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Advancing Molecular Diagnostics to the Point of Care

Interim results (to Dec-19)

4 February 2020

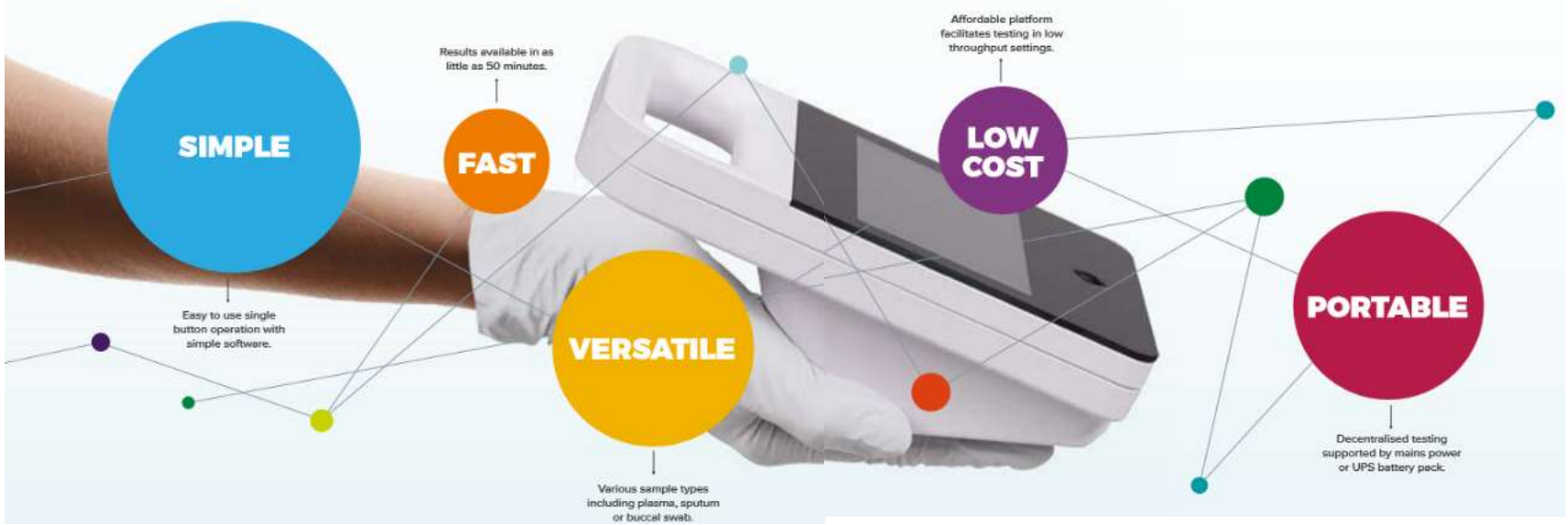
ADVANCING MOLECULAR DIAGNOSTICS TO THE POINT OF CARE

Handheld, portable generic testing system

Crude sample inputs (plasma, sputum, buccal swab)

Single-button operation

Data Management through Smartphone App



STRATEGY: 3 OF 4 ASSAYS DELIVERING SIGNIFICANT REVENUE BY END 2022

On-Market

Genedrive® HCV the first approved decentralised qualitative molecular test

- > 50m people globally undiagnosed
- Registered in 14 countries
- WHO PQ in process and due Q1/Q2 calendar 2020
- Indian registration now obtained

Early Market Entry

Antibiotic Induced Hearing Loss Assay

- Estimated western market ~£35m, UK ~£3.5m
- Funded product development in process
- Launch calendar 2020

On-Market

Bio-threats (US DoD)

- £0.3m of revenue in H1
- Supplier issue resolved ~$0.5m revenue impact
- Nov-19 contract extended by up to $2m

In-Development

mTB Detection & Drug Resistance

- Large and well funded markets
- Successful development locked for follow on funding

HIGHLIGHTS 6 MTHS TO DEC 2019

Revenue & Cash

- Revenue £0.6m (2018: £1.5m). Grant income reduced as expected but commercialisation of on-market products slower than anticipated
- DoD supplier issues estimated to have cost $0.5m in delayed revenue
- Cash £3.5m at Dec-19 (June 2019: £5.2m)
- Consumption of £1.7m after £0.97m of R&D tax cash received

