Genetic Signatures

ASX Code: GSS
29 November 2023

Chairman's Address and CEO Presentation at Annual General Meeting

Genetic Signatures Limited (ASX:GSS) is pleased to release the Annual General Meeting Chairman's Address and CEO presentation.

Chairman's Address:

Good morning, and welcome to the Genetic Signatures 2023 Annual General Meeting. On behalf of the Board, I would like to thank you all for attending and for your ongoing support.

I am pleased to provide an update on a pivotal moment in our company's evolution. We stand at the threshold of launching our inaugural FDA-approved product, the *EasyScreen*™ Gastrointestinal Parasite detection kit, into the U.S. market. This achievement signifies a substantial milestone, paving the way for a transformative phase in our company's history.

However, it's important to address the challenges we've faced leading up to this point. Delays in submitting our FDA file and recent issues with our FluB product have impacted on our financial standing, including our cash position. In response to these challenges, we've implemented strategic cost reductions. These measures are part of our proactive approach to managing resources efficiently until we secure FDA clearance and commence product sales in the US market.

Looking ahead, we will leverage the lessons learned to build a more resilient future. Our confidence in the potential of our FDA-approved product remains unwavering, and we anticipate positive outcomes for both the Company's growth and global standing.

Before handing over to our CEO and Managing Director, Dr John Melki, I would like to provide a high-level overview of some of the significant achievements Genetic Signatures has made during the financial year 2023, and more importantly, the great prospects I see for the company as we head into 2024.

During the COVID-19 pandemic, Genetic Signatures saw robust demand for the *EasyScreen*™ SARS-CoV-2 Detection Kit, leading to heightened awareness of the Genetic Signatures' brand and the unique advantages of **3base®** technology in key markets. Subsequently, following a rapid decrease in public health molecular SARS-CoV-2 testing, the 2023 fiscal year saw revenue contract to $16.9 million. This decline had been anticipated by the Company, with a planned strategic focus to transition both existing and newly acquired customers to our well-established syndromic testing solutions. During the year, the Company experienced subsequent revenue expansion from these established non-COVID testing solutions, serving as a testament to our sustainable growth trajectory, and showcased Genetic Signatures' advantageous position to capitalise on the escalated global demand for syndromic testing.

The revenue generated during the COVID-19 pandemic was invested into product development, with at least five new product groupings now in various stages of development. In addition, the Company continues to work towards future registration of key syndromic solutions in Australia, Europe and North America. We have progressed development of our next generation, fully automated sample-to-answer instrument for high-volume testing. This instrument is expected to further drive demand for *EasyScreen*™ kits in targeted markets, and further embed **3base®** technology in the workflow of our existing customer base.

This year, we continued to deliver high-impact marketing initiatives to further increase awareness and positioning of Genetic Signatures as a leading competitor in global molecular diagnostics in the lucrative United States (US) and European markets.

In the US, Genetic Signatures remains focused on the commercial launch of the *EasyScreen*™ Gastrointestinal Parasite Detection Kit. With the goal of capturing 40% of the estimated addressable market of 5.5 million tests per annum, this innovative diagnostic solution offers faster and more accurate detection of a comprehensive range of gastrointestinal parasites in a single test. This advanced approach not only facilitates early patient management but also presents substantial cost efficiencies for diagnostic laboratories and the healthcare system. The 510(k) FDA application was submitted in September this year and we are continuing to work with the FDA as we head towards FDA clearance and Genetic Signatures' commercial launch in the US.

To support this commercial launch, the Company has invested in establishing a highly experienced team in North America. This team has commenced working with a select group of pre-qualified sites who are evaluating the workflow and poised to potentially adopt the kit into routine use upon FDA clearance. To support sales in the North American region, this product was also cleared for sale in Canada, further extending our reach and sales potential in this market.

