Avacta

Affimer®

pre|CISION™

Interim Results for the 6 Months Period Ending 30th June 2020

September 28th 2020

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Introduction

Group Overview

Avacta®

LSE: AVCT ~£400M market capitalisation

Therapeutics Division

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

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

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)

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cytiva

ADEPTRIX

BBI™ ABINGDON HEALTH

Today's Team

Dr Alastair Smith, CEO

- Over 14 years experience as a life sciences public company CEO.
- Science background with 13 years in academia – established a leading UK biophysics group.
- Founded Avacta in 2006.
- World class scientific and technical knowledge with a highly commercial mindset.

Tony Gardiner, CFO

- Over 20 years senior financial and operational experience across multiple sectors.
- 4 years as CFO of AIM listed Fusion IP plc, 5 years as Finance Director of Aedas/AHR Architects.
- Joined Avacta in 2016.

Neil Bell, Chief Development Officer

- Neil is responsible for late stage pre-clinical and early clinical development of Avacta's pipeline of pre|CISION™ pro-drugs and Affimer® immunotherapies.
- Over 30 years' experience in the drug development industry, having held senior positions in global pharmaceutical companies and innovative biotechs including Eisai, Pfizer and Ipsen, Teva, Daiichi-Sankyo and Autolus.
- Extensive experience of designing and leading Phase I to III clinical studies.

Interim Results for the Period Ended 30 June 2020

Operational Highlights for the Period Ended 30th June 2020

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Therapeutics

- Established a joint venture in South Korea with Daewoong Pharmaceutical Co. Ltd., (KSX: 069620), a leading Korean pharmaceutical company, to develop the next generation of cell and gene therapies, incorporating Affimer proteins.
- Demonstrated initial proof-of-concept for its proprietary new class of drug conjugate, "TMAC™", in a pre-clinical animal model of cancer.

Operational Highlights for the Period Ended 30th June 2020

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Diagnostics

- Collaboration with Cytiva (formerly GE Healthcare Life Sciences) to develop a rapid test for the COVID-19 coronavirus antigen for mass population screening.
- Collaboration with Adeptrix (Beverly, MA, USA) to develop a high throughput Affimer-based antigen test ("BAMS™" test) to diagnose COVID-19 infection, to be used on hospitals' existing installed base of mass spectrometers.
- Exclusive distribution agreement announced with Medusa19 Limited ("Medusa19") for direct-to-consumer sales of a saliva-based rapid test for the SARS-CoV-2 spike protein antigen.
- Collaborative work with the Centre for Virus Research at the University of Glasgow showed that certain Affimer reagents which bind to the SARS-CoV-2 virus spike protein prevent infection of human cells by a SARS-CoV-2 model virus and therefore provide a potential therapy for COVID-19 infection.

Financial Highlights for the Period Ended 30th June 2020

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Financial highlights

- Fundraisings completed during the period raising £53 million to expand Diagnostics and Therapeutics programmes.
- Cash balances increased to £54.5 million (30 June 2019: £5.6 million; 31 December 2019: £8.8 million).
- Revenues increased to £1.8 million (6 months to 30 June 2019: £1.1 million; 17 months to 31 December 2019: £5.5 million).
- Operating loss £8.1 million (6 months to 30 June 2019: £6.6 million; 17 months to 31 December 2019: £18.0 million), with research and amortisation of development costs increasing to £4.2 million (6 months to 30 June 2019: £2.9 million; 17 months to 31 December 2019: £10.1 million).
- Increased R&D investment leading to reported loss of £7.0 million (6 months to 30 June 2019: £5.7 million, 17 months to 31 December 2019: £15.6 million).

Interim Results for the Period Ending 30th June 2020: Income Statement

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	6 months ended 30 June 2020 (£m)	6 months ended 30 June 2019 (£m)	17 months ended 31 December 2019 (£m)
Revenue	1.81	1.06	5.51
Gross profit	1.22	0.64	4.07
Gross margin	68%	60%	74%
R&D & Amortisation costs	(4.24)	(2.98)	(10.06)
Admin, Dep'n & SBP costs	(5.08)	(4.27)	(12.04)
Operating loss	(8.10)	(6.61)	(18.03)
Financial income/(costs)	(0.01)	0.00	(0.02)
Taxation	1.12	0.88	2.44
Retained loss	(6.99)	(5.73)	(15.61)
Loss per share	3.74p	5.12p	12.98p

Interim Results for the Period Ending 30th June 2020: Cash Flow and Balance Sheet

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	30th June 2020 (£m)	30th June 2019 (£m)	31st Dec 2019 (£m)
Operating activities	(5.48)	(5.12)	(13.72)
Working capital	1.08	(0.47)	(0.72)
Tax and interest	(0.01)	0.01	1.43
Investment	(1.02)	(1.43)	(2.53)
Financing	51.09	(0.07)	19.11
Net cash inflow/(outflow)	45.66	(7.08)	3.57
Cash and deposits	54.45	5.63	8.79
PPE	2.70	3.56	3.08
Intangible assets	12.02	12.86	11.80
Other net assets/(liabilities)	2.26	0.37	2.14
Net assets	71.43	22.42	25.81

Highlights Post-Period End

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Avacta Therapeutics

- Expansion of its collaboration and license agreement with Daewoong Pharmaceutical Co. Ltd. (KSX: 069620) and AffyXell Therapeutics, the joint venture established in South Korea by the two companies, to develop stem cell treatments incorporating Avacta's neutralising Affimer therapy for the treatment of seriously ill patients with COVID-19 and to also prepare to rapidly develop similar therapies for future global pandemics.
- Appointment of Neil Bell as Chief Development Officer of Avacta Life Sciences responsible for the late stage pre-clinical and early clinical development of Avacta's pipeline of pre|CISION pro-drugs and Affimer immunotherapies.
- Expansion of existing multi-target collaboration and development agreement with LG Chem Life Sciences (LG Chem), the life sciences division of the South Korean LG Group, to include new programmes incorporating Avacta's Affimer XT™ serum half-life extension system.

