EDISON

Avacta Group

Interim results

ADC, partnerships as easy as one, two, three

Pharma & biotech

Avacta's 12-month results to July 2019 highlight ongoing momentum, as evidenced by three new partnerships (LG Chem, ADC Therapeutics and New England Biolabs), advancement of its pipeline towards the clinic and robust revenue growth in its research and diagnostic reagents division. Avacta recently announced a multi-target (focused on cancer) collaboration and licensing agreement with ADC Therapeutics to develop Affimer drug conjugates, providing further validation for Avacta's technology. Avacta's pro-doxorubicin compound AVA6000 (utilising Tufts' linker technology) is expected to start clinical trials in Q220, while lead Affimer AVA004 (PD-L1) is shortly expected to complete cell line development. We value Avacta at £47m or 40p/share.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
07/17	2.7	(7.9)	(9.8)	0.0	N/A	N/A
07/18	2.8	(10.4)	(13.5)	0.0	N/A	N/A
12/19e	4.5	(11.1)	(8.1)	0.0	N/A	N/A
12/20e	4.5	(12.7)	(9.3)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

New partnerships highlight strong momentum

In the partnership with ADC, Avacta will select the Affimers, after which ADC will be responsible for all preclinical research in relation to the creation of Affimer drug conjugates and subsequent clinical development. As all R&D costs are covered by ADC, Avacta benefits from limited upfront financial risk, with potential upside from the option on each target that could provide long-term milestones and royalties. This partnership adds to multiple deals signed in the past 12 months, including a notable collaboration with LG Chem worth more than $300m (plus royalties) to develop a range of therapeutic Affimers. Also in H119, Moderna exercised its option on an Affimer developed in partnership with Avacta.

Assets hitting milestones on the way to the clinic

Avacta's pro-doxorubicin compound AVA6000 (utilising Tufts' FAPα cleavable linker) has demonstrated positive data in preclinical models that support its path to the clinic. Avacta plans to submit an IND (to treat soft tissue sarcomas) by end of Q120 to begin patient dosing (n=15) in Q220. Initial data are currently forecast for the second half of 2020. Cell line development of AVA004 (PD-L1 Affimer) is expected to complete shortly while pre-clinical development and IND-enabling studies will be paused while the company focuses its resources on rapidly moving AVA6000 into the clinic. AVA004/100, which combines AVA004, FAPα cleavable linker and I-DASH toxin, is set to generate first animal efficacy data by year end.

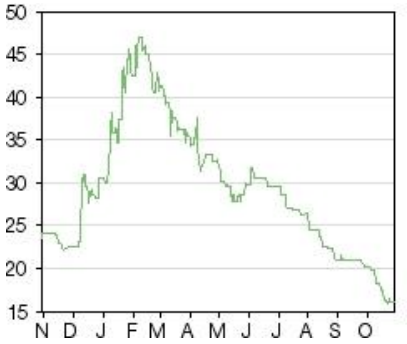
Valuation: £47m or 40p/share

We value Avacta at £47m (or 40p/share) vs £51m (or 44p/share) previously. The reduction is due to lower net cash. In addition, we have rolled forward our model and updated for FX. We do not currently include in our valuation the proposed share issue of 59.8m shares at 15p/share, which should raise gross proceeds of up to £9m. The share issue will be voted on at the upcoming AGM on 4 November.

29 October 2019

Price	**16p**
Market cap	**£19m**
	$1.30/£, €1.16/£, €0.90/$
Net cash (£m) at end July 2019	6.51
Shares in issue	116.2m
Free float	78.9%
Code	AVCT
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(21.0)	(39.1)	(31.9)
Rel (local)	(20.3)	(37.7)	(35.9)
52-week high/low		47p	16p

Business description

Avacta is focused on the development of its Affimer technology for use in therapeutic and diagnostic/reagent applications. Assets include AVA004 (PD-L1), AVA021 (PD-L1/LAG-3) and AVA004/100 (PD-L1/I-DASH).