To support an ongoing pipeline of FDA registered products in the US, we have initiated a clinical trial for the *EasyScreen*™ Essentials Respiratory Detection Kit. This product is a syndromic test designed to detect the most common, clinically relevant respiratory infections, including SARS-CoV-2. **3base®** technology is particularly well-suited for the detection of seasonal viral respiratory pathogens, as the tests are more resilient to genetic changes that occur with the emergence of new strains. This trial has progressed well to date, with 510(k) FDA submission for this detection kit and workflow targeted in 2024.

In Europe, Genetic Signatures is well-positioned to further lift sales across the existing portfolio of registered detection kits and automated systems. This year has seen further expansion of Genetic Signatures' laboratory facility at the BioHub in Birmingham, United Kingdom, and the establishment of the Germany subsidiary. This will provide further support for European sales and marketing activities, as well as technical support for our European customers and distributors.

In closing, I extend my gratitude to all employees for their contributions to our successes in the past year. Additionally, I appreciate the support and guidance from my fellow Directors, which has made my role as Chairman both enjoyable and fulfilling.

Finally, let me take this opportunity to thank you, the shareholders, for your continuing support of this wonderful company. I look forward to continuing to share this exciting journey with you.

Dr John Melki, our Managing Director and CEO, will now provide a review on Genetic Signatures' operations, corporate strategy and milestones in the coming year.

Dr Nick Samaras
Chairman

- END –

Authorisation and Additional Information

This announcement was authorised by the Board of Directors of Genetic Signatures Limited.

Genetic Signatures

Transforming Molecular Diagnostics

2023 Annual General Meeting

29th November 2023

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What does Genetic Signatures do?

Genetic Signatures develops and markets molecular diagnostic testing kits for syndromic testing for infectious diseases used by pathology laboratories

- **Infectious diseases are a leading cause of death**
  - This is often preventable through more accurate diagnosis and timely treatment
- **Molecular PCR diagnostic tests target unique genetic signatures (DNA)**
  - These DNA sequences (Genetic Signatures) are screened in patient samples and flagged if a pathogen is detected
  - The simultaneous testing for all the pathogens that can cause the same symptoms in a patient is known as "syndromic testing"
  - This method is highly accurate and can test for a wide range of infectious diseases including respiratory, enteric (intestinal illness) and sexual health
- **Genetic Signatures' unique 3base® technology** simplifies syndromic testing for infectious diseases
  - **Benefits for patients** – single test to screen for multiple infections which supports faster diagnosis and treatment
  - **Benefits for pathology laboratories** – less time evaluating samples and more testing results per patient specimen

Executive Summary

Proprietary 3base® technology underpinning an automated diagnostic workflow	• A revolutionary approach to **molecular diagnostic** assays for infectious diseases • Detects a wide range of clinically relevant targets, **in one test – Syndromic Testing** - testing for multiple pathogens that all can cause the same signs and symptoms • Uniform sample processing conditions regardless of sample type allowing for a **simplified workflow** • Robust pipeline with **multiple products cleared for sale** in Australia and Europe • Over **5 million patients** have been tested to date in multiple markets
Molecular diagnostic market (MDx) estimated at ~A$35b with growing syndromic testing segment expected to reach A$4.3b by 2026	• The MDx market is a high growth segment, representing ~40% share of infectious disease testing • Growing adoption of syndromic testing to support early disease diagnosis and improved patient management • **High gross margins** achieved by being embedded in the diagnostic laboratory workflow
First product to be launched in the US: addresses unmet need	• *EasyScreen*™ Gastrointestinal Parasite Detection Kit provides the **broadest molecular syndromic test for 8 clinically relevant GI parasites** • Currently no FDA cleared molecular tests which detects more than 3 parasites • **Displaces traditional testing** which is manual, slow, labour intensive and unreliable • Molecular **reimbursement code** already in place

