
# Preliminary Results for the Period Ending 31st December 2019

## Business Update and Outlook

May 6th, 2020

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# Avacta Group Overview

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**LSE: AVCT ~£240M market capitalisation**

## Therapeutics Division

- Based in Cambridge, UK
- R&D Centre: 33 (inc 20 PhDs) scientists/ technicians
- In-house focus on immuno-oncology
- Global partnerships (oncology, autoimmune, cell and gene therapy)

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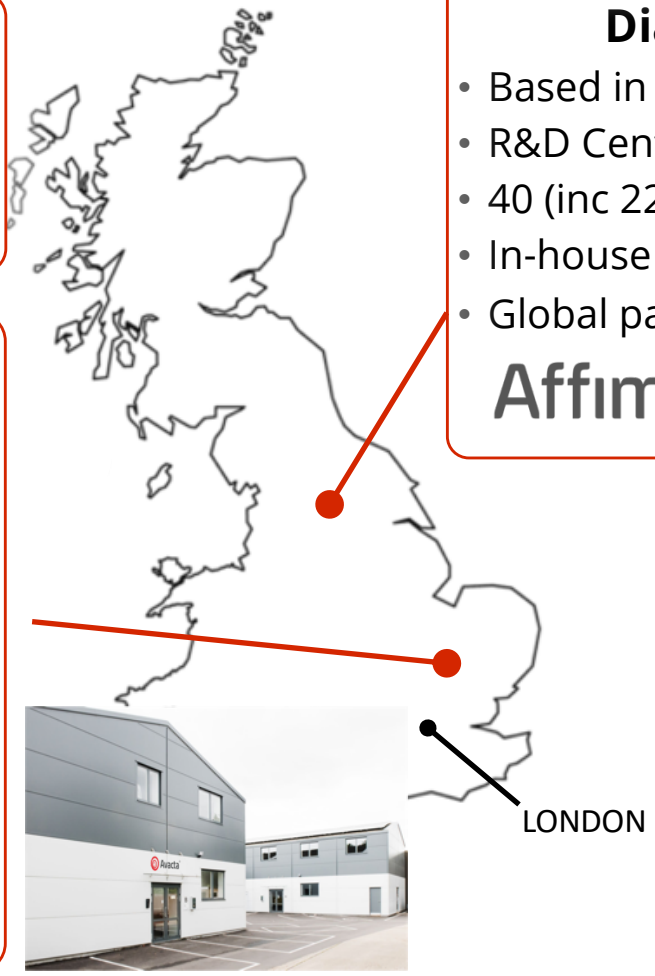


## Diagnostics Division

- Based in Wetherby, Yorkshire
- R&D Centre and plc Headquarters
- 40 (inc 22 PhDs) scientists/technicians
- In-house product development
- Global partnerships (undisclosed)

Affimer®



cytiva

ADEPTRIX

moderna ADC THERAPEUTICS DAEWOONG PHARMACEUTICAL CO.,LTD. LG Chem Life Sciences

# Introductions

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Dr Alastair Smith
Chief Executive Officer

Tony Gardiner
Chief Finance Officer

# Results for the 17 Months Period Ending 31 Dec 2019

# Operational Highlights for the Period Ended 31st December 2019

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- **LG Chem partnership: progressing well and expanding to new targets**
  Major therapeutics development partnership worth potentially $300 million, plus future royalties on product sales. All of Avacta's research costs also covered.

- **Collaboration with ADC Therapeutics: partnership to develop Affimer-drug conjugates**
  Collaboration agreement with ADC Therapeutics SA (Lausanne, CH) to develop Affimer-drug conjugates combining Affimer technology with ADC Therapeutics' PBD warhead and linker technologies.

- **Partnership with Moderna Therapeutics: enters next phase as Moderna exercises commercial option**
  Moderna Therapeutics Inc exercised its option to enter into an exclusive licensing agreement for Affimer candidates against an undisclosed target; part of an ongoing research collaboration between the two companies.

