Avacta Group plc

Avacta's preliminary results demonstrate that the company is making significant progress with its in-house therapeutic programmes and first-in-man clinical data for its flagship LAG-3/PD-L1 bi-specific therapy is expected in 2020. This is complemented by the company's growing pipeline of valuable therapeutic assets and an expanding range of partnerships which provide the potential for significant long term revenue growth.

Avacta's second therapeutic programme focused on the field of immuno-oncology (I-O) is progressing well. A LAG-3 inhibitor has enabled the company to leapfrog the planned clinical trial for a PD-L1 inhibitor and aim for first-time-in-human clinical data on a LAG-3/PD-L1 bi-specific therapy which is a potentially more valuable asset than a monotherapy alone. This programme is expected to be progressed on a similar timescale to the original plan and results are expected in 2020 barring major slippages.

Avacta has also completed the pre-clinical development of an Affimer based drug half-life extension technology caller Affimer XT™. This technology is based around combining an Affimer therapeutic, such as a PD-L1 inhibitor, with a larger protein based molecule so that the combined molecule is not as rapidly cleared from the body through the kidneys before the Affimer can bind to its target. Affimer XT™ could equally be used to extend the half-life of any small therapeutic molecule and the company is now exploring the licensing opportunities for this platform.

Avacta's discovery programme is also continuing to deliver a pipeline of earlier stage Affimer binders to other I-O targets for future partnering and development opportunities. In particular, the group in conjunction with Tufts University Medical School, has filed jointly for a patent for the innovative concept of combining an Affimer (with I-O active targeting) with a drug conjugate and releasing it into the tumour environment with the aim of delivering a cytotoxin (chemotherapy) that causes a large inflammatory response to recruit the immune system to kill the tumour cell. This is a highly novel approach which has already attracted attention from large pharma according to Avacta.

Avacta is also making solid progress with Iksuda Therapeutics (formerly Glythera) with initial work on drug conjugates leading to new drug development collaboration while in the field of gene delivery, the collaboration with Moderna has been extended to allow Moderna more time to evaluate the Affimer assets that Avacta has provided.

Avacta has also established gene delivery collaborations with OncoSec to develop innovative gene delivery of therapeutic Affimers and the company's collaboration with FIT Biotech has completed a proof-of-concept study with excellent data demonstrating sustained production of Affimer molecules by muscle tissue in mice.

Avacta made several key appointments during the financial year including highly experienced pharma/biotech professional, Dr Eliot Forster as Chairman. The company also augmented its US focused operations with a new Boston-based VP of Therapeutics Business Development and a Business Development team in the US with personnel located on both the east and west coasts. Avacta also intends to appoint a Chief Medical Officer within the coming months.

Post year end, Avacta raised net proceeds of £10.9m with which to invest in key areas across the whole business. Over £6m of these funds will be used to drive progress within the Therapeutics business targeting both in-house programmes and third party collaborations with the view to commercialising several near term opportunities. Combined with existing cash, we believe that Avacta has sufficient resources to expedite its plans through to 2020.

Stock Data

Share Price:	23.5p
Market Cap:	£27.1m
Shares in issue:	115.5m

Company Profile

Sector:	Healthcare
Ticker:	AVCT
Exchange:	AIM

Activities

Avacta is a biotechnology company which has developed the proprietary Affimer® technology platform, a unique engineered alterative 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 chart

Source: LSE

Turner Pope contact details

Turner Pope Investments (TPI) Ltd
6th Floor
Becket House
36 Old Jewry
London
EC2R 8DD

Tel: 0203 621 4120
Email: info@turnerpope.com
Web: www.turnerpope.com

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Barney Gray **Research analyst**
Tel: 0203 621 4120
barney@turnerpope.com

Financial results comment

Avacta reported revenue of £2.76m for the year ended July 2018, flat on the previous year. Revenue generated by the company's Affimer business, Avacta Life Sciences increased slightly by from £1.15m to £1.94m as the number of custom Affimer projects and funded FTE (full time equivalent) development projects transitioned during the year following the completion of a major funded FTE project and the transfer across to the customer's in-house development team.

Revenue from Avacta Animal Health, a legacy business, was broadly flat at £1.57m as the division re-focused on its core pet/equine allergy tests with certain non-core tests and services phased out gradually during the year.

