GENEDRIVE PLC (LON:GDR)

Overlooked Story Entering the Launch of their HepC Diagnostic Kit

KEY INVESTOR MESSAGES

- Genedrive (LON:GDR) on track to become a commercial stage, point-of-need diagnostics company
- Launch of Genedrive® Hepatitis C (HCV) test at IFCC World Lab October 2017, with commercial sales expected in the coming quarters (African markets)
- Distribution agreement signed for HCV test for Asia Pacific
- Collaboration with the US Defense Department (bio-hazard program) to generate further income (c. $1.9mln) in the current fiscal year
- Re-launch of Genedrive® MTB (tuberculosis) test is being reassessed
- Management actively engaged in the disposal of the legacy service business (preclinical research and pharmacogenomics)
- Cash position of £4.2mln as of 30 September 2017, enough to finance the ongoing business well into fiscal year 2019
- Our SOTP valuation yields an equity value of c. £24mln, over 3x current market capitalization

COMPANY OVERVIEW

Genedrive (LON:GDR), an innovative diagnostic company, focuses on the development and commercialization of a novel, point-of-care diagnostic system, also called Genedrive® (in line with Company's policy, "genedrive" refers to the business, whereas "Genedrive®" indicates the diagnostic product).

Genedrive (LON:GDR) is the first firm to launch a decentralized Hepatitis C diagnostic kit, entering a large market at a time when new curative therapies for this severe disease are transforming opportunities for testing and treatment. We also note that the Company's diagnostic technology has a wide range of potential applications, ranging from the diagnosis of many other infectious diseases, to biohazard detection and applications in industrial settings (e.g. aquaculture).

Figure 1: Genedrive® diagnostic unit

Source: Genedrive investors' presentation (October 2017)

PHARMA & BIOTECH

15/11/2017

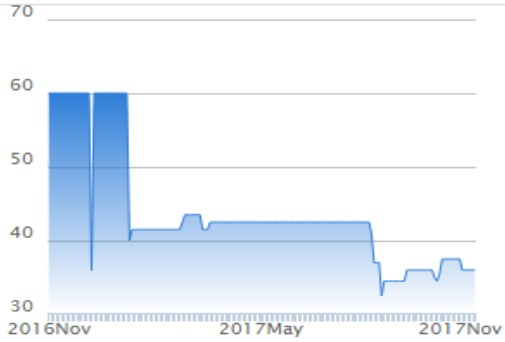
SHARE PRICE	52 WEEK LOW
▲ 37.50p	▲ 32.50p
MARKET CAP	52 WEEK HIGH
▲ £7.01m	▲ 62.50p
CASH	NET ASETS
▲ £5.1m	▲ £3.44m

MAJOR SHAREHOLDERS

1) Calculus Capital : 17.80%
2) Odey Asset Management: 10.69%
3) Hargreave Hale: 8.60%

Shares in Issue	18.69m
Avg Volume	14,807
Primary index	AIM
EPIC	LON:DGR
Next Key Announcement	-
Sector	Pharmaceuticals and Biotechnology

SHARE PRICE CHART



Company Information

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But first, let's took a brief look at the Company's history. Genedrive was originally founded as Epistem in 2000 and was then listed on London's AIM in 2007. Epistem operated as a niche contract research organization (CRO), providing pre-clinical research services in areas such as stem cell regeneration and pharmacogenomics. At the same time Epistem kept investing in internal R&D, building up a significant expertise in biomarkers and assays. To compliment this internal expertise, the Company bought Visible Genomics in 2010 to acquire the Genedrive® diagnostic platform. Genedrive® was first launched in 2016 in India, as a point of care test for the diagnosis of tuberculosis and the simultaneous assessment of rifampicin resistance (MTB/RIF test).

Unfortunately the launch of Genedrive® MTB test in India was compromised by a technical issue (a specific sample preparation problem arose that was unique to the MTB assay and isolated to one of the smallest components in the assay kit). Whilst the technical fault is now largely resolved, genedrive is re-assessing the best way to reengage this potentially large MTB opportunity – with the existing solution that is suitable for MTB instances in India or a second product that will satisfy both India and the wider global market where MTB burdens require more sensitive diagnostic tests. We also note that the Company has recently announced the termination of the commercial agreement they had in place with Xcelris for India and other Southern Asia markets. Accordingly, we don't forecast revenues from the MTB program, at least until fiscal year 2020.