- **pre|CISION™ chemotherapy platform: enormous opportunity as "*chemotherapy without side effects*" and in novel Affimer drug-conjugates (TMACs)**
  Research collaboration and licensing agreement for chemistry developed at Tufts University Medical School for tumour activation of chemotherapy pro-drugs.

# Operational Highlights for the Period Ended 31st December 2019

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- **In-house Affimer therapeutic programmes: first candidate completes cell line development**

  Critical milestone of selecting the first Affimer clinical candidate for first-in-human trials for the Affimer platform has been achieved and initial GMP manufacturing steps completed.

- **Affimer diagnostics reagents: strong revenue growth and progress with partners towards licensing deals**

  Strong growth in revenue reported at £0.8 million for Affimer diagnostics reagents business.

  Appointment of David Wilson, a diagnostics industry veteran with over 25 years of experience, as Commercial Director for Affimer diagnostics reagents.

- **Post-period highlights: further therapeutic and diagnostic partnerships adding significant value to the Group**
  - JV in South Korea with Daewoong Pharmaceutical Co. Ltd., (KSX: 069620) to develop the next generation of cell and gene therapies, incorporating Affimer proteins to enhance the immune-modulatory effects. Avacta owns 45% of the JV. All of Avacta's research costs are covered by the JV.
  - Paul Fry appointed as Non-executive Director. Paul is Chief Financial Officer of Vectura Group plc, an industry-leading inhaled drug delivery specialist listed on the FTSE Main Market.
  - Collaboration with Cytiva (formerly GE Healthcare Life Sciences) to develop and manufacture a rapid test for the COVID-19 coronavirus antigen for mass population screening.
  - Partnership with Adeptrix to develop and commercialise a BAMS™ assay for COVID-19 diagnostics.

# Financial Highlights for the Period Ended 31st December 2019

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**Financial Highlights**

- Initial up-front milestone payment of $2.5 million received from LG Chem Life Sciences.
- Revenues of £5.5 million for 17-month period to 31 December 2019 (12-month period to 31 July 2018: £2.8 million)
- Operating loss of £18.0 million for 17-month period to 31 December 2019 (12-month period to 31 July 2018: £10.4 million)
- Increased R&D investment, driven by strong progress in therapeutic programmes, leading to reported loss of £15.6 million (2018: £8.8 million)
- Fundraising completed in November 2019 raising gross proceeds of £9.0 million in order to progress the AVA6000 programme into clinical trials.
- Cash balances at 31 December 2019 of £8.8 million (31 July 2018: £5.2 million)
- Additional fundraise completed in April 2020 raising gross proceeds of £5.75 million to support ongoing operations during 2021.

# Business Update and Outlook

# A Strong Base to Grow Long Term Sustainable Shareholder Value

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## Therapeutics

**Pre-clinical and clinical pipeline**
**Licensing/development partnerships/JVs**

### Affimer®

Fully human antibody mimetic
- Immunotherapies
- Engineered cell therapies
- Gene delivery
- Drug conjugates

Avacta®
In-house immunotherapy pipeline

LG Chem moderna
ADC THERAPEUTICS
>$500m combined potential value

DAEWOONG PHARMACEUTICAL CO.,LTD.
Stem cell therapy JV "AffyXell"
Comparators recently acquired >$1bn

**Affimer Comparator** Ablynx
Acquired by Sanofi January 2018 for $4.8bn

### pre|CISION™

Tumour activated chemo
- Improved safety, tolerability and efficacy
- AVA6000 pro-doxorubicin
- AVA3996 pro-velcade

Avacta®
In-house chemotherapy pipeline

Avacta® Tufts UNIVERSITY School of Medicine
Novel TMAC drug conjugates

## Diagnostics

**Product pipeline and services**
**Licensing/OEM**

### Affimer®

In-house product pipeline
- Addressing gaps in large testing markets using superior Affimer performance
- Infectious diseases
- Drug monitoring
- Point-of-care