On-Market

- Genedrive® HCV-ID kit obtained regulatory approval for Indian launch
- In process for WHO Pre-Qualified status, but taking longer than expected
- Excellent HCV analytical data in all evaluation sites but commercialisation behind plan
- DoD extended contract value by $2.0m to support future ordering

Early Market Entry

- AIHL assay trials commenced in Manchester and Liverpool Hospitals
- AIHL on track for commercial launch in 2020 following successful completion of hospital trials

In Development

- Tuberculosis assay and durable designed and grant programme successfully completed

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ON-MARKET

ON MARKET - HCV

The WHO and HCV

- In 2016, the WHO issued its 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 decentralised 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	• India registration (the largest funded HCV market) achieved Dec-19 • Sysmex engaged in Africa and Apac with regulatory authorities but behind plan – unpredictable processes and need for in-country validations
Product Performance	• 6 Independent studies and in-country evaluations are now complete • In almost 2,000 patients that have been characterised, the results have been excellent: accuracy has ranged from 96.5% to 100% and specificity has been 100% in all studies
WHO-PQ	• Pre-Qualification allows the product to appear on the WHO's 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 availability at the WHO lab, and the need to re-perform experiments to follow the accepted protocol: expected Q1/Q2 2020
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 • India represents a different market with different commercial opportunities

ON MARKET – PATHOGEN DETECTION / DOD

Market Overview

- Genedrive® was contracted by the United States Department of Defense (DoD) to develop Genedrive as a handheld bio-warfare testing system in 2014
- Contract has been worth ~$10m to date
- Development completed in early 2018 and now in commercial deployment stage

Progress

- £0.3m of revenue in the period: cost of supplier issues estimated at $0.5m – issues now resolved
- Customer extended contract value by $2m in Nov-19
- DoD purchasing body being transitioned internally – expect approx. 12 months for transfer
- Expectation that the Genedrive® product is to be de-restricted to allow sales to other national militaries

Outlook

- Orders received for 2019/20 at historic rates
- DoD internal transfer to complete before any material order escalation

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EARLY MARKET ENTRY

ANTIBIOTIC INDUCED HEARING LOSS

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 as facilitated through grant award and partnership with NHS 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

ANTIBIOTIC INDUCED HEARING LOSS

Progress

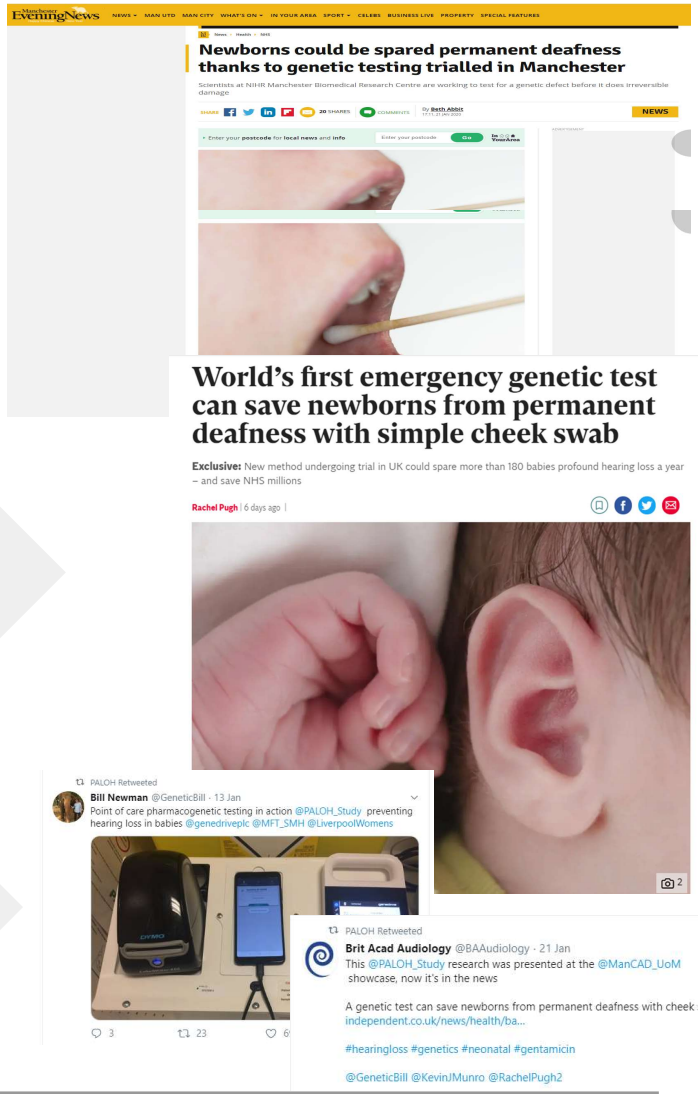
- Test is now CE marked and under evaluation
- Clinical trials commenced in January (Manchester & Liverpool)
- Positive progress already seen

