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Genedrive PLC
10 July 2020

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genedrive plc
("genedrive" or the "Company")

Trading Update

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, provides an unaudited trading update for the 12 months ended 30 June 2020 and an update on regulatory and commercial progress relating to the Genedrive® 96 SARS-CoV-2 Kit ("CoV-2 Test").

Highlights

- Revenue for the year to 30 June 2020 in line with expectations at £1.0m (2019: £2.4m)
- Year-end cash of £8.2m (Dec 2019: £3.5m) following an equity fundraise in May 2020
- Balance sheet further strengthened through conversion of the US$8.0m GHIF bond
- Over £1.0m of indicative orders for Genedrive® 96 SARS-CoV-2 kit, pending regulatory approvals
- Further orders for the CoV-2 test are anticipated through a widened network of distributors

Year-end Trading Update

Revenue for the 12 month period to 30 June 2020 was £1.0m, in line with market expectations but below the same period in the prior year (2019: £2.4m) owing, as previously announced, to the significant impact of COVID-19 on the Company's pre-existing business activities. The Company ended the financial year with a much stronger balance sheet and is well-funded to execute on new opportunities in Coronavirus testing as well as the wider product development pipeline. The Company closed the year with cash balances of £8.2m (31 December 2019: £3.5m) after the successful fundraise in May 2020. Following the conversion of the US$8.0m GHIF bond on 16 June 2020 the Company has also significantly reduced the level of debt on the balance sheet.

CoV-2 Test Update

Following CE marking of the Genedrive® 96 SARS-CoV-2 kit on 22 May, the Company has been actively working to obtain country specific regulatory approvals. The Company has received significant interest from customers and distribution partners for this assay and genedrive has now signed additional distribution contracts in respect of 11 countries to work non-exclusively alongside its existing distributor network. To date, the Company has received over £1.0m of indicative orders for the Genedrive® 96 SARS-CoV-2 test, but regulatory approvals are required to fulfil these orders and ship the product.

Obtaining country specific regulatory approvals remains the crucial next step and the Company is in the process of registering the Genedrive® 96 SARS-CoV-2 Kit in multiple overseas regions. In general, regulatory approvals are taking longer than anticipated and the regulatory agencies we are engaged with are unable to provide definitive timelines for approvals, which we believe is due to a significant increase in their workload.

The Company's main commercial efforts are focussed on India, Africa and the United States:

- Indian approval was applied for in mid-June and the process is ongoing. The Company remains very confident that rapid commercial roll out could be achieved in India through both existing distribution partners and DIVOC Health, a new COVID focussed partner in India.

- The Company has signed a number of distributors across Africa and is in the process of registering the product locally. The CoV-2 Test was submitted for WHO approval in early June, although this is not a primary focus for market entry as many African countries have their own approval processes.

- In the United States, Emergency Use Authorisation (EUA) has been applied for and remains under consideration by the FDA. The Company has been in discussion with several interested partners to access the US market, but all discussions have been subject to receipt of EUA approval.

The Company is also working to ensure that CE marking claims for the Genedrive® 96 SARS-CoV-2 test can be expanded to include a broader range of laboratory systems, and therefore increase the potential customer base for this test. The Genedrive 96 SARS-CoV-2 test is a high volume laboratory assay compatible with multiple third party platforms. It was initially CE marked with data generated from the Roche Lightcycler 480 II, and the Company is now validating the data for the ABI 7500 FAST and BioRad CFX96 systems to expand its claims.

In addition, the Company has announced separately the launch of its new CE marked Genedrive® 96 Exporter, a new IVD software module for automated results interpretation of the Genedrive® 96 SARS-CoV-2 Kit. Genedrive® 96 Exporter offers a significant improvement to the native software found on third party PCR platforms.

Outlook

The Company has pathogen detection orders to fulfil for the US DoD and is confident of first half sales of both Genedrive® units and assays to this customer. As previously announced the expectation remains to sign a new contract with the US DoD in autumn 2020 and achieve new sales volumes following commencement of their new fiscal year.

Despite some initial concerns around the impact of lockdown on the Antibiotic Induced Hearing Loss (AIHL) project, the NHS evaluation programme has continued to run during the past few months. After a slow period, the programme pace has increased somewhat as lock-down measures have eased and the Company remains optimistic of completing the project and achieving the Autumn 2020 timeframe for commercial launch with Inspiration Healthcare Plc.

The impact of COVID-19 on the HCV market is less clear as many developing world healthcare systems continue to focus on the pandemic. The Company achieved WHO prequalification status for its HCV product in May 2020 but only expects to see moderate sales traction in the near-term as countries focus on Coronavirus.

The development of a CoV-2 point of care test for the Genedrive® system remains targeted for the end of the calendar year and the Company remains excited about the unique characteristics of the Genedrive® system to address current issues of testing for the Coronavirus.

David Budd, Chief Executive Officer of genedrive plc, said: *"We remain encouraged by the interest in our Genedrive® 96-SARS-CoV-2 test. We are working to secure regulatory approvals in the territories we are focused on, which are also key to signing additional*

partners to expand our commercial footprint. The critical role of testing is absolutely clear as the world continues to deal with the pandemic and while the competitive landscape and overall markets continue to evolve, our target markets combined with the unique aspects of the CoV-2 Test give us significant confidence in delivering successful commercial outcomes in the near future."

The Company expects to announce results for the 12 months ended 30 June 2020 in October 2020.

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About genedrive plc (http://www.genedriveplc.com)
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. The Genedrive® mt-RNR1-ID kit has received CE-IVD Certification and will be launched into Europe and other markets following full evaluation by the UK National Health Service. The Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The company recently announced the development of the high throughput SARS-CoV-2 assay, based on Genedrive PCR chemistry.

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