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Advancing Molecular Diagnostics to the Point of Care

Preliminary results (to Jun-20)
16 November 2020

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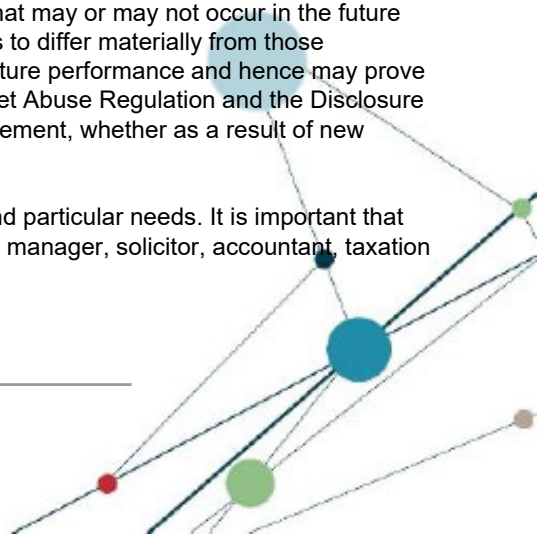


Overview : Genedrive PLC (LSE : GDR)

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

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

- Develop highly accurate molecular diagnostic assays for use on our Genedrive® instrument
- Strong development, manufacturing and commercial relationships
- Leveraging discrete opportunities in attractive markets

Infectious Diseases

- Hepatitis C
- 96-SARS-CoV-2
  - High throughput
  - P.O.C (in development)
- Tuberculosis (in development)

Other

- US DoD Pathogen detection
- Antibiotic Induced Hearing Loss

4 Tests On-Market; SARS P.O.C AND MTB to follow

ON MARKET

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

CE marked, WHO prequalification obtained, commercial traction ongoing

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

- Development contract worth over $10m to date
- Expect to enter a supply contract – potentially ordering ~500 Genedrive® units over first 3yrs

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

- Believed to be world's first Point of Care genetic test in neonatal acute care setting
- Under implementation evaluation by the NHS, with global product potential
- Initial Distribution to UK/I via Inspiration Healthcare plc

4. Genedrive® 96-SARS-CoV-2 Kit

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

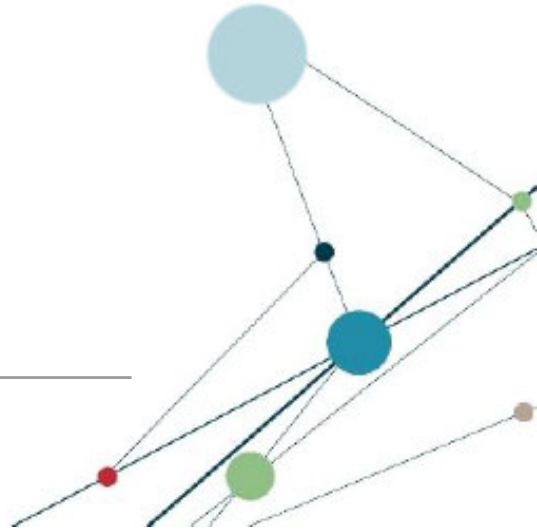
IN DEVELOPMENT

1. Genedrive® SARS-CoV-2 PoC Kit

- Point of Care Coronavirus test for use with a Gene drive instrument
- Target - Fast turnaround time of 15 minutes for a positive and 20 for negative from saliva
- Preliminary RUO test Dec-20 based on current and CE product to follow circa Mar-21

2. Genedrive® mTB/RIF

Point of Care test for Tuberculosis – launch slated for 2022



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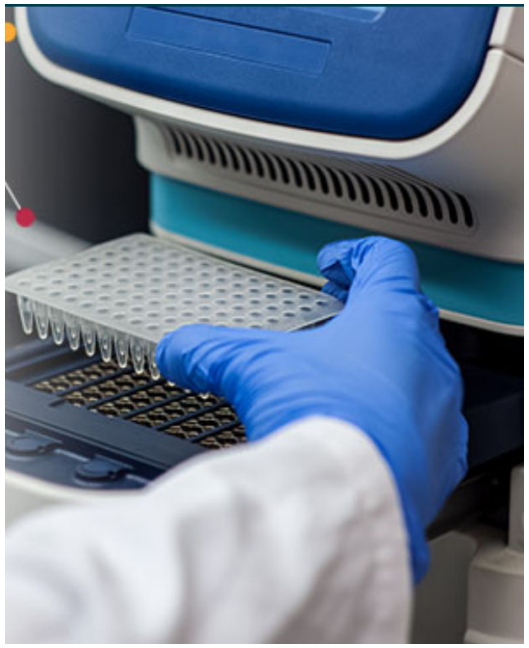
Progress Review

Genedrive® 96 SARS CoV-2 Kit



Development Background

- Initial product CE marked 22nd May 2020. Developed in partnership with Cytiva using proprietary manufacturing process
- Initial product for use on Roche Lightcycler with manually extracted RNA
- Subsequently, 2 more kit variants developed over July and August, and added to the CE mark family (ABI and Biorad)
- Genedrive® Exporter automatic interpretation software
- Initial sales and +£1m orders in July contingent on regulatory approvals

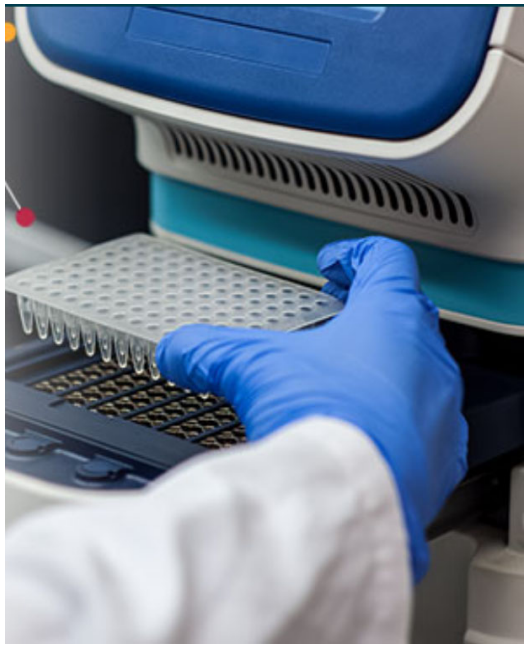
Commercial Partner Strategy

- Utilise existing distributors (e.g. Sysmex)
- Establish new route to lucrative US market (e.g. Beckman and/or others)

Targeted Opportunities

- Product well suited to mass volume testing with unified workflow
- Larger single customers/networks rather than individual end users

Genedrive® 96 SARS CoV-2 Kit - Regulatory



Initial Progress

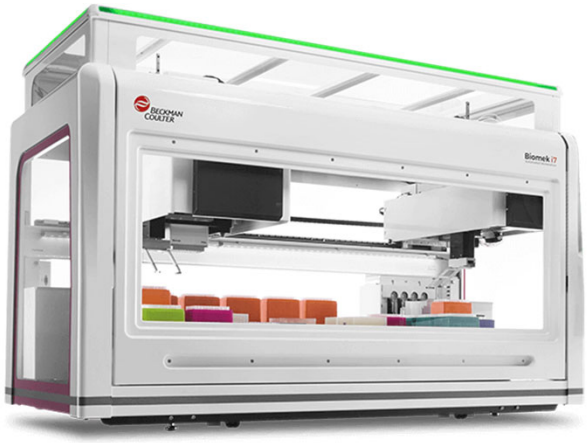
- Feedback and engagement with Regulators has been frustratingly slow.
- The rapid day/weeks approvals manufacturers received back in April no longer exist, caused by application backloads and less urgency in markets, but we are confident we'll achieve what we need
- In field expansion of product claims required for customer adoption caused requests for supplemental/ additional data
- South African approval in Sept-20 validates the kit in its intended setting with new automated extraction claims

Status

- Indian approval still in progress
- Initial FDA feedback – requested additional data in November as a consequence of their revised requirements since the time of our application
- WHO – requested additional data in November
- Unable to provide definitive timeframes due to limited information forthcoming from regulators

Genedrive® 96 SARS CoV-2 Partnership

Decentralising molecular diagnostics



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

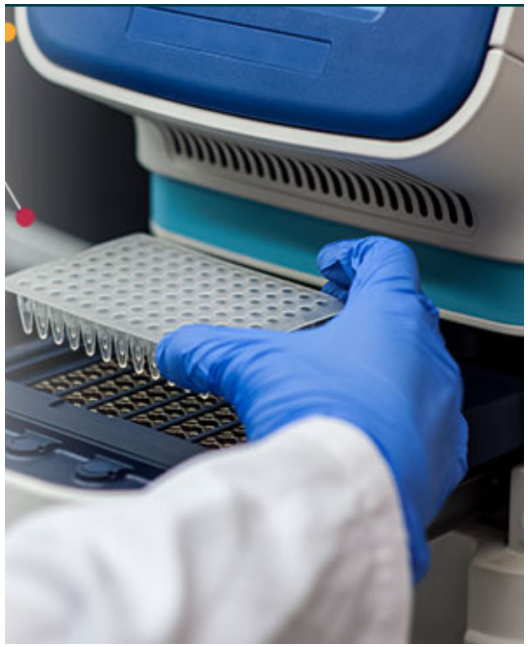
Automation of Genedrive 96 SARS-CoV-2 with Beckman Biomek i7

- Goal of automating asymptomatic saliva testing on Biomek
- Starting with symptomatic patients in swabs and saliva
- Initial laboratory partner currently evaluating

* https://www.beckman.com/about-us

Genedrive® 96 SARS CoV-2 Kit

Decentralising molecular diagnostics



Outlook

- Registration delays were unexpected, and frustrating
- Significant opportunity with MoH of a European country – if converted into a sale, would be low double digit millions of pounds to be delivered in Q1 of 2021.
- Relationship with Beckman Coulter can bring to market a mass volume solution to both US and Europe.
- A number of other early interest contracts are in the pipeline
- Despite the recent welcome news 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

Genedrive® 96 SARS CoV 2 PoC Kit

Decentralising molecular diagnostics

Progress

- Core product requirements confirmed: speed and saliva based
- Assays chemistry designed as circa 15 minutes for positive, negative 20 minutes
- Limit of detection within the accepted UK Government defined target product profile
- Time to result and sensitivity and specificity appropriate to market requirements

Outlook

- Initial commercial discussions can now begin on the initial data set
- Intending to focus on markets closer to UK
- Full clinically relevant data set required to substantiate our claims
- Research use product targeted by the end of Dec-20
- Q1 2021 expect CE marked Genedrive® assay to run on Genedrive®
- Version II test to follow using beads that provide cost and scalability advantages

PHASE I
Positive result in 15 minutes with...

15 mins

… a limit of detection in line with the UK's MHRA Target Product Profile sensitivity requirements

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Genedrive® HCV ID Kit

Decentralising molecular diagnostics

Market

- 70m people worldwide infected with 1.75m new infections p.a.
- New DAAs becoming available at affordable prices
- Molecular tests

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
- WHO pre-qualified status allowing access to global tenders
- Moderate sales expected as Healthcare systems return to normal from Covid
- Will look at additional, targeted Distribution opportunities.

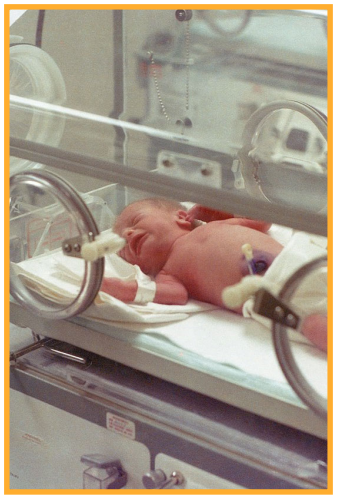
World Health Organization

sysmex

arkray

Genedrive® mt-RNR1 ID Kit – Antibiotic Induced Hearing Loss

Decentralising molecular diagnostics



"…We hope that the hearing of thousands of children will be saved by quickly identifying those who are particularly sensitive to antibiotics…"

Dr. Ralph Holme, Executive Director of Research at Action on Hearing Loss

Market

- genetic mutation, risk of profound hearing loss from gentamicin
- No point of care (PoC) test available
- Rapid PoC test could support a new standard of care

Progress

- Rapid test developed under £0.5m funding in 2019
- Hospital trials commenced Jan-20
- Inspiration Healthcare (IHC)contracted as distributor
- Initial Clinical Evaluation to be completed Nov-20, 3mths over plan owing to COVID-19 interruptions

Outlook

- First to market opportunity capitalising on portable and rapid Genedrive®
- Targeting Early Adopters in a first phase within UK and Ireland (strong Distributor coverage)
- Early Adopter data and support to build reimbursement and funding streams if needed
- Leverage IHC's global distributor network in a targeted approach following positive UK/I experience
- Evaluating the Quality, Regulatory, and reimbursement landscape to enter the US market longer term

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Genedrive® Pathogen Detection / Military

Decentralising molecular diagnostics

Background

- Genedrive® contracted by US DoD development team since 2014
- To date contract worth over $10m including approx. 200 Genedrive® units
- Development programme complete in 2019, now in commercial stage

Progress

- Believe we are the only contracted developer to complete the multiplex requirements
- Fully validates our core technology
- Development income and commercial sales supported our cash position

Outlook

- Expecting the first DoD ‘internal’ customer to contract, ~ 500 units / 3 years
- Owing to Covid, expect clarity early in calendar year 2021
- Moderate sales continued into 2020/21 following change to new lyophilisation supplier.

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Financial summary

Cashflow for year ended Jun-20

	Jun-20 £'000	Jun-19 £'000
Revenue	1,059	2,362
Operating Costs	(6,699)	(6,811)
OP Loss	**(5,604)**	**(4,391)**
Working capital	847	(210)
Capex	(40)	(97)
Tax	971	980
Interest	(2)	18
FX	1	(10)
	(3,827)	(3,710)
Fund raise	7,546	5,609
Interest on GHIF	(685)	-
Earn-out (Visible Genomics)	-	(300)
Discontinued operations	-	56
Net cash flow	3,034	1,655
B/F	5,184	3,529
Cash at bank	**8,218**	**5,184**

- Revenue of £1.1 (£2.4m) in line with expectations
- £8.2m of cash at Jun 20
- £0.7m of interest paid on conversion of the $9m GHIF loan
- EBITDA broadly in line with PY with continued development programmes
- R&D tax claim submitted after accounts signed-off. £1.1m expected by Mar-21
- Unaudited cash at 31 October 2020 of £5.1m
- High cash consumption since Jun-20 securing long lead time supplies and building initial stock

Debt summary

	GHIF	BGF	CASH LIABILITY
30/6/2019	£6.0m	£2.2m	£8.2m
Conversion	(£6.0m)	-	(£6.0m)
30/6/2020	**£ nil**	**£2.5m**	**£2.5m**
Conversion	-	(£1.0m)*	(£1.0m)*
31/10/2020	-	£1.5m*	**£1.5m***

	GHIF	BGF	CONVERT LIABILITY
30/6/2020	-	£9.1m	£9.1m (non-cash)

Debt

- Book value of cash debt £2.5m (2019: £8.2m)
- Total liability £11.6m (2019: £8.5m) includes liability on option to convert loan to shares “non-cash”

BGF

- £2.5m cash debt at 30th June 2020.
- Interest of 7% deferred until Dec-21
- Loan matures Jun-25 if unconverted

Conversions

- Jun-20 GHIF converted $8m bond plus accrued interest
- 7.1m ordinary shares issued and cash interest of £0.7m
- Sep-20 BGF converted £1m of debt into 4.5m shares
- BGF outstanding debt would convert to 6.7m shares at a conversion price of 22.3p

* Unaudited post year end position

News flow

Decentralising molecular diagnostics

0-6 Months

- Registration updates – FDA, WHO and India
- Material contracts as won
- Research use Genedrive SARS Cov-2 P.O.C. product
- Commercial launch of AIHL and initial sales
- CE Marked Genedrive® SARS CoV-2 P.O.C.

6-12 Months

- Update on DoD contract progression – expected early calendar 2021
- Version II Genedrive® SARS CoV-2 P.O.C with freeze dried bead and price-point for scale

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

- SARS-CoV 2 Kits expected to continue to provide revenue stream post any vaccine
- Successful traction of AIHL in UK/I and expansion to additional markets (USA in scope)
- DoD confirmation on order rate and market sizing
- mTB launch on plan for Jun- 22

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Thank you