Technology evaluations (mostly undisclosed)
- Rapid point of care testing
- Infectious diseases
- Drug monitoring
- Fertility/women's health
- Other

ADEPTRIX
cytiva

Strong growth (130%) in early stage revenues from partnered developments and manufacturing


Therapeutics Business Update

# Therapeutics Division Business Update: preCISION Pro-drugs

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**Tumour specific activation limits systemic exposure, improves safety, tolerability, therapeutic index and efficacy**

pre|CISION™

Circulating pro-drug is inactive so does not damage healthy tissues

Drug is activated in tumour by FAPα

Tufts University School of Medicine

Avacta's proprietary preCISION platform based on intellectual property exclusively licensed from Tufts University

## Clinical Benefits

- Increased maximum tumour exposure of active drug
- Improved tolerability, safety and therapeutic index
- Improved efficacy

Designed to address dose-limiting toxicities and side-effects across a wide range of drug classes, including:

**Anthracyclines** – cardiotoxicity

**Proteasome Inhibitors** – peripheral neuropathy

**Taxanes** – neutropenia and peripheral neuropathy

**AKT Inhibitors** – erythematous and stomatitis

For an introduction to preCISION pro-drugs see "https://avacta.com/wp-content/uploads/2020/02/Avacta-Investor-Presentation-February-2020_v2.pdf"

# Therapeutics Division Business Update: AVA6000 Pro-doxorubicin

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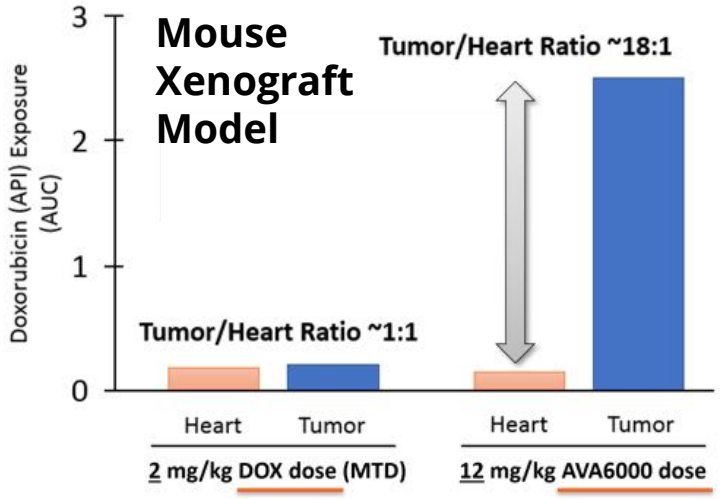
## AVA6000 is a tumour activated pro-drug form of doxorubicin

### Background

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 toxicity 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.




### Market Opportunity

For three indications (ASTS, breast and ovarian cancer) peak sales for a safer and more efficacious form of doxorubicin in the US/EU alone is estimated to be **$1.5BN.**

Assuming 50% market penetration in ASTS; 5 – 10% penetration in key target settings within metastatic disease (3L+ HER2– / HR+ and 1L TNBC); 40% within adjuvant/neo—adjuvant setting for breast cancer; 20-30% as a 2L treatment in ovarian cancer.

### Phase I Timeline

Clinical trials in the UK have been largely halted due to pressure on hospital resources. This is expected to be relaxed in Q3 but priority is then expected to be given by the regulator to COVID19 therapies.

Good progress has been made with CTA filing and and drug product manufacture so that AVA6000 phase I will start as soon as the situation allows.