Avacta Diagnostics

- Appointed BBI Solutions, part of BBI Group ("BBI"), and Abingdon Health to manufacture the saliva-based rapid SARS-CoV-2 antigen test being developed with Cytiva.
- Commenced collaboration with the UK government's CONDOR programme to evaluate and clinically validate the high throughput COVID-19 bead-assisted mass spectrometry ("BAMS™") laboratory assay developed with Adeptrix (Beverly, MA, USA).
- Entered into a collaboration with the Liverpool School of Tropical Medicine ("LSTM") to provide clinical validation of the rapid, saliva-based coronavirus antigen test.
- Announced launch of an ELISA laboratory test for the SARS-CoV-2 spike protein to support global research efforts into the coronavirus that causes COVID-19.
- Collaboration with Integumen plc (AIM: SKIN) ("Integumen") to evaluate recently generated Affimer reagents that bind the SARS-CoV-2 spike protein for the detection of the coronavirus in waste water, to provide a real-time alert system to warn of localised COVID-19 outbreaks.


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Business Update

Key Near-term Value Drivers

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Multiple, significant near-term value drivers across the Group

1. Data from phase I clinical trial of AVA6000 Pro-doxorubicin
   - Aiming for UK regulatory filing (CTA) 4Q20
   - Anticipated dosing of first patient 1Q21
   - Initial data from mid-2021

2. SARS-CoV-2 rapid antigen test
   - Aiming for clinical validation 4Q20
   - Initial CE self-certification for professional use
   - CE marking for consumer self-testing running in parallel
   - Additional commercial opportunities for SARS-CoV-2 spike protein Affimers

3. Licensing and commercial partnerships both Dx and Tx
   - Core Dx business licensing opportunities
   - Partnering of therapeutic assets and/or new collaborative development partnerships

The pre|CISION™ Platform
Tumour Targeted Activation of Cancer Therapies

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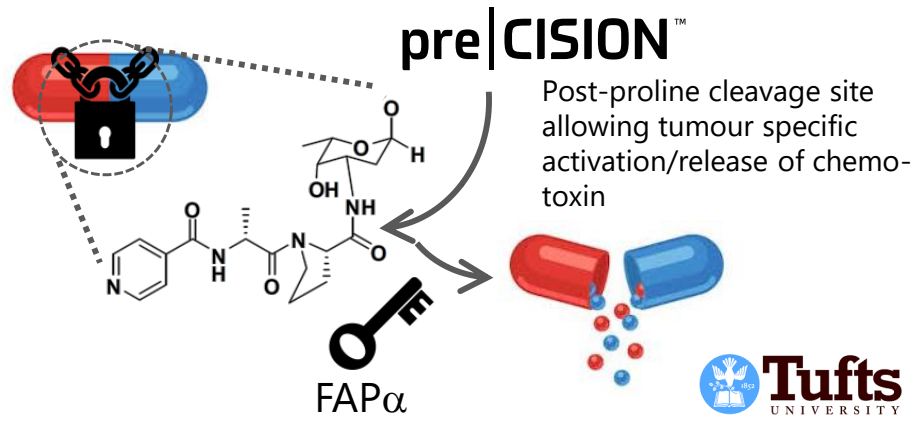
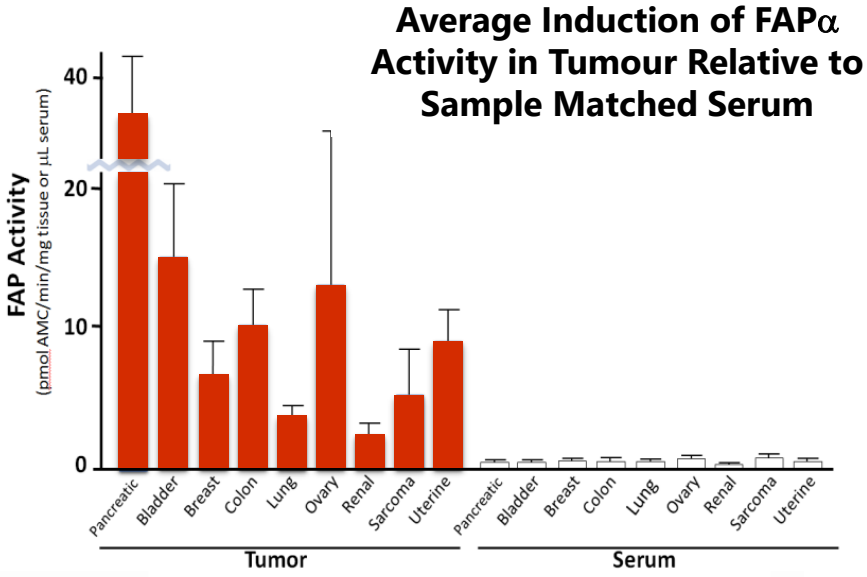
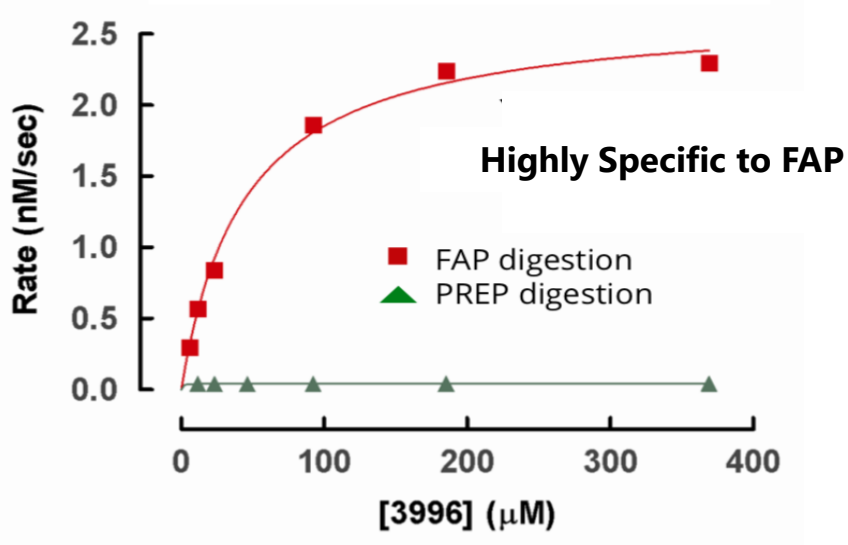
- **What is pre|CISION?**
- pre|CISION is a **highly specific** substrate for **fibroblast activation protein-α (FAPα), an enzyme** that is **highly upregulated in most solid tumours**
- pre|CISION prevents chemotoxins from entering cells **rendering them inert until activated in the tumour microenvironment** by FAP
- Pre|CISION can also be incorporated into a **drug conjugate linker for release of the warhead in the tumour microenvironment**
- Substrate exclusively licensed from Tufts University







pre|CISION Pro-drugs
AVA6000 Pro-doxorubicin

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AVA6000 addresses the safety issues of a $1bn generic chemotherapy

Background

Doxorubicin has been a standard of care treatment for advanced soft tissue sarcoma (ASTS) for 40 years.

