



**Advancing molecular  
diagnostics to the point of care**

Interim Results (to Dec-18)

28 March 2019



# OVERVIEW GENEDRIVE PLC (LSE : GDR)

**Rapidly developing, commercial-stage molecular diagnostics business**



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

- Designed for challenging settings where speed and access are critical

## Our focus is on Global Health

- Hepatitis C – on market
- Tuberculosis – in development

## with attractive opportunities in

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

## Significant new commercial footprint

- Access to global markets-through Sysmex and Arkay distribution channels

## ON MARKET

## Genedrive® HCV is the first approved decentralised qualitative molecular test

- > 50m people globally undiagnosed
- Up to 30 product territory registrations targeted by 30 Jun-19 to support revenue ramp and WHOPQ (in progress)

## Bio-threats (US DoD)

- Now in commercial phase
- 2 end-users within DoD, \$1.4m recent orders and expectation of more

## DEVELOPMENT

## Antibiotic-Induced Hearing Loss Assay

- Global TAM >~£35m, UK TAM c. £3.5m
- Funded product development in process, anticipated launch ~Sept-20

## mTB Detection & Drug Resistance

- Large and well funded markets
- £1.1m Innovate UK grant part-funding

## HIGHLIGHTS FOR PERIOD ENDED 31 DEC 2018



£1.5m Revenue



\$0.9m DoD Order



£5.8m Cash Dec-18



£6.0m Fundraise



Amended GHIF and  
Visible Genomics Earn-out

- Revenue and other income increased 15% to £1.5m (2017: £1.3m)
- First Commercial DoD order shipped \$0.9m
- £6.0m fund raise from combination of £2.5m debt and £3.5m equity
- Genedrive® HCV-ID Kit submitted to World Health Organisation for Pre-Qualified status
- HCV registrations progressing, but commercialisation behind plan as most territories requiring in country studies: do not expect any significant private laboratory sales until Summer 2019
- GHIF and Visible Genomics agreements amended resulting in accounting gains of £1.0m (non-cash)

### Post Period Trading Update

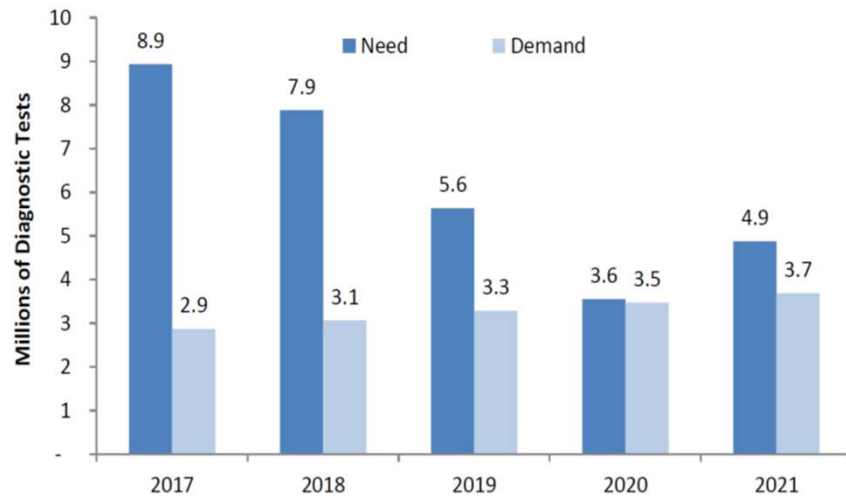
- Second DoD order \$0.5m to be shipped in the next couple of months
- WHO site audit completed Jan-19
- Further 7 country registrations, 11 now in total and 4 classed as 'priority'
- Cash at March 27<sup>th</sup> £4.7m (unaudited) with R&D (£1.0m) and payment of DoD first commercial order (\$0.9m) due in the coming weeks

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ON-MARKET



## ON MARKET - HCV

- Only 20% of the 70m HCV-infected persons (14m) have been diagnosed
- In 2015, 7.4% of those diagnosed with HCV infection (1.1m persons) had started treatment
- Low- and middle-income countries account for the largest proportion of persons living with HCV (72%)

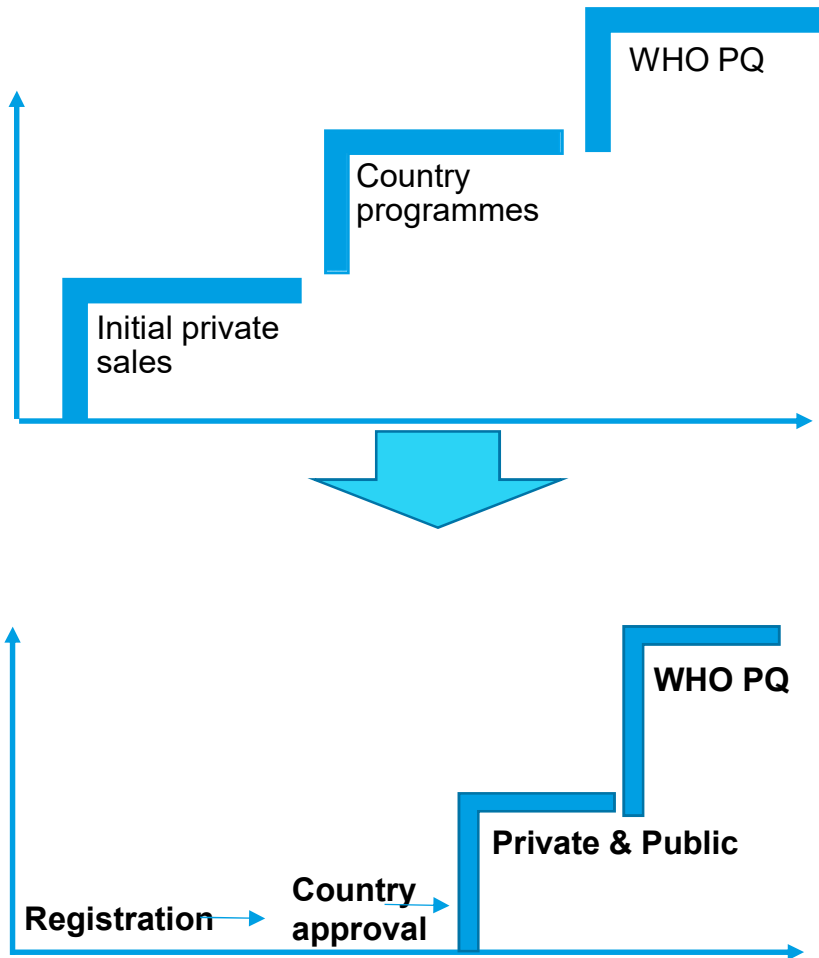


ANNUAL NEED FOR WHO'S 2030 ELIMINATION TARGETS VS ANNUAL DEMAND FOR CONFIRMATION AND MONITORING TESTS 2017 - 2021

### Genedrive® Well Positioned

- Genedrive is the first to market point-of-need qualitative molecular test available
- Independent field testing - sensitivity and specificity of 100% vs laboratory standard
- WHO Pre-Qualification application is in process to support in country funding availability; update by end of calendar year
- Only point of need molecular HCV product in WHO PQ process, and granted accelerated review
- FY2019 target of ~ 30 country registrations to drive future revenues
- Global distributors secured via Sysmex Europe, Sysmex Asia and Arkray in India while also working to secure additional countries & partners, e.g. South America

## ON MARKET - HCV



### Sales Process Expectation

- Market entry plan assumed gradual private lab sales initially, followed by country programmes and WHO PQ

### Updated Expectation

- In-country performance studies are required before public *and* private sales
- Larger public bodies can procure outside of national guidelines and currently several tenders for country wide programmes
- Sales growth to be positively impacted by WHO PQ
- Behind our initial expectation on the timing of revenue

## ON MARKET – DOD BIO-THREAT APPLICATIONS

### **Development Programme** Completed in May 2018

- Genedrive® was contracted by the United States Department of Defense (DoD) to develop Genedrive as a handheld bio-warfare testing system.
- Development contract worth \$6.7m since 2014

### **Commercial Orders**

- \$0.9m invoiced in Dec-18, instruments and assays
- Further order \$0.5m received after shipping above order and expected to ship in the next couple of months
- End-user does not provide demand planning visibility but feedback has been very positive.
- Two customers within the DoD expected to order in the medium term. Expectation of cyclical re-ordering of assays with shelf life restrictions



Next

- Customer discussions to plan next phase
- Medium term orders now anticipated

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IN DEVELOPMENT





## Attractive market in high income countries

- ## Compelling clinical case to test for known issues

- ## Genedrive has specific advantages

- 
- The diagram illustrates a four-step process for testing for the GeneDrive:
- Step 1:** A hand is shown swabbing the inside of a nose.
  - Step 2:** The swab is inserted into the top of a handheld device.
  - Step 3:** The device's screen displays the results: "Result: DETECTED MUTANT".
  - Step 4:** A hand is shown holding the device.
- A large green arrow indicates the cycle, with the text "<30 mins" in the center, suggesting the entire process takes less than 30 minutes.

- Rapid results <30 minutes
- First to market opportunity
- Intuitive, Portable, Relatively inexpensive
- Non-Invasive cheek swab
- 1:500 – saves potentially 200 hearing impaired babies per annum

## AIHL – IN DEVELOPMENT

### Progress

- £0.5m grant funding secured
- Access to samples via clinical trials
- Proof of principle test at <30 mins

### Next steps

- Finalising assay design and costs-
- Commence clinical trials –Autumn 2019
- Potential commercial partner assessment –Jan 2020

### Timing

- CE certification now required
- Targeting commercial revenues in the year ending June 2021

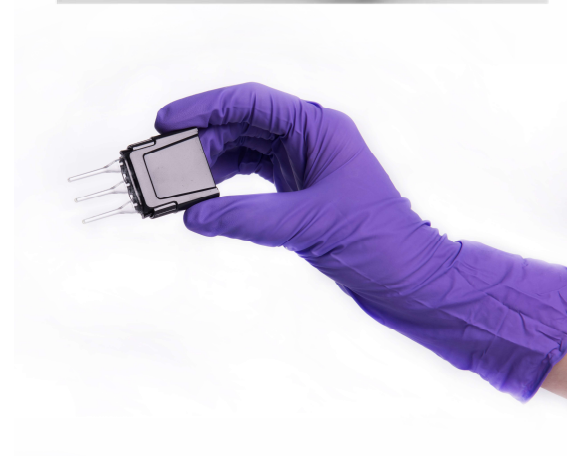


*“...We hope that the hearing of thousands of children will be saved by quickly identifying those who are particularly sensitive to antibiotics...”*

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

## MTB – IN DEVELOPMENT

- Innovate UK grant £1.1M
  - Target sensitivity higher than smear microscopy, using bacterial enrichment technology
  - Working to improved biosafety in sample handling vs smear microscopy
  - Companion “durable” for Genedrive to reduce user interaction
  - Keeping our core ethos of low manufacturing costs, low/no maintenance
- 
- Assay redesigned to a single tube
  - Goal of 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
- Secured distributors for target regions, separated India out
- Selected design

### Next steps

- Selecting final design for durable
- Confirming the mTB concentration methodology
- Finalising assay design and costs
- Moving to prototype build
- Verification, Validation, clinical trials

### Timing

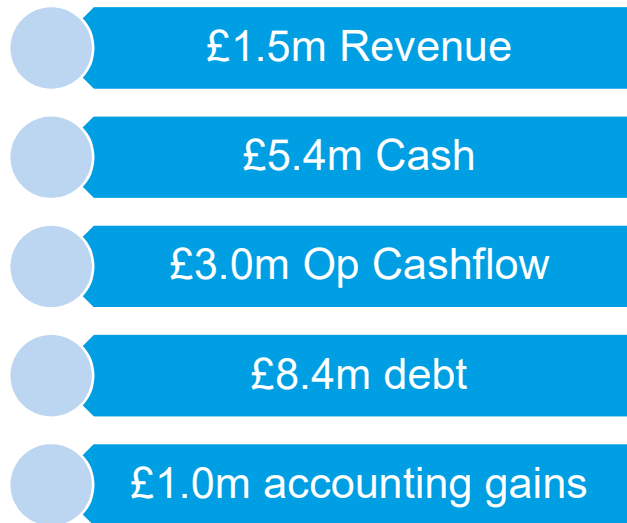
- CE certification
- Country specific registrations via Sysmex and Arkray
- Product launch in year ending June-2021



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## FINANCIAL SUMMARY

## FINANCIAL HIGHLIGHTS FOR PERIOD ENDED 31 DEC 2018



- Diagnostic income £1.5m (2017: £1.3m)
- DoD revenue on shipment of 54+20 units and assays, \$0.9m
- Grant funded expenditure related £0.7m
- Dec-19 Fund raise of £6.0m, (net £5.4m after expenses and earn-out)
- Accounting gains of £1.0m on amendments associated with fund raise
- Unaudited cash £4.7m 27th March 2019
  - R&D tax credit of £980k due shortly
  - DoD December invoice, \$0.9m payment still outstanding

## DEBT SUMMARY POST FUND RAISING

Cash flows:	Capital	Deferral	Interest
Jun-19	-	-	-
Dec-19	-	-	-
Jun-20	-	-	-
Dec-20	-	-	-
Jun-21	-	-	-
Dec-21	-	(£0.6m)	
Jun-22	-	(£1.2m)	(£0.26m)
Dec-22	-	-	(£0.26m)
Jun-23	-	-	(£0.26m)
Dec-23	(\$9.0m)	-	(£0.26m)
Jun-24	-	-	(£0.26m)
Dec-24	-	-	(£0.26m)
Jun-25	(£2.5m)	-	(£0.26m)

### Debt

- Fair value of book debt is £8.4m (10% discount rate)
- Book debt is \$9.0m and £2.5m
- Nearly 3yrs to first cash interest payments

### Equity

Visible Genomics amendment to earn-out,

- £0.6m non-cash accounting gain
- 869,565 shares to be issued Dec 2019 (~3%)
- 500,000 shares to be issued Dec 2021 (~1%)

## CASHFLOW FOR PERIOD ENDED 31 DEC 2018

	<b>Dec-18</b>	<b>Dec-17</b>
	<b>£'000</b>	<b>£'000</b>
EBITDA	(1,978)	(1,665)
Working capital	(1,021)	(376)
Capex	(70)	(12)
Tax	0	1,220
Interest	5	6
FX	(9)	(7)
	<u>(3,073)</u>	<u>(834)</u>
Fund raise	5,684	-
Earn-out (Visible Genomics)	(300)	-
Discontinued operations	-	256
	<u>2,311</u>	<u>(578)</u>
Net cash flow		
B/F	3,529	5,129
Cash at bank	<b>5,840</b>	<b>4,551</b>

- £5.8m of cash with R&D tax credit (£1.0m) and DoD order (£0.6m) still to come
- EBITDA down on mix of business, current year includes grant claims that are funded expenditure
- Large working capital consumption owing to timing on debtors: DoD shipped end of Dec (\$0.9m) and grant cycle end of Nov
- R&D tax claim submitted after the December fund raise – meaning payment delayed versus PY, due shortly
- £3.1m consumption from operating activities (2017: £0.8m)
- Net fund raise of £5.4m after payment to settle Visible Genomics earn-out
- Cash at 27th March £4.7m (unaudited)



## NEWS FLOW

### 0-6 Months

- Ship \$0.5m DoD order
- WHO PQ performance studies completed
- Commercial traction and sales of HCV
- Registrations achieved and progress towards 30 country goal
- Further agreements to expand distributor footprint

### 6-12 Months

- WHO pre-qualification completed
- Commencement of AIHL in hospital validations and distribution partner discussions
- 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

- 3 Assays on market with material revenue and significant market potential
- Fully established commercial footprint for all 3 assays

# RAPIDLY DEVELOPING COMMERCIAL-STAGE MOLECULAR DIAGNOSTICS BUSINESS

- 1 £1.5m Revenue and £5.8m cash, expected year end revenue growth of around 25%
- 2 HCV kits expected to contribute to sales in year end 30 June 2020
- 3 HCV kit progress through WHO pre-qualified status
- 4 Two significant orders from US DoD, customer indications for medium term orders
- 5 Continued progress on AIHL and mTB development products
- 6 Cash position allows AIHL and TB to be commercially launched, and supports commercialisation of HCV
- 7 Further clarity on DoD orders expected later in the year

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APPENDIX



# GENEDRIVE® TECHNOLOGY

The power of  
molecular  
diagnostics outside  
of the hospital



- **Rapid results in small hospitals, clinics and in the field**
  - Prompt clinical decisions are possible
  - Sample to result in as little as 50 minutes vs days from a service laboratory
- **Ease of Use**
  - Single use, disposable reagent cartridge revenue model
  - Limited training required for operation
- **Real-World robustness**
  - Operates in hot and humid conditions present outside laboratories
  - Can be configured with UPS to withstand fluctuating power availability
- **Versatile**
  - Same instrument platform is used across a range of applications
- **Affordable**
  - System and test price point targeted to be accessible in world-wide markets

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THANK YOU

