

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.

Analysts

Lala Gregorek

lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Lala Gregorek

lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franco Gregori

fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Disclaimer

Trinity Delta Research Limited ("TDRL"; firm reference number: 725161), which trades as Trinity Delta, is an appointed representative of Equity Development Limited ("ED"). The contents of this report, which has been prepared by and is the sole responsibility of TDRL, have been reviewed, but not independently verified, by ED which is authorised and regulated by the FCA, and whose reference number is 185325.

ED is acting for TDRL and not for any other person and will not be responsible for providing the protections provided to clients of TDRL nor for advising any other person in connection with the contents of this report and, except to the extent required by applicable law, including the rules of the FCA, owes no duty of care to any other such person. No reliance may be placed on ED for advice or recommendations with respect to the contents of this report and, to the extent it may do so under applicable law, ED makes no representation or warranty to the persons reading this report with regards to the information contained in it.

In the preparation of this report TDRL has used publicly available sources and taken reasonable efforts to ensure that the facts stated herein are clear, fair and not misleading, but make no guarantee or warranty as to the accuracy or completeness of the information or opinions contained herein, nor to provide updates should fresh information become available or opinions change.

Any person who is not a relevant person under section 21(2) of the Financial Services & Markets Act 2000 of the United Kingdom should not act or rely on this document or any of its contents. Research on its client companies produced by TDRL is normally commissioned and paid for by those companies themselves ('issuer financed research') and as such is not deemed to be independent, as defined by the FCA, but is 'objective' in that the authors are stating their own opinions. The report should be considered a marketing communication for purposes of the FCA rules. It has not been prepared in accordance with legal requirements designed to promote the independence of investment research and it is not subject to any prohibition on dealing ahead of the dissemination of investment research. TDRL does not hold any positions in any of the companies mentioned in the report, although directors, employees or consultants of TDRL may hold positions in the companies mentioned. TDRL does impose restrictions on personal dealings. TDRL might also provide services to companies mentioned or solicit business from them.

This report is being provided to relevant persons to provide background information about the subject matter of the note. This document does not constitute, nor form part of, and should not be construed as, any offer for sale or purchase of (or solicitation of, or invitation to make any offer to buy or sell) any Securities (which may rise and fall in value). Nor shall it, or any part of it, form the basis of, or be relied on in connection with, any contract or commitment whatsoever. The information that we provide is not intended to be, and should not in any manner whatsoever be, construed as personalised advice. Self-certification by investors can be completed free of charge at www.fisma.org. TDRL, its affiliates, officers, directors and employees, and ED will not be liable for any loss or damage arising from any use of this document, to the maximum extent that the law permits.

Copyright 2021 Trinity Delta Research Limited. All rights reserved.

More information is available on our website: www.trinitydelta.org