Treatment is limited to six cycles due to cumulative cardio-toxicity.

Nevertheless, the global market for this generic drug is $1bn.

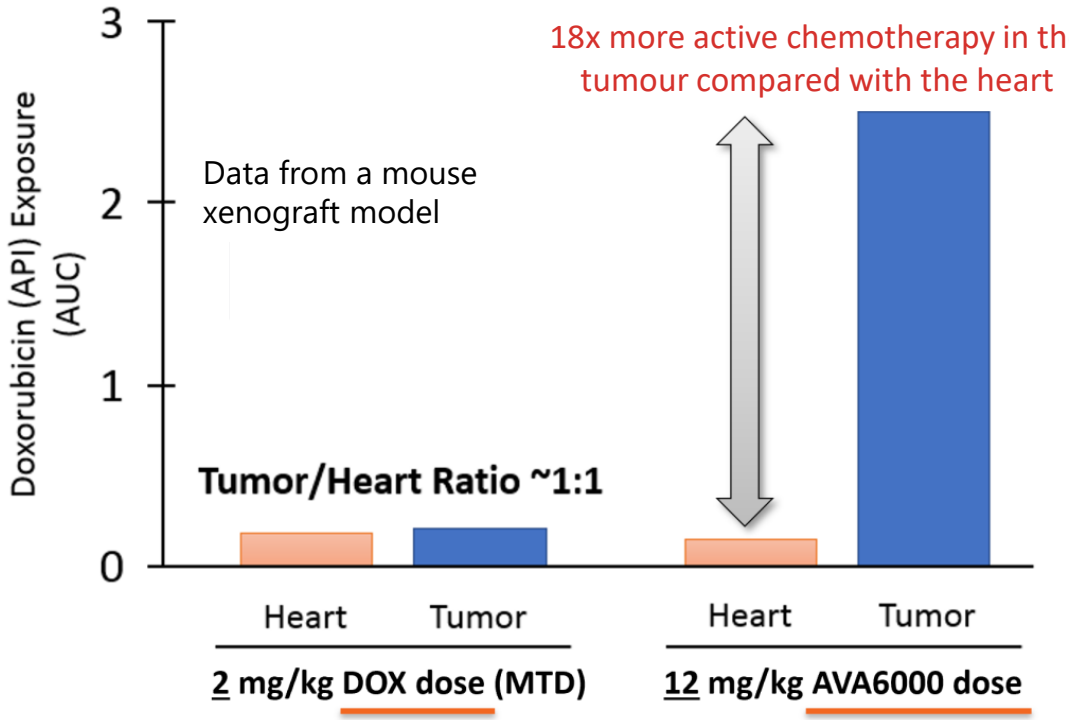
Improved safety could permit many more cycles of treatment per patient at the same dosing level.

AVA6000 Market Opportunity

For three indications only (ASTS, breast and ovarian cancer) peak sales for a safer/more efficacious form of dox in the US/EU alone is estimated to be **$1.5bn* pa with a 5-10% royalty to Avacta plus development milestones in near term.**

* Commercial Evaluation: AVA6000 (Globe Life Sciences, March 2020)

Targeting of Drug to Tumour Spares Heart Tissue



AVA6000 Phases I Design and Timeline

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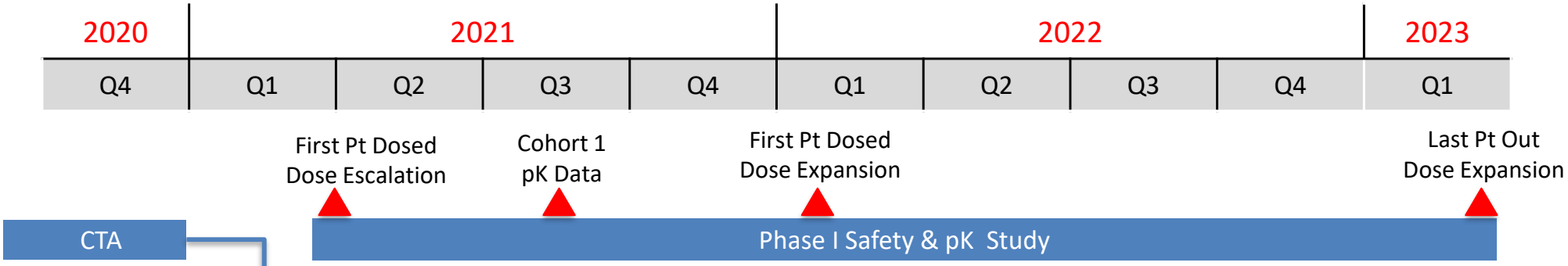

Phase I – Part A (Dose Escalation)

Part A

- **Objective:** Assess safety and tolerability of AVA6000; determine the MTD and/or recommended dose for further development
- Approximately 4 Cohorts to Achieve Maximum Tolerated Dose
- **15 to 20 patients**
- **Patient Population:** Locally advanced and/or metastatic breast, ovarian, pancreatic, non small-cell lung cancer and/or soft-tissue sarcoma

Phase I – Part B (Dose Expansion)

Part B

- **Objective: c**onfirm safety and tolerability of AVA6000 at the MTD (or recommended dose) determined in Part 1; explore preliminary anti-tumour activity
- **30 to 40 patients**
- **Patient Population:** determined based on Part 1 data; anticipated to be locally advanced and/or metastatic ovarian and/or soft-tissue sarcoma; previous anthracycline exposure ≤ 200 mg/m^2 dox permitted