The Hepatitis C test development is a significant step in a strategic realignment of the company to exploit the opportunities Genedrive® presents in point-of-care applications. The Company estimates a diagnostics market worth over $1bn for its infectious disease pipeline but, at present, this is delivered from expensive, hospital-based settings. In Hepatitis C, new drugs which have the potential to cure the disease are now being made genericized in certain low and middle income countries at affordable prices, opening up a significant diagnostic market opportunity to find patients eligible for the new therapies. The Genedrive® test is uniquely positioned to support a strategy of testing and treatment in these markets.

Three significant milestones were achieved in recent weeks for Genedrive® HCV test: the CE mark obtained in September and a distribution agreement with Sysmex Europe GmbH announced in October. Those milestones opened the door for the launch of Genedrive® HCV test during fiscal year 2018, and were followed in November by the announcement of a distribution deal with Sysmex APAC for the Asia-Pacific region (with the exclusion of India). Both agreements will leave genedrive in charge of product development and manufacturing, whereas Sysmex European and APAC subsidiaries will lead distribution and marketing efforts for the Genedrive® platform.

The Genedrive® HCV test was launched to the market at the IFCC World lab in Durban, South Africa. Initial efforts will be directed towards market entry in several African markets. It is expected that the increased availability of new and highly efficacious Hepatitis C therapies will drive demand for point-of-care diagnostics in decentralized (rural) laboratories in emerging markets. Given the Company's aspirations to launch the products globally, we would expect further distributor agreements in the coming months.

We also note that the collaboration with the US Defense department (biohazard program) is progressing well and is expected to deliver $1.9mln income in fiscal year 2017/2018 ($1.4mln of development income and $0.5mln of product sales). Ongoing revenue is expected, but the quantum of this is unknown to management as the DoD is not forthcoming with details owing to the nature of the product.

Source: Genedrive investors' presentation (October 2017)

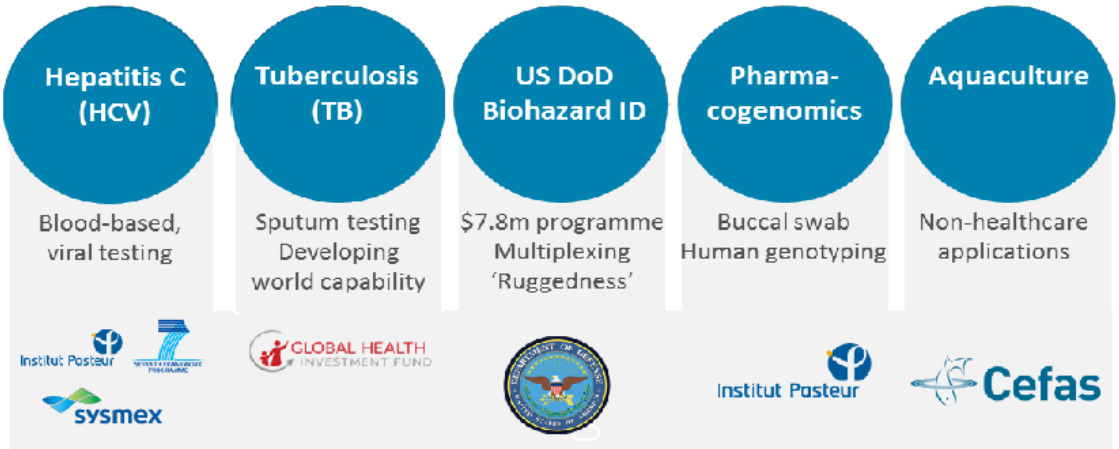
Figure 2: Genedrive® diagnostic technology compared to centralized methodologies

As a point of need solution, Genedrive® is uniquely positioned to support FIND*'s HCV strategy	Lab-based PCR	Genedrive®
		