Income statement summary, full year to July (£'000)

Income statement (Year-end July)	2017A	2018A
Life Sciences revenue	1,148	1,194
Animal Health revenue	1,587	1,569
Total revenue	**2,735**	**2,763**
Cost of sales	-941	-893
Gross profit	**1,794**	**1,870**
R&D	-2,597	-3,783
Admin	-7,178	-8,518
Operating profit	**-7,981**	**-10,431**
Finance income	88	41
Profit before tax	**-7,893**	**-10,390**
Taxation	1,526	1,561
Profit after tax	**-6,367**	**-8,829**

Source: Avacta, RNS

Operating costs

Avacta expensed £3.78m of research and development (R&D) costs in the year ended 31 July 2018 of which £2.64m related to costs associated with in-house Affimer therapeutic programmes. In line with other therapeutics based companies within the sector, these costs are expensed at the pre-clinical stages of development.

The company did capitalise £1.94m of development costs in the period and an amortisation charge of £1.14m was recognised against previously capitalised development costs derived from the custom Affimer reagents and diagnostics programme and new Animal Health allergy tests.

Administration costs increased from £7.2m to £8.5m as the scale of the Affimer business increased over 2018 and business operations including development, production and sales continued to grow. Within this cost base, depreciation was stable at £0.97m compared to £0.93m last year and an impairment charge of £0.82m was recognised against goodwill in relation to the Animal Health business following an impairment review as the company phased out non-core tests and services during the financial year.

A loss of £10.4m was offset partially by a tax credit of £1.56m in the full year. Avacta claims each year for R&D tax credits which, since it is loss making, it elects to surrender for a cash rebate. This reduced the loss after tax to £8.8m for the full year against a loss of £6.4m in 2017.

Cash flow and balance sheet

At the end of July 2018, the company reported cash and short term deposits of £5.2m compared to £9.2m at the end of July 2017. This cash movement was predominantly as a result of ongoing operating cash outflow which was approximately £6.8m in the year ended 31 July 2018. Additional to this, the company incurred slightly lower capital expenditure of £0.58m in 2018 (2017: £0.66m).

Net assets as of 31 July 2018 were £21.4m, down from £29.9m predominantly as a function of the reduced cash balances. The group remains debt free.

Balance sheet for year ended July (£'000)

Balance sheet (Year-end July)	2017A	2018A
Intangible assets	12,299	12,204
PPE	3,453	3,054
Total non-current assets	**15,752**	**15,258**
Inventories	158	187
Trade receivables	1,277	1,288
Income taxes	1,200	1,500
Short term deposits	4,000	0
Cash and cash equivalents	9,166	5,220
Total current assets	**15,801**	**8,195**
Total assets	**31,553**	**23,453**
Trade creditors	1,324	2,040
Contingent consideration	340	0
Total current liabilities	**1,664**	**2,040**
Total liabilities	**1,664**	**2,040**
Net assets	**29,889**	**21,413**

Source: Avacta, RNS

Post balance sheet events

Since the end of the financial year, Avacta completed a fundraising to raise net proceeds of £10.9m through the placing of a total of 46.5 million new shares at 25p per share. The placing was announced on 30 July 2018 although the funds were received during August 2018, post year end; boosting Avacta's cash balance substantially.

Avacta has earmarked these funds to enable the company to enter into new drug development partnerships, develop the Affimer therapeutic pipeline, licence Affimer reagents and also seek to achieve a clinic-ready candidate for first-in-man trials of its PD-L1/LAG3 bi-specific therapy.

The company intends to invest approximately £6.2m in its Therapeutics business of which £2m will be deployed into the PD-L1/LAG3 bi-specific programme during 2018/19. Avacta will also invest £1.2m into the PD-L1 Drug Conjugate programme in partnership with Tufts Medical Center (outlined in the next section of this report). A further £0.75m is earmarked for investment into the targeted agonists in order to achieve in-vivo pharmacology data in 2020 for partnering or development and £1.0m will be invested into the Avacta's discovery pipeline to continue to build the Affimer immuno-oncology (I-O) assets for future collaborative projects. Finally, Avacta has targeted £1.25m of investment in staffing costs related to the group's clinical and regulatory team which will include the appointment of a Chief Medical Officer, business development and long term IP protection.