MTD - Maximum Tolerated Dose

AVA6000 Phases I Design and Timeline

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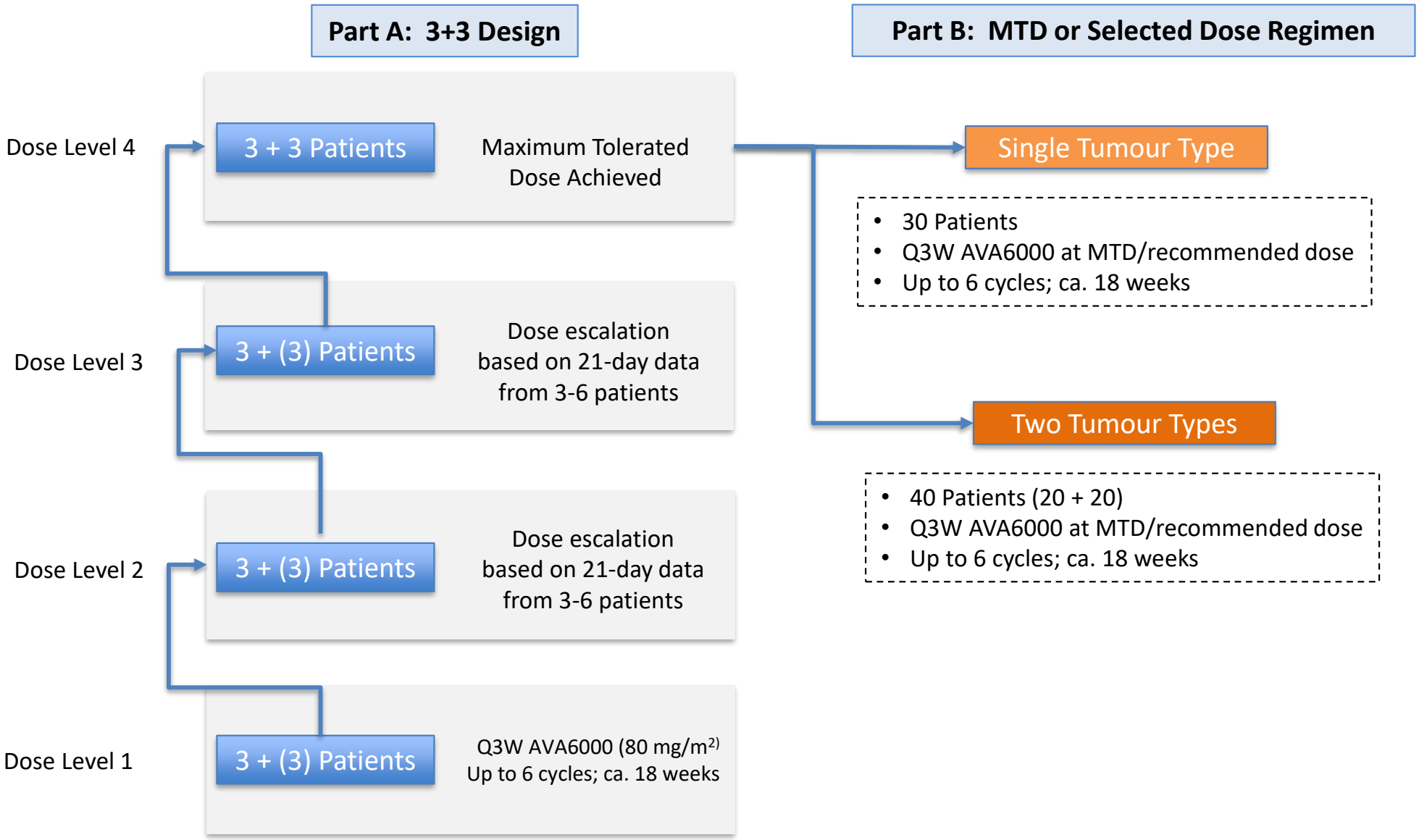

The Wider pre|CISION Pro-drug Opportunity

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pre|CISION can be widely applied to a range of other chemotherapies in a market worth $56.5B with CAGR of 11.50% driven by increased cancer detection rates

Example: Velcade

- Bortezomib (Velcade, Takeda Pharmaceuticals) had annual sales of $1.2bn (2018)
- **BUT – approval limited to multiple myeloma because of dose limiting toxicities,**
- **AND - coming off patent by 2022.**
- Pre-clinical development of AVA3996 pro-velcade will be restarted using placing proceeds.

Example: Taxanes

- Taxanes, such as the generic Paclitaxel, are used to treat a range of cancers such as prostate, breast and cervical.
- Paclitaxel has global sales of $2.96bn (2018) and is expected to generate revenue of $6.63bn by end of 2025.
- **BUT - significant toxicities, such as myelosuppression and peripheral neuropathy, limit the effectiveness of paclitaxel-based treatment regimens.**

Ideal for pre|CISION tumour activation to create safer and proprietary pro-drugs.

Conservatively assume the pre|CISION prodrug versions of these can achieve similar market sizes delivering 5-10% royalty to Avacta plus development milestones.

Potential for a pipeline of pre|CISION pro-drugs, some of which have already been synthesized, with an addressable market of many $bn pa.

Including but not limited to:

- preCISION Velcade
- preCISION Paclitaxel
- preCISION Oxaliplatin
- preCISION Gemcitabine
- preCISION Capecitabine
- preCISION PARP inhibitor
- preCISION PD-1 Inhibitor
- preCISION AKT inhibitor
- preCISION Balixafortide

SARS-CoV-2 Spike Affimer Reagents: Performance in ELISA Laboratory Test

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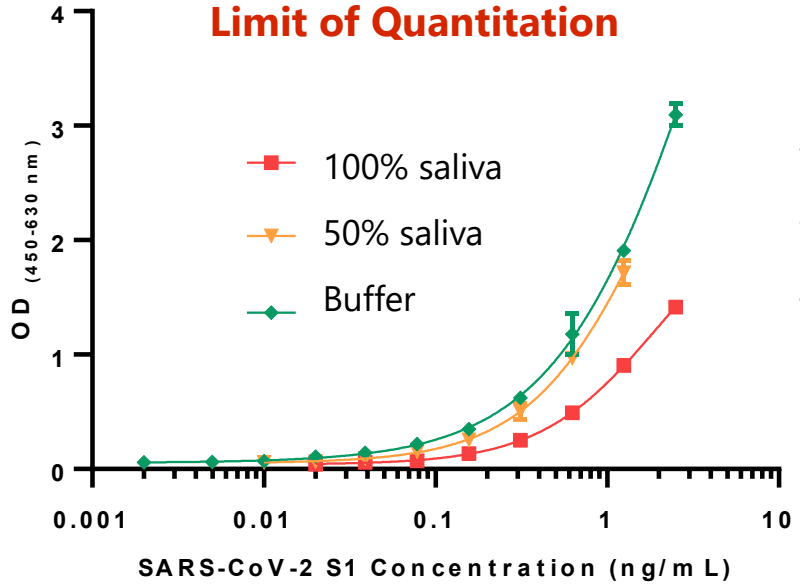
Excellent sensitivity and specificity in ELISA bodes very well for lateral flow test performance

