ASX Announcement

17 May 2021

Update - AnteoTech signs manufacturing contract with Operon

Highlights

- AnteoTech signs EuGeni COVID-19 ART contract manufacturing agreement with Operon.
- AnteoTech to enhance Quality Management System (QMS) and seek MDSAP certification to facilitate single audit process for major market regulatory authorities.
- Saliva use case on track for CE Mark update in June 2021.

AnteoTech Ltd (ASX: ADO) ("AnteoTech" or "the Company") is pleased to announce that it has finalised and signed a manufacturing contract for its COVID-19 Antigen Rapid Test (ART)[1] with Zaragoza (Spain) based contract manufacturer Operon.

The execution of the agreement follows the successful completion of the technology transfer in March, the completion of several reel-to-reel lateral flow strip scaled up production runs including full commercial sized run, and the quality agreement connecting AnteoTech's ISO-13485 Quality Assurance testing with the Operon manufactured COVID-19 ART. Under the terms of the manufacturing agreement, AnteoTech and Operon have agreed to an exclusivity period of three years, during which Operon has the first right of refusal to manufacture AnteoTech's COVID-19 ART's to supply the European market, exercisable only if Operon has the capacity to produce the quantity of EuGeni COVID-19 ART to meet AnteoTech's European demand.

The signing of this initial agreement with Operon establishes a key relationship within AnteoTech's EuGeni manufacturing strategy. Operon has a manufacturing capacity of 8 million complete tests (test strip and cassettes assembly and packaging) per annum and a test strip production capacity of approximately 20 million lateral flow strips per annum. This capacity will provide AnteoTech with enough capacity to fulfil initial demand for the EuGeni ART and an option to scale manufacturing across the EuGeni test suite to meet anticipated sales. Currently, Operon is producing EuGeni COVID-19 ART tests to supply all sample and market seeding activities being undertaken around the world.

Lateral flow manufacturing capacity around the world has increased dramatically during the COVID-19 pandemic, and key manufacturers have invested heavily to meet the demand generated by the

[1] The AnteoTech Antigen Rapid Test detects the SARS-CoV-2 active virus that causes the disease called COVID-19.

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development of tests for COVID-19. Operon themselves are investing in new plant that will more than triple their capacity and will be available during 2023. Locally, Ellume have invested very heavily in lateral flow assembly capability in Brisbane, which is now operational, and are currently duplicating that capability in Maryland, U.S.A.

Given AnteoTech's developed competency to transfer our technology to an outsourced manufacturer successfully and our developing relationships in the lateral flow manufacturing sector, we are confident that we will be able to bring manufacturing capability online for the entire suite of EuGeni tests as demand increases.

Quality Management System Reinforcement and MDSAP Certification

AnteoTech is now a legal manufacturer of a medical device which requires the Company's Quality Management System (QMS) to be compliant with ISO 13485 regulatory audits, international regulatory authorities, and clinical organisations. Over the next 12 months, AnteoTech intends to submit a range of tests to the TGA, FDA and IVDR (In Vitro Diagnostic Regulation) in Europe. In some jurisdictions, including Australia, this will require us to extend the current scope of our ISO 13485 certification. Additionally, AnteoTech intends to apply for accreditation under the Medical Device Single Audit Program (MDSAP). This is a strategic decision to facilitate easier market entry and ongoing compliance in jurisdictions with regulatory authorities participating in the Program. The Program allows for a single MDSAP audit to be submitted to participating regulatory authorises, including Australia, Brazil, Canada, Japan and the United States. MDSAP is also observed by the European Union (EU), United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) and The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme. [2]

To achieve this certification program and de-risk any potential of failing large market regulatory review processes, we need to enhance our QMS and extend the scope of our ISO 13485 certification during our annual certification audit.

Australian Market for Antigen Rapid Testing

Australia has little to no COVID-19 community transmission and closed international borders. Travel in Australia is possible when internal borders are open, and flights regularly occur with standard mask-wearing and hygiene protocols. With international borders closed, there is no requirement for large-scale passenger screening.

Where screening has been required for the control of outbreaks, Australian Government organisations have chosen traditional lab-based testing processes (PCR) to provide decision support for isolation. Recently we have been encouraged by the comments of Prime Minister Morrison regarding the use of ART for screening purposes in the future. In the near term, however, the Federal Budget announcements from last week suggest that the Government is not likely open its borders to international travel until late 2021at the earliest, suggesting that the need for screening in Australia and the potential use of ART as a facilitation tool will not materialise until later this year at the earliest.

TGA Submission

Due to an emerging need to enhance our QMS to support the continued international rollout of EuGeni tests in markets with high demand, we have decided to bring forward this year's ISO 13485 audit by 3 months. Simultaneously we have decided to delay our TGA submission by a similar time frame in order to capture the enhanced QMS and MDSAP accreditation as part of our submission for the EuGeni platform in Australia. We consider the benefits gained by enhancing our QMS and gaining MDSAP certification to support a thorough submission for EuGeni in the Australian market completely

[2] https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

outweighs the sacrifice of a 3-month market window opportunity in Australia in light of the very small comparative market opportunity currently observed.

The deferral will not hinder the current roll-out and distribution of the ART internationally. In fact, we believe the international markets provide a much stronger opportunity. To date, a high level of enquiries for the ART have been fielded from jurisdictions in which our CE Mark is accepted or where other regulatory approvals or emergency use authorisations are required.

Saliva Use Case

The laboratory validation of the saliva samples is currently underway. Pending analysis and results of the saliva samples, an updated CE regulatory submission will be made to amend the Instruction For Use (IFU) of the current EuGeni SARS-CoV-2 ART to include oral saliva sampling. The test and all components remain the same. AnteoTech remains on track to submit the update to the CE Mark in June 2021, pending results.

Distribution Agreements & EuGeni Rollout

AnteoTech is continuing to field a large number of enquiries from organisations and distributors globally. The enquiries have come from a wide range of parties, including resorts, mining camp suppliers and traditional distributors of IVD devices. Validation of the EuGeni product in the hands of these customers via an independent trial as a precursor to a purchase has been a stipulated requirement in every market interaction to date. We are currently sending readers and test kits to interested parties to facilitate those processes. The first sale of EuGeni readers and initial seeding quantity of tests was made days after our launch, and these tests will be used to screen workers in mining facilities in Papua New Guinea.

To increase visibility in the European and Indian markets, AnteoTech has appointed on the ground company representatives in France and India. Similar arrangements are being sought for Germany and the UK which will aid in facilitating discussion with distributors and laboratories. We expect to make those additional appointments shortly. These resources are also facilitating the completion of clinical trials required for individual country marketing authorisation. We are currently conducting in-country validation studies in India and France as part of the country-specific roll-out strategy.

This announcement has been authorised for release by the Board.

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ABOUT ANTEO GROUP – AnteoTech Ltd (ASX:ADO)

AnteoTech is a surface chemistry company with Intellectual Property ("IP") in its core technology product groups AnteoCoat™, AnteoBind™ and AnteoRelease™. The Company's purpose is to create shareholder value by identifying and solving important global industry problems by providing unique value-add solutions for its customers. Customers operate in the life sciences, diagnostics, energy and medical devices markets.

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