



ASX Announcement

23 September 2021



Therapeutic Goods Administration Registration Submitted

Highlights

- ❖ **AnteoTech seeking TGA approval for registration of EuGeni Reader platform and SARS-CoV-2 Antigen Rapid Diagnostic Test**
- ❖ **Documentation submitted for processing – following completion of compliance audit and receipt of updated ISO 13485 certificate**
- ❖ **AnteoTech continues to work with Australian distributor Abacus dx on sales opportunities**

AnteoTech Ltd (ASX: ADO) ("AnteoTech" or "the Company") is pleased to advise that it has submitted documentation with the Australian Therapeutic Goods Administration (TGA) to commence the registration process of the EuGeni Reader platform and SARS-CoV-2 Antigen Rapid Diagnostic Test (RDT)¹ in the Australian Register of Therapeutic Goods (ARTG). If granted, TGA approval for registration will allow the Company to progress the marketing, sale and use of its products in Australia. TGA approval for registration, if granted will also be a significant benchmark for the efficacy and quality of the products in other large markets.

AnteoTech CEO Derek Thomson said, *"If TGA approval for registration is secured it will be another key milestone in commercialising EuGeni for the Australian market and establishing its reputation as the gold standard rapid test for SARS-CoV-2."*

"As well, a number of other countries in the region with large populations regard TGA approval as a critical benchmark of a products efficacy, so we expect this initiative, if successful, to open up additional sales channels for the Company."

Under the TGA guidelines, AnteoTech is seeking to register the EuGeni Reader platform as a Class I IVD Medical Device, and its SARS-CoV-2 RDT as a Class III IVD Medical Device.

The submissions follow the completion of an ISO 13485 annual compliance audit by independent auditors and the issuance of an updated ISO 13485 certificate. This highlights that AnteoTech's Quality Management System (QMS) is compliant with international standards.

The TGA has received AnteoTech's application and will now commence the evaluation process. The TGA is currently expediting the COVID-19 IVD Medical Device application process.

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

In anticipation of TGA registration, AnteoTech has been working closely with Australian distributor Abacus dx Pty Ltd (Abacus) to progress distributor training and business development activities. Abacus has built a strong pipeline of potential customers across the public and private healthcare, and screening markets. If TGA approval for registration is provided, the Company anticipates that first sales will occur shortly after listing on the ARTG.

This announcement has been authorised for release by the Board.

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About 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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