Avacta

Consumer testing CE mark received for AffiDX LFT

22 December 2021

- Avacta has received the CE mark for consumer self-testing for its AffiDX SARS-CoV-2 lateral flow test (LFT). This is the first UK-developed LFT to be approved for self-testing and allows its use across the UK and Europe (as well as other geographies that recognise the CE mark). The CE mark for professional use was received in June, with first shipments made during the last quarter. Medusa Healthcare has exclusive rights to commercialise the product globally, under the brand name MeduFlow.
- Clinical validation studies have demonstrated that AffiDX SARS-CoV-2 LFT has a clinical sensitivity of 98.0% and clinical specificity of 99.0%, with later data showing specificity of 99.6%. The LFT is proven to be effective in detecting the Alpha, Beta, Gamma, and Delta variants (Omicron was not a variant of concern when the approval filing was made). The test is simple to take, with a single nasal swab from the anterior nasal area (not the nasopharyngeal area) showing consistent and reliable results within less than 20 minutes.
- While the CE mark is an important step in commercialising AffiDX as the antigen testing market moves from professional use to increased adoption of self-testing, forecasting likely revenues remains fraught with difficulties. Influencing factors range from the macro (such as the political and scientific arguments for point of care testing with LFTs), to micro (eg where will LFT pricing settle given downward price pressure from Chinese manufacturers), and pragmatic (eg can Avacta manufacture sufficient tests to satisfy expected demand). Unfortunately, visibility is unlikely to improve in the near term, thus our expectations are little more than educated guesswork.
- CE marking is a powerful validation of the value of Affimer technologies in diagnostic applications and highlights the progress that has been achieved. The rapid creation of an accurate, sensitive, robust, and competitive test has established Avacta's skills and abilities within the industry; for instance, Affimer-based reagents were identified and generated within five weeks of the SARS-CoV-2 structure being made public. Attention now shifts to commercial execution; however, the challenging market environment limits the near-term revenue visibility.

Price	125.4p
Market Cap	£318m
Primary exchange	AIM
Sector	Healthcare
Company Code	AVCT
Corporate client	Yes

Company description:

Avacta owns two novel technology platforms: Affimer and pre|CISION. Affimer proteins are antibody mimetics being developed as diagnostic reagents and oncology therapeutics. pre|CISION improves potency and reduces toxicity of cancer drugs by only activating them inside the tumour. Successful clinical trials would be transformative for Avacta.

Trinity Delta view: Avacta's Diagnostics business has come of age during the COVID pandemic, demonstrating laudable technical abilities, speed of response, integrated development, and the ability to work with multiple partners. Irrespective of the commercial outcome of its Affimer-based COVID LFT, AffiDX SARS-CoV-2, this business has matured into a true diagnostics player. The near-term opportunities for AffiDX, while difficult to accurately quantify at this stage, are clearly attractive; however, we expect the Therapeutics pipeline to drive greater long-term value with the Affimer and pre|CISION platforms having the potential to generate an extensive pipeline of prospective products. Our Avacta valuation is £710m (280p/share), with the Diagnostic opportunities representing £133m and the Therapeutic pipeline rNPV £559m.

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