Next steps

- Commercialisation plans on-going
- Meet non-UK stakeholders
- Other in–market clinical trials assessment likely Summer 2020

Timing

- Initial commercial revenues expected to follow launch in calendar 2020
- Material UK revenues expected after approval in clinical guidelines



IN DEVELOPMENT

MTB – IN DEVELOPMENT

- Innovate UK grant £1.1M successfully completed in December
- Developed functional prototypes of Genedrive companion sample prep system and sample prep cartridge
- Targeting sensitivity higher than smear microscopy, using our bacterial enrichment technology
- 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 and isolates TB from sputum in 15 minutes
- Single tube - keeping our core ethos of low manufacturing costs, low/no maintenance
- Follow-on funding needed to progress project

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FINANCIAL SUMMARY

FINANCIAL HIGHLIGHTS FOR DEC-19

Revenue

- Revenue £0.6m (2018: £1.5m)
- Development revenue declined in line with grant programmes conclusions
- DoD and HCV revenue unable to offset the planned grant reductions

Expenditure

- Total costs down £0.3m period over period
- Headcount and development spend tightly managed

Cash

- Dec-19 £3.5m
- Debt of £9.3m, with no cash payments until Dec-21
- Low cash burn since Jun-19 (£1.7m) owing to R&D tax receipt (£1.0m)

CASHFLOW FOR PERIOD ENDING DEC-19

	6 mths Dec-19 £'000	6 mths Jun-19 £'000	6 mths Dec-18 £'000	6 mths Jun-18 £'000
Rev	627	874	1,488	651
OP Loss	(2,526)	(2,413)	(1,978)	(2,664)
Working capital	(133)	736	(946)	74
Capex	(1)	(27)	(70)	(12)
Interest	10	13	5	7
FX	0	(1)	(9)	1
	(2,650)	(1,692)	(2,998)	(2,594)
Tax	971	980	0	0
Discontinued operations	0	0	0	1,565
Fund raise	0	0	5,309	0
Net cash flow	(1,679)	(712)	2,311	(1,029)
B/F	5,128	5,840	3,529	4,558
Cash at bank	**3,449**	**5,128**	**5,840**	**3,529**

- £3.5m of cash at Dec-19
- Operating loss broadly in line with prior 6 month periods
- Working capital spikes uncommon and mainly associated with DoD shipments
- Circa £1m of R&D tax credit received once per annum
- R&D tax claim received in the period – no further receipt until at least Dec-20
- Average pre-R&D cash burn is £2.4m for a 6 month period
- Timing of DoD shipments meant Dec-19 trade receivables +£0.3m higher than Jun-19

DEBT SUMMARY

Cashflows	GHIF $m	BGF £m
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 £9.3m (10% discount rate)
- Book value of debt £10m (£2.7m and $9.9m)
- Approx. 24 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 placing 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

- WHO PQ result expected
- Details on HCV study data results
- Initial Indian HCV sales
- Completion of AIHL in hospital validations

6-12 Months

- Commercial launch of AIHL and initial sales to early adopters
- Post India and WHO – underpinning on HCV opportunity
- Expect clarity on DoD internal transition and new on-going order rate

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 in calendar 2020

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THANK YOU