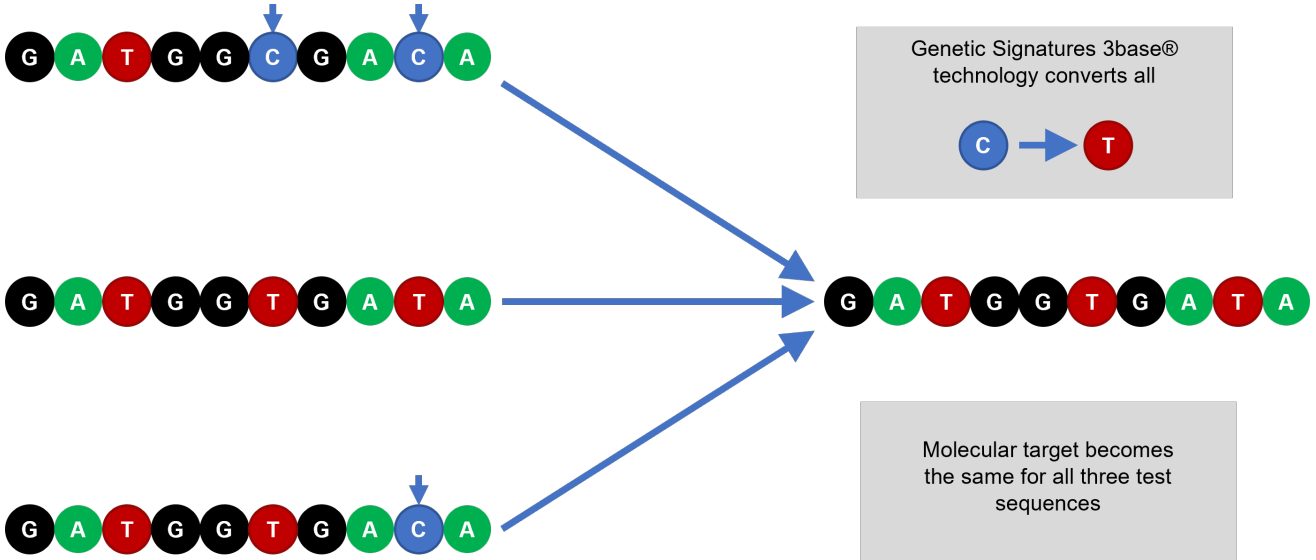
Neil Gunn
Non Executive Director

- Currently based in the US
- Former President of Roche Sequencing Solution & VP Roche's Molecular Diagnostic business unit
- Responsible for over 120 diagnostic product launches for Roche

Caroline Waldron
Non Executive Director

- Deep ASX experience in businesses that intersect heavily with regulation
- Cross-border commercial and M&A transaction experience
- Risk and governance expert

Proprietary 3base® technology simplifies molecular targets



* Human Papilloma virus sequences

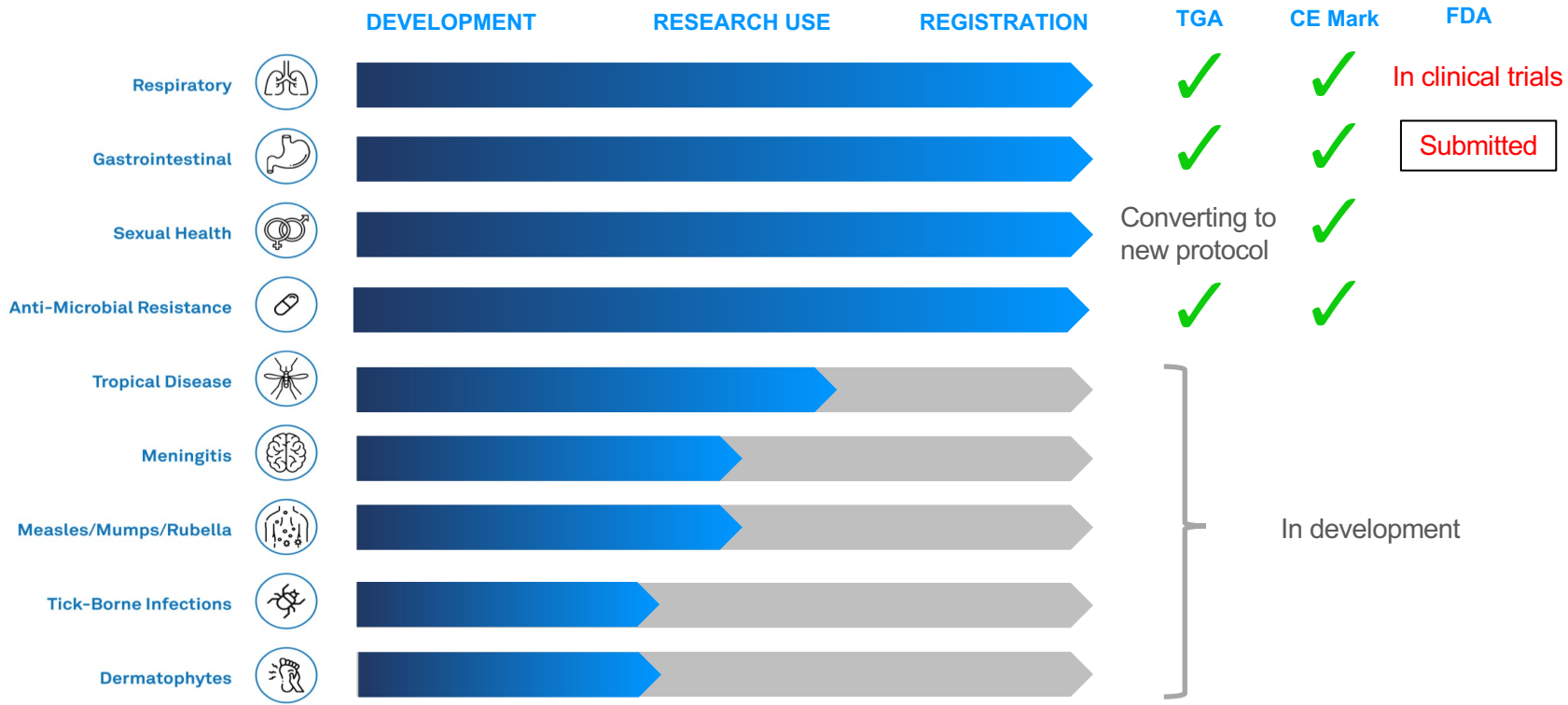
- **Molecular diagnostic tests are based on DNA/RNA sequences**
  - DNA/RNA is unique to each organism
- **Genetic Signatures 3base®** makes multiplex testing easier:
  - **More informative** – detect related pathogens/genes using fewer tests
  - **Simpler** – fewer reagents with better matched, reaction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