Approach	Lab-based PCR based tests for viral DNA run on blood samples. High-cost platforms in centralised, high-resource labs	Field-based PCR based test in development for viral DNA to be run on blood samples at patient location
Providers	Numerous providers: Abbott/ Qiagen/ Roche/ Siemens/ Cepheid	Genedrive
Diagnosis	✓	✓
Viral Detection	✓	✓
Diagnose Active Infection	✓	✓
Decentralised use	✗	✓
Service Turnaround Time*	Slow (weeks/ days)	Fast (90 mins)
Price	$20-30	$20-35
Sensitivity at LOD	100%	> 99%

As the market opportunity for Genedrive® became clearer in its size and appeal, the company's board was of the view that keeping two increasingly different businesses under the same roof wasn't any longer in shareholder's best interests. As such they decided to concentrate their efforts on the launch of Genedrive® diagnostic system and, at the same time, to explore strategic options for the legacy CRO operations.

The company plans to commercialize their Genedrive® platform with a classic razor-razorblade model, largely implemented through distribution agreements, such as the one recently signed with Sysmex.

Figure 3: Genedrive® technology can address a broad range of applications



Source: Genedrive investors' presentation (October 2017)

Although the development of Genedrive® has been largely focused on infectious diseases, it is worth noting that its technology is potentially suitable for a wide range of applications, as testified by the ongoing collaborations with the UD Department of Defense (battlefield biohazards testing) and with CEFAS (fish cultures water testing).

GENEDRIVE®: HOW IT WORKS

Genedrive® is a small, portable device for the diagnosis of infectious diseases, based on the analysis of body fluids samples.

It is a CE-marked, lower cost option for the diagnosis of infectious diseases at point-of-care. It is based on polymerase chain reaction (PCR) technology, which has so far been confined to larger desktop analyzers. By contrast Genedrive® is about the size of a book, weighs 1kg and works on either grid or battery power. As such, it represents an ideal option for small and medium size rural labs and clinics in developing countries. As the average clinic using Genedrive® is likely to run about 10-15 tests per week, it would likely be uneconomical for them to purchase a sophisticated desktop analyzer.

The system can run one test at the time, with results ready in about one hour.

Genedrive® ease of use and affordability make it an ideal tool for rural clinics and labs serving communities that would otherwise be left out of any other molecular diagnostic option.

From patients' perspective, the cost of a test conducted with Genedrive® is comparable to the cost of a test done with traditional desktop analyzers at large hospitals' centralized laboratories ($20-$30 in emerging markets).

However Genedrive® use at point-of-care allows for treatments to start straight away, rather than waiting a few days or longer for test results. That is assuming access to larger diagnostic centers is available, which is rarely the case in emerging countries rural communities.

MARKET OPPORTUNITY

The global market for HepC testing is estimated by the WHO at around $500mln, of which approx. 25% or $125mln in high-burden developing countries. Given the current lack of point-of-care diagnostic options we believe that the launch of Genedrive® may significantly expand this market over time.

