

Genedrive PLC

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Genedrive 'confident' of WHO approval for hepatitis C test by autumn

Genedrive PLC (LON:GDR) "remains confident" that the World Health Organisation will 'pre-qualify' its HCV ID hepatitis C test within the next few months, despite some delays to the clinical trial.

Part one of the qualification - a quality audit - has already been completed, but part two - an independent clinical trial - is taking longer than expected due to a lack of low viral load samples for analysis.

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Still, Genedrive believes the study should complete "in the short term" as more samples become available, and bosses hope to update investors on the result of the qualification in the autumn.

The overall commercialisation of the HCV ID kit is progressing more slowly than expected though, with only 12 country registrations having been completed, below the internal target of 30 before the end of June.

This, coupled with the delays to the WHO qualification process, means Genedrive expects revenue for the year to June 2020 "to fall short" of current forecasts, although growth should still be in double digits.

"We are optimistic about the long-term opportunity that HCV presents and expect commercial uptake to occur during the financial year to 30 June 2020, however the slower rate of country registrations and ongoing WHO pre-qualification process will have an impact on our overall rate of short-term growth," said the company in Tuesday's trading update.

US DoD continues to order

On a more positive note, Genedrive's development of an antibiotic-induced hearing loss test with the NHS is ahead of schedule, with in-hospital trials expected to begin in the autumn after CE marking requirements.

The company pointed out that this screening assay has the potential for distribution across all NHS emergency settings to help prevent hearing loss in children, as well as application in Europe and the rest of the world.

Over in the US, the Department of Defense ordered £900,000 worth of biohazard identification tests last year, and the repeat order is "proof of the platform's utility", according to 'house' broker Peel Hunt.

Importantly, Genedrive "remain[s] positive of forward revenue momentum" with the DoD in the year ahead.

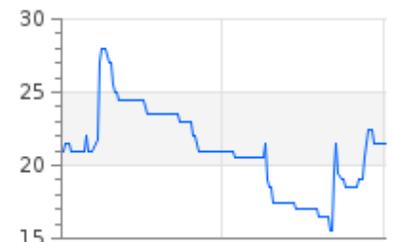
Moving forward, albeit slowly

For the 12 months ended 30 June, revenue rose to £2.4mIn (2018: £1.9mIn), broadly in line with forecasts. At £5.2mIn, cash was ahead of expectations (2018: £5.8mIn).

Price: 21.5

Market Cap: £7.31 m

1 Year Share Price Graph



December 2018 May 2019 December 20

Share Information

Code: GDR

Listing: AIM

52 week High Low
30 13

Sector: Pharma & Biotech

Website: www.genedrive.com

Company Synopsis:

Genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications.

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"The commercialisation of our HCV ID kit is progressing more slowly than we would have hoped," said chief executive David Budd.

"However, we continue to progress WHO pre-qualified status and the registration of the product in our target countries and so reasonably expect an upturn in demand in the future.

"Our supply of Genedrive to the US DoD and its contribution to the year and the outlook for 2019/20 continues to grow; we expect further orders for both assays and units during the forthcoming year."

Shares were down 16.3% to 18p in early deals on Tuesday.

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