Executive Summary

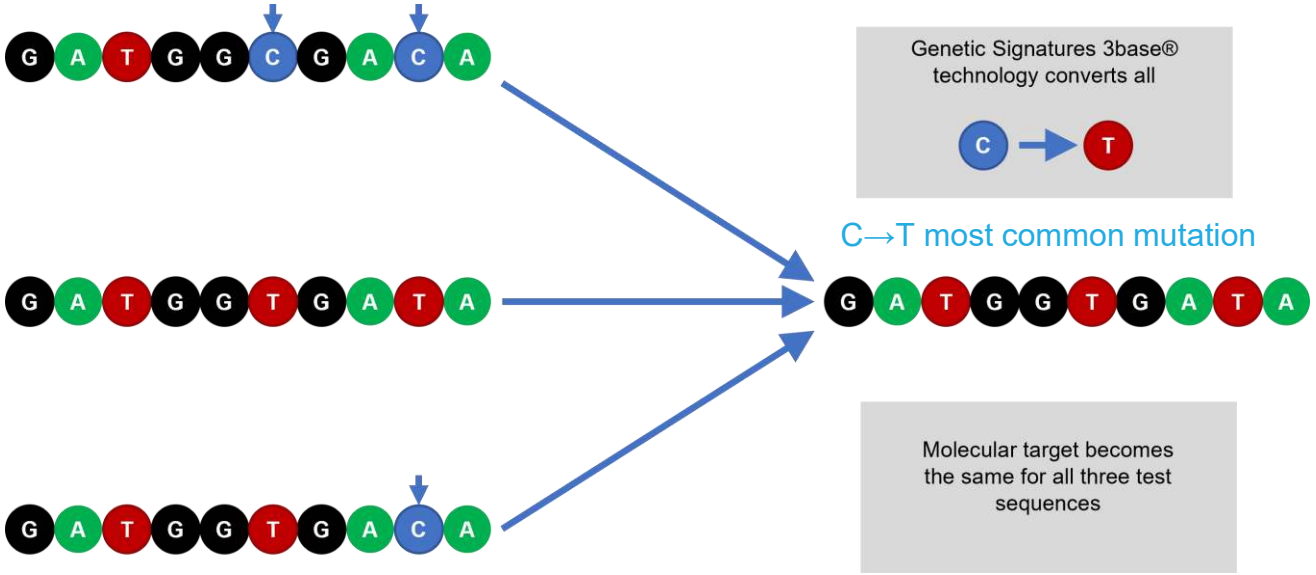
Next Generation Instrument development to drive future growth

- Will enable customers to conduct automated, high-throughput syndromic testing **improving efficiency, economics and patient diagnosis**
- Single platform which **consolidates multiple tests** that are currently conducted on numerous instruments
- **Embeds the use of 3base®** with high-throughput customers
- Sample-to-answer instrument expected to **improve gross margins and attract large global customers**

Significant news flow and catalysts expected in the near term

- Anticipating US FDA clearance of the *EasyScreen*™ Gastrointestinal Parasite Detection Kit
- Complete US clinical trial for next *EasyScreen*™ product, for respiratory indications
- Increase sales and channel partners in the UK and EMEA markets
- Further R&D initiatives for new products and technology improvements

Proprietary 3base® technology simplifies molecular targets



* Human Papilloma virus sequences

- **3base®** converts the original 4-base microbial genome to 3-base
- **3base®** can identify a wider array of patient infections and can detect multiple pathogen strains by reducing complexity

Able to detect all known pathogen variants (i.e. strains or subtypes) – more tolerant of mutations

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

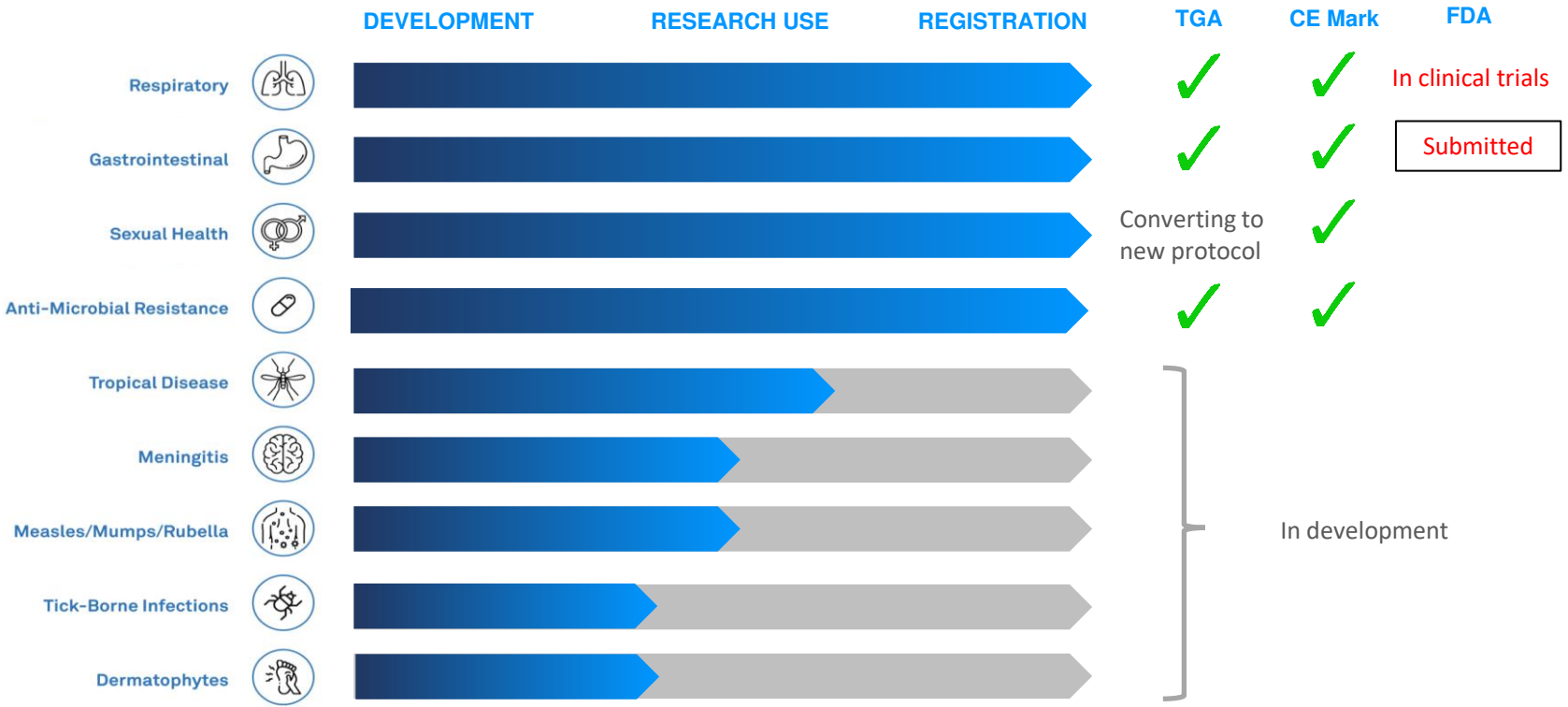
3base® simplifies syndromic testing – *EasyScreen™* kits

- **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 a **single test** to determine the potential cause of a disorder

- **Genetic Signatures' *EasyScreen*™ is ideal for syndromic testing**
  - Tests available for over 100 different types of pathogens
  - 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

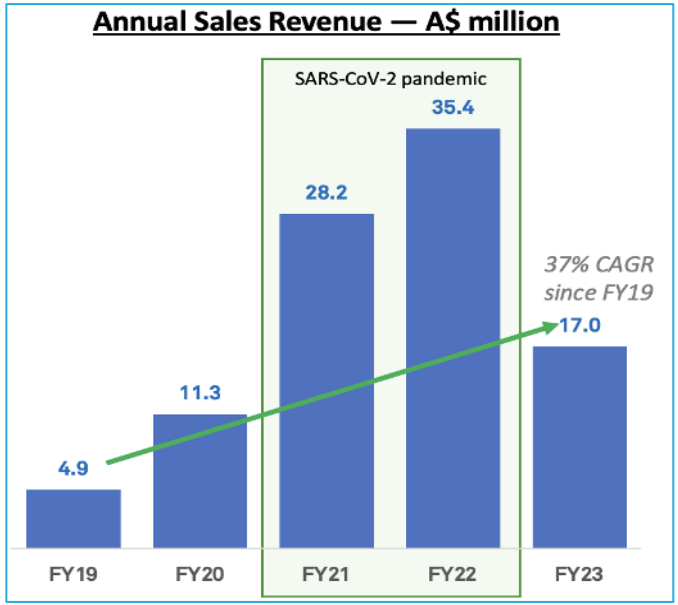
Robust pipeline with multiple products cleared for sale

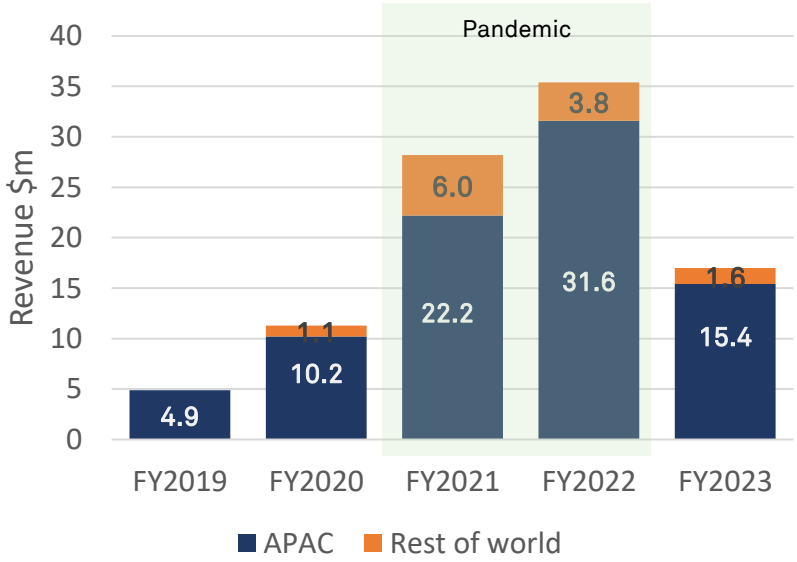


Strong underlying growth in core revenue streams

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 significantly with increased EU presence and as products cleared in US



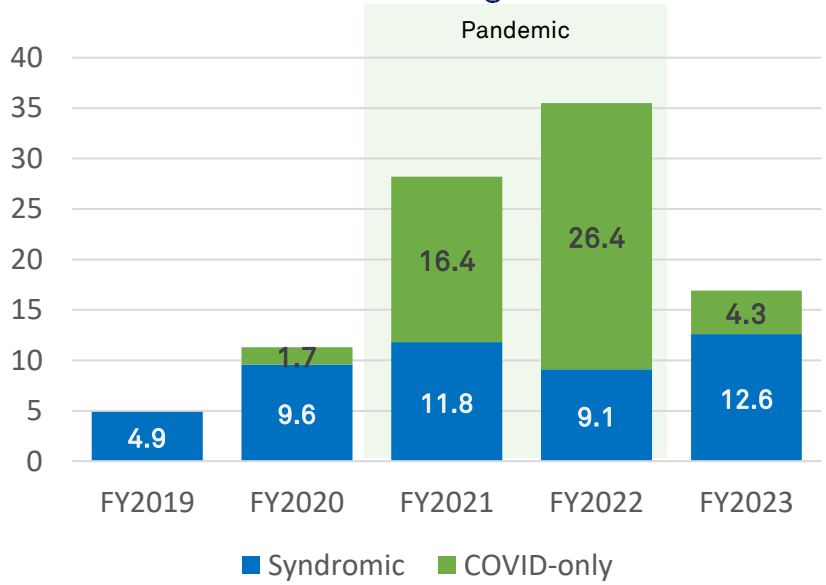


NOTE: *EasyScreen™* SARS-CoV-2 Detection Kit sales commenced during FY2020

Strong underlying growth in syndromic revenue

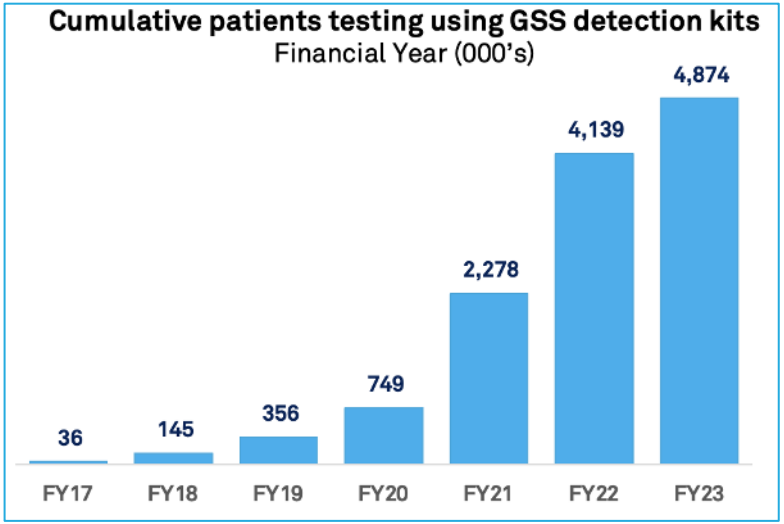
Core syndromic testing now accounts for 75% of sales in FY2023

- Growth of 38% in the financial year
- Increased demand for COVID-19 testing being incorporated in syndromic respiratory solution rather than stand-alone testing



Transitioning to higher value patient testing

- Over 5m patients tested to date
- Patients increasingly tested for multiple targets post-pandemic – higher revenue per patient test
- Pandemic demonstrated ability to scale operations to meet customer demand



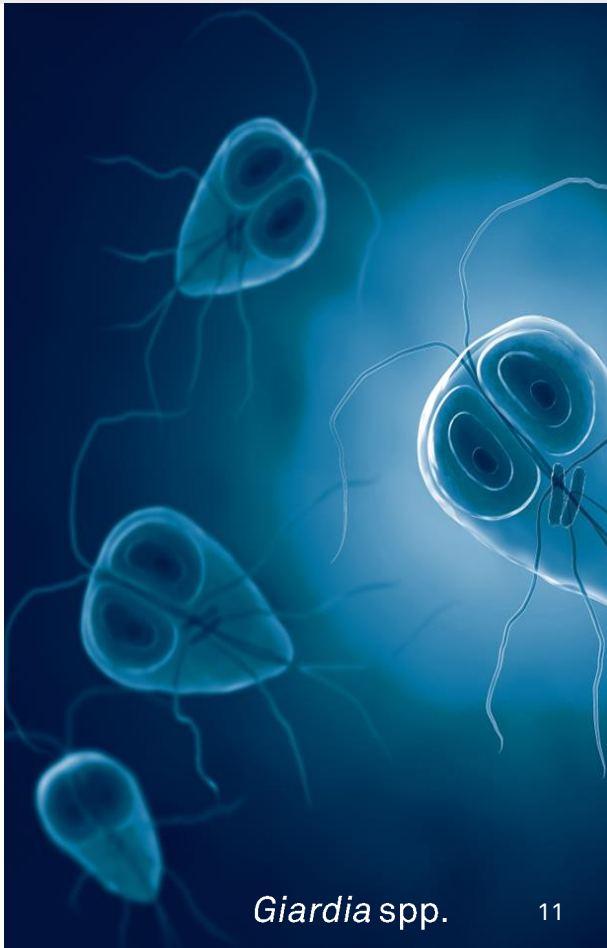
Compelling opportunity in the US

- **First product, the *EasyScreen*™ Gastrointestinal Parasite Detection Kit submitted to FDA for sales clearance**

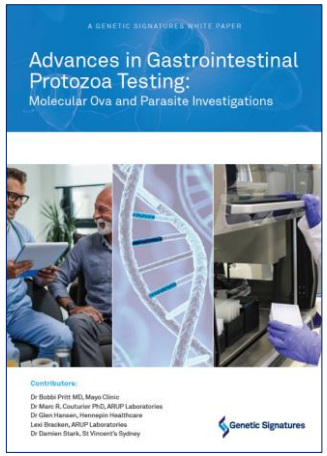
- **The product addresses an unmet need**
  - Broadest molecular syndromic test for 8 clinically relevant GI parasites
  - No current FDA cleared molecular test detects >3 parasites

- **~5.5 million traditional tests conducted in the US / year**
  - Traditional tests are manual, slow, labour intensive & unreliable
  - Current testing is not profitable for pathology laboratories

- **Molecular reimbursement code already in place**
  - Higher reimbursement rate than traditional microscopic tests



Investments undertaken to support US launch



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

- Clinical trial commenced in 2020 in 3 US sites forming part of the FDA application
- A select, limited number, of pre-qualified customer experience sites in the US are currently evaluating the *EasyScreen*™ Gastrointestinal Parasite Detection Kit
- Highly experienced sales team in place in preparation for commercial launch
- Distribution, warehouse and laboratory facilities in place
- Engagement with key opinion leaders to understand product appeal and positioning
- Attendance at conferences and delivery of white papers to increase brand awareness in preparation for launch

Four distinct customer segments – all targets

*EP005 = *EasyScreen*™ Gastrointestinal Parasite Detection Kit

Target segments	GI parasite testing requirements	Potential TAM = 5.5 m tests	Share of targeted 2.2m EP005* tests by segment	Potential customers
Large commercial reference labs	High volume LabCorp / Quest = >1500 tests / day Others ~100-300 tests / day	1.65 million 30% of TAM	50%	• LabCorp • Quest • Sonic Health • BioReference Laboratories • Clinical Reference Laboratory
IDN / core labs (large hospitals)	Low to medium volume, Some sites high volume Average ~50-100 tests / day	3.03 million 55% of TAM	32%	• Kaiser Permanente • Baylor Scott and White • Northwell Health • Cleveland Health Clinic • Sutter Health
Specialty reference labs	Medium to high volume Average ~40-100 tests / day	0.28 million 5% of TAM	12%	• ARUP Laboratories • Mayo Clinic • Wadsworth Center • University of Nebraska • Emory Medical Laboratory
Independent hospitals	Low to medium volume, Average ~20-40 tests / day	0.55 million 10% of TAM	6%	• 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

Next Generation Instrument development

Design input received by laboratory leaders including Johns Hopkins, Mayo Clinic, Quest Diagnostics, Texas Children's and Baylor Scott & White

"Sample-to-result" Instrument

- Highly automated
- High-throughput (~400 samples/shift)
- Can run multiple tests across mixed sample types at the same time
- Embed use of **3base®** with customers

Value Position

- Address a market gap for automated high-throughput syndromic testing
- Provide operational efficiency in our target market
- 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

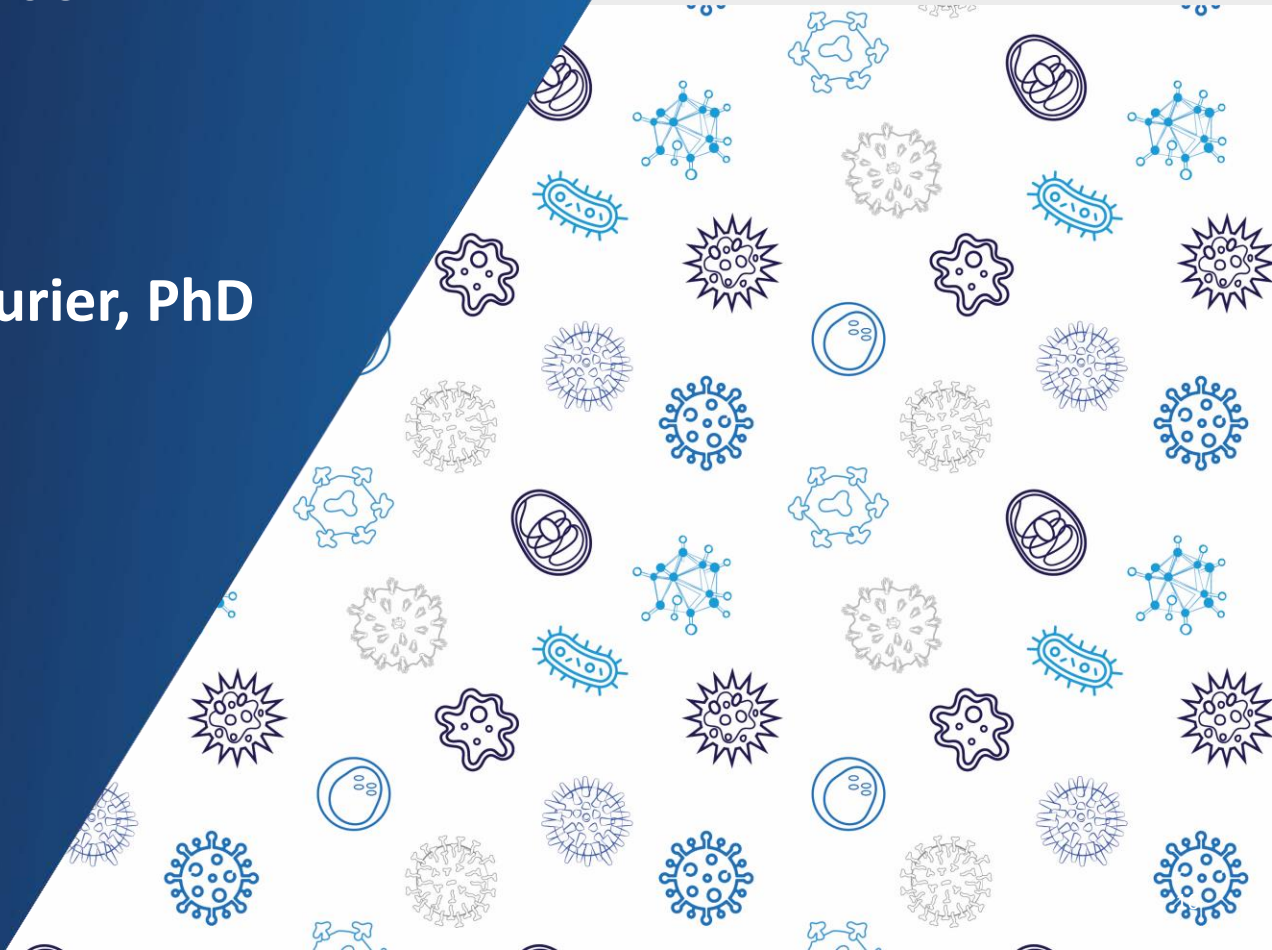
2022 2023 2024 2026

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
  - 510(k) submission for *EasyScreen*™ Essentials Respiratory Detection Kit
- **Increase sales and presence in UK and EMEA markets**
  - Contracts with new customers
  - Increase channel partners in EMEA
- **R&D initiatives for new products**
  - New *EasyScreen*™ detection kits
  - Technology and workflow improvements
  - Development of Next Generation Instrument prototype

Genetic Signatures
Transforming Molecular Diagnostics

Presentation by
Professor Marc Couturier, PhD
ARUP Laboratories
United States



Professor Marc Couturier, PhD

Medical Director, Microbial Immunology, Parasitology and Fecal Testing, and Infectious Disease Rapid Testing, ARUP Laboratories

Professor of Pathology at the University of Utah

- Professor Couturier is a global leader in clinical microbiology with a passion for understanding and detecting gastrointestinal parasites
- Throughout his extensive career, Marc has focused on the advancement in laboratory diagnostics and management of infectious diseases to improve patient health and reduce risk
- Marc is a keen advocate for cutting-edge diagnostic solutions
- Today, Marc will share his thoughts on the diagnostic need for Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit

Genetic Signatures
Transforming Molecular Diagnostics

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