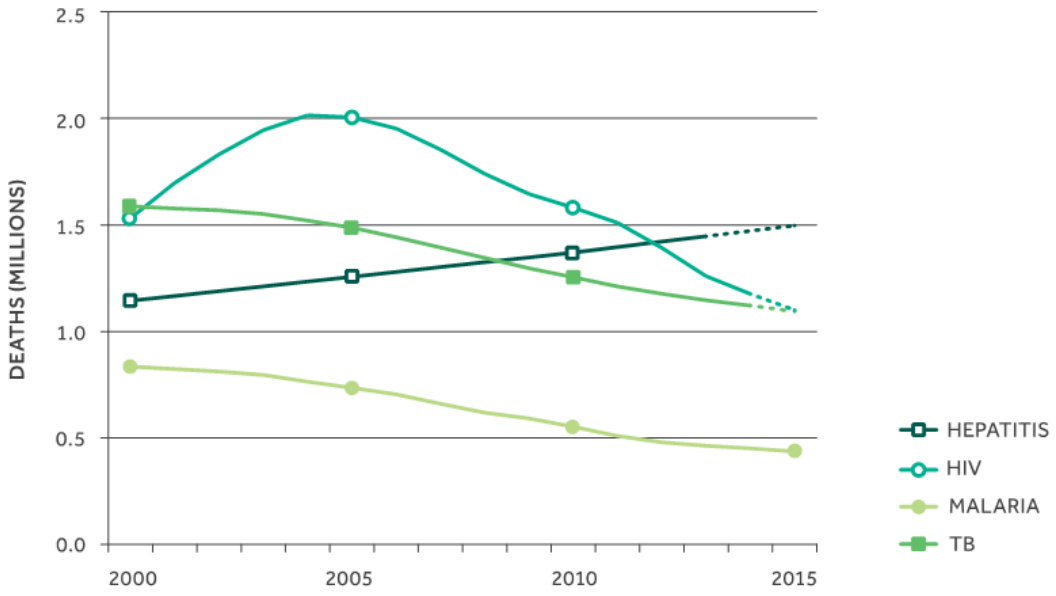


Figure 4: Global number of death from selected infectious diseases ***(Source: GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS, 2016–2021, WHO, 2016)***

Of course having a diagnosis is only important as long as treatments are available. In this respect it is important to highlight the increasing access to latest generation HepC medicines in emerging markets. A 12-week treatment course for the cure of HepC still fetches a price close to $100,000 (per patient) in US and Europe but is now being made available in emerging markets for $300-$900.

According to the WHO, tuberculosis remains a top killer in emerging countries, with over 10 million cases every year and almost 2 million deaths. Almost 80 million sputum spear microscopy tests are performed each year, but market share is progressively being gained by molecular diagnostic systems that are able to test both for the disease and for the antibiotic resistance profile.

VALUATION

As the Company has announced their intention to dispose the services business, we value Genedrive using a SOTP approach, as follows:

- Diagnostic business: following the launch of the HCV test in FY2018 and the expected re-launch of the MTB test in FY2020, we forecast this segment to generate revenue of approx. £15m in FY2025. Three years after launch we expect the growth rate to progressively decrease and reach a low-double digit level in FY2025. All in, this would represent a c. 34% revenue CAGR for the diagnostics business between FY2018 and FY2025. In line with diagnostic companies valuation, genedrive could then be valued at about 3x sales, yielding a £45mln valuation in 2025. Using a discount rate of 10% we obtain a present value of c. £24mln

- Services business: we believe that a niche research services and pharmacogenomics business should be sold at a sales multiple in the 0.5-1.5 range. However, given the length of time the Company has been trying to secure a disposal, it is likely that they will be at the lower end of this range, so we obtain a valuation of £2.0mln

- Based on current cash burn rate, we estimate a net debt position of £1.4mln as of 31 December 2017

- This leads to an equity value of c. £24mln, versus a current market capitalization of about £7mln

Figure 5: genedrive SOTP valuation

genedrive SOTP valuation					
	EV (£m, present value)	Discount rate	EV (£m, 2025)	Sales multiple	Sales (£m, 2025)
Diagnostics (Genedrive®)	23.8	10%	46.3	3.0	15.4
	EV (£m, present value)	Sales multiple	Recurrent sales (£m)		
Services	2.0	0.6	3.2		
genedrive EV	25.8				
Cash (CN estimate as of 31/12/2017)	3.9				
Debt (CN estimate of covertible bond value as of 31/12/2017)	5.3				
Net debt	1.4				
genedrive equity value	24.3				
Latest market cap	7.0				

Source: CN analysis

KEY FINANCIALS

Genedrive® HCV: in order to estimate the revenue potential of Genedrive® HCV test, we have built a simple model covering the first 3 years of launch. It is based on the following assumptions:

Genedrive® diagnostic price / unit	£2,000
Assays run per unit / quarter	150 (approx. 10-15 per week)
Assays price / unit	£15

Assuming the launch trajectory shown below, this would lead to revenues of approx. £200k, £2.2mln and £6mln in FY2018, FY2019 and FY2020 respectively.