**Expected CTA filing Q3 2020 and dosing first patients late 2020/early 2021.**

# Therapeutics Division Business Update: Tumour Microenvironment Activated Drug Conjugates (TMAC™)

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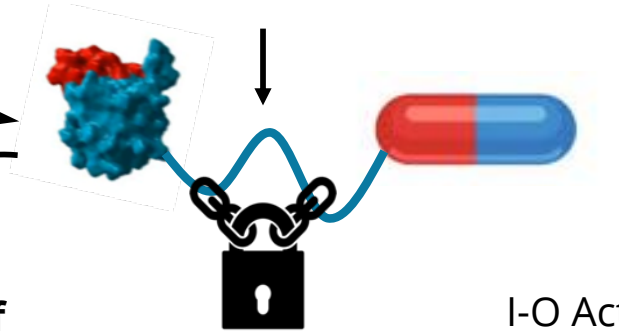
## Targeting and release of pro-inflammatory drugs in the tumour microenvironment synergises the innate and adaptive immune responses

**Affimer I-O Targeting**

pre|CISION™
**FAP Sensitive Linker**

**Synergistic Toxins**



**Induction/maintenance of adaptive immune response** overcoming immune evasion.

- PD-L1, other immune-checkpoints, bispecifics and costimulatory receptors
- Additional tumour targeting

I-O Active warheads **targeting "bystander" cells**, including macrophage, NK cells, etc. and supporting tumor stroma – e.g:

- I-DASH = DPP8/9 inhibitor
- Proteasome; AKT; CDK inhibitors
- STING; TLR7/8 agonists

For further information about TMACs please see https://avacta.com/alastair-smith-provides-update-on-tmac-programme/

# Therapeutics Division Business Update: AVA04-VbP

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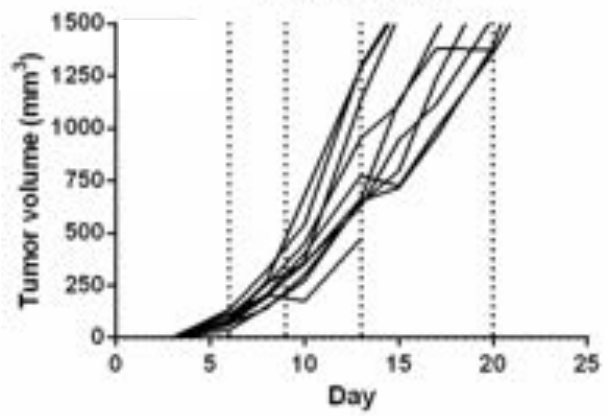
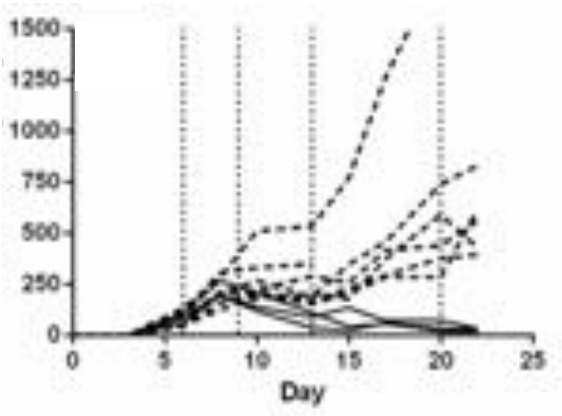
## In the colorectal tumour model CT26, VbP TMACs produce full regression of the tumours

**Control**



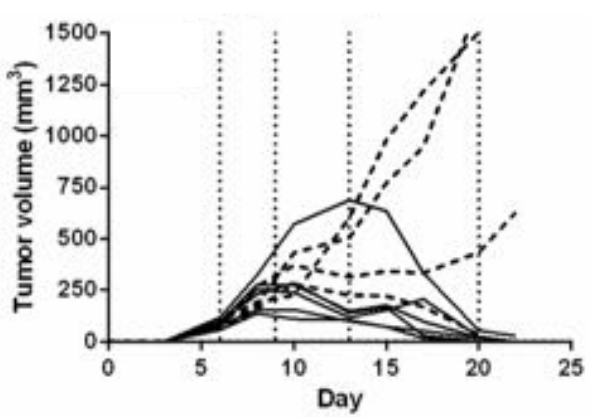

**AVA04 anti-PD-L1 | VbP TMAC**

30% complete regression




**Undisclosed Affimer | VbP TMAC**

60% complete regression




- The CT26 model is renowned as a tough, "cold" tumour, model.
- We have not only produced full regression of the tumours, but further data from the National Cancer Institute also show a T-cell mediated immunity to re-challenge with the same tumour more than a month after drug dosing has stopped.

