Avacta

AffiDX LFT sales paused to improve Omicron detection

10 January 2022

- Avacta has announced it has paused sales of its AffiDX SARS-CoV-2 lateral flow test (LFT). This move follows Avacta's analysis of laboratory testing of the LFT's performance against the Omicron variant at lower viral loads. Performance was as expected at higher viral loads; however, the sensitivity fell short of expectations at lower viral loads.
- The issue appears to lie with one of the test components, a commercially sourced antibody. The AffiDX LFT contains both a proprietary Affimer reagent and a commercially available antibody. Reassuringly, the Affimer reagent appears to retain the same high sensitivity, across differing viral loads, to the Omicron variant as to previous COVID variants; however, the performance of the antibody component is impacted by Omicron's diverse mutation profile.
- For context, clinical validation studies have demonstrated that the AffiDX SARS-CoV-2 LFT has a clinical sensitivity of 98.0% and clinical specificity of 99.0% (later data showed a specificity of 99.6%) and it 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 AffiDX SARS-CoV-2 sales are paused, Avacta will work on replacing the antibody within the test to ensure that test performance with the Omicron variant is comparable to that demonstrated with other mutations. These efforts aim to improve test sensitivity to Omicron, the dominant variant in many regions globally, and create a next generation antigen test with greater resilience to future mutations to maximise the long-term COVID-19 commercial opportunity. Development and regulatory timelines for the new LFT are at present uncertain.

Price	115p
Market Cap	£292m
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: This clearly disappointing news effectively pushes back the commercialisation of the AffiDX SARS-CoV-2 LFT. The positives are that management has identified the issue and responded promptly and, importantly, the issue does not lie with the Affimer technology. Avacta's Diagnostics business demonstrated its technical abilities and the ability to react rapidly to problems when creating the original LFT, hence it will hopefully resolve this issue quickly too. We note that there is also the possibility that the sensitivity of other marketed COVID-19 LFTs to Omicron may be similarly impacted. The uncertainties around timelines, in addition to the challenging market environment, prompt us to suspend our forecasts and valuation until there is greater visibility. Our prior Avacta valuation was £710m (280p per share), with the Diagnostic opportunities representing £133m. We continue to view the Therapeutics pipeline as the greater driver of long-term value; our £559m rNPV for the Affimer and pre|CISION platforms is unaffected by this announcement.

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

Franc 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 of 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.

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