3base® conversion does not impact sensitivity or specificity and does not require any extra user steps

3base® simplifies syndromic testing – *EasyScreen™* kits

- **Syndromic testing:** 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
  - 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 all known pathogen variants (i.e. strains or subtypes)
  - Detect >20 different pathogens from a single sample
  - Flexibility to configure solutions to the laboratory's needs
- **~5m patients have been tested with at least one 3base® *Easyscreen*™ detection kit, many with multiple kits** covering viral, bacterial, parasites and other targets

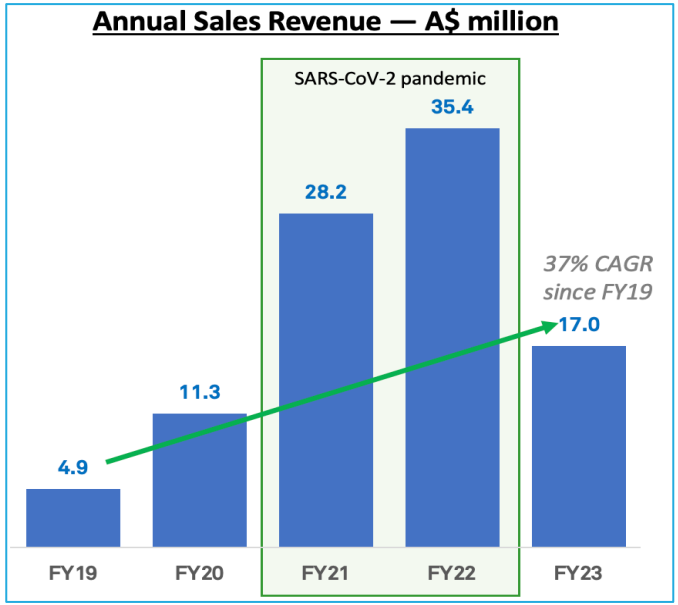
Robust pipeline with multiple products cleared for sale

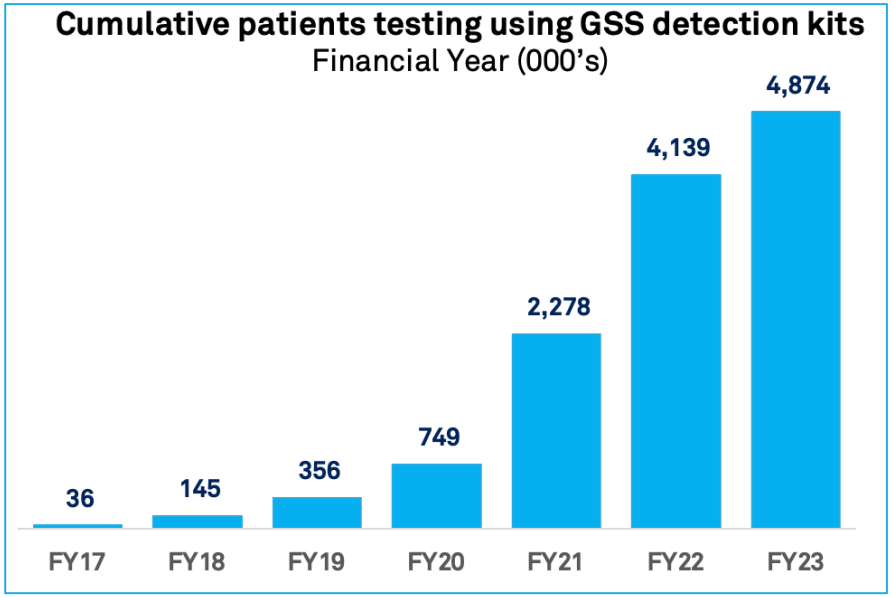


Strong underlying growth in core revenue streams

FY23 sales $16.9 million

- Anticipated decline in pathogen-specific molecular testing for SARS-CoV-2 experienced across the industry
- Replaced with growing syndromic respiratory sales— long-term, durable market
- Non-Covid Only sales up 38% in FY23 and account for 75% of sales in FY23
- 9% sales to international customers—set to grow with increased EU presence and as products cleared in US





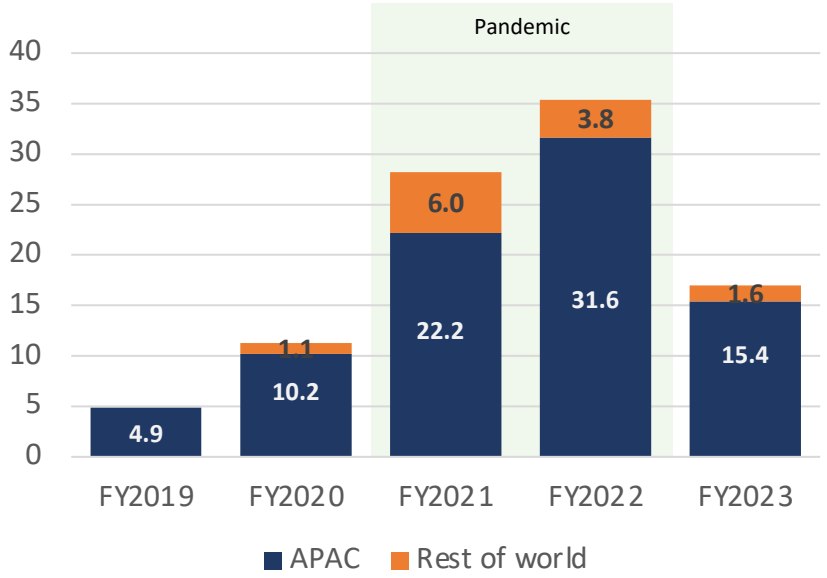
NOTE: *EasyScreen™* SARS-CoV-2 Detection Kit sales commenced during FY2020