These data give us strong belief that the VbP TMACs hold great promise as a transformative therapy for cancer patients.

Next Milestones:

- Further pre-clinical and IND enabling studies to support clinical candidate selection in 2021

# Therapeutics Division Business Update: Partnered Programmes

Affimer® pre|CISION™

## Fully funded programmes with partners and retention of the commercial rights to the Affimer molecules outside of the collaboration

LG Chem

**Multi-target development partnership and licensing deal worth up to $310m with $2.5m upfront, $5m in near-term milestones, royalties on future products and full research costs**

The LG Chem Partnership continues to advance, with LGC having selected two additional targets – one being a new therapeutic target and the other being a PK/ADME modifier for modifying the biodistribution and tissue retention of Affimers.

Next Milestones:

- Affimer candidates generated against 2nd and 3rd targets: 2H20
- Multiple pre-clinical milestones : 2021/22 up to $5m
- First IND filing milestone: 2021/22 (undisclosed payment)

ADC THERAPEUTICS

**Three target deal to develop Affimer-drug conjugates incorporating ADCT's proprietary PBD warheads (licensed from AZ). Fully funded by ADCT with development milestones and royalties on future sales.**

ADC Therapeutics have selected the first target and work has commenced to generate Affimer leads for ADCT to evaluate in cell killing assays and then to progress into animal models.

Next Milestones:

- Affimer candidates against first target generated and characterised 2H20
- Affimer candidates transferred to ADCT 2H20/1H21
- Option payments to take Affimer candidates forwards into development: 2021 (undisclosed payments)

# Therapeutics Division Business Update: Partnered Programmes

Affimer® pre|CISION™

## Fully funded programmes with partners with retention of the commercial rights to the Affimer molecules outside of the collaboration

DAEWOONG PHARMACEUTICAL CO.,LTD.

**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.**

AffyXell has moved forward quickly with the first three candidate Affimer programs underway along with the generation by AffyXell of GMP-compliant banks of mesenchymal stem cells (MSCs) to be engineered to express the Affimers at the site of inflammation.

Next Milestones:
- Affimers generated against first three targets transferred to AffyXell 2H20/1H21 for incorporation into MSCs

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.**

Commercial option exercised by Moderna in 1Q2019 to take Affimer lead molecules against one particular target into clinical development.

Next Milestone:
- Moderna to complete IND enabling studies and file IND: timing entirely at Moderna's discretion (undisclosed payment).


Diagnostics Business Update

# Diagnostics Division Business Update

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## Developing an in-house pipeline of diagnostic assets/products for licensing/sale and working with global partners to develop Affimer diagnostic reagents

**Product development partnerships and in-house pipeline**

- Building on early traction with major diagnostic companies with appointment of experienced industry Commercial Director
- ~30 custom Affimer development partnerships/evaulations ongoing
- In-house pipeline of Avacta diagnostic products for OEM/licensing addressing key gaps in the market and building on the Affimers platform's unique properties:
  - Infectious diseases
  - Drug monitoring
  - Point-of-care

**Affimer pharma services**

- Focus on "easy" turn-key projects with high success rate and good margin: anti-idiotypic binders
- Numerous projects currently ongoing with multiple repeat customers

**David Wilson**

**Commercial Director**

- Over 25 years commercial experience of in-vitro diagnostic medical devices industry.
- Led the sales, marketing and business development functions at Genzyme Diagnostics.
- Chair of Point-of-Care Testing Interest Group of BIVDA