Next events

AVA017 LAG-3 candidate selection	End 2019
AVA004/100 TMAC animal model POC	End 2019
AVA6000 IND application	Q120

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Edison profile page

Therapeutic pipeline: Clinical data by end 2020

Avacta is progressing its therapeutic Affimers towards the clinic through both in-house programmes and with partners. It has selected a clinical candidate for its lead Affimer (AVA004) programme and is expected to shortly complete cell line development. Following the announcement of a proposed £9m capital raise, focus will now be on the clinical development of AVA6000 (pro-doxorubicin) in 2020. As a result of this, the GMP production and IND-enabling studies for AVA004 will be paused. The potential of the Affimer technology lies in its formatting capabilities, particularly in the creation of bispecific and TMAC (Tissue Microenvironment-Activated Conjugates) Affimer drug conjugates (AfDC). Avacta's first bispecific to enter the clinic will be its PD-L1/lymphocyte activation gene 3 (LAG-3) product candidate (AVA021), which we forecast will start clinical development from 2022.

The first of Avacta's TMAC Affimer drug conjugates to be tested will be AVA004/100, which utilises the AVA004 PD-L1 Affimer linked to an I-DASH toxin with a novel fibroblast activation protein (FAPα) cleavable linker. In addition to the aforementioned clinical development plan for AVA004, Avacta plans to test the FAPα cleavable linker in the clinic before utilising it as part of an AfDC. Together with Tufts University, a clinical trial will commence in 2020 testing the FAPα cleavable linker attached to pro-doxorubicin. Doxorubicin is a well-known and commonly used chemotherapy drug for many cancers. However, like most chemotherapeutic agents, its use is often limited by an unfavourable safety profile. As doxorubicin is administered systemically, it attacks healthy cells throughout the body (by blocking topoisomerase, an enzyme used in the replication of cells), which leads to various side effects including cardiotoxicity (heart failure). Pro-doxorubicin (AVA6000) aims to limit these adverse events as it is inactive in its administered form and will only become activated on the cleaving of the attached FAPα linker. Based on preclinical data so far, this linker has been shown to be predominately activated in the tumour microenvironment, which should lead to a localised, tumour-specific activation of doxorubicin.

To test the effect of AVA6000 on cardiotoxicity, a mouse model was dosed with classical doxorubicin and pro-doxorubicin (AVA6000). Results demonstrated that classical doxorubicin was distributed 1:1 between the tumour and heart, while activated doxorubicin from AVA6000 was distributed 18:1. These early data are promising and show the potential for an improved safety profile. This could allow for improvement in patient outcomes (compared with classical doxorubicin) as patients experience less serious safety problems and are able to remain on treatment for longer. Additionally, an improved safety profile (compared with classical doxorubicin) could potentially expand the eligible patient population, for example to include older patients who were unable to be treated with classical doxorubicin due to cardiotoxicity concerns. Additionally, at 60 days, 100% of mice treated with AVA6000 were alive compared with 0% treated with classical doxorubicin.

Avacta plans to submit an IND for AVA6000 by end Q120, potentially enabling dosing of the first patient by the end of Q220. Initial clinical data could then be available in H220. Avacta is now actively promoting AVA6000 to potential licensees to ensure prompt execution of any potential deal post Phase I data readout.

Partners: Therapeutic potential being recognised

Avacta continues to increase the number of partners, notably with therapeutic applications, demonstrated by the recent collaboration with ADC Therapeutics. The potential of Affimers, particularly in relation to formatting capabilities, is proving a key attraction to partners. An overview of all current active partnerships can be found in Exhibit 1 below.

