

25 March 2020

genedrive plc
(“genedrive” or the “Company”)

Business Update and
Rapid Development of Coronavirus (SARS-COV-2) tests
Plan for high throughput SARS-COV-2 test to be available in 8 weeks

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, provides an update on trading in the current market conditions and a redirection in assay development focus to include Coronavirus (SARS-COV-2).

Business Update

On Market - Pathogen detection (DoD)

The Company has now received confirmation that a long-term supply contract with the US Department of Defense (“DoD”) will be agreed that will enable ordering from Autumn 2020 onwards for a period of three years. While final unit numbers and associated assays will be subject to confirmation and allocation of funding in the US Government’s new fiscal year (October), the DoD has advised the Company to expect a contract to cover the fielding of around 500 *Genedrive*[®] units and associated assays over the time period.

On Market - HCV Test

The *Genedrive*[®] HCV ID kit has started to gain commercial traction since the start of the calendar year. The full year sales to June 2020 had been predicated on growing sales across various end markets, in part supported by gaining WHO qualified status, during the second half of the Company’s financial year. Unsurprisingly, with countries increasingly in lock-down and healthcare systems focused on coronavirus testing and treatment, it is now impossible to predict the duration, speed, and impact of the pandemic on the HCV business. The Company continues to support its partners with test supply and technical support.

On Market – Antibiotic Induced Hearing Loss (AIHL)

The implementation trial of the *Genedrive*[®] MT-RNR1 ID Kit has progressed in Manchester and Liverpool Hospitals over the past few months. It has been rewarding to see the positive impact of this new test on patients. The Company cannot at this time though predict continuity at the same pace as NHS resources are understandably progressively diverted to address COVID-19.

Coronavirus test development

With a rapid global shift of healthcare emphasis towards testing and treatment of COVID-19, the Company has refocused a significant part of its core resources towards development of two SARS-COV-2 tests.

The Company’s first assay, already in development, is an instrument-agnostic molecular assay (the *Genedrive*[®] 96 SARS-COV-2 test) that can be performed on a variety of high throughput molecular testing platforms already installed in many laboratories around the world. The test will determine if a patient has an active SARS-COV-2 infection. The Company anticipates that a clinically validated high throughput test format could be available in approximately eight weeks.

The *Genedrive*[®] 96 SARS-COV-2 test is designed as a one-step, ready-to-go freeze dried assay. Based on discussions with sizable third party suppliers the Company expects it could have the ability to ramp quickly to high production volumes of over 10,000 tests per hour, and thus this could be both a material revenue generator for the Company and significant contributor to addressing the global pandemic. Freeze dried assays require no refrigeration and are stable in transport, which is a significant logistical advantage for rapid shipment and global distribution.

A second test will also be developed by the Company where it will adapt its formulations to run on the *Genedrive*[®] instrument platform to provide a rapid point-of-care SARS-COV-2 test to allow testing outside of the main hospital

environment in places such as clinics, intensive care units, or where rapid and accurate testing for SARS-COV-2 might be required. The rationale for the two-stage development is that the testing, logistics, validation, and trial work to provide testing on a turnkey instrument system like *Genedrive*[®] takes additional time compared to an agnostic assay format.

The Company believes that the principal risks on SARS-COV-2 assays development are related to business continuity and supply chain robustness for raw materials in the market, as opposed to technical challenges. The Company is also actively seeking development partners, distributors and non-dilutive funding to support the most rapid development possible.

Trading Outlook

Based solely on sales to date and purchase orders in hand, the Company would achieve revenues for the year to 30 June 2020 of circa £1.0m. The COVID-19 pandemic has created significant uncertainty across all businesses and whilst we continue to pursue a number of attractive commercial opportunities which could make a significant difference to the year-end revenue outcome, the risk associated to these has inevitably increased markedly.

Based on delivering circa £1.0m in sales to 30 June 2020 the Company has a cash runway of 6-9 months, this excludes any funding or additional revenues from HCV, AIHL and the SARS-COV-2 assays, but does assume genedrive utilises various UK Government support packages. With the current cash runway, the improving visibility of revenues from the DoD and the re-allocation of resources towards validating a commercial ready SARS-COV-2 assay, genedrive can navigate the next few months and potentially make a significant contribution to the fight against COVID-19 whilst also continuing to progress its other commercial opportunities.

David Budd, Chief Executive Officer of genedrive plc, said: *“It is a critical time for our industry’s expertise to contribute towards testing and treatment of the Coronavirus pandemic. Our novel experience in developing molecular assays, the rapid workflows we can achieve with Genedrive[®] compared to centralised testing, and our scalable manufacturing capability give the Company an opportunity to contribute very significantly to the global crisis. Given the continued uncertainty and focus of healthcare providers on COVID-19, we expect to experience some disruption to our HCV and AIHL activities but are focused on managing our resources over the coming months so that we can benefit from these growth opportunities when global priorities normalise.”*

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Notes to Editors

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).