# Diagnostics Division Business Update

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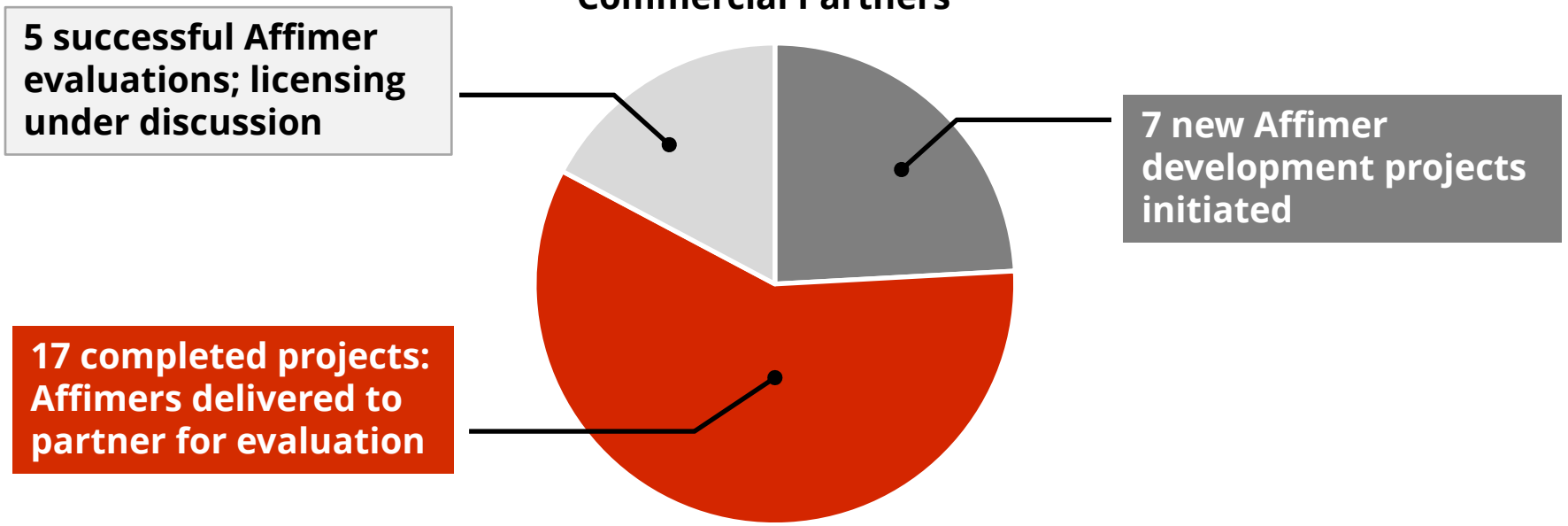
**Strong recent growth in revenue/order book and substantial pipeline of commercial opportunities the first group of which are moving to licensing discussions**

| | 12 months to 31/7/18 £k | 17 months to 31/12/19 £k |
|---|---|---|
| **Revenue** | 345 | 812 |
| **Revenue + order book** | 512 | 1,329 |

**Current Affimer Projects with Commercial Partners**



# Diagnostics Division Business Update

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## Most advanced in-house Affimer diagnostic test developments addressing gaps in large markets

