

ASX Code: GSS
20 November 2020

Chairman's Address and CEO Presentation at Annual General Meeting

Genetic Signatures Limited (ASX: GSS, "**Genetic Signatures**" or the "**Company**"), is pleased to release the Chairman's Address and CEO presentation to be made at the Annual General Meeting.

Chairman's Address:

Good Morning and a warm welcome to the Genetic Signatures 2020 Annual General Meeting. On behalf of the Board, I would like to thank you all for attending and for your ongoing support.

The last 12 months have been an exciting year for Genetic Signatures as we continue to play a leading role in the fight against infectious diseases and building on our strong reputation as a global supplier of molecular diagnostic tests. I would like to take this opportunity to reflect on the Company's recent achievements and I will then pass over to CEO and Managing Director, Dr John Melki to provide additional detail on our international expansion strategy and the FY21 milestones that will continue to deliver value to our shareholders.

During FY20, Genetic Signatures generated sales revenue of A\$11.3 million, representing a 131% increase on FY19. The strong revenue growth across the year culminated in a maiden profit for the second half of FY20, an important milestone for the Company. We also went on to achieve record quarterly revenue of \$10.5 million in 1Q FY21, a 585% increase on the previous corresponding period. The strong financial performance across FY20 has brought increased interest from investors and growing trading activity. This, along with the increase in the market capitalization of Genetic Signatures, has led to our inclusion in the S&P / ASX All Ordinaries Index. This achievement will further help bring our business and its global potential to the attention of a wider array of investors internationally.

The step change in revenue has been underpinned by strong demand for the *EasyScreen*TM SARS-CoV-2 Detection Kit and increasing sales to customers across APAC and Europe. The funds raised in late 2019 placed the Company in a strong position to rapidly respond to COVID-19 and the Company was able to quickly and effectively bring the *EasyScreen*TM SARS-CoV-2 Detection Kit to market in key target regions. This is a clear demonstration of our operational flexibility and adaptability as well as the broad applicability of our **3base**TM technology.

Manufacturing was substantially increased within our existing infrastructure to deliver reliable supplies to our international customer base. Genetic Signatures can proudly claim that none of its direct customers have been without product to undertake testing to date. The Company remains focused on maintaining the highest degree of customer service that has underpinned the strong relationships we have built with our customers. To support our existing and new customers, the Company continues to invest in expanding our sales and field support teams with several new hires joining the European team and more than doubling our US based personnel during FY2020.

International expansion is well underway within Europe, which now represents a rapidly growing proportion of Genetic Signatures sales revenue. The most recent quarter alone has seen European reagent sales increase by more than 70% relative to the previous quarter and was more than 15% of total quarterly revenue. We also placed additional instrumentation with customers in Europe, which provides strong foundations for future growth.

COVID-19 remains a major challenge in North America, and our US sales team are actively pursuing COVID-19 opportunities in the US. Investments in inventory, including raw materials,

consumables and instrumentation has been undertaken to ensure we can rapidly facilitate new customers acquisitions. North America is the largest diagnostics market globally and represents an exciting opportunity to expand in FY21 and beyond.

Widespread testing for SARS-CoV-2 has formed a vital part of the global response to COVID-19. Diagnostic testing for respiratory pathogens such influenza, Rhinovirus and other coronaviruses becomes increasingly important during flu season and comprehensive testing continues to play an important role in keeping populations safe. As Europe and North America approach winter we expect to see greater demand for SARS-CoV-2 and respiratory tests from these regions.

While our near-term focus remains on opportunities for the *EasyScreen*TM SARS-CoV-2 Detection Kit, Genetic Signatures is also looking beyond the pandemic and continues to drive global sales of existing products and expanding the range of diagnostic products available for sale. Genetic Signatures is anticipating CE-IVD registration for *EasyScreen*TM STI / Genital Pathogen Detection Kit in the coming months. Clinical trials are also recommencing for the *EasyScreen*TM Enteric Protozoan Detection Kit in North America and work is set to recommence for the *EasyScreen*TM Flavivirus / Alphavirus Detection Kit CE-IVD and TGA registrations.

Many regions around the world that were hit the hardest by the COVID-19 pandemic were slow to implement accurate, reliable and widespread diagnostic solutions. The recent pandemic has highlighted infectious diseases as a serious and concerning global health threat. Our proprietary **3base**TM technology enables hospitals, testing centres and pathology groups to screen for a wide array of infectious pathogens with a high degree of specificity in a rapid throughput (time to results) environment, which saves lives and improves patient outcomes.

Genetic Signatures is well positioned to expedite global sales, expand our market share of the rapidly growing molecular diagnostics market, and obtain further regulatory approvals. We are also developing new products and instrumentation to further drive future growth. The global pandemic has provided us with an accelerated pathway to introduce new customers to the full suite of *EasyScreen*TM multiplex kits, which we expect to provide a strong pipeline for our sales teams to execute on.

At our last AGM Phill Isaacs retired from the Board and I advised a search for a replacement would commence in the new year. This search for an appropriately qualified Director with strong international experience has progressed but has been significantly hampered by global travel restrictions. Despite this, we have made good progress with high-quality candidates with top-tier Molecular Diagnostics experience and I look forward to announcing an appointment in the very near term.

The significant achievements over the last year would not have been possible without the hard work of our executive and support teams across APAC, EMEA and North America. I would like to congratulate each and every one of them on their impressive work to date. Finally, let me take this opportunity to thank our shareholders for their ongoing support of Genetic Signatures and I look forward to continuing to share this exciting journey with you going forward.

Dr John Melki, our Managing Director and CEO, will now provide a comprehensive review on Genetic Signatures' operations, business development and updated outlook.

Dr Nick Samaras
Chairman

- END -

For further information, see our website (www.geneticsignatures.com) or contact us as below:

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About Genetic Signatures Limited: Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, **3base**[™]. Genetic Signatures designs and manufactures a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the *EasyScreen*[™] brand. Genetic Signatures' proprietary MDx **3base**[™] platform technology provides high-volume hospital and pathology laboratories the ability to screen for a wide array of infectious pathogens, with a high degree of specificity, in a rapid throughput (time-to-result) environment. Genetic Signatures' current target markets are major hospital and pathology laboratories undertaking infectious disease screening.



AGM Presentation

November 2020



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Year in Review

November 2019

Successful \$37.5m capital raising

March 2020:

First shipments and regulatory submission for COVID-19 kit

April 2020:

CE-IVD received for SARS-CoV-2 kit

April 2020:

TGA registration of SARS-CoV-2 kit

June 2020:

Included in S&P/ASX All Ordinaries index

June 2020:

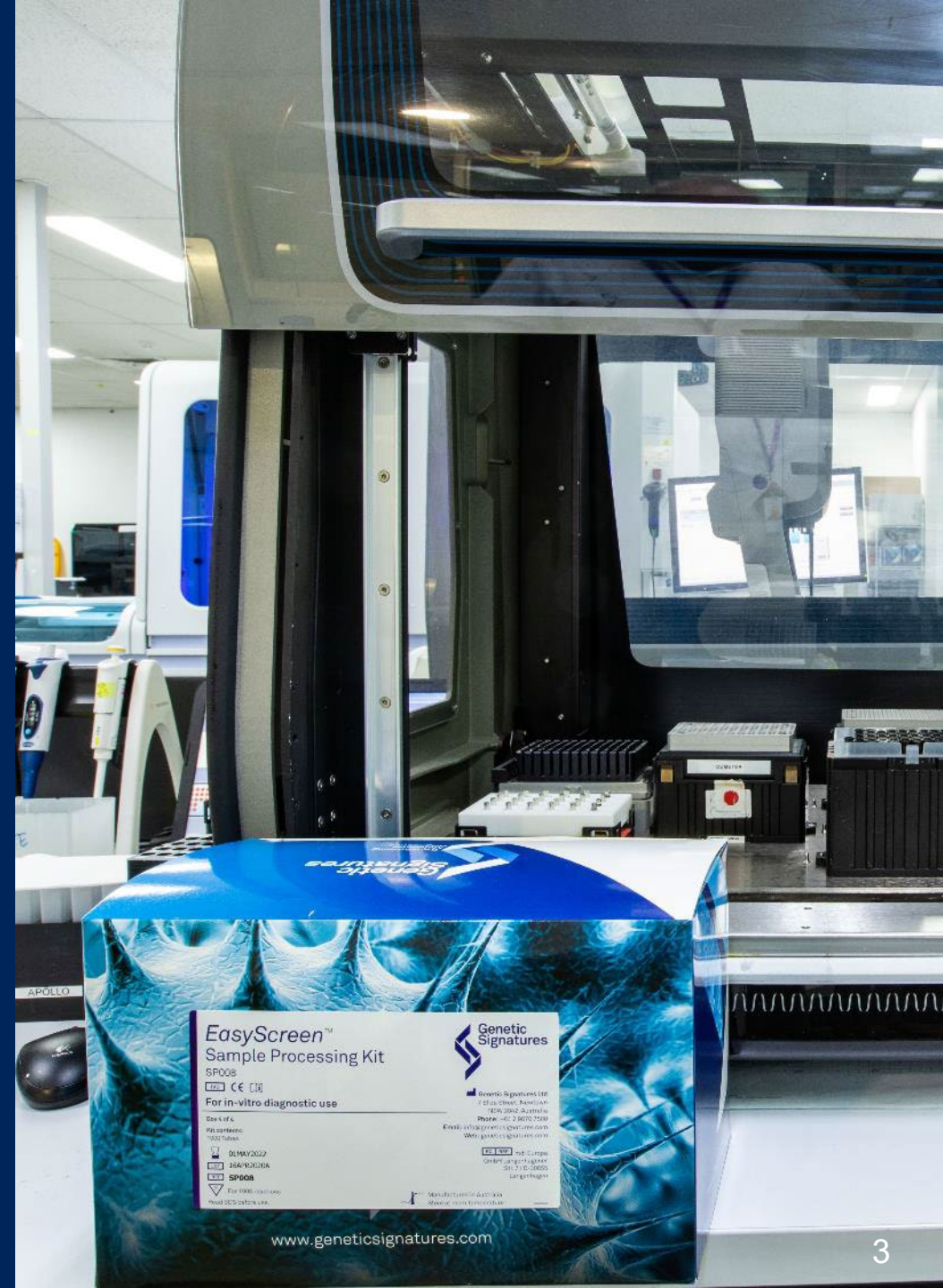
Record quarterly revenue up 351% on pcip

September 2020:

Record quarterly revenue up 585% on pcip

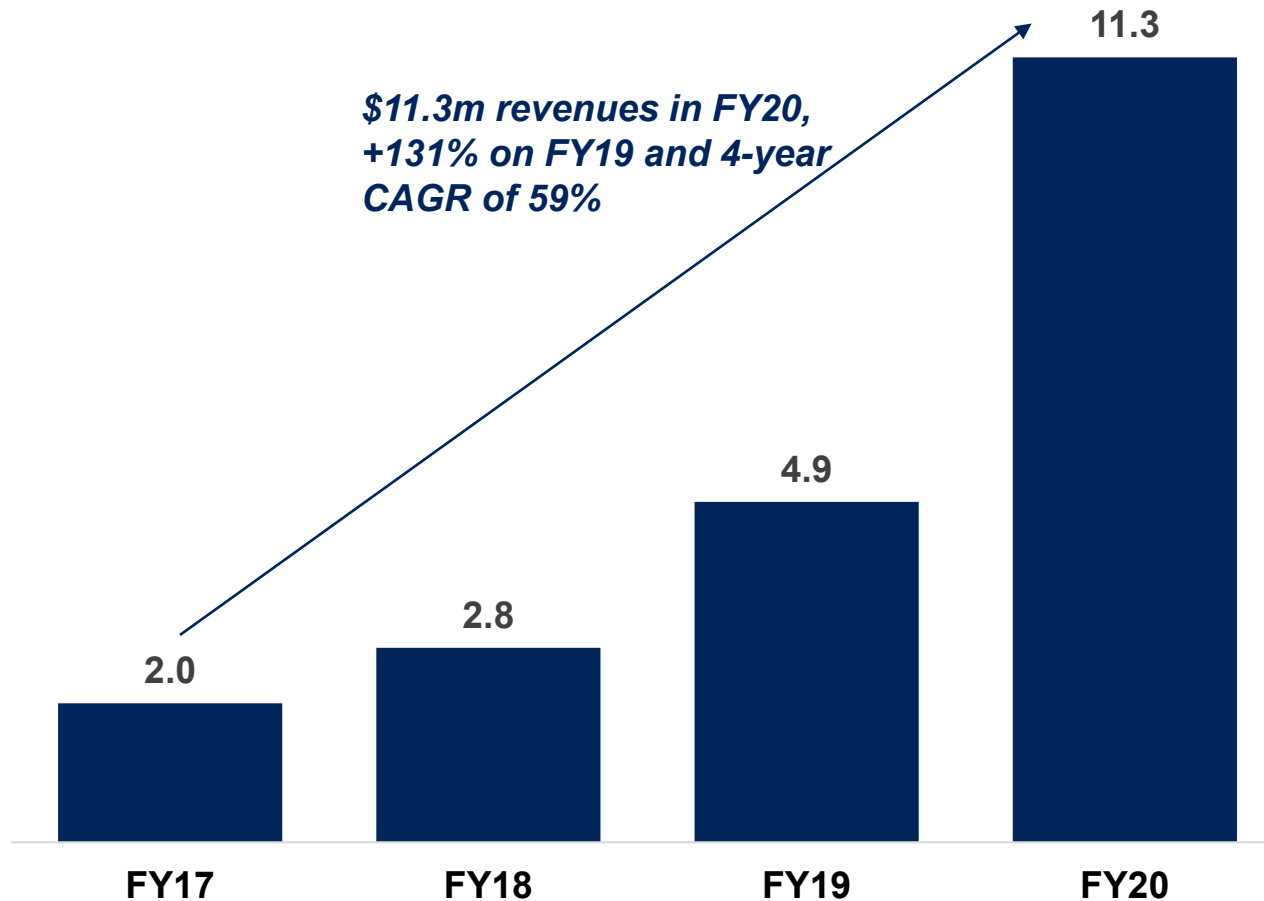


Genetic Signatures



Impressive YOY Revenue Growth

Revenue from operations (A\$m)



- Revenue for FY20 of \$11.3m, a **+131% on pcp**
- Growth largely attributed to **increasing demand for the SARS-CoV-2 kit**
- **First material sales from EMEA** in 2H FY20 and **strong demand** from domestic customers
- **Increased manufacturing capacity** within existing infrastructure
- Bolstered inventory holdings globally to facilitate **new international customers**

FY20 Financial Summary

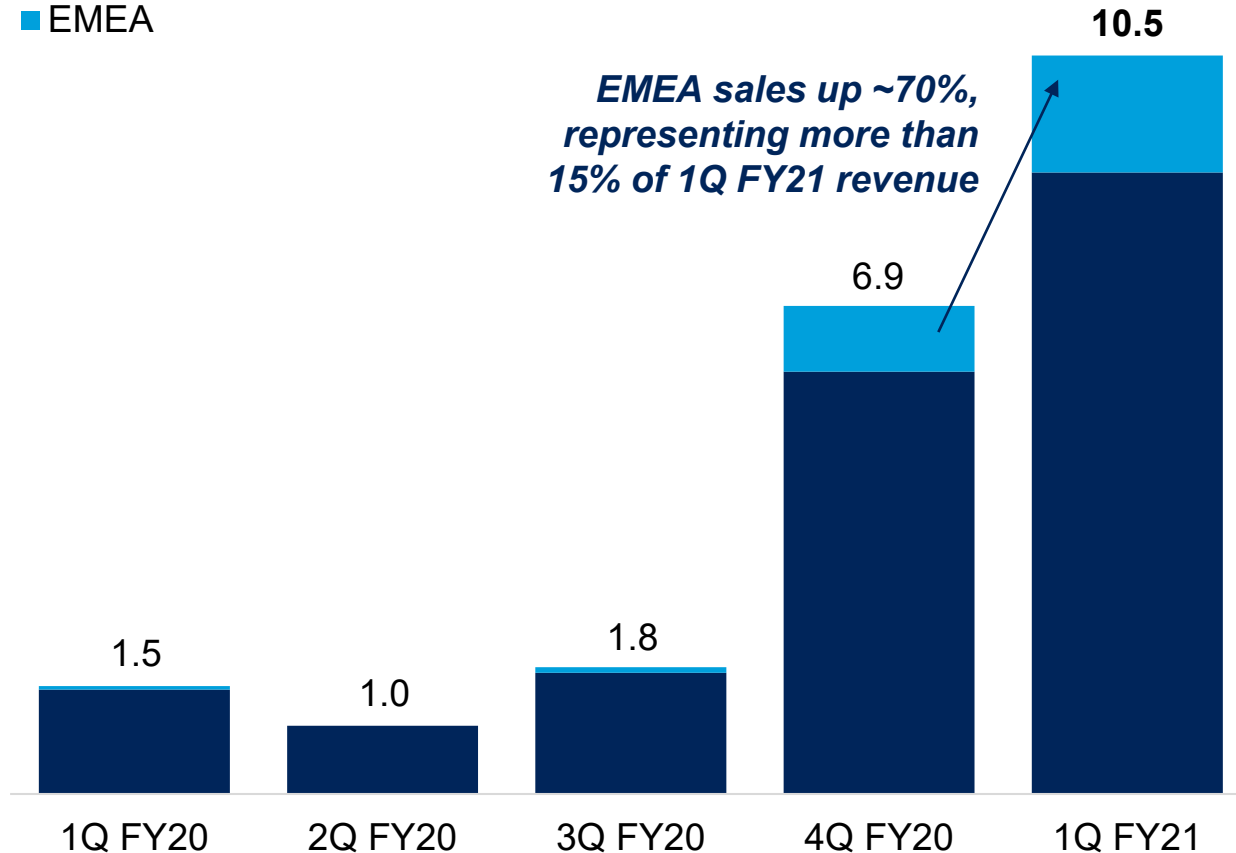
A\$000	Year ending 30 June 2020	Year ending 30 June 2019
Revenue from operations	11,263	4,866
Other income	2,910	2,327
Total revenue	14,173	7,193
Cost of materials	(4,305)	(1,686)
Employee benefits expense	(6,671)	(4,933)
Other expense items	(4,367)	(3,594)
EBITDA	(1,170)	(3,020)
Depreciation and amortization	(883)	(471)
EBIT	(2,053)	(3,491)
Finance costs (AASB 16 leases)	(33)	(1)
(Loss) / profit before tax expenses	(2,086)	(3,492)
Income tax benefit / (expense)	-	-
Net (loss) / profit after tax	(2,086)	(3,492)
Earnings per share (cents)	(1.64)	(3.36)

- Revenue of \$11.3m ,**+131% on pcp** driven by **demand for SARS-CoV-2 test**
 - Other revenue includes R&D tax rebate of \$2.6m
- Expense up ~35% relative to pcp with:
 - **Additional personnel** added to the teams in Europe, USA and locally across all functions
 - Scientific consumables increased 50% on pcp, reflecting the **work on SARS-CoV-2**
 - R&D projects and initial clinical trial activity for the **FDA Enteric Protozoan submission**
- Net loss of \$2.1m in FY20, a **+\$1.4m improvement** over FY19
 - **2H FY20 was a maiden profit** of \$0.3m, showing the impact of higher sales

Significant Quarterly Revenue Growth

Revenue from operations (A\$m)

- APAC
- EMEA



- **+585%** on pcp and **+50%** on previous quarter
- **Strong demand for tests** in 1Q FY21 following second wave of COVID-19
- **Multiple new instruments** installed across FY20 and 1Q FY21
- New instrument placements will continue to support **future demand for tests**
- **Positive cash quarter** 1Q FY21 and cash balance of **\$33m** positions the Company well to **drive future growth**

Customer Testimonial

A representative from Royal Marsden Hospital in London explains why they adopted Genetic Signatures EasyScreen products. The video may be accessed via this link

<https://geneticsignatures.com/au/investors/presentations/>

Genetic Signatures is a molecular diagnostic (MDx) company focused on the development and commercialisation of its proprietary 3base™ platform technology. Our aim is to become a global leader in the supply of diagnostic solutions for the rapid detection of infectious diseases to enable faster treatment and facilitate improved patient outcomes.

Asia Pacific Update

- ✓ FY20 revenue **increased 116% to \$10.2m** (FY19: \$4.7m) and includes instrument sales of \$0.7m
- ✓ Received TGA registration and **launched *EasyScreen*™ SARS-CoV-2 Detection Kit** across Australia
- ✓ Underpinned by **strong demand for *EasyScreen*™ SARS-CoV-2 Detection Kit** – which is currently being used both as a standalone test and in combination with the broader ***EasyScreen*™ Respiratory Pathogen Detection Kit** by new and existing customers
- ✓ Significantly **increased production capacity** to meet current demand and **more production expansion underway**
- ✓ Application lodged with **TGA for *EasyScreen*™ STI / Genital Pathogen Detection Kit**
- ✓ Work is set to recommence on the ***EasyScreen*™ Flavivirus / Alphavirus Detection Kit** to support a future **TGA registration**

EMEA Update

- ✓ **Europe is a key focus** through FY21 and beyond
- ✓ **Additional sales and support staff appointed** to support growing pipeline of opportunities
- ✓ Direct presence in **UK, Netherlands and Germany** and distributors in **Greece, Ireland, Italy, Spain, Benelux and Poland**
- ✓ **Achieved European registration** (CE-IVD) for the *EasyScreen*™ SARS-CoV-2 Detection Kit and product launched
- ✓ FY20 revenue **increased 580% to \$1.1m**, (FY19: \$0.2m), including instrument sales of \$0.3m, representing 10% of total FY20 revenue (FY19: 3%) – and grew to 15% in 1Q FY21
- ✓ **New customers established**, including three new European distributors – **strategically partnering** with customers interested in the broad range of *EasyScreen*™ Detection Kits
- ✓ European applications for *EasyScreen*™ STI / Genital Pathogen Detection Kit lodged

North America Update

- ✓ **Largest market opportunity globally**, representing an estimated **42%** of the global molecular testing market¹
- ✓ Pursuing a **direct sales approach** with **approved laboratories**
- ✓ **Expanded sales team appointed** with strong pedigree in the industry
- ✓ **Legally able to sell *EasyScreen*™ SARS-CoV-2 Detection Kit** to US laboratories certified to perform high complexity testing. The FDA allows sales under a EUA Section **IVc exemption**²
- ✓ Initial **clinical trials have commenced** for FDA clearance of the ***EasyScreen*™ Enteric Protozoan Detection Kit**, despite disruptions caused by COVID-19
- ✓ **Canadian distributor appointed** – Somagen Diagnostic, Inc
- ✓ **New warehouse facility** established and stocked in Los Angeles



1. Global market size (A\$m per annum) - Kalorama Information, Molecular Testing Markets for Infectious Diseases (Sepsis, Respiratory Diseases, HIV, Hepatitis, TB Testing, STIs and Other Tests), July 2019, and company estimates; 2. The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)² Under the exemption the manufacturer must have validated the kit and is required to notify the FDA of their intent to supply the test. The use of the test is limited to laboratories that have been certified under CLIA (Clinical Laboratory Improvement Amendments) to perform high complexity testing and the laboratory is required to disclaim the status of the test on all results that are issued using the test. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)

Multiple *EasyScreen*TM Kits Targeting Significant Addressable Markets

Commercial products available...



Enteric

TGA / CE-IVD

~\$537m p.a¹



Respiratory

TGA / CE-IVD

~\$627m¹ / \$6.3bn
SARS-CoV-22 p.a²



ESBL & CPO

TGA / CE-IVD

Emerging market



STI / Genital

Submitted TGA/CE-
IVD

~A\$1.9bn p.a¹

...and continued development of new products



Alpha / Flavivirus

~\$69m p.a¹



Meningitis

\$156m p.a¹



Atypical Respiratory

See Respiratory



Undisclosed

Products under development



1. Global market size (A\$m per annum) - Kalorama Information, Molecular Testing Markets for Infectious Diseases (Sepsis, Respiratory Diseases, HIV, Hepatitis, TB Testing, STIs and Other Tests), July 2019, and company estimates; 2. Molecular Diagnostics Markets in the COVID-19 Era (Markets for Molecular COVID-19 IVD Tests, Respiratory Tests, Blood Screening, Cancer Markers and Other IVD Tests) Kalorama Information, Published: 9/7/2020

Looking Forward

Multiple growth opportunities to be pursued in tandem, creating significant upside potential



Focus on long-term customer contracts and customer satisfaction

- Focus on securing long-term customer contracts with high throughput pathology groups, hospitals or government run programs
- Provide reliable and quality customer service to strong customer relationships
- Favourable unit economics expected to underpin growth through FY21 and beyond



Leverage COVID-19 momentum and promote new tests to existing customers

- Increasing international recognition through the *EasyScreen*TM SARS-CoV-2 launch creates new avenues to expand the customer base
- Tests become embedded in workflow and customers typically adopt new tests once workflow established leading to favourable unit economics
- Targeting first North American contracts



Development of new *EasyScreen*TM Kits

- FDA submission for the *EasyScreen*TM Enteric Protozoan Detection Kit
- CE-IVD and TGA registration for *EasyScreen*TM STI / Genital Pathogen Detection Kits
- CE-IVD and TGA registration for *EasyScreen*TM Flavivirus / Alphavirus Detection Kits
- Continued development of other new kits



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