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Advancing Molecular Diagnostics to the Point of Care

Preliminary results (to Jun-19)

7 October 2019

GDR (LSE) – A COMMERCIAL STAGE DIAGNOSTICS BUSINESS

Genedrive®: our Point-of-Need, molecular diagnostic gene reader

- Designed for challenging settings where speed and access are critical

Our focus is on Global Heath

- Hepatitis C – on market
- Tuberculosis – in development

with attractive opportunities in

- Bio-threats (US DoD)- on market
- Antibiotic Induced Hearing Loss – in development

Significant commercial footprint

- Access to global markets through Sysmex and Arkray distribution channels

ON MARKET

Genedrive® HCV is the first approved decentralised qualitative molecular test

- > 50m people globally undiagnosed
- Registered in 12 countries
- WHO PQ in process
- Indian registration anticipated by January

Bio-threats (US DoD)

- £0.9m of revenue 2018/19
- Orders received for 2019/20 and expectation of more

DEVELOPMENT

Antibiotic-Induced Hearing Loss Assay

- Global TAM circa £35m, UK TAM circa £3.5m
- Funded product development in process, anticipated launch ~Autumn 20

mTB Detection & Drug Resistance

- Large and well funded markets
- £1.1m Innovate UK grant part-funding
- Design locked and launch expected Jun-21

HIGHLIGHTS FY TO JUNE 2019 AND RECENT UPDATES

Revenue	• Revenue increased ~22% to £2.36m (2018: £1.94m) • £0.9m of unit and assay orders fulfilled for DoD
Cash	• £6.0m fund raise from combination of £2.5m debt and £3.5m equity • Cash at Sept 26th £3.9m (unaudited)
On Market	• Genedrive® HCV-ID Kit in process for WHO Pre-Qualified status • HCV registrations including India progressing, but commercialisation behind plan • Excellent HCV analytical data in all evaluation sites reporting to date • Further DoD orders delayed due to supplier quality issues (now resolved)
In Development	• AIHL assay design complete and hospital training established at Manchester and Liverpool Hospitals • NHS performance trials begin Nov-19 • Tuberculosis and AIHL remain on plan for revenues to June 2022

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ON-MARKET

ON MARKET - HCV

THE WHO and HCV

- In 2016, the WHO issued it's report on Viral Hepatitis, calling for all countries to mobilise and eliminate HCV by the end of 2030*
- Genedrive partnered with the Institute Pasteur to develop a molecular diagnostic test that could be used in decentralized setting to identify patients that would benefit/respond to the newly available direct acting antiviral therapies
- Patients are normally first diagnosed with an inexpensive antibody based test to see if they have been exposed to HCV, and then a molecular test is used to confirm if they remain infected or if the virus has naturally been eliminated by their immune system.
- Low and middle income countries account for the largest proportion of persons living with HCV (72%)

Genedrive® Positioning

- Genedrive is the first to market point-of-need qualitative molecular test available
- Only point of need molecular HCV product in WHO PQ process, and granted accelerated review in Aug 18
- Global distributors secured via Sysmex Europe, Sysmex Asia and Arkray in India while also working to secure additional countries & partners, e.g. South America

*GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS 2016–2021 TOWARDS ENDING VIRAL HEPATITIS

ON MARKET - HCV

Country Registrations	• Distribution Partners engaged with regulatory authorities • Overall number of registrations behind plan – unpredictable processes and need for in country validations • India registration – the largest funded HCV market, looks probable for Jan-20
Product Performance	• 6 Independent studies and in-country evaluations are now complete • In almost 2,000 patients that have been characterized, the results have been excellent. The accuracy has ranged from 96.5% to 100% and the specificity has been 100% in all studies
WHO-PQ	• Pre-Qualification allows the product to appear on the WHOs list of recommended products, and may funnel funding to those products listed • Process has been much longer than anticipated. Delays are attributed to slow set-up, lack of sample available at the WHO lab, and the need to re-perform experiments to follow the accepted protocol…..expected Dec-19
Customers	• Customer base remains small due to delay in registrations • Funding has not entered the market in the way WHO would have liked, putting pressure on adoption rates and affordability

ON MARKET – PATHOGEN DETECTION / DOD

Market Overview

- Genedrive® was contracted by the United States Department of Defense (DoD) to develop Genedrive as as a handheld bio-warfare testing system in 2014
- Development contract was worth $6.7m
- Programme completed in 2018 and now in commercial deployment sage

Progress

- £0.9m of revenue in the period across multiple orders of Genedrive® units and assays
- Sub-component supplier issue delayed shipment of further orders; issue resolved post year-end
- Dual supply of reagents now established - customer supportive in process
- Additional orders planned for shipping Autumn 19

Outlook

- Orders received for 2019/20
- Expectation of more

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IN DEVELOPMENT

AIHL – IN DEVELOPMENT

Attractive market in high income countries

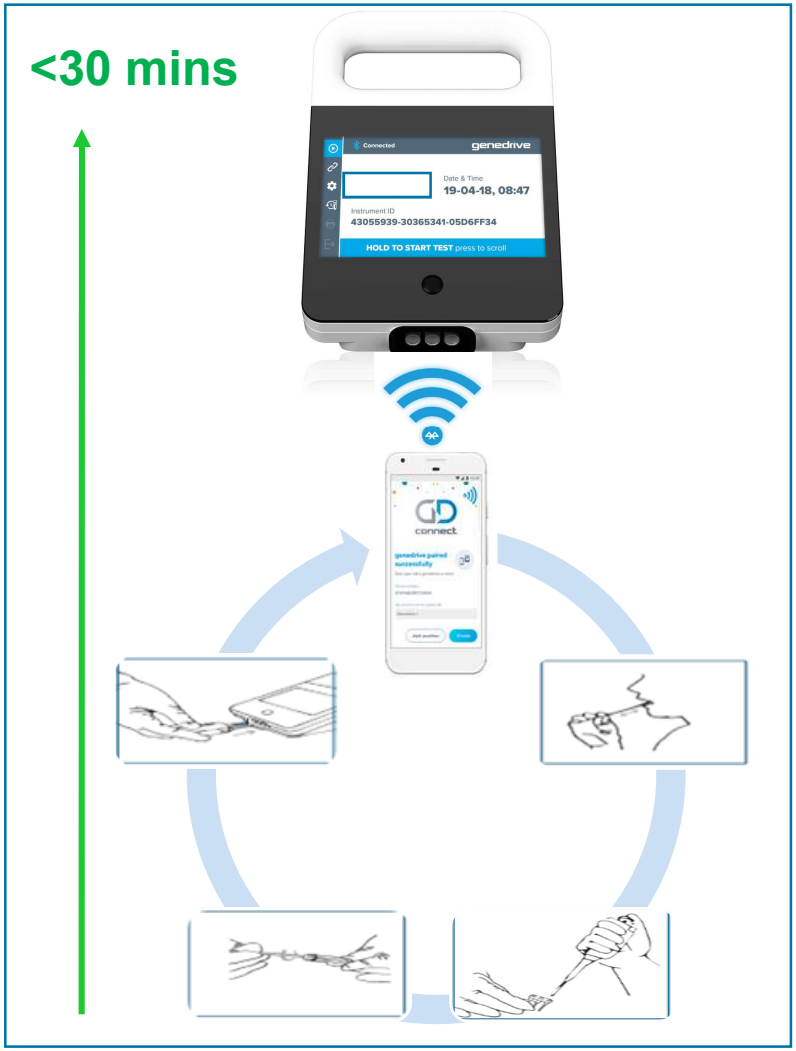
- UK potential of 90k tests per year, modelled £35 per test
- European and North America market each approx. x5 times the size of UK market potential

Compelling clinical case to test for known variant

- Only Point-of-Care tests can deliver care in the required timeframe
- Heath economics vs cochlear implants (£50k per case)

Genedrive has specific advantages

- First mover - clinical validation for followers difficult- facilitated through grant award and partnership with Trusts
- Single menu device appropriate for NICU use
- Cost of deployment is economical



Genedrive® Well Positioned

- Rapid results <30 minutes
- First to market opportunity
- Intuitive, Portable, inexpensive

AIHL – IN DEVELOPMENT

Progress

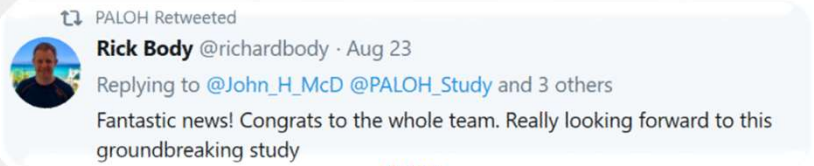
- £0.55m grant funding secured
- Assays designed and confirmed
- Hospital training completed

Next steps

- Commence clinical trials Nov 19
- Commercial partner assessment Jan 20
- Meet non-UK stakeholders

Timing

- Commercial revenues expected to follow launch in Autumn 2020



MTB – IN DEVELOPMENT

- Innovate UK grant £1.1M
- Target sensitivity higher than smear microscopy, using bacterial enrichment technology
- Performance expected to be equivalent to incumbents but with operational and cost advantages
- Working to improved biosafety in sample handling vs smear microscopy with inactivation of live TB within the cartridge
- Companion “durable” for Genedrive to reduce user interaction
- Single tube - keeping our core ethos of low manufacturing costs, low/no maintenance
- Goal of significantly reducing manufacturing costs of assay cartridge

MTB – IN DEVELOPMENT

Progress

- £1.1m grant funding secured
- Engaged Sagentia in Cambridge to drive durable and consumable development
- Selected design

Next steps

- Move to commercial equivalent model
- Confirm the mTB concentration methodology
- Lock-down the sputum assay design
- Verification, Validation, clinical trials

Timing

- CE certification
- Country specific registrations via Sysmex and Arkray
- Product launch in year ending Jun 21 (instrument, cartridge and assay)

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FINANCIAL SUMMARY

FINANCIAL HIGHLIGHTS FOR JUN-19

Revenue

- Diagnostic income £2.4m (2018: £1.9m)
- DoD revenue £0.9m
- Development revenue of £1.4m

Expenditure

- Total costs down £0.4m year on year
- Headcount and development spend tightly managed
- Non-cash accounting gains of £0.4m

Cash

- Dec-18 Fund raise of £6.0m, (net £5.3m after expenses and earn-out)
- Debt of £8.5m, with no cash payments until Dec 21
- Unaudited cash £3.9m 26th Sept 19 and low burn expected to Dec-19

CASHFLOW FOR YEAR ENDED JUN-19

	Jun-19 £'000	Jun-18 £'000
OP Loss	(4,391)	(4,329)
Working capital	(210)	(302)
Capex	(97)	(24)
Tax	980	1,220
Interest	18	13
FX	(10)	1
	(3,710)	(3,421)
Fund raise	5,609	-
Earn-out (Visible Genomics)	(300)	-
Discontinued operations	56	1,821
Net cash flow	1,655	(1,600)
B/F	3,529	5,129
Cash at bank	**5,184**	**3,529**

- £5.2m of cash at Jun 19, excludes $0.5m of DoD orders and R&D tax £1.0m
- EBITDA broadly in line with PY with continued development programmes
- R&D tax claim submitted after accounts signed-off. £1.0m expected late November early December
- Net fund raise of £5.3m after payment to settle Visible Genomics earn-out
- £56k from disposal of Services Divisions – part period and still expecting £0.3m in total

DEBT SUMMARY

Cashflows:	GHIF	BGF
Jun-19	-	-
Dec-19	-	-
Jun-20	-	-
Dec-20	-	-
Jun-21	-	-
Dec-21	-	£0.5m
Jun-22	$1.4m	£0.1m
Dec-22	$0.2m	£0.1m
Jun-23	$0.2m	£0.1m
Dec-23	$8.2m	£0.1m
Jun-24	-	£0.1m
Dec-24	-	£0.1m
Jun-25	-	£2.6m

Debt

- Fair value of debt is £8.5m (10% discount rate)
- Book value of debt £10.0m (£2.5m and $9.0m)
- Approx. 30 months to first cash interest payments

BGF

- £2.5m at 7% since Dec 18 fund raise; came with £1.0m equity
- Matures Jun 25
- Conversion at 28.75p (125% of Dec 18 share price)
- Interest deferred until Dec-21

GHIF

- $9.0m since Jul 14 – amended twice
- Matures Dec-23
- Converts $2.2m at 28.75p and remainder at 150p
- Interest deferred until Dec 21

NEWS FLOW

0-6 Months

- Ship $0.5m DoD orders
- WHO PQ result expected
- Indian registration process complete and sales commence
- Commencement of AIHL in hospital validations

6-12 Months

- AIHL market readiness activities
- Post India and WHO – underpinning on HCV opportunity
- Expect clarity on DoD on-going order rate
- HCV Registration phase I nearing completion and working on targets for phase II countries

3 Year objective – material revenues from x3 assays by June 2022

- HCV opportunity confirmed via WHO and India
- DoD clarity on order rate and market sizing
- AIHL launch expected in Autumn 2020
- mTB launch on plan for Jun- 21

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THANK YOU