



Advancing Molecular Diagnostics to the Point of Care

Year End Results, Jun-21

November 2021



DOCUMENT INFORMATION

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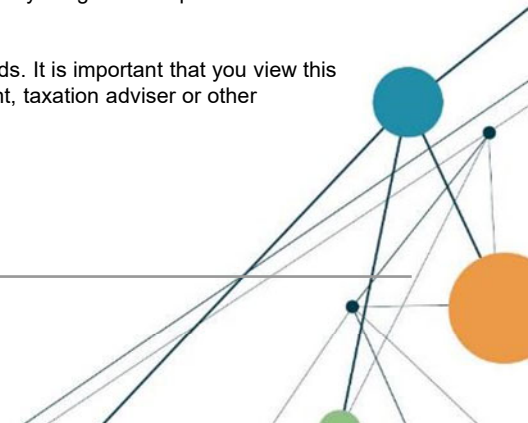
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GENEDRIVE PLC (LSE : GDR):

Genedrive® is a proven point of care (POC) molecular diagnostic technology platform

Significant competitive advantages for target applications

New at-launch revenue opportunities:

- **World's first commercial Antibiotic Induced Hearing Loss (AIHL) system**
- **Fast POC Covid-19 molecular testing system**



THE GENEDRIVE® TECHNOLOGY PLATFORM



Rapid Results where needed

- Technology at your fingertips

Ease of Use

- Single use, disposable reagent cartridge
- Single Push button operation
- Smartphone enabled option for remote result transmission

Versatile platform to build upon

- Same instrument technology is used across a range of applications

Affordable

Extensively Performance Validated

SHORT AND MEDIUM TERM REVENUE TO BE DRIVEN BY COVID AND AIHL

GENEDRIVE® MT-RNR1
ANITIBIOTIC INDUCED
HEARING LOSS

KOL
LAUNCH
PHASE
Oct-21

- Novel Point of Care genetic test for neonatal acute care setting

GENEDRIVE® COV-19 ID KIT
(SARS COV-2 POC)

LAUNCH
PHASE
end of
cal year

- Point of Care product with performance differentiating features

BIOPLEX® US MILITARY

GENEDRIVE® HCV-ID

GENEDRIVE®
96 SARS-COV-2

ON-MARKET

- new US commercial partner established
- capitalize on drug funding available post-Covid
- small opportunities remain, e.g. Africa

ADDITIONAL TARGETED ASSAYS

- Development opportunities for menu build on technology platform



At-Launch Products
Antibiotic Induced Hearing Loss (AIHL)
Genedrive MT-RNR1 Kit



AIHL - Antibiotic Induced Hearing Loss (Genedrive® MT-RNR1 ID Kit)

Opportunity

- A new standard of care
- 180 site in the UK TAM market ~£30-35m Europe and ~£20-25m USA



Progress

- peer reviewed publication accepted in prestigious journal.
- New Genedrive® System CE marked Sept 2021



Outlook

UK

- KoL launch in UK has begun
- Targeting x5 installations before end CY2021
- Recruited 3 BD staff post fundraise to drive adoption and promote updates to clinical guidance

EU

- Pilot site in EU already commenced
- Utilise CE mark in Europe

USA

- Future US entry desirable- large cost and time commitment

AIHL - NEW Genedrive® System for the Modern Hospital Setting

Compact, benchtop system providing rapid, near patient molecular testing in modern hospital settings, a focus area for genedrive

Evolution of our device following deployment in AIHL trials

- Remains a small gene amplification technology platform
- Designed for ease of use in time critical situations
- Simple workflow with fail safe solutions and improved usability
 - Direct and indirect Connectivity to Hospital LIMS and point of care middleware solutions
 - Software interface specific for NICU needs
 - Touchscreen workflow with nurse user ID scanning
 - Cartridge lock-in



EXCITING AND UNIQUE OPPORTUNITY FOR GENEDRIVE



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At launch products
Genedrive[®] SARS COV19 ID kit

GENEDRIVE® SARS COV-2 ID KIT

Opportunity

Progress

Outlook

- Rapid PoC molecular tests should have strong place in many market opportunities for a considerable period of time
- Superior sensitivity and detection window vs LFT
- Newest COVID drugs optimal if given as early as possible in infection, when viral load is high (molecular testing)

SELECTED COMPETITOR LANDSCAPE

Manufacturer	Genedrive	Abbott	Roche	Thermo	Optigene	Oxford Nanopore	Quantum Dx	DRW	Novacyt	DnaNudge	Randox Biosciences
Product	SARS-CoV-2 ID Kit	Covid-19	Cobas SARS-CoV-2 and Influenza A/B	Accula Sars-Cov-2 test	Covid-19 Direct Plus	LamPORE Covid-19	SARS-CoV-2	Sars-Cov-2 test	PROmate Covid-19	DnaNudge COVID Bubble Test	Vivalytic SARS-CoV-2 Rapid
Platform	Genedrive	ID-NOW	cobas Liat	Accula Dock	Genie II/III	MinION	Q-POC	Samba II	genesig q16/q32	DnaNudge	Vivalytic
Technology	Real-Time LAMP	Real-Time RPA	RT-PCR	RT-PCR LFT	RT-LAMP	LAMP/sequencing	Real-time shuttle-flow PCR	Isotherm al/LFT	qPCR	Real-Time PCR	Real time qPCR
Sample type	Swab	Swab	Swab	Swab	Swab/Saliva	Saliva	Swab	Swab	Swab	Swab/ Phlegm	Swab
No of genes Type	2 Orf1a/N	1 RdRp	2 Orf1ab/N	1 N	1 Orf1ab	3 E/N/Orf1a	3 S/N/Orf1	2 Orf1ab/N	1 Orf1ab	3 E/Rd/Rp/N	1 E
Time to result (mins)	10-20	13	20	30	20	90	30	86-101	80	90	39
Storage (°C)	2-30	2-30	2-8	15-30	-20	-20	RT	2-37	-20	2-25	15-25
Pipetting requirement	Dropper	Transfer cartridge	Transfer pipette only	Transfer pipette only	Calibrated pipettes	Calibrated pipettes	Calibrated pipette	NO evidence	Calibrated pipette	Transfer cartridge	Calibrated pipette
LoD (cps/mL)	<1000	125	12	150	1000	No evidence	1000	250	960	1000	No evidence

GENEDRIVE® SARS COV-2 ID KIT

Opportunity

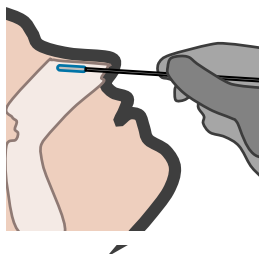
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Progress

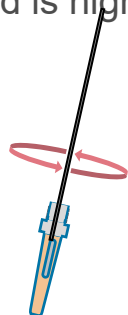
- Similar workflow to LFTs
- Positives in as little as 10 mins
- Full cycle to negative 20 mins
- Self certified CE-IVD, full registration c2 week after self-certifying (Brexit requirement)

Outlook

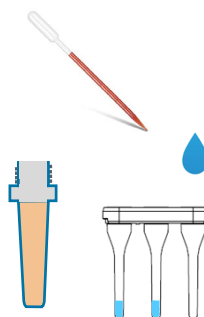
- Product and data pack to go to partners for evaluation
- Expecting feedback and commercial indications early CY2022
- Initial focus EU owing to CE-IVD marking
- UK to follow following increased requirements by DHSC



SWAB PATIENT



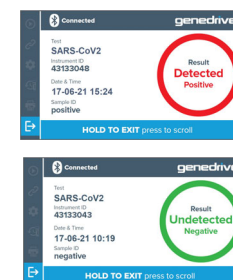
SWAB INTO BUFFER
TUBE & MIX



DISPENSE INTO GENEDRIVE
CARTRIDGE



INSERT
CARTRIDGE



(+) as-little-as 10 minutes
(-) 20 minutes

GENEDRIVE® SARS COV-2 ID KIT | TARGETED LAUNCH APPROACH

Opportunities
leveraging speed
to result

10
mins



20
mins



Sample Market Requirements for Molecular Tests

- Confirmatory test following a lateral flow (sensitivity)
- Travel requirements, flight, quarantine
- Occupational Health / return to work

Market requirement for rapid results

- Urgent travel...*failure of postal system and other walk-in's*
- Risk of transmission...*large care homes, dentists, elite sports, cruises*
- Emergency care....*Healthcare workers*
- Private provision - *pharmacies*

Route to market

- Commercial Partners focussed on service provision, rather than end users
- Expect transfer price of £20-30 per test and units around £2,000

Post CE Marking term

- UK entrance via existing providers of testing solutions



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On market update

GENEDRIVE® 96 SARS COV-2 KIT



Background

- Entrepreneurial opportunity based on Genedrive® chemistry, not platform
- Initial product CE marked May 2020.
- Developed in partnership with Cytiva using proprietary manufacturing process
- EUA approval submitted summer 2020 but missed initial “burst” of approvals and effectively sat in abeyance
- Many labs established testing processes and difficult to convert to Genedrive® test

Outlook

- Vaccine roll-out reducing testing requirements
- Small pockets of demand exist across various geographies
- Screening opportunities may present over time

GENEDRIVE® OTHER ASSAYS

Genedrive® Military

- **Fielding:** Opportunity live for c500 units over 3 years. Initial Mar-20 delayed owing to Covid and now c18mths overdue, purchasing decision expected to resolve in Q1. No material progress on news.
- **Deployment:** Defense Threat Reduction opportunities against emerging threats and country/ region specific initiatives (smaller, ad-hoc demand)



Genedrive® HCV ID Kit

- 2021 FIND study over 465 patients – 100% sensitivity over all genotypes
- WHO prequalified status: but may be lost in the short-term owing to inability of WHO to reconfirm Level of Detection (LoD).
- Real-world trials and FIND study evidence that supports LoD detection well below WHO findings





Summary Financials



SUMMARY FINANCIALS

Income statement

	Jun-21	Jun-20
	£'000	£'000
Revenue	687	1,059
Operating costs	(6,169)	(6,699)
Operating loss	(5,482)	(5,640)
Finance income	3,630	(14,744)
LBT	(1,852)	(20,384)
Tax	1,161	965
LAT	(691)	(19,419)

Cashflow

	Jun-21	Jun-20
	£'000	£'000
Cashflow from operations	(5,237)	(5,604)
Working capital	(933)	847
Taxation	1,018	971
Other	-	(41)
Net cashflow from operations	(5,152)	(3,827)
Settlement of convertibles	(358)	(685)
Proceeds from share issue	46	7,546
Net cash flow	(5,464)	3,034
Cash at bank b/f	8,218	5,184
Cash at bank c/f	2,574	8,218

Income statement

- £0.7m of revenue split equally across Military and 96-well plate products
- Operating costs £0.5m lower year-over-year owing to reduced activity
- Settlement of last convertible Laon Notes generated finance income, contributing to £3.6m income in the year

Cashflow

- Cash consumption from operations broadly level year over year at £5.2m
- Working capital consumed £0.9m versus £0.8m inflow in 2020 – mainly reduction in creditors
- £1m receipt from HMRC R&D tax credit scheme
- Final convertible loan notes settled, £0.4m outflow
- Post year end fund raise £6.6m (net) and unaudited cash at 31 October £7.3m

ANTICIPATED NEWS FLOW

End of Calendar Year 2021

- Clinical test data available on Genedrive® COV19-ID Kit
- Genedrive® COV19-ID Kit CE mark
- KOL sites installation for AIHL in UK

H1 Calendar Year 2022

- Commercial partner launch of Genedrive® COV19-ID Kit.
- Publication of AIHL Performance Trial Data
- CoV-POC sales target updates
- Launch of AIHL assay in EU
- Military application, opportunity for DoD “Deployment” sales
- Military application, decision on DoD “Fielding” sales

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Thank you.