On the Reagents side of the business, Avacta has outlined plans to deploy £3.3m of new funds, of which £0.8m will be devoted to business development. This investment will seek to deliver 10-20 royalty bearing licences by 2021, at least one major diagnostic licence deal with seven figure royalty potential and 50-100 paid for projects by 2021. Additionally, this investment will fund Avacta future attendance at industry conferences and exhibitions and a full time global business development team.

The company has indicated that it will spend £2.5m on further R&D to extend the pipeline of diagnostic Affimer assets for licensing and also grow the R&D team. At group level, a further £1.0m will be made available for capex, working capital and additional IP costs where they arise.

Five year financial summary

Full year ended July Item	FY 2014 £'000	FY 2015 £'000	FY 2016 £'000	FY 2017 £'000	FY 2018 £'000
Revenue	3,180	1,813	2,165	2,735	2,763
Profit before tax	-2,043	-5,541	-5,565	-7,893	-10,390
Profit after tax	-1,492	-4,893	-4,647	-6,367	-8,829
EPS (p)	-0.04	-20.09	-6.86	-9.31	-13.49
Net cash (debt)	11,480	7,330	19,521	13,166	5,220

Source: Company

Avacta's business model

Avacta's focus is its proprietary Affimer® technology, a novel engineered alternative to antibodies. Antibodies are blood proteins produced in response to and counteracting specific antigens. In particular, they combine chemically with substances which the body recognises as alien such as bacteria, viruses and foreign substances in the blood to trigger an immune response.

By contrast, Affimer technology is based on a much smaller human protein which can be developed quickly to bind with high specificity and affinity to a range of targets. Affimer proteins can be developed as therapeutic molecules and can be used in a wide range of other life sciences applications within research and diagnostics (a device or substance used for the analysis or detection of diseases or other medical conditions).

Developing the licencing model

Avacta is developing Affimer technology for both the therapeutic and non-therapeutic markets, focusing on building a profitable business through licensing Affimer reagents to research tools and diagnostics developers in order to power their own products. Coupled with this, Avacta is also developing a pipeline of Affimer therapeutic candidates for in-house development and licensing.

The management believes that Affimer technology is a disruptive, next generation platform for drug development and diagnostics and Avacta ultimately has the potential to take significant market share away from the $100 billion market currently dominated by the antibodies based platform.

Avacta has demonstrated the efficacy of Affimers since acquiring the technology in 2012 and the company's progress over the last five years has de-risked the platform to the point where Affimers are demonstrated to work well and often surpass the efficacy of antibodies in many applications.

Operational review

Affimer Therapeutics

Avacta has focused its investment in therapeutics within the field of immuno-oncology (I-O) due to the high levels of commercial interest in this sector. In particular, the company's therapeutic development strategy is focused on delivering three primary objectives. These are:

1. Progress the first Affimer into the clinic to demonstrate safety and tolerability in humans
2. Build a pipeline of commercially valuable Affimers for partnering
3. Secure long term partnering and licensing deals

Ultimately, the successful culmination of these objectives will enable the company to establish the Affimer technology as the next generation therapeutics platform which could attract a valuation on exit similar to its comparator, Ablynx, which was recently fought over by Sanofi and Novo Nordisk resulting in a $4.8bn acquisition by Sanofi.

Progress to the clinic

Avacta is making good progress towards the first in-human clinical trials for the Affimer technology platform in 2020. In particular, an Affimer inhibitor of PD-L1, one of the immune checkpoints, represents the company's lead programme and Avacta has already generated and characterised 50 Affimer binders to PD-L1. However, progress in the development of Affimer inhibitors of the immune checkpoint, LAG-3, has also been sufficiently positive for Avacta to leapfrog the first step of taking a simple PD-L1 inhibitor into the clinic and instead take a PD-L1/LAG-3 bi-specific into clinic trials. This is driven by evidence that a combined PD-L1/LAG3 asset has shown significantly greater reduction in tumour growth compared to anti-PD-L1 monotherapy alone.

Whilst the development of a bi-specific compared with a simpler PD-L1 inhibitor provides greater technical challenges to the company and there is potential for operational slippages, Avacta believes that the same timeline can be achieved in the development of a bi-specific solution leading to phase I clinical data in 2020/21.

Building a pipeline of drug assets

Beyond the development of PD-L1 and LAG-3, Avacta is developing a pipeline of Affimers specifically for partnering with third parties. In particular, the company along with Tufts University Medical School, has filed jointly for broad patent protection for the innovative concept of combining a drug conjugate that is released into a tumour environment with immuno-oncology active targeting. In tandem with Tufts, Avacta has developed a new class of targeted chemotherapy referred to as an 'Affimer drug conjugate' (AfDC).

This first example of this novel AfDC will combine to an Affimer inhibitor of the immune-checkpoint PD-L1, which is increased on many tumour cells, and serves to target the chemotherapy to the tumour with a toxin developed and clinically tested at Tufts. This combination is expected to have the effect of significantly improving response rates in cancer patients.

The concept of combining immune-checkpoint inhibitors with toxins that act in the tumour microenvironment is highly novel and can be applied to a wide range of different checkpoints and toxins. The Company has spoken with several large pharmaceutical companies about this new concept and has received very encouraging feedback leading management to believe that, with pre-clinical data in hand, it should be possible to secure early licensing deals.

In other developments, Avacta has achieved a key milestone in the completion of its pre-clinical development of an Affimer half-life extension technology called Affimer XT™. This technology is based around combining an Affimer therapeutic, such as a PD-L1 inhibitor, to a larger molecule that it not as rapidly cleared from the body via the kidneys, compared to smaller molecules, before the Affimer can bind to its target.

Avacta has already demonstrated good drug serum half-life of Affimers that are attached permanently to a portion of a larger antibody and by combining a PD-L1 inhibitor with Affimer XT™ in a bi-specific molecule, the serum half-life of the PD-L1 drug is also extended by piggy-backing on serum albumin. Consequently, Avacta notes that Affimer XT™ provides a powerful way of modulating the half-life of Affimer based drugs in addition to any third party protein or peptide therapeutic.

Long term partnerships

Avacta operates a strategy to focus its internal resources on a small number of programmes while utilising its partnership agreements in other areas and applications to generate data through third parties that could lead to future deals with larger pharmaceutical companies. One of the main areas that Avacta is operating this strategy is in the field of gene delivery.

The company has a research partnership with Moderna Therapeutics under which Avacta provides Affimer molecules for mRNA gene delivery. The group has worked on a number of targets with Moderna with the objective of providing Affimers that meet Moderna's specifications for mRNA delivery during 2018. This partnership has now been extended to allow Moderna more time to evaluate the Affimers that Avacta has provided.

During the last financial year Avacta also established two additional collaborations in the field of gene delivery with NASDAQ listed OncoSec and Finland's FIT Biotech Oy.

Avacta also notes that Affimers are ideal for creating conventional drug conjugates that have a well-established mechanism of action compared with the highly novel invention with Tufts described above. In a conventional drug conjugate a chemical toxin is linked to an Affimer, or antibody, that is used to target the toxin into a patient's tumour. The toxin is then internalized into the tumour cells with the intention of killing the tumour from within. Avacta is collaborating with Iksuda Therapeutics Ltd (formerly Glythera Ltd) to generate in vitro and in vivo packages for a drug conjugate using Iksuda's linkers and toxins.

The company is also partnered with Memorial Sloan Kettering Cancer Center in the US to demonstrate the potential for Affimers to replace the currently used antibody technology. Avacta is currently screening its Affimer library to identify a suitable candidate for targeting CAR-T cells to tumours and expects to provide Memorial Sloan with suitable Affimer molecules in the coming months.

Research Reagents and Diagnostics

Avacta is confident that Affimer technology has commercial and technical benefits in markets outside therapeutics and is making solid progress in securing licensing deals to generate long term revenue through the sale by third parties of products containing Affimers instead of antibodies. With several third parties currently evaluating the technology platform Avacta anticipates further licensing deals being announced over the remainder of 2018 and beyond.

In particular, Avacta is focusing on markets and applications where Affimer reagents are differentiated strongly from antibodies. In particular, this relates to diagnostics, bio-assays and affinity separations. For sensitive commercial reasons, a range of collaborative companies evaluating the Affimer platform in the US and Europe can't be named at this stage. However, two commercial users of Affimer reagents have already spoken publically about the success that they have seen with the Affimer technology platform over the last year.

Covance, part of LabCorp, has already presented data at an international conference in regard to anti-idiotypic Affimers and this success is helping Avacta generate a number of Affimer reagent projects with large pharma in this application area. In addition, Heptares, a subsidiary of Sosel Pharmaceuticals, has provided a testimonial for use in Avacta's business development meetings regarding its successful experience of using Affimers to bind to a class of drug target called GPCRs.

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