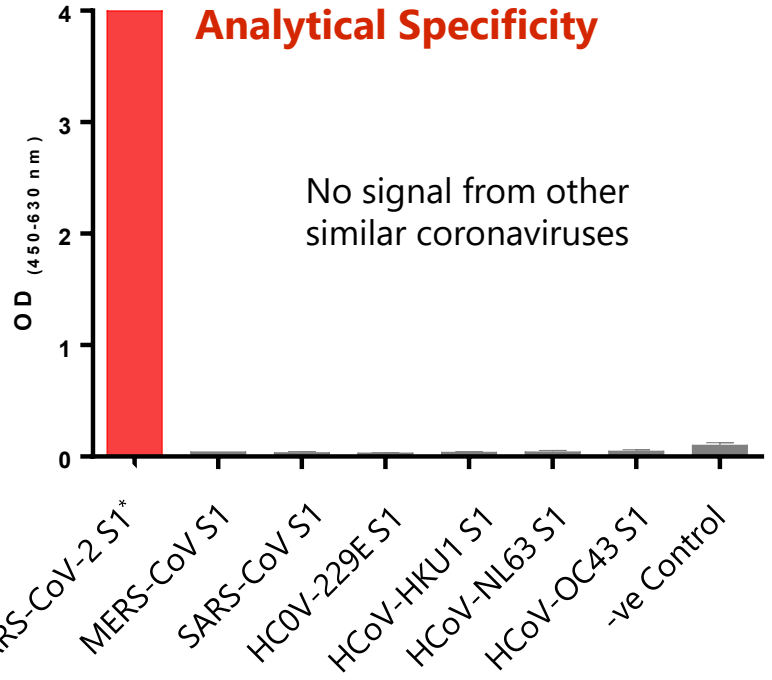
Limit of Quantitation



	Buffer	100% saliva
Upper Limit of Quantitation (ULOQ)	0.625 ng/mL	2.5 ng/mL
Low Limit of Quantitation (LLOQ)	5 pg/mL	40 pg/mL

Data acquired at Liverpool School of Tropical Medicine show that the ELISA test detects the presence of spike protein from live virus in saliva samples with as little as a few thousand virus particles per ml which is at the lower end of the infectious range.

Analytical Specificity



* Note: Including the D614G mutant of SARS-CoV-2 S1

For comparison:

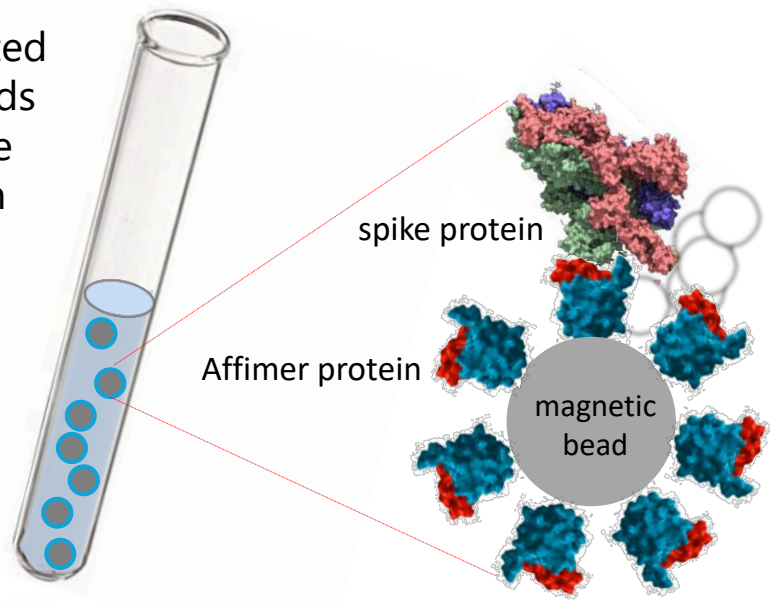
https://www.abcam.com/covid-19-spike-protein-elisa-kit-ab274342.html

LLOQ (in buffer) 2.7 ng/ml ~500x less sensitive

BAMS™ Assay Update

Affimer-based mass spectrometer assay for clinical microbiology laboratory use

1. Affimer coated magnetic beads capture spike protein from sample



2. Any captured spike protein is washed off beads and into BAMS sample plate for mass spectrometer analysis

3. Pattern recognition used to provide simple yes/no output

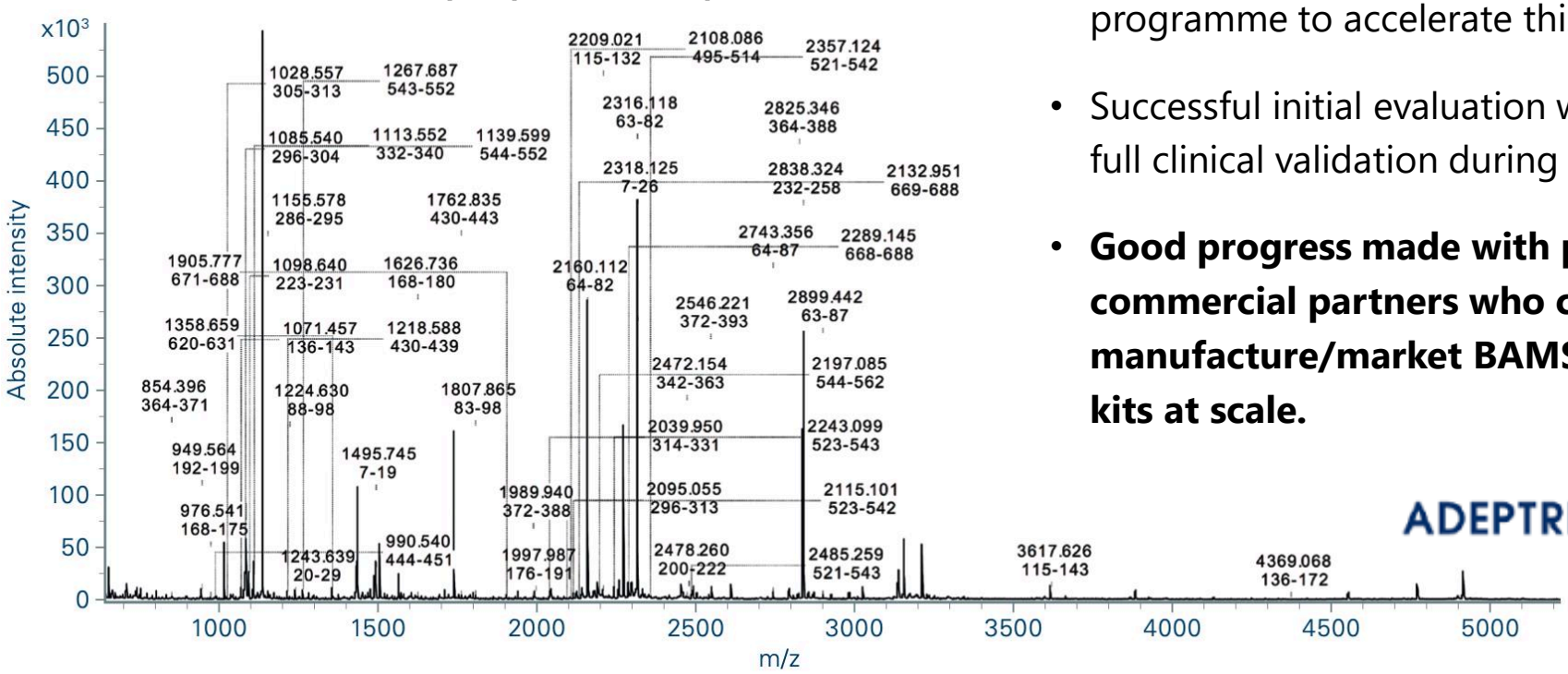
ADEPTRIX

BAMS™ Assay Update

Affimer-based mass spectrometer assay for clinical microbiology laboratory use

- **Highly sensitive** detection of the S1 spike protein of SARS-CoV-2 from as little as **one** bead.
- **Exquisite specificity** endowed by Affimer capture combined with mass spectrum fingerprint.

The S1 spike protein mass spectrum



- Engaging with clinical sites in the UK to carry out clinical validation of the BAMS assay developed with Adeptrix has been much slower than expected and we are working with UK government and the CONDOR programme to accelerate this.
- Successful initial evaluation will lead to full clinical validation during Q4.
- **Good progress made with potential commercial partners who can manufacture/market BAMS assay kits at scale.**

ADEPTRIX

SARS-COV-2 Rapid Antigen Test: Collaboration with Cytiva

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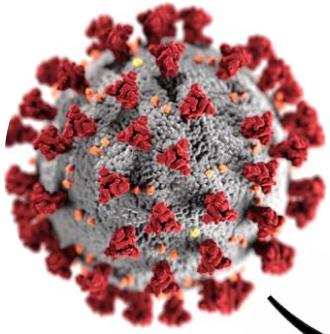
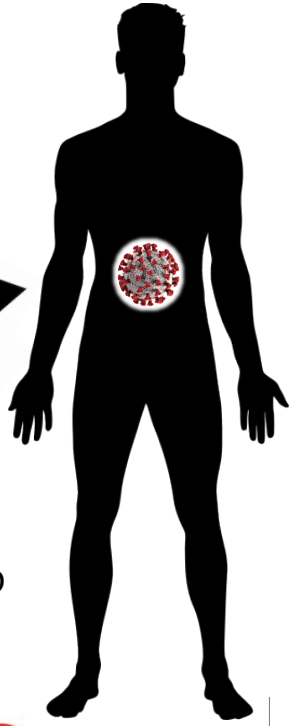
Have I **Got** COVID-19 ?
"Antigen Test"



Person infected with coronavirus



Saliva sample or NP swab

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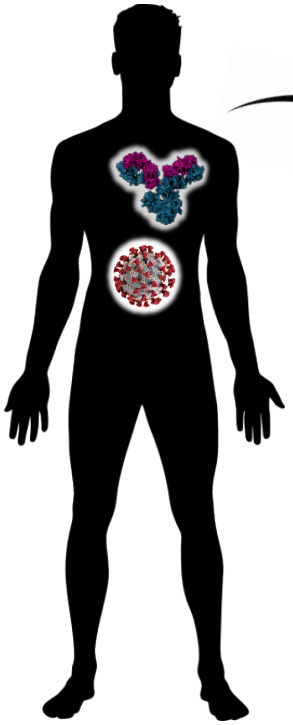
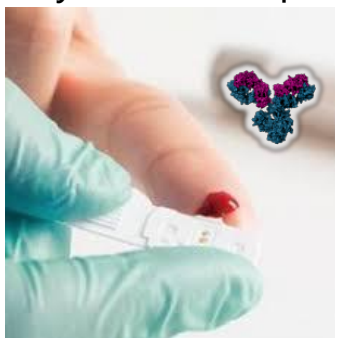
Results in 10-15 minutes
Some antigen tests beginning to emerge

7-14 days for the body to develop antibodies (IgG/IgM) against the virus[1].

Have I **Had** COVID-19 ?
"Antibody Test"



Usually blood sample



Results in 10-15 minutes.
Many "Antibody Tests" (IgG/IgM) available

1. Wolfel et al; Nature 2020 May;581(7809):465-469.

PCR vs Antigen vs Antibody

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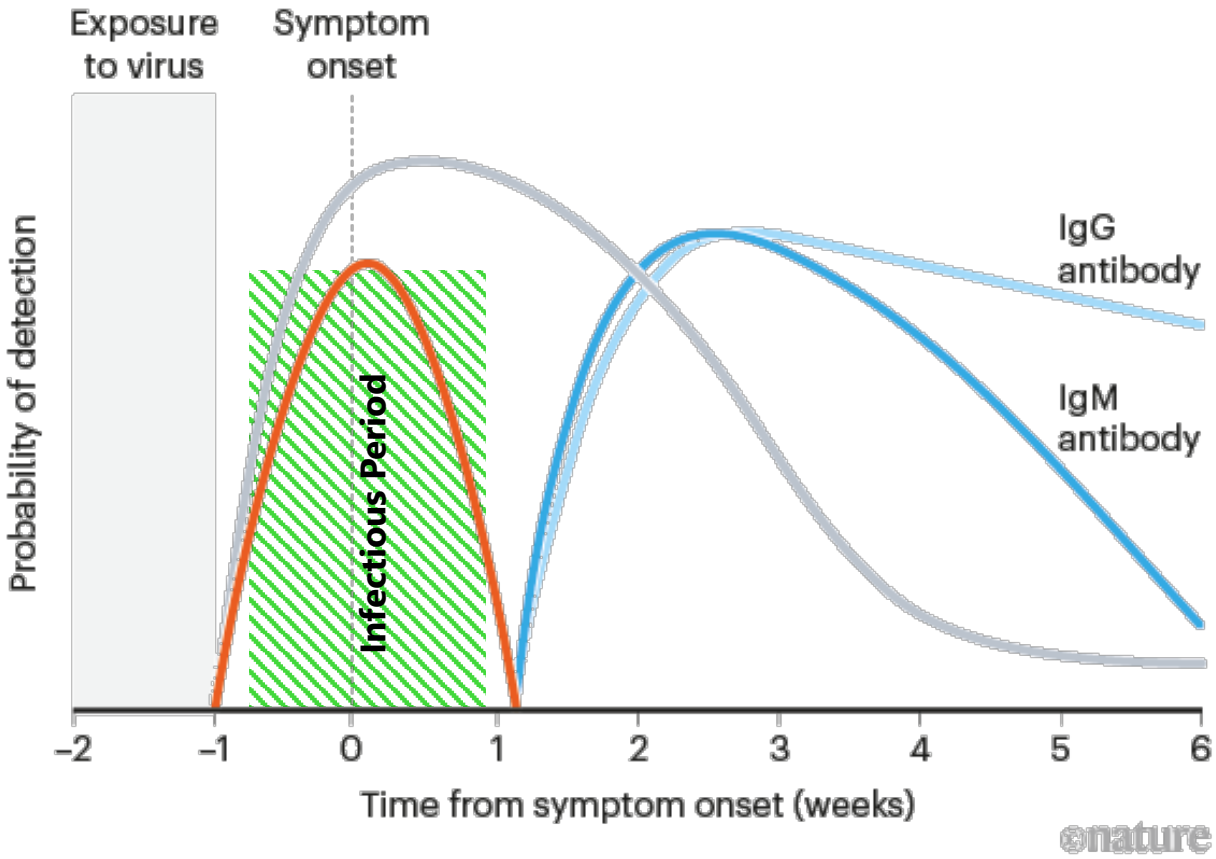
Testing for infectious individuals can only be done effectively using PCR or antigen tests



PCR- based tests can detect small amounts of viral genetic material, so a test can be positive long after a person stops being infectious.

Rapid antigen tests detect the presence of viral proteins and can provide screening test for the most infectious people.

Antibody tests detect the body's immune response to the virus and are not effective in the early part of the infection when people are most infectious.

https://www.nature.com/articles/d41586-020-02661-2#ref-CR1

Avacta's Lateral Flow Test Use Case: Infectious vs Infected

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The objective of rapid antigen tests for COVID-19 is to identify infectious individuals so that they can be isolated to reduce transmission

- Presence of the SARS-CoV-2 virus infectious material is highest in upper respiratory tract (nose and throat) early in the course of the disease for a couple of days before onset of symptoms and for 7-10 days after symptoms appear[1,2].
- During this period people are likely to be infectious.
- Pre-symptomatic transmission is thought to account for around 50% of infections[3].
- Truly asymptomatic transmission, i.e. by individuals who never show symptoms, has been difficult to quantify.

1. Lauer SA, Grantz KH, Bi Q et al. The Incubation Period of Coronavirus Disease 2019 (COVID-19). Ann Intern Med 2020 doi: 10.7326/M20-0504. 10.
2. Wolfel R, Corman V, Guggemos W et al Virological assessment of hospitalized cases of coronavirus disease 2019. doi: 10.1101/2020.03.05.20030502.
3. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/transmission

Avacta's Lateral Flow Test Use Case: Infectious vs Infected

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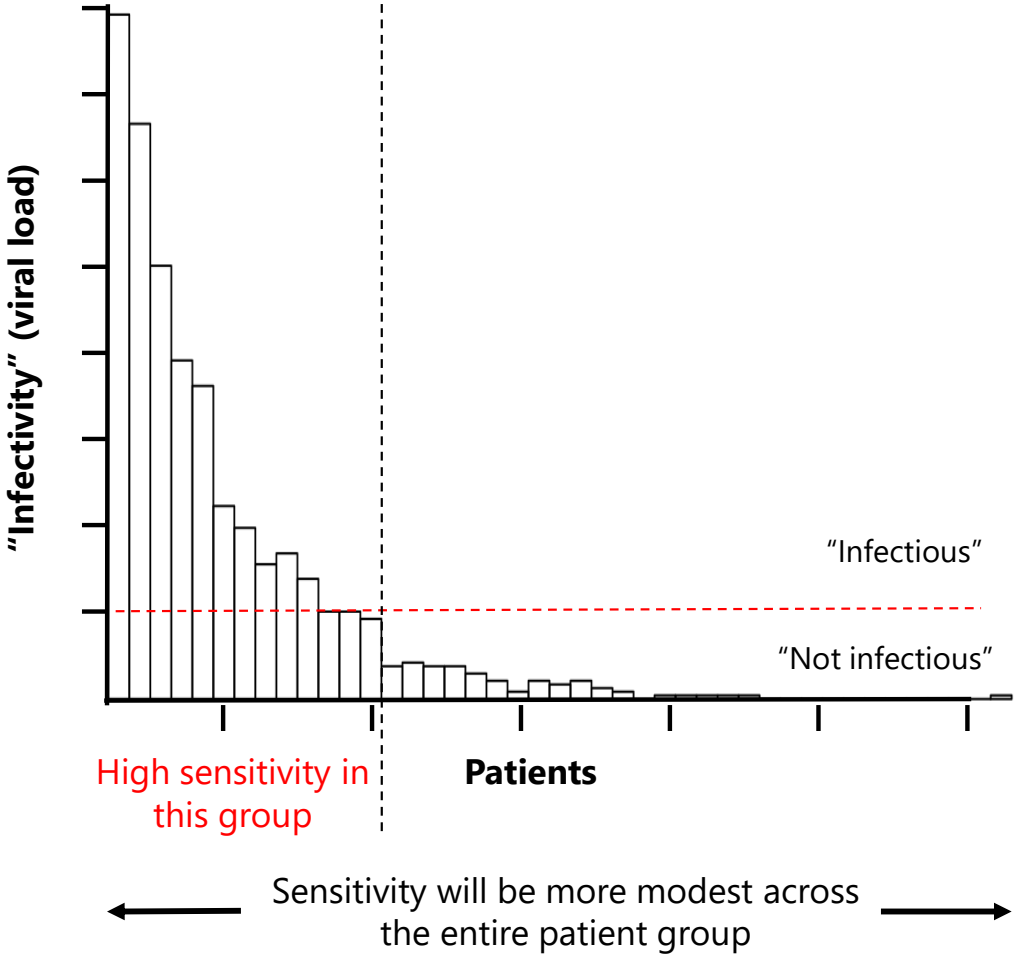
Mass screening to identify infectious people requires high specificity and high sensitivity within the infectious group



- Clear focus by authorities on frequent testing to identify infectious people[1-4].
- High specificity is essential to avoid very large numbers of false positives being referred for follow-up.
- Sensitivity must be high (>90%) within the infectious group.

1. National COVID-19 Test and Tracing Action Plan: The Rockerfeller Foundation, July 2020.
2. https://www.medrxiv.org/content/10.1101/2020.06.22.20136309v2 Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance Daniel B Larremore et al
3. https://blogs.jwatch.org/hiv-id-observations/index.php/rapid-inexpensive-home-testing-for-covid-19-may-get-us-out-of-this-mess-before-a-vaccine/2020/07/05/
4. https://www.healthaffairs.org/do/10.1377/hblog20200909.430047/full/

Avacta's Product Strategy

Self-certification for professional use first, followed by certification for consumer self-testing

"Professional Use" Case

- **Workplace**
- **Testing station**
- **GP surgery**
- Hospital

"Self-testing" Case

- **Home**
- **Workplace**

High Level Product Profile

- Saliva sample for ease of use.
- "Visual" read-out to avoid the need for a device which limits deployment.
- Smartphone app to provide objectivity, data connectivity and record of result.

novarum™ mobile reader solutions

BBI™

COVID-19 Testing Market: UK

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Avacta is addressing the very significant COVID-19 testing opportunity in UK first and will continue to scale manufacturing to meet global demand

- Effective disease control (R < 1) probably requires 30M people in the UK are tested/test themselves once per week: the potential UK only market size is ~120M tests per month.
- Therefore the commercial opportunity for Avacta is determined by supply capacity not demand.
- Supply capacity is dependent upon multiple factors including:
  - Raw materials supply (nitrocellulose strip (Cytiva), Affimer reagents (Avacta), other reagents.
  - LFD strip manufacture and assembly.
  - Plasticware (saliva collection tube, transfer pipette).
  - Test kit assembly and logistics.
- OEM deals have the potential to expand the commercial opportunity for Avacta.

Progress Update

Coordinating multiple third party workstreams on path to product launch

- Avacta is expanding its in-house Affimer production facilities and putting in place very large scale contract manufacturing partners; Affimer supply will not be a limiting factor and nor will nitrocellulose strip.
- Avacta has partnered with BBI Solutions and Abingdon Health to date, who can manufacture several millions of lateral flow test strips per month.
- UK strip manufacturing capacity needs to be scaled rapidly to address the anticipated volume requirements and additional capacity is being put in place overseas.
- Kit assembly is a challenge and partners in the UK have been identified and additional resources overseas are being put in place.
- Detailed discussions with regulatory authorities, governments and healthcare providers are ongoing but are strictly confidential.

Progress Update

Pilot batch production is the next key milestone

- The Affimer based lateral flow test developed with Cytiva is in the process of technology transfer to BBI Solutions.
    - This process involves scale-up of the manufacturing processes and optimisation of the performance of devices manufactured with the scaled up processes; the first pilot batch will be 10,000 units.
    - Clinical validation can only be conducted on devices made using the scaled-up process to satisfy CE regulations.
    - We expect clinical validation to be completed in Q4 dependent on pilot batch availability.
- The clinical validation and lay user studies are being designed with Liverpool School of Tropical Medicine.
- Completion of verification and validation will allow Avacta to self-certify for professional use, and completion of the lay user study, will lead to an audit by Avacta's notified body for CE marking for consumer use.
- **When the manufacturing development phase is completed and the pilot batch is available, the timeline to clinical validation, CE marking and product launch will be defined more precisely.**

Summary

Major value inflection points in the near term across the Group

- Therapeutics: some COVID related delays due to social distancing in labs at Avacta and at sub-contractors since the start of lock-down, but good progress has been maintained.
  - AVA6000 pro-doxorubicin aiming for CTA submission 4Q20 and first-patient-in 1Q21; planning for IND filing in US.
  - Partnered programmes all progressing well plus expansion of LG Chem agreement to include Affimer XT™ and expansion of Daewoong partnership to cover SARS-CoV-2 neutralising therapies.
  - In-house Affimer immunotherapy and pre|CISION pro-drug pipeline expansion underway.
- Diagnostics: good progress in bringing COVID-19 lateral flow antigen tests to market plus multiple additional COVID and core-business partnering opportunities.
  - Completion of first pilot batch of lateral flow tests is the next key milestone that will define time to market much more clearly.
  - Good engagement with authorities, regulators and healthcare providers.
  - BAMS clinical evaluation now beginning after long delays in the sample access process.
  - Significant additional third party commercial interest in spike protein Affimer binders (including several global IVD companies, bioprocessing companies and research reagents suppliers).
- Strong balance sheet to support core businesses and COVID opportunities.

Joint Broker and Nomad
FinnCap, London
Geoff Nash / Giles Rolls/ Tim Redfern
gnash@finncap.com tredfern@finncap.com
www.finncap.com
T +44 (0) 207 220 0500

Joint Broker
Zeus Capital, London
Nick Cowles, John Goold
nick.cowles@zeuscapital.com
john.goold@zeuscapital.com
www.zeuscapital.com
T +44 (0) 203 829 5000

US Investor Relations
TKDY Advisors, New York
Thomas Lawrence
Thomas@tkdyadvisors.com
www.tkdyadvisors.com

Yellow Jersey PR, London
Sarah Hollins / Henry WIlkinson
Avacta@yellowjerseypr.com
www.yellowjerseypr.com
T +44 (0)203 004 9512