Exhibit 1: Current active partners

Partner	Notes
ADC Therapeutics	In October 2019, Avacta announced a collaboration and licensing agreement with ADC Therapeutics to develop multiple Affimer drug conjugates. The conjugates will combine Avacta's Affimers with ADC's pyrrolobenzodiazepine (PBD) dimer warhead and linker technology. The collaboration is multi-target and will aim to generate Affimer binders to three undisclosed cancer targets. PBDs are potent toxins that have been shown to actively kill cancer cells in preclinical models, and the technology is being tested by ADC in multiple late-stage clinical trials. ADC will be responsible for all preclinical research and development except for Affimer selection, which will be carried out by Avacta. The agreement includes an option on each target to gain an exclusive clinical and commercial licence. Avacta will also be eligible to receive option fees, development and commercial milestones and single-digit royalties. Additionally, ADC will cover Avacta's costs during the collaboration. No further financial details were announced.
LG Chem Life Sciences	In December 2018, Avacta announced a partnership with LG Chem Life Sciences to develop therapeutic Affimers for multiple targets. Avacta is responsible for generating Affimers to the undisclosed targets and for early optimisation work. Both parties will then collaborate to progress the candidates through to drug candidate selection, after which LG Chem will be responsible for all preclinical and clinical development in addition to worldwide marketing. LG Chem aims to have the first clinical trial regulatory submission in 2021. At H119 results, further financial information on the deal was disclosed. The deal included an upfront payment of $2.5m, near-term milestone payments of $5.5m and long-term clinical milestones of $180m. LG Chem will reimburse Avacta for any incurred R&D costs associated with the collaboration and pay Avacta royalties on any potential future product sales. In addition, if LG Chem exercises its option for additional targets, Avacta will be eligible to receive up to $130m in option fees and milestones.
Moderna	In May 2015, Avacta entered into a licensing partnership ($500,000 upfront) with Moderna Therapeutics to develop Affimers for undisclosed targets. Under the terms of the agreement, Moderna has exclusive access to the Affimer technology for certain targets and Moderna is able to extend the partnership to other targets. Moderna was also liable to pay Avacta for R&D relating to preclinical work. In February 2019, Moderna opted in on an undisclosed target that granted the company an exclusive product licence. Under the terms of the agreement, Avacta can now potentially receive clinical development milestones and royalties (on potential future sales) on the asset. The scope and size of any milestones are undisclosed and we have no information regarding when clinical development will initiate or if it will at all.
OncoSec	In January 2018, Avacta and OncoSec entered into a collaboration to develop gene therapy delivery of therapeutic Affimers. OncoSec's gene delivery technology, ImmunoPulse, has clinically demonstrated safe and efficient delivery into a patient's tumour in previous clinical trials. The collaboration will test whether ImmunoPulse can deliver clinically relevant concentrations of Affimers including AVA04 (PD-L1) in in-vivo tumour models.
Memorial Sloan Kettering Cancer Center (MSK)	In November 2016, Avacta entered into a research collaboration with MSK to use Affimers for CAR-T therapies. The collaboration is led by Renier J. Brentjens, MD, PhD, director of cellular oncology and was originally focused on developing Affimer CAR-T cells that target CD19. Generating Affimers to CD19 proved problematic, research has now shifted to finding binders to CD22.
New England Biolabs	In October 2018, Avacta agreed an Affimer reagent licensing deal with NEB to commercialise a product incorporating the Affimer technology. The product is for use in both life science research and diagnostic assays and is in final stages of product testing. Under the terms of the agreement Avacta will receive royalties on sales (may occur as soon as 2019). NEB and Avacta will continue its collaboration with the aim to generate further products.
Tufts/Bach Biosciences	In July 2018, Avacta announced a collaboration with Bach Biosciences, a company founded on the research of William Bachovchin at Tufts University School of Medicine, Boston. The collaboration aims to develop novel AfDC using Tufts' novel linker chemistry that is designed to release attached drugs in only a tumour. The first proof-of-concept AfDC will involve the use of a PD-L1 Affimer and an I-DASH small molecule inhibitor. AVA004/100 (PD-L1/I-DASