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Interim Results to 31 December 2020

Advancing Molecular Diagnostics to the Point of Care

25 March 2021

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Overview : genedrive plc (LSE : GDR)

Rapidly developing, commercial-stage molecular diagnostics business

David Budd | Chief Executive Officer

Appointed in March 2016

Over 20 years of international commercial and operational experience, including in the molecular and Point of Care diagnostics fields.

Matthew Fowler | Chief Financial Officer

Appointed in December 2016

Over 15 years of experience in senior positions in the healthcare and manufacturing industries

Leveraging attractive opportunities in discrete markets

- Develop molecular diagnostic assays for use on the Genedrive® instrument platform.
- Strong development and manufacturing relationships, go-to-market via experienced distributors
- Decentralising molecular diagnostics away from the hospital lab

Global Market Products

- 96-SARS-CoV-2 - High throughput
- US DoD Pathogen detection (BioPlex)
- Antibiotic Induced Hearing Loss (RNR1)
- 96-SARS-CoV-2 PoC - In development

Low and Middle Income Market Products

- Hepatitis C (HCV)
- Tuberculosis (mTB) - In development

Test Portfolio

ON MARKET

1. Genedrive® 96-SARS-CoV-2 Kit

- 1-step “ready-to-go” RT-PCR test
- High volume lab assay- compatible on specific 3rd party platforms

2. Pathogen Detection (BioPlex) : supplier to the US military

- Development contract worth over $10m to date
- Expected to enter a supply contract – potentially ordering ~500 Genedrive® units over first 3yrs
- Mountain Horse contracted to expedite DoDs procuring

3. Genedrive® Antibiotic-Induced Hearing Loss (Genedrive® mt-RNR1)

- World’s first rapid Point of Care genetic test in neonatal acute care setting
- Evaluated by the NHS, with global product potential
- Initial Distribution to UK/I via Inspiration Healthcare plc

4. Genedrive® HCV-ID : first decentralised qualitative molecular HCV test

- CE marked, WHO prequalification obtained

IN DEVELOPMENT

1. Genedrive® SARS-CoV-2 PoC Kit

- Point of Care coronavirus test for use with a Genedrive® instrument
- Targeting – Rapid turnaround time of 15 minutes for a positive and 20 for negative from saliva or swabs
- Product release planned for calendar Q2 2021

2. Genedrive® mTB/RIF

Point of Care test for Tuberculosis – launch slated for 2022/23 but development was paused during COVID and timelines under review

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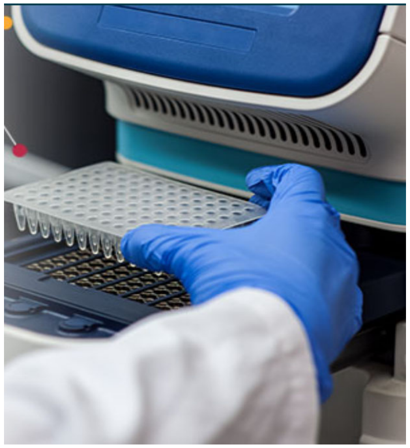
Progress Review

Genedrive® 96 SARS CoV-2 Kit



Regulatory Body	Status
FDA EUA	In-progress, commercializing without EUA
WHO	In-progress, commercializing without EUA
India	In-progress. New product under review
S. Africa	Sep-20
Thailand	Feb-21

Development Background

- Initial Lightcycler product CE marked May 2020. Developed in partnership with Cytiva using proprietary manufacturing process
- Product subsequently developed for ABI Fast and BioRad machines.

Regulatory Processes

- Regulatory approval slower than expected. No updated data in most jurisdictions to predict timeline or probabilities.
- Approvals received in some countries and excellent external studies validate performance in the intended setting.
- India in progress but shifting requirements and undocumented processes may mean reducing our efforts.

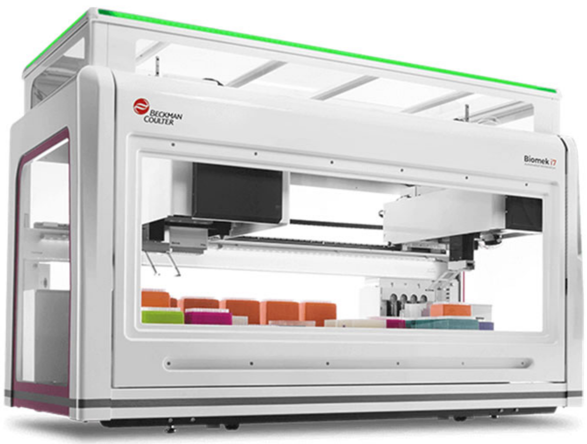
Commercialisation

- genedrive managing direct approaches where contacts known (eg PHE and with Euro. Ministry of Health opportunity (which remains live)
- New distributor agreement with Beckman Coulter Life Sciences.
- Sales cycle required, but initial orders of ~US$400k
- Beckman conducting broad marketing campaigns and increasing numbers of front line sales

High Clinical Performance Studies

Site	TriCore Laboratories, New Mexico	Hospital Cruces, Bilbao, Spain	CAST, Chieti, Italy	IRESSEF, Dakar, Senegal	Total
Comparator	Quidel Lyra, Roche cobas	ThermoFisher	AB Analitica & ThermoFisher	Seegene & Abbott RealTime	
Total specimens	88	51	83	90	312
True positive	24	17	27	15	83
False Negative	0	0	3	1	4
False Positive	0	0	0	2	2
True Negative	63	34	53	72	222
Failed tests	0	0	0	0	0
Sensitivity %	100 (86.2 to 100)	100 (81.6 to 100)	90 (74.4 to 96.5)	93.8 (71.7 to 99.6)	97.6 (91.8 to 99.6)
Specificity %	100 (94.3 to 100)	100 (89.9 to 100)	100 (93.2 to 100)	97.3 (90.7 to 99.5)	98.2 (95.5 to 99.3)

Genedrive® 96 SARS CoV-2 Distribution Agreement



Beckman Coulter Life Sciences

- Global Leader in the Provision of Laboratory analysis and automation
- Over 275,000 instruments installed across a broad range of technologies

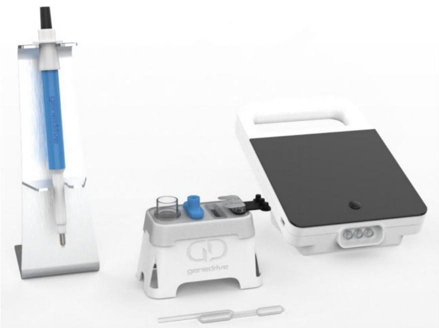
Agreement

- Initial collaboration agreement in summer 2020
- Excellent progression and outcomes resulting in distribution agreement signed 28th January 2021
- First sales to US 17th February 2021 ~$0.4m

Outlook

- Beckman engaged and focussed on delivering sales
- Opens up the huge market and easily served via the lyophilised (temperature stable) plate format
- Exciting opportunity to sell into US via global blue-chip entity
- Headwinds from EUA status and fluctuation on infection rates

Genedrive® 96 SARS CoV 2 PoC Kit Development



PHASE I

Positive result in 15 minutes from saliva

15 mins

PHASE II

- Excellent development progress, but consistency in saliva hampered by performance of synthetic commercial virus targets; swabs also perform well.
- Maintain a winning set of product targets – saliva or swabs, no extraction, rapid, multigene targets, freeze dried, biosafe
- Critical to release product meeting distinct requirements
- "Learning to live with COVID" - market is growing and evolving.

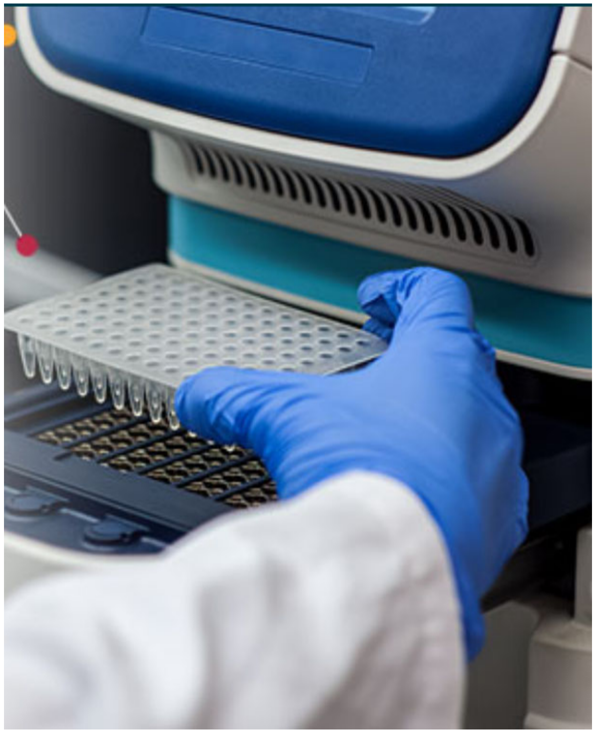
Status

- Continued development to maximize robustness of the assay
- Maintaining product definition with clear competitive advantages

Outlook

- Expect molecular tests at the point of care to be fundamental to future Covid strategy
- CE marked Genedrive® assay to run on Genedrive® targeted by calendar Q2 2021
- Version II test to follow using Cytiva beads

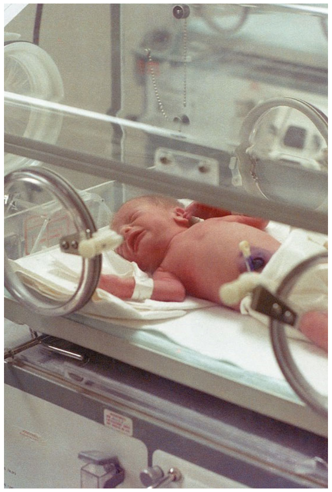
Genedrive® 96 SARS CoV-2 Kit



Outlook

- Selling without EUA in US since February 2021: but registration delays remain frustrating and impact full commercial opportunity
- Relationship with Beckman Coulter has significant potential and can bring to market a mass volume solution to both US and Europe
- Significant opportunity with European MoH remains live and has progressed positively since Dec-20: if converted would be low double digit millions of pounds to be delivered in a short period of time
- A number of other customer opportunities and other early interest contracts are in the pipeline
- Point of Care Covid test now targeted for calendar Q2 2021
- Despite the recent progress on vaccines, high degree of confidence that high throughput and point of care Covid-19 testing opportunities will be a critical part of controlling the pandemic for a considerable period of time

Antibiotic Induced Hearing Loss



Market

- Rare genetic mutation (~1:500) risk of profound hearing loss from gentamicin and no PoC test currently available
- To avoid the risk, must test all neonatal admissions

Progress

- Rapid test developed under £0.5m funding in 2019 and CE marked 2019
- Clinical evaluation commenced Jan-20 (x2 sites)
- Clinical Evaluation completed Nov-20
  - 100% accuracy of tests confirmed via sequencing
  - Proven that a genetic test can be incorporated into the clinical pathway with no detriment to care

Outlook

- Working with distributor (inspiration Healthcare plc) to exploit this first to market opportunity capitalising on portable and rapid Genedrive®
- Launch Summer 21 - targeting 'Early Adopters' in a first phase within UK and Ireland (strong Distributor coverage)
- Evaluating the Quality, Regulatory, and reimbursement landscape to enter the US market longer term

Genedrive® Pathogen Detection / Military

Background

- Genedrive® contracted by US DoD development team since 2014 (had been worth +$10m including approx. 200 Genedrive® units)
- Development completed in 2019, now in commercial stage
- DoD 'internal' customer indicated potential demand of ~500 units over 3 years and customer still in very early stages of engagement
- Progress on contracting with customer pushed back owing to Covid issues and other funding priorities

New Commercial Partner

- Contracted with Mountain Horse Solutions (MHS) in Mar-21
- Specialist US military supplier
- Existing frameworks with the DoD that significantly simplifies business with the military
- Contacts and specialised knowledge in the CRBNE arena

Outlook

- Moderate sales (£0.3m) in H1 2020/21
- Contract opportunity remains for circa ~ 500 units/ 3 years but timing uncertain, MHS expected to expedite
- In addition to existing opportunity, MHS will develop a broader customer base

DEPARTMENT OF DEFENSE · UNITED STATES OF AMERICA

MOUNTAIN HORSE SOLUTIONS

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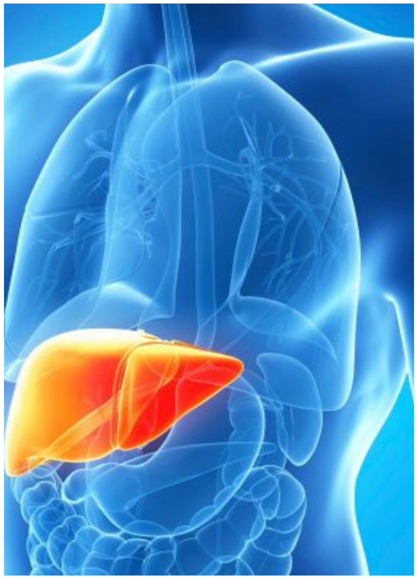
Genedrive® HCV ID Kit



Market

- 70m people worldwide infected with 1.75m new infections p.a.
- New DAAs becoming available at affordable prices
- Molecular tests required to confirm the infection prior to administering drugs

Genedrive well positioned

- First to market qualitative point-of-need test
- WHO prequalified
- Global distributors via Sysmex EMEA, Sysmex Asia and Arkray India

Outlook

- Covid 19 still impacting ability of distributors to call on customers and only moderate sales expected as Healthcare systems return to normal from Covid
- WHO PQ under annual review.

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Financial Summary

Financial Summary Dec-20

INCOME STATEMENT	Dec-20 £'000	Dec-19 £'000
Revenue	355	627
Operating costs	(3,286)	(3,193)
Operating loss	**(2,931)**	**(2,566)**
Finance costs	3,552	(765)
PBT	621	(3,332)
Tax	370	290
PAT	**991**	**(3,042)**

BALANCE SHEET	Dec-20 £'000	Jun-20 £'000
Non-current assets	479	194
Inventory	707	413
Tax	1,018	971
Other	828	656
Cash	3,793	8,218
Trade & other payables	(1,282)	(2,196)
Long term liabilities	(214)	(11,599)
Net assets/(liabs)	**5,329**	**(3,342)**

- Revenue of £0.4m (2019: £0.6m) with operating costs in line with PY
- Conversion of Loan Notes creates £3.5m credit to interest and further £8.0m credited directly to equity
- Non-current assets increased owing to IFRS16 leases (premise rental)
- Investment in inventory: increasing inventory position versus June and timing affects trade payables
- R&D tax payment £1.0m due shortly
- Convertible loan notes with BS value of £11.6m now gone – Group is debt free
- Credit on convertibles– Group in positive net asset position
- High cash consumption since Jun-20 securing long lead time supplies and building initial stock

6 Month Cashflows

	6 mth Dec-20 £'000	6mth Jun-20 £'000	6 mth Dec-19 £'000
Revenue	355	432	627
Operating Costs	(3,286)	(3,506)	(3,193)
OP Loss	**(2,931)**	**(3,074)**	**(2,566)**
Working capital	(1,220)	986	(139)
Capex	(61)	(39)	(97)
Tax	-	-	971
Other	34	(5)	41
FX	(14)	1	(10)
	(3,827)	(2,131)	(3,710)
Fund raise	-	7,546	-
Interest	(370)	(696)	9
Discontinued operations	137	-	56
Net cash flow	(4,425)	4,719	1,655
B/F	8,218	3,499	3,529
Cash at bank	**3,793**	**8,218**	**3,499**

- Working capital investment to secure long lead time stock items
- R&D tax credit due shortly £1.0m
- Interest payments made to BGF to settle convertible debt - £0.4m
- Company is debt free
- Unaudited cash at 15 Mar-21 £2.8m
- Unaudited cash at 15 Mar-21 excludes debtors and R&D tax credit, (adds £1.4m)
- Underlying burn rate of approximately £0.4m pcm
- Cash burn rate normalizing after high consumption over summer 2020 to build Covid stocks

Newsflow

0-6 Months

- Update on European MoH
- Registration updates – FDA, WHO and India
- Launch of Genedrive® SARS CoV-2 P.O.C. in calendar Q2 2021
- Commercial launch of AIHL and initial sales

6-12 Months

- Confirmation on order rate and market sizing for BioPlex/ DoD
- Version II Genedrive® SARS CoV-2 P.O.C with freeze dried bead and reduced price-point for scale

3 Year objective – material revenues from x3 assays by June 2023

- SARS CoV-2 P.O.C. expected to continue to provide revenues into future periods
- Successful traction of AIHL in UK/I and expansion to additional markets (USA in scope)
- mTB launch and additional pipeline.

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Thank you