| Biomarker | Test / Market Opportunity | Global Market Size | Status |
|---|---|---|---|
| **SARS-COV-2 antigen** | **COVID-19 infection**: **No current rapid point of care antigen test** for mass population screening. | Emerging market but expected to be >100 million tests per month | See next section. |
| **TRAIL and CRP** | **Sepsis**. **Differentiation between bacterial and viral infection** to allow correct clinical decision making around antibiotic prescription. | $1.1 bn by 2027, expanding at a CAGR of 9.4%.[1] >1.7 million adults in U.S. suffer from sepsis, which leads to around 270,000 deaths. | Both Affimer tests now available for potential licensees to evaluate for clinical assay development. |
| **Estradiol (E2)** | E2 is measured during **fertility treatment** and menopause. **Current tests lack sensitivity** and dynamic range and are 'negative-read' assays which makes them harder to interpret. | Estradiol testing is a significant part of the larger endocrine testing market worth $8.03 bn in 2018 and expected to reach $15.09 bn by 2026, at a CAGR of 8.1%.[2] | Affimer-based positive-read assay with good sensitivity and dynamic range now available for evaluation by potential licensees. |
| **D-Dimer** | A **cardiac marker** used to detect thromboses such as pulmonary embolism. **Current tests lack specificity** and are not suitable for point-of-care. | $2.0 billion by 2025, growing at a CAGR of 2.4% primarily driven by increased coagulation and hemostasis testing worldwide.[3] | A label-free assay has been developed which can be evaluated by potential licensees. Work ongoing to develop an agglutination assay. |
| **Vitamin B12** | Vitamin B12 deficiency can cause **anemia**, and may cause severe and irreversible damage to the brain and nervous system. **Current widely used blood test only measures the total amount of vitamin B12 in your blood whether it is active or not.** | The global active B12 test market is expected to grow at a CAGR of 7.2% to reach $220m by 2023.[4] | Affimer reagents that detect 'active' VitB12 with complete freedom-to-operate around existing antibody IP held by Abbott. Assay development completing in near future. |

1. https://www.grandviewresearch.com/press-release/global-sepsis-diagnostics-market
2. https://www.reportsanddata.com/report-detail/endocrine-testing-market
3. https://www.ihealthcareanalyst.com/coagulation-hemostasis-testing-d-dimer-testing-market/
4. https://www.marketresearchfuture.com/reports/active-b12-test-market-4199

# SARS-COV-2 Rapid Antigen Test: Collaboration with Cytiva (formerly GE Healthcare)

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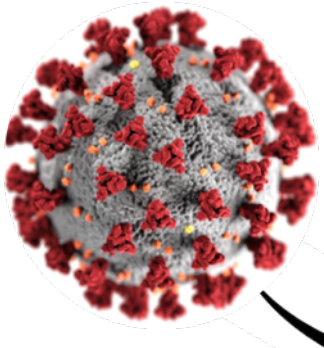
## Have I **Got** Coronavirus ? vs Have I **Had** Coronavirus ?



Person infected with coronavirus

Saliva sample

Avacta®

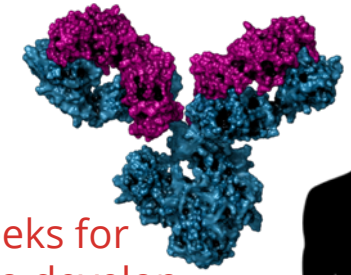
cytiva

Results in 10 minutes
Simple to use by anyone

Nasal or throat swab

"PCR" tests
Lab test results in 1-2 days

1-2 weeks for body to develop antibodies



Blood sample

Results in 10 minutes
"Serological Tests" Available

# COVID-19 Antigen Testing Market: Not Just a Short Term Opportunity

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**The 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.**

- PCR testing will not be able to provide daily testing for millions of people; **a rapid point-of-care antigen test using saliva[1] is ideal for mass screening of populations for COVID 19 infection**.

- The vast majority of rapid tests being developed world-wide are for antibodies against the coronavirus[2]. FIND is evaluating more than 50 tests of which only 5 are rapid antigen immunoassays. Out of 72 FDA Emergency Use Authorisations none are for rapid antigen immunoassays[3].