Figure 6: Genedrive® HCV sales model

Genedrive® HCV	FY2018			FY2019				FY2020			
	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Diagnostic units sold (new)	5	10	20	40	60	75	90	99	109	120	132
Diagnostic units sold (cumulative)	5	15	35	75	135	210	300	399	508	628	759
Price per unit (£)	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000	2000
Diagnostic units sales	10,000	20,000	40,000	80,000	120,000	150,000	180,000	198,000	217,800	239,580	263,538
Assays per unit/quarter	150	150	150	150	150	150	150	150	150	150	150
Assays sold	750	2,250	5,250	11,250	20,250	31,500	45,000	59,850	76,185	94,154	113,919
Price per assay (£)	15	15	15	15	15	15	15	15	15	15	15
Assays sales	11,250	33,750	78,750	168,750	303,750	472,500	675,000	897,750	1,142,775	1,412,303	1,708,783
Total Genedrive® HCV sales (£)	21,250	53,750	118,750	248,750	423,750	622,500	855,000	1,095,750	1,360,575	1,651,883	1,972,321

Source: CN analysis

As Genedrive has announced their intention to divest the services business, we show our revenue forecast split between the diagnostic and the soon-to-be disposed services businesses. We also note that the services business generates an EBITDA contribution of approx. £0.2-0.3mln a year (on c. £3.2mln sales).

Figure 7: genedrive key financials

Summary Financials Year to 30 June (GBPm)	2016 A	2017 A	2018 E	2019 E	2020 E	2021 E	2022 E
Diagnostics segment (Genedrive®)	1.9	2.6	1.9	2.4	6.5	8.7	10.9
Services segment (legacy)	3.2	3.2	3.2	3.2	3.2	3.2	3.2
Revenue	5.1	5.8	5.1	5.5	9.7	11.9	14.1
Growth		14.3%	-11.9%	8.7%	75.7%	22.3%	18.6%
Contract costs	(3.3)	(3.0)	(3.1)	(3.2)	(4.9)	(5.8)	(6.4)
Margin (% of sales)	64.9%	51.8%	61.7%	58.5%	49.9%	48.9%	45.4%
R&D	(4.8)	(5.1)	(4.8)	(3.9)	(4.0)	(4.2)	(4.4)
Margin (% of sales)	95.5%	87.9%	94.8%	69.8%	40.9%	35.1%	31.1%
SG&A	(2.4)	(2.6)	(2.7)	(3.0)	(3.3)	(3.7)	(3.8)
Margin (% of sales)	46.8%	45.2%	53.9%	54.5%	34.1%	30.7%	27.2%
EBIT	-5.4	-7.3	-5.6	-4.6	-2.4	-1.8	-0.5
EBIT adjusted for exceptional items	-5.4	-4.9	-5.6	-4.6	-2.4	-1.8	-0.5
Pre-tax profit	-6.5	-7.5	-5.9	-4.9	-2.8	-2.2	-0.7
Net income	-5.9	-6.4	-5.0	-4.1	-2.4	-1.9	-0.6
EPS (GBp)	(56.1)	(34.9)	(27.0)	(22.4)	(12.8)	(10.1)	(3.1)
Cash & cash equivalents	1.1	5.1	1.1	(2.0)	(3.9)	(5.1)	(4.7)
Change in cash	(3.8)	4.0	(4.0)	(3.1)	(1.9)	(1.2)	0.4
Working Capital	1.3	0.2	0.5	0.5	0.9	1.1	1.3
CapEx	0.2	0.1	0.1	0.1	0.1	0.1	0.1

Source: CN analysis

Based on our forecasts, Genedrive will be self-funded into FY2019 but likely to require some injection during 2019. This assumes no contribution from the expected sales of the services business.

NEXT STEPS

In the coming quarters we expect Genedrive to update the market on several key fronts:

- Genedrive® HCV launch trajectory, following the distribution agreement signed with Sysmex Europe
- Further distributor agreements for other territories
- Divestment of the services business (estimated value in the £1.6-4.8mln range)
- Reassessment of the commercial strategy for Genedrive® MTB test in India

Further developments for other Genedrive® applications (bio-hazards, aquaculture, etc.)