Strong underlying growth in syndromic revenue streams

Annual Sales Revenue (A$m)

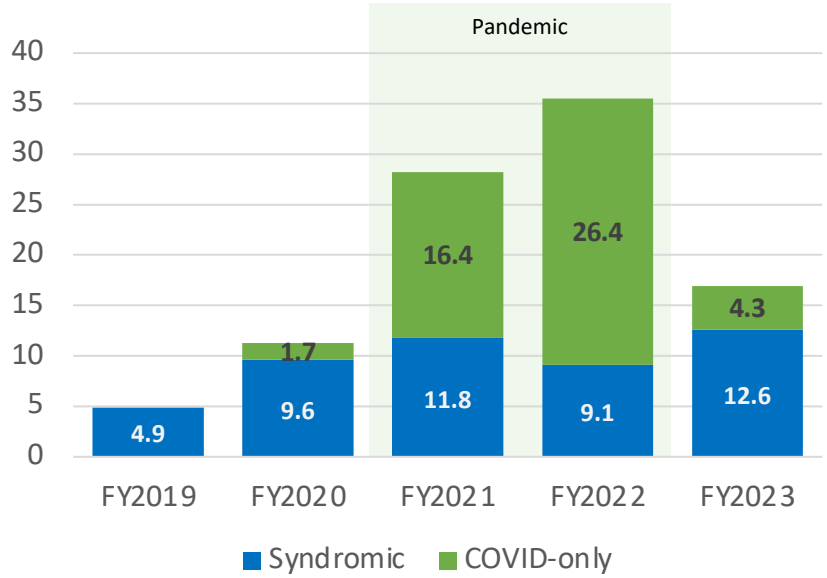
Focusing on increasing sales revenue from EU and US

- Company has invested for growth in international markets, particularly in Europe and the United States
- Like AU, COVID-19 Only sales reduced but more sustainable syndromic testing support sales in 2023
- Transition continues in EMEA



Core syndromic testing solutions lift 38% in FY2023

- Now account for 75% of sales
- Demand for COVID-19 Only testing shifts to be included within a broader syndromic respiratory solution



FY 2023 financial results

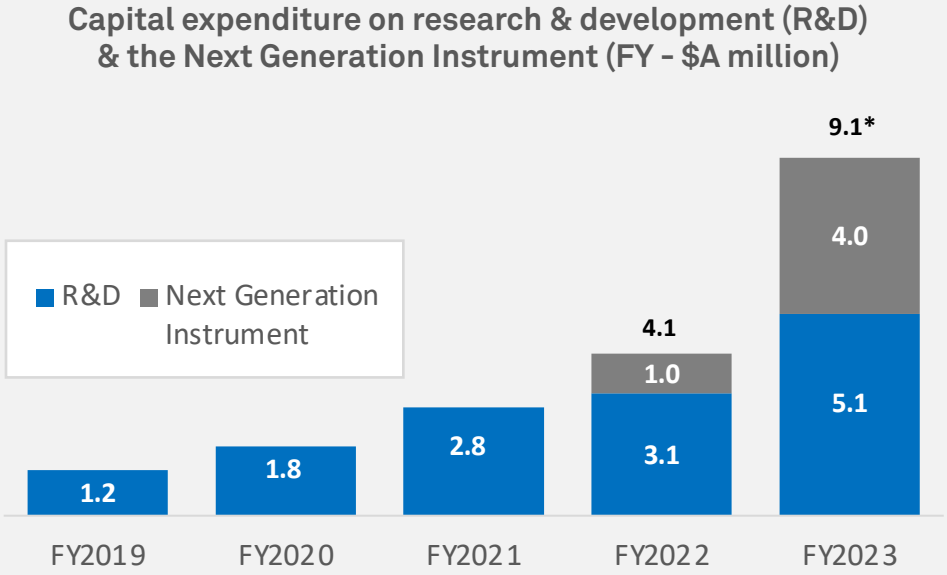
A$'000s	FY23	FY22
Sales revenue	16,939	35,421
Cost of materials & freight	(7,996)	(11,989)
Gross profit	**8,943**	**23,432**
Employee benefits expense	(15,037)	(11,948)
Scientific consumables & clinical	(5,119)	(3,133)
Other expenses	(6,429)	(3,889)
EBITDA	**(17,642)**	**4,462**
Depreciation & amortisation	(1,526)	(1,616)
EBIT	**(19,168)**	**2,846**
Other income	5,116	217
(Loss)/profit before tax	**(14,052)**	**3,063**
Income tax	-	-
Net (loss)/income	**(14,052)**	**3,063**
Net cash inflows/(outflows)	**(20,548)**	**6,776**
Cash balance (30 June)	**16,349**	**36,897**

Reduced SARS-CoV-2 molecular testing replaced with growing syndromic respiratory sales:

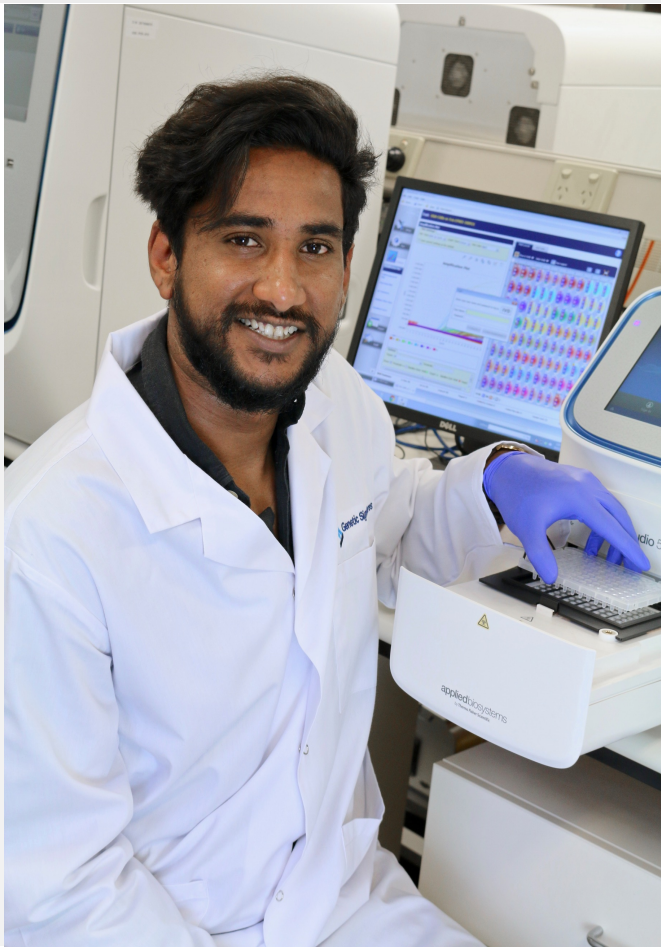
- Sales revenue of $16.9 million compared to $35.4 million in FY22;
- Non-COVID-19 only sales up 38% in FY23 and account for 75% of sales in FY23
- Gross margin on materials 60% compared to 70% p.c.p. primarily attributable to provision for obsolescence during the year
- **R&D Tax Incentive receivable of $6.9m** expected based on increase in eligible expenditure during the year

Substantial investments made in growth

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



*NOTE: *Anticipating A$6.9 million rebate under the R&D Tax Incentive for R&D in FY2023*



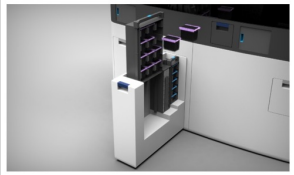
Next Generation Instrument development

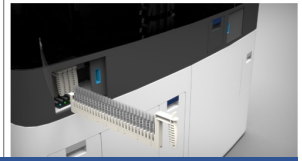
"Sample-to-result" Instrument

- Highly automated, little hands-on time
- High-throughput (~400 samples/shift)
- Same testing parameters for all panels – **3base®**
- Can run multiple products and mixed specimen types in a single run
- Highly flexible
- Embed use of **3base®** with customers

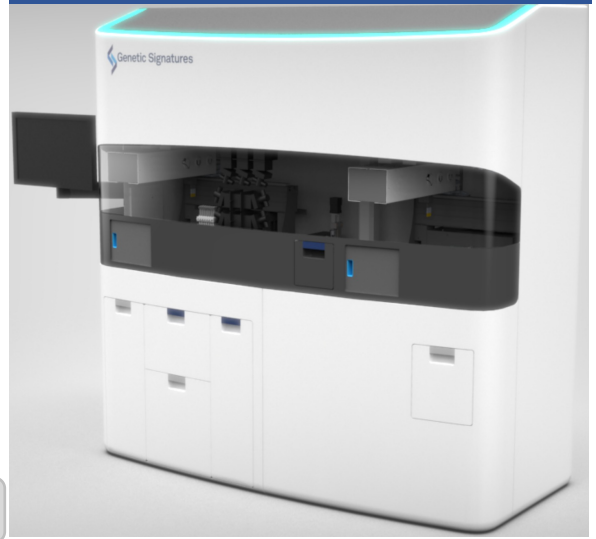
Value Position

- Future proof GSS in global MDx market
- Address a market gap for automated high-throughput syndromic testing
- Provide operational efficiency in our target market
- Single platform to consolidate multiple tests that are currently conducted on numerous instruments



Images are concepts only



Concepts, design, specification
- Research
- OEM review
- Form design
- Concept testing

Prototype developed
- Design development
- Sample to answer build
- Consumable build
- GUI development

Beta testing at customer sites
- Performance testing
- User feedback
- Informatics
- Design lock

Instrument in production
- Manufacturing partnership
- Support training
- Pre-marketing

Reg. clearance & product launch
- FDA/IVDR submission
- Regulatory clearance
- Product launch

2022 2023 2026

Case Study – Sales ramp in Australian customer

Excellence customer support and product performance supports long-term customer relationship

- Early Adopter evaluated **3base®** *Easyscreen*™ detection kits for enteric infections (parasite, bacterial and viral) in comparison to traditional methods
- The lab was initially contracted for only 20 enteric samples/day
- Genetic Signatures' unique syndromic solutions became embedded into the laboratory's workflow
- Higher demand quickly ramped to 50+ samples/day
- Also adopted respiratory testing and STI testing as they were released
- Tested 10,000 patient samples/day during peak of pandemic

2014
Initial trial of *EasyScreen*™ Gastrointestinal Detection Kits

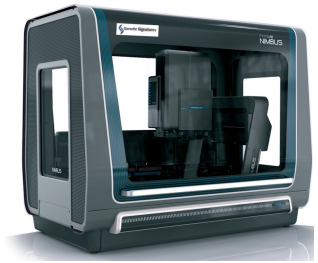
2017
Launched Respiratory kit
Customer adopted
Also adopted STI testing

2018
Sales ramping due to service offered

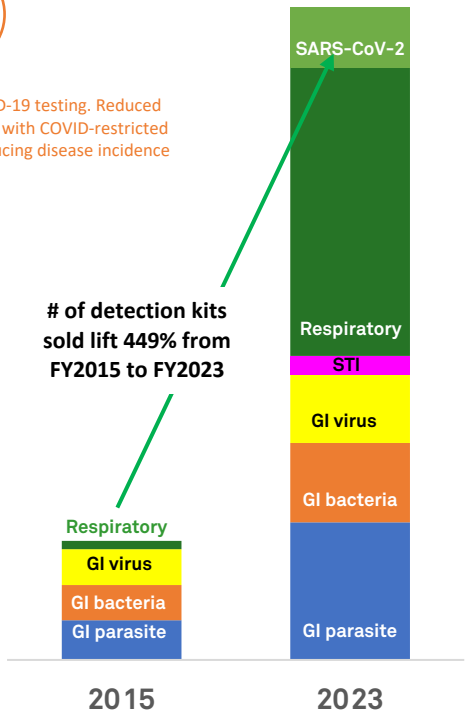
2020
EasyScreen™ SARS-CoV-2 Detection Kit added to workflow
+ increased syndromic respiratory testing