- Performance is key – the best performing test will become the most successful: **Avacta has the advantage of Affimer reagents that are highly specific to the SARS-COV-2 spike protein.**

1. "Saliva is more sensitive for SARS-CoV-2 detection in COVID-19 patients than nasopharyngeal swabs" medRxiv preprint doi: https://doi.org/10.1101/2020.04.16.20067835. this version posted April 22, 2020
2. https://www.finddx.org/covid-19/sarscov2-eval-immuno/
3. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev

# SARS-COV-2 Rapid Antigen Test: Progress Update

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- 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.
- On April 22 Avacta announced that it had successfully generated more than 50 Affimer reagents specific to the SARS-COV-2 spike protein.
- **Avacta owns all the commercial rights to the Affimer reagents and any tests developed with them and has sole discretion to commercialise the reagents however it chooses.**

**Progress Update**

- Quantities of the Affimer binders to SARS-COV-2 spike protein are being manufactured by Avacta to be provided to Cytiva (and others) in the next few days.
- Cytiva aims to develop prototype lateral flow tests over the next few weeks.
- The test will then be clinically validated using patient samples at sites in the UK initially.
- Avacta aims to have validated and CE marked the test for professional and consumer use as soon as possible in the summer.
- Avacta has also announced a partnership with Adeptrix 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.

# Summary

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**Long term sustainable growth in shareholder value based on world-class therapeutic and diagnostic platforms**

- Proprietary platform technologies with broad applications in therapeutics and diagnostics.
- SARS-COV-2 rapid antigen test market is expected to lead to a very significant revenue stream which could fund Avacta's other programmes.
- Global therapeutic partnerships potentially worth $500m+ with further discussions ongoing.
- Pipeline of in-house Affimer therapeutics and diagnostics, and unique preCISION chemotherapies.
- Substantial near-term news flow anticipated.


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# Preliminary Results for the Period Ending 31st December 2019: Income Statement

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| | 2019 (£m) (17 months) | 2018 (£m) (12 months) |
|---|---|---|
| Revenue | 5.51 | 2.76 |
| Gross profit | 4.07 | 1.87 |
| Gross margin | 74% | 68% |
| R&D costs | (10.06) | (3.78) |
| Admin costs | (12.04) | (8.52) |
| Operating loss | (18.03) | (10.43) |
| Financial income | (0.02) | 0.04 |
| Taxation | 2.44 | 1.56 |
| Retained loss | (15.61) | (8.83) |
| Loss per share | 12.98p | 13.49p |

# Preliminary Results for the Period Ending 31st December 2019: Segmental Analysis

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| | Diagnostics (£m) | | Therapeutics (£m) | | Animal Health (£m) | |
|---|---|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 | 2019 | 2018 |
| Performance | | | | | | |
| Revenue | 0.81 | 0.34 | 2.52 | 0.85 | 2.18 | 1.57 |
| Gross profit | 0.36 | 0.21 | 2.23 | 0.62 | 1.48 | 1.04 |
| Gross margin | 44% | 60% | 89% | 73% | 68% | 66% |
| R&D costs | (2.22) | (0.67) | (7.24) | (2.65) | (0.60) | (0.46) |
| Admin costs | (4.27) | (3.14) | (3.05) | (1.50) | (1.86) | (1.26) |
| Operating loss | (6.13) | (3.60) | (8.06) | (3.53) | (0.98) | (0.68) |
| | | | | | | |
| Investment | | | | | | |
| Development costs capitalised | 1.66 | 1.58 | 0.00 | 0.00 | 0.22 | 0.36 |
| Plant and equipment | 0.10 | 0.19 | 0.50 | 0.35 | 0.02 | 0.02 |

# Preliminary Results for the Period Ending 31st December 2019: Cash Flow and Balance Sheet

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| | 2019 (£m) | 2018 (£m) |
|---|---|---|
| Operating activities | (13.72) | (7.11) |
| Working capital | (0.72) | 0.34 |
| Tax and interest | 1.43 | 1.30 |
| Investment | (2.53) | (2.52) |
| Financing | 19.11 | 0.04 |
| Net cash inflow/(outflow) | 3.57 | (7.95) |
| | | |
| Cash and deposits | 8.79 | 5.22 |
| PPE *(inc. IFRS16 property leases)* | 3.08 | 3.05 |
| Intangible assets | 11.80 | 12.20 |
| Other net assets/(liabilities) | 2.14 | 0.94 |
| Net assets | 25.81 | 21.41 |