

Stock Data

Share Price:	110.0p
Market Cap:	£228.8m
Shares in issue:	208.0m

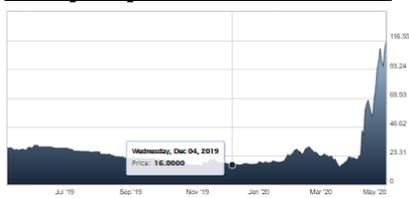
Company Profile

Sector:	Healthcare
Ticker:	AVCT
Exchange:	AIM

Activities

Avacta Group plc ('Avacta', 'the Group') is a biotechnology company which has developed the proprietary Affimer® technology platform, a unique engineered alternative to antibodies. Affimer proteins can be developed quickly for drug development and a wide range of life sciences applications in the diagnostics and research sectors.

Share price performance



Source: [LSE](#)

Past performance is not an indication of future performance.

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Avacta Group plc

Avacta has announced its Preliminary Results for the 17-month period ending 31 December 2019. Its accounts reflect strong revenue growth and a healthy balance sheet; its statement highlights the establishment of multiple, major long-term growth opportunities. Significantly, post period-end the Group also announced two partnerships established to develop Affimer-based COVID-19 antigen tests, having also completed a £5.75 million fundraising that left the business well capitalised with a £10.5 million net cash position as at 30 April which capitalises the business through into 2022 on its current plans. This ideally positions the Group, with planned first dosing for its potentially transformational Phase I study of AVA6000 pro-doxorubicin in cancer patients commencing Q4 2020/Q1 2021, while its Affimer technology contributes to a giant, potentially reputation-building global opportunity through its rapid development of highly specific diagnostic reagents for SARS-COV-2 antigen testing across multiple diagnostic platforms. As such, Avacta presently finds itself in an enviable and well-funded development position relative to most of its peers, while shareholders remain reassured that its management and product direction is focussed on maximising the Group's near and longer-term commercial opportunities for its platform.

COVID-19 Antigen Testing Opportunity

The urgent need for SARS-COV-2 antigen testing has shone a spotlight on Avacta's Affimer platform for diagnostics, along with its ability to quickly develop reagents suitable for a rapid response saliva test strip. This offers potential to generate a very significant revenue stream, as well as drive wider longer-term commercial interest.

A consensus view is that hundreds of millions of antigen tests will be required per month to support the fight against the Pandemic and initial easing of the lock-down during 2020, and to deal with the long-term challenge of endemic COVID-19. The performance of any such product of course is key, with only best performing tests likely to be successful. Here Avacta has the advantage of Affimer reagents that are highly specific to the virus' spike protein.

Beyond the obvious reputational and commercial, albeit presently unquantifiable, short and longer-term opportunities that could emerge from its new partnerships with Cytiva and Adeprix, such developments represent a major inflection point along with potential for creation of significant value for Avacta, while it also continues to forward its other partnered programmes and licensing relationships for its diagnostics reagents.

AVA6000 Phase 1 trial appears fully funded

New funds raised in April are also being directed towards the Group's other key objective, that of completing the Phase I clinical trial of AVA6000 (pro-doxorubicin). Based on this, its anticipated burn for the COVID-19 test strip and other existing programmes, TPI now estimates Avacta should still hold cash c.£7.5m by its December 2020 year end. This suggests the Group is fully funded through 2021 to complete the Phase I trial of its lead asset which, assuming dosing commences on the currently expected schedule, suggests possible delivery of initial data during summer 2021.

Results for the 17-month period to 31 December 2019

The Group reported revenues of £5.5 million for the 17-month period to 31 December 2019 (compared to the 12-month period to 31 July 2018: £2.8 million), leading to an operating loss of £18.0 million (12-months to 31 July 2018: £10.4 million). Increased R&D investment, driven by strong progress in therapeutic programmes, resulted in a loss of £15.6 million (2018: £8.8 million), or loss per ordinary share 13.0p (2018: 13.5p).

Following receipt of an initial upfront milestone payment of US\$2.5 million received from LG Chem Life Sciences and equity fundraising completed in November 2019 that raised gross proceeds of £9.0 million in order to progress the AVA6000 programme into clinical trials, cash balances at year end amounted to £8.8 million (31 July 2018: £5.2 million). A post-period end £5.75 million fundraising ensured the Group remains well capitalised with a strong net cash position in anticipation of formal commencement of Phase 1 trials and investment in its development collaborations with Cytiva and Adeprix.

AVA6000 Phase I Timelines

AVA6000 is a tumour activated pro-drug form of doxorubicin that utilises the Group's pre|CISION™ technology. Doxorubicin has been a standard of care treatment for advanced soft tissues sarcoma ('ASTS') for 40 years. Treatment is limited to six cycles due to cumulative cardiotoxicity which leads to irreversible heart failure. As a result, median progression free survival for ASTS patients is approximately 6 months, with median overall survival of 12-15 months.

AVA6000's market opportunity therefore, for three indications (ASTS, breast and ovarian cancer) peak sales for a safer and more efficacious form of doxorubicin in the US or EU alone is estimated to be US\$1.5bn.