2021
High COVID-19 testing. Reduced syndromic with COVID-restricted travel reducing disease incidence

TODAY
Back to core business strength with growth in syndromic testing



# of detection kits sold lift 449% from FY2015 to FY2023



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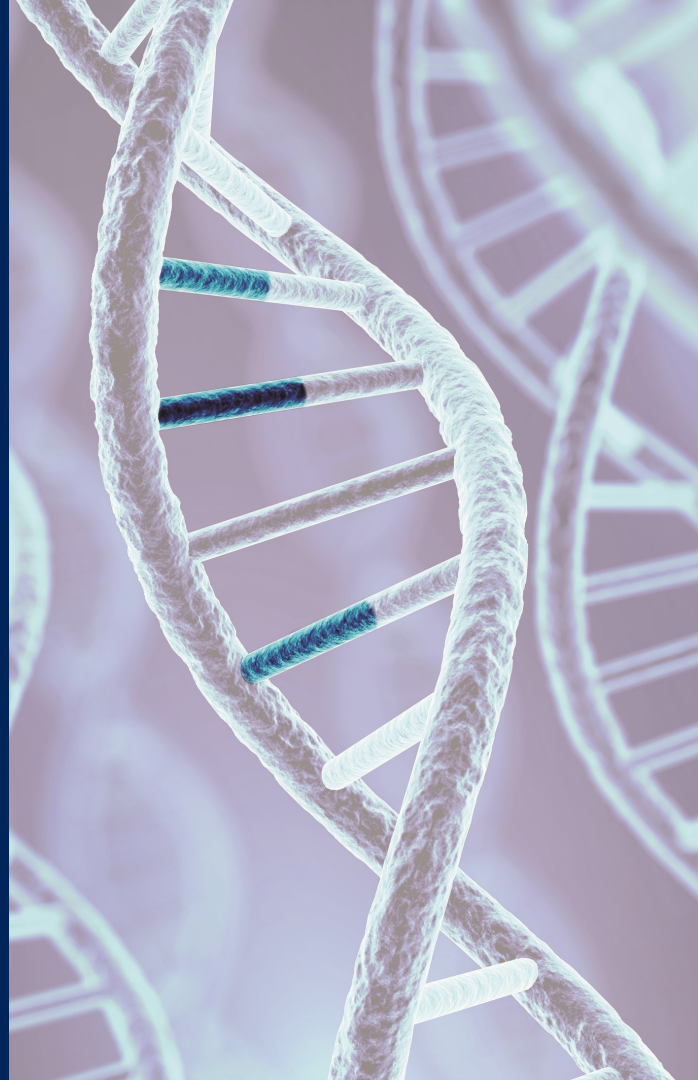
FDA filing for *EasyScreen*™ Gastrointestinal Parasite Detection Kit

Launching into World's Largest Molecular Diagnostic Market



Current testing protocols are complex and inefficient

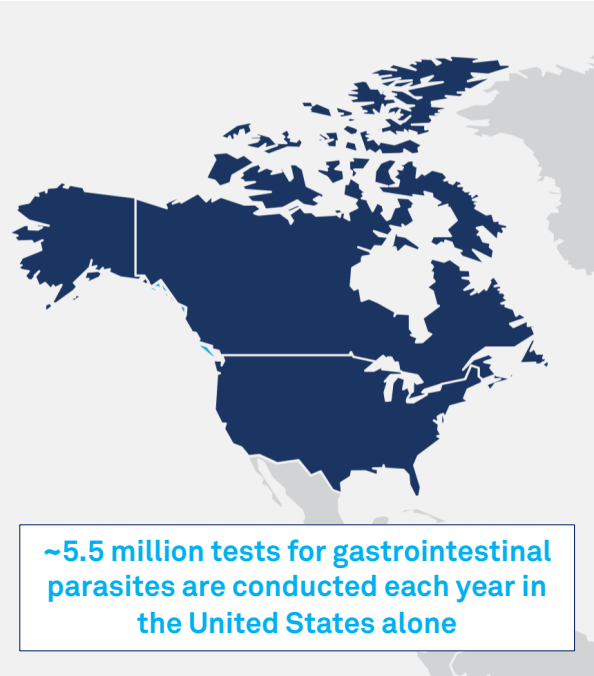
EasyScreen™ Gastrointestinal Parasite Detection Kit is expected to disrupt traditional standard ova & parasite testing

"The majority of diagnostic parasitology testing is categorized as high complexity, requiring a high level of interpretation & judgement – particularly related to microscopy" Lynne Garcia

	Traditional Microscopic Ova & Parasite (O&P) Examinations	_EasyScreen_™ Gastrointestinal Parasite Detection Kit
Number of tests required	Multiple — repeats for negative results	Single test — positive and negative controls
Patient samples that can be processed	One at time	1-to-60 in a single batch*
Reliability	Staining unreliable and varied performance	Testing – controlled and reproducible
Accuracy	Many false negatives - ~55% sensitivity	Improved sensitivity and specificity
Pathogen coverage	Not all pathogens tested or reported	Tests for 8 most clinically relevant pathogens
Duplicate testing	Testing multiple samples is recommended	Only one sample required – high sensitivity
Labour required	Extensive hands-on time	Minimal — many automated steps
Time to result	Many hours or days	Result in few hours
Training	Requires highly skilled, experienced staff	No specialised experience or training required
Need to outsource	Often due to skills and labour required	Ability to bring testing back in house

*NOTE: *31-60 Samples in a single batch requires 2 PCR machines*

North America represents 40% of diagnostic market



- **United States has a significant commercial opportunity for testing for gastrointestinal parasites**
  - 5.5 million tests conducted in the US per annum
  - No competing FDA approved molecular tests for detection of 8 parasites
  - Traditional tests are a manual process — slow, labour intensive, unreliable
  - Detects leading clinically significant protozoan infections
  - Existing reimbursement code in place
- ***EasyScreen*™ Gastrointestinal Parasite Detection Kit fills an unmet need**
  - Syndromic, molecular solution provides a more sensitive, rapid, and broad detection for 8 leading gastrointestinal parasites
  - The number of targets differentiates Genetic Signatures' product
  - Results in hours instead of days or weeks, seen with traditional diagnostics
- **510(k) submitted with US FDA in September 2023**

Positive feedback from users in US testing laboratories

"Molecular is going to impact patient management in three ways. Your results will come back quicker, they will potentially be more accurate, and they will also help ***redirect the evolving differential diagnosis by providing both positive and negative results with accuracy and efficiency."***

Dr Glen Hansen
Medical Director, Hennipin Country Medical Center *(now Chief Medical Officer at Seegene (US))*

"One of the things I really liked about the EasyScreen™ method was the range of targets that it can detect. I've seen a lot of other molecular testing that has a narrower range of targets. So ***the fact that this one has eight was wonderful to me****."*

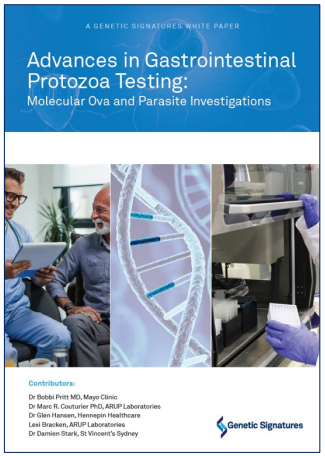
Lexi Bracken
Research Scientist, ARUP Laboratories

*"Once ordering physicians have used molecular for parasite screening, they become users. They are not going back to O&P**"*

Professor Marc R. Couturier
Medical Director, ARUP Laboratories

* O&P = Ova (egg) and parasite testing using culture and microscopy

4 Year investment in US opportunity



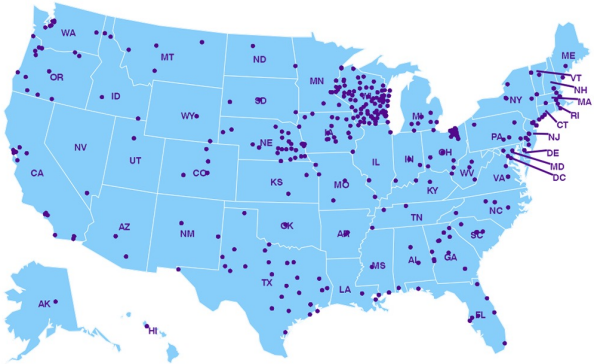
US team representation at ASM Microbe 2023 conference in Houston, Texas.

- **US market preparation activities since 2019**
  - Clinical trial commenced in 2020 in 3 US sites
  - Delivery of an educational webinar series and white paper involving industry parasitology experts with global reach
  - US focus group executed with key opinion leaders to deep dive into product appeal and positioning
  - Sales and marketing presence at leading international conferences in US

- **A select, limited number of pre-qualified customer experience sites in the US are currently evaluating the *EasyScreen*™ Gastrointestinal Parasite Detection Kit**
  - Establish the 3base® technology in their laboratories
  - Demonstrate the benefits of employing the 3base® molecular syndromic testing for gastrointestinal protozoan infections

Preparations for commercial sales in the US well advanced

- **Focused prospects**
  - Targeting the top 30-50 mid to high throughput laboratories in the US
  - 80/20 rule with majority of tests conducted by 20% of sites
  - Allows direct sales effort
- **Direct sales model**
  - Highly experienced sales team represented across the country
    - Actively developing customer relationships and the sales pipeline
  - Also supported by a team of technical and clinical operations experts in the region, and from HQ in Australia
- **US infrastructure established**
  - Distribution and warehouse facility in California
  - Working laboratory which houses instrumentation and enables R&D capabilities, and training support for the local market

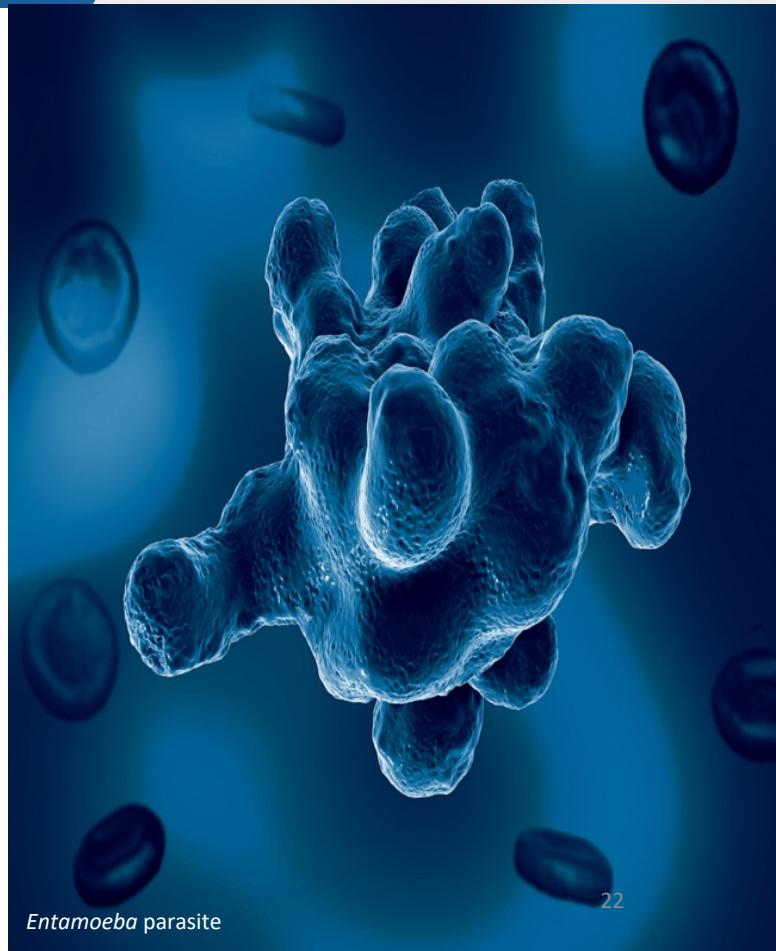


Participating laboratories in The National Respiratory and Enteric Virus Surveillance System (NREVSS). Source: CDC

Laboratory facility at BioLabs at the Lundquist Institute, California, United States

Preparations for commercial sales in the US well advanced

- **Commercial sales expected to start soon after FDA clearance**
  - Customer experience sites expected to transition to a purchasing customer
  - Solid opportunity pipeline supported by sales and marketing efforts in preparation of FDA clearance
  - Aiming for 40% market share of ~5.5 million tests / year
- **Existing reimbursement code covering use of the test**
- **Product diversification for future 3base® products to follow**
  - Regulatory dossier relevant for other *EasyScreen*™ products



Entamoeba parasite

Four distinct customer segments – all targets

	Projected GSS tests / site (% of testing)	Testing requirements	Potential test volume	Potential customers
Large Commerical Reference Labs	 50	High volume LabCorp / Quest = >1500 tests / day Others ~100-300 tests / day	1.65 million 30% of TAM	• LabCorp • Quest • Sonic Health • BioReference Laboratories • Clinical Reference Laboratory
IDN/Core Labs (Large Hospitals)	 33	Low to medium volume, Some sites high volume Average ~50-100 tests / day	3.03 million 55% of TAM	• Kaiser Permanente • Baylor Scott and White • Northwell Health • Cleveland Health Clinic • Sutter Health
Speciality Reference Labs	 12	Medium to high volume Average ~40-100 tests / day	0.28 million 5% of TAM	• ARUP Laboratories • Mayo Clinic • Wadsworth Center • University of Nebraska • Emory Medical Laboratory
Independent Hopsitals	 6	Low to medium volume, Average ~20-40 tests / day	0.55 million 10% of TAM	• Scripps Laboratories • Sharp Laboratories • John Hopkins • Tampa General • Henry Beaumont

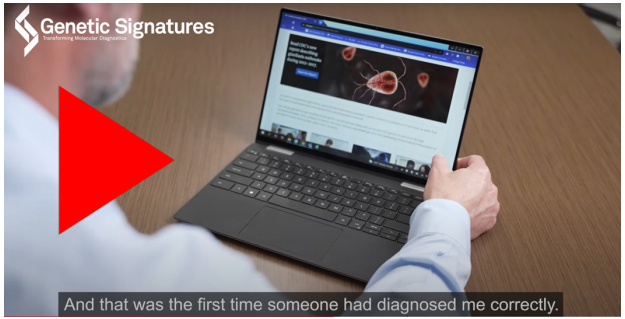
Target size and TAM modelled from various data sources listed here

- 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
- DeciBio 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

Advantages for US customers

Advantages for laboratory diagnostic services

- Fast time to result — improve laboratory workflow
- Highly reliable and sensitive test
- Ease of use — support diverse technical experience
- Minimal ‘hands on’ time
- Able to scale up or down, dependent on demand
- Auto-reporting capabilities with direct reporting to LIS systems
- Favourable economics (reimbursement v test cost)
- Access to technical support specialists
- Configurable panels to meet workflow and specific needs of the laboratory



Advantages for the clinician… and patient!

- Fast time to result — rapid diagnosis allowing timely and appropriate patient management
- More accurate solutions — reduced risk of untreated infection from false negatives
- Reduced need for multiple testing requirements and able to detect co-infecting pathogens
- Epidemiological / disease surveillance to inform infection control / management

Outlook - near term value drivers

- **US *EasyScreen*™ Gastrointestinal Parasite Detection Kit**
  - 510(k) clearance
  - Launch product once clearance is granted
- **Complete US clinical trial for next *EasyScreen*™ product**
  - Syndromic detection kit for common respiratory infections
  - Targeting a 510(k) submission for *EasyScreen*™ Essentials Respiratory Detection Kit
- **Increase sales and presence in UK and EMEA markets**
  - Contracts with new customers
  - Direct sales force and distributor appointments
  - Expansion of BioHub laboratory in Birmingham, UK
- **R&D initiatives for new products**
  - New *EasyScreen*™ detection kits
  - Technology and workflow improvements
  - Development of Next Generation Instrument prototype

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Appendix

Genetic Signatures revenue model

Products

- **3base®** *EasyScreen*™ detection kits span across a broad range of disease areas; many available as registered products in Europe, Canada and Australia
- GSS can cater for an end-to-end, low to high-throughput syndromic testing workflow. This is supported by the GS-mini, GS1, GS1-HT & GS-1000 automated systems, and GS-Call results interpretation and calling software
- Universal sample processing and shared PCR cycling conditions support product diversification across the testing portfolio

Customers

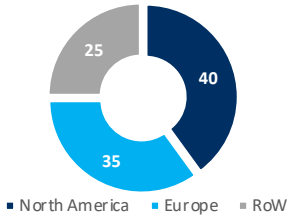
- Customers are commercial or private laboratories, reference laboratories, hospitals, or government run programs
- Customers purchase kits from GSS – then reimbursed by the government or insurers
- To speed up customer acquisition, GSS may fund new customer installations, particularly offshore
  - High ROI – will recoup a multiple of initial outlay via long term consumable revenue

Contracts

- Customers sign a 3-5 year contract, securing price and expected volumes - Consumable revenue model - price per test
- Volumes are relatively predictable with good visibility
- Monthly orders with fast payment terms – quick cashflow and low working capital
- Tests become embedded in diagnostic lab workflow with the flexibility to expand product the range, when required

Executing a global strategy for commercialisation

Global MDx market – Regional market share (%)



Sources:
- MDX demand: Global market from reported figures from Markets and Markets Research and Grand View Research (2021)
- MDx Infectious diseases: Kalorama

1 Australia: Expansion of local footprint

- ✓ 11 tests now registered with TGA for sale to detect respiratory, gastrointestinal infections and antimicrobial resistance testing
- ✓ Already secured 1 of the 3 major pathology customers
- ✓ Winning significant market share, with expanding customer base in Western Australia & diversified syndromic product uptake from existing customers
- ✓ New products approaching TGA registration with ongoing product development and workflow improvements to meet customer needs

Executing a global strategy for commercialisation

2 Established and growing presence in Europe and Middle East

- ✓ Solid sales and marketing efforts driving increased brand recognition in the region
- ✓ Broad range of CE-IVD Marked tests available for sale in Europe
- ✓ Direct representation and laboratory facilities in United Kingdom, and an established subsidiary in Germany
- ✓ Multiple warehousing facilities support reliable and timely product delivery
- ✓ Multiple channel partners appointed in Europe and Middle East, with a strategy for further expansion in the region
- ✓ Large pipeline of customers / tenders. Customer trials in progress

Executing a global strategy for commercialisation

3 North America: Preparation for market entry underway, with first 510(k) submission to FDA for gastrointestinal parasite test

- ✓ *EasyScreen*™ Gastrointestinal Parasite Detection Kit submitted to FDA for regulatory clearance in Sep 2023
- ✓ Aspire to capture 30-40% of market share of potential 5.5 m tests p.a, over the next 5 years, supported by a solid opportunity pipeline
- ✓ Commenced clinical testing of a second **3base®** product for the US market for syndromic testing for respiratory infection
- ✓ ASR sales of gastrointestinal bacterial, viral and parasite pathogens at a number of customer sites in the United States
- ✓ An established team with expertise in Sales, Marketing, Technical Support, Clinical and Commercial Operations

3base® supports appropriate treatment for infection

Protozoan Pathogen	Symptoms	Antibiotic
Giardia lamblia/intestinalis	Common set of symptoms from all gastric protozoan infections which include: • Abdominal pain • Diarrhea • Greasy stools • Nausea or vomiting • Gas or bloating • Dysentery • Fatigue • Weight loss	Metronizadole, tinidazole, nitazoxanide
Cryptosporidium spp.		Nitazoxanide (some patients)
Entamoeba histolytica		Metronizadole, tinidazole
Cyclospora cayetanensis		Trimethoprim-sulfmethoxazole
Enterozytozoon bieneusi		Nitaoxanide (no established guidelines)
Encephalitozoon intestinalis		Albendazole
Dientamoeba fragilis		Lodoquinol (US), secnidazole, ornidazole
Blastocystis hominis		Metronizadole, tinidazole,

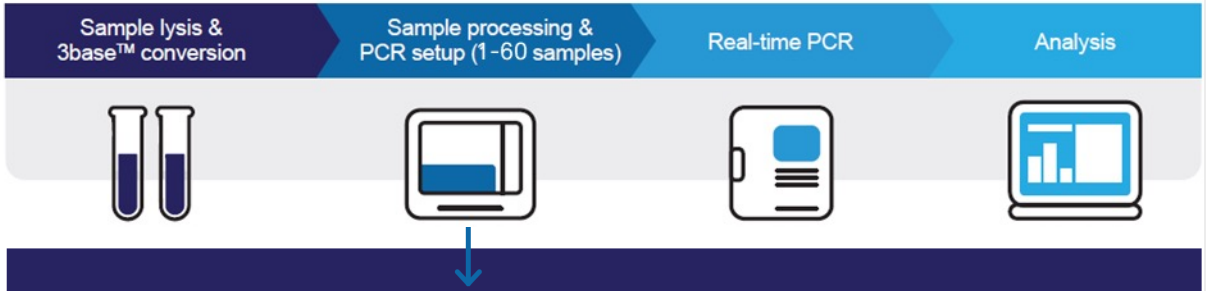
- **3base®** simplifies the conditions for multiplexing several pathogen tests into a single tube
- **3base®** enables the detection of different strains and variants of pathogens within the same test

Business development activity in expanding markets

- **Recent Key appointments**
  - Distributor Channel Manager – Europe
  - Regulatory Affairs and Quality Assurance Manager – Europe
  - Head of Clinical Operations – North America
- **New channel partners appointed**
  - Europe, Israel & Middle East
- **Industry meetings with solid brand exposure**
  - Europe – ECCMID and others
  - USA – ASM and others
- **Customer trials**
  - Local and international customer sites trialing other *EasyScreen*™ gastrointestinal & respiratory detection kits for adoption

EasyScreen™ Gastrointestinal Parasite Detection Kit
Automated syndromic workflow

- Higher sensitivity and specificity
- Workflow automation
- Able to combine multiple targets into single assay
- Quicker turnaround times



Genetic Signatures' GS1 automated system allows the processing of up to 60 samples.

For a medium-throughput workflow (30 samples):*

- Time to last result: ~4.5 hours.
- Hands-on-time: ~20 minutes.
- 8 targets: *Giardia lamblia/intestinalis*, *Cryptosporidium spp.*, *Entamoeba histolytica*, *Cyclospora cayetanensis*, *Enterocytozoon bieneusi*, *Encephalitozoon intestinalis*, *Dientamoeba fragilis*, *Blastocystis hominis*.

* Pre-analytical sample handling time varies according to sample number, prior to 3base™ conversion.

> *Since using **Genetic Signatures'** molecular panel for GI infections, I am able to **rationalize and streamline our workflow.** That allows for **significant staff savings and cost savings.** The only reason we would do microscopy now is if it's a specific request for something that is not on the molecular panel"*

Principal Hospital Scientist, Australia

Genetic Signatures
Transforming Molecular Diagnostics

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