Good progress has been made with Clinical Trial Authorisation ('CTA') filing and drug product manufacture so that AVA6000's Phase I is expected to start as soon as the situation allows. Clinical trials in the UK have been largely halted due to pressure on hospital resources. This is expected, however, to be relaxed somewhat in Q3, even if priority is then expected to be given by the regulator to COVID19 therapies. As such, formal CTA filing for the molecule is expected in Q3 2020, with dosing of first patients anticipated late 2020/early 2021.

COVID-19 Antigen Testing

Quite simply, polymerase chain reaction ('PCR') testing will not be able to provide daily testing for millions of people; a rapid point-of-care antigen test using [saliva is much more suitable](#) for mass screening of populations for COVID-19 infection.

The majority of rapid tests being developed world-wide are for [antibodies against the coronavirus](#). The Foundation for Innovative New Diagnostics ('FIND'), for example, is evaluating more than 50 tests of which only 5 are [rapid antigen immunoassays](#); out of 72 of the US's Food and Drug Administration ('FDA') Emergency Use Authorisations, none are for rapid antigen immunoassays. In this respect, Avacta has the key advantage that its Affimer reagents are highly specific to the SARS-COV-2 spike protein.

On April 8, Avacta announced a partnership with Cytiva (formerly GE Healthcare Life Sciences) to develop an Affimer-based, rapid saliva test strip for SARS-COV-2 antigen testing. Quantities of the Affimer binders to SARS-COV-2 spike protein are being manufactured by Avacta and expected to be provided to Cytiva (and others) in the next few days. Cytiva then aims to develop prototype lateral flow tests over the next few weeks. The test will then be clinically validated, initially using patient samples from sites in the UK. Avacta aims to have the test validated and CE marked for professional and consumer use as soon as possible this coming summer.

Avacta has also announced a partnership with Adeprix to develop a BAMS™ assay for COVID-19 infection to be run on the existing hospital installed base of mass spectrometers.

Avacta is also in discussion with other commercial partners to provide access to the SARS-COV-2 Affimer reagents to develop and commercialise other forms of diagnostic tests.

The scale of the global opportunity created by the COVID-19 Pandemic for diagnostics and vaccine development companies is clearly huge. A post-Pandemic world will also likely find significant new government and health agency-inspired funding available to ensure the world is much better prepared to cope with similar future situations. Avacta is clearly well positioned to benefit from such longer-term opportunities, both independently and through partnered programmes.

Putting hard figures down on the opportunity being presented to Avacta should its rapid saliva test strip development programme with Cytiva successfully commercialise, is a highly uncertain exercise. One illustration could possibly be the £250m-plus incremental value created by Novacyt's (AIM:NYCT) COVID PCR test. Another might be the industry's initial estimates that suggest a potential cost of sales of c.US\$2 per test strip (based on high volume production) for the developer with a unit sale price to the end consumer of, perhaps US\$30 each.

Considering Avacta retains ownership of the commercial rights to the reagents supplied, this suggests this partnership offers near-term potential to generate cash flow sufficient to fully fund all the Group's existing development programmes.

Therapeutics Division - Partnered Programmes

Avacta has fully funded programmes with four different partners, namely LG Chem, ADC Therapeutics, Daewoong Pharmaceutical Co. and Moderna, all of which ensure its retention of the commercial rights to the Affimer molecules outside of the collaboration. All programmes have progressed further in the opening months of 2020, while establishing clear 'next milestones' into 2021.

- **LG Chem:** Multi-target development partnership and licensing deal worth up to US\$310m with US\$2.5m upfront, US\$5m in near-term milestones, plus royalties on future products and full research costs.
- **ADC Therapeutics:** A three target deal to develop Affimer-drug conjugates incorporating ADCT's proprietary PBD warheads (licensed from AstraZeneca). Fully funded by ADCT with development milestones and royalties on future sales.
- **Daewoong Pharmaceutical Co.:** Established JV January 2020 to develop next generation engineered stem cell therapies that secrete immuno-modulatory Affimer proteins, with an initial focus on autoimmune diseases. AffyXell is focusing on both anti-inflammatory and tissue regenerative applications. Avacta owns 45% of AffyXell.
- **Moderna:** First therapeutic partnership established in 2015 which triggered Avacta's therapeutic programmes and the establishment of the therapeutics business unit. Multi-target research collaboration to develop Affimer drug candidates for mRNA delivery.

Diagnostics Division

Avacta is developing an in-house pipeline of diagnostic assets/products for licensing/sale and working with global partners to develop Affimer diagnostic reagents. It is now building on early traction with major diagnostic companies with the appointment of an experienced industry Commercial Director, Mr David Wilson, who brings 25-years of experience within the in-vitro diagnostic medical devices industry.

Presently, the Group has 30 custom Affimer development partnerships/evaluations ongoing and an in-house pipeline of Avacta diagnostic products for OEM/licensing addressing key gaps in the market and building on the platform's unique properties in infectious diseases, drug monitoring and point-of-care.

Current Affimer projects with commercial partners include 5 successful evaluations, with licencing deals under discussion, 17 completed projects with Affimers delivered to partner for evaluation plus 7 new Affimer development projects indicated. For the 17 months to end-December 2019, the division's revenue plus order book amounted to £1.33m (12 months to end-December 2018: £0.51m); TPI expects it to register further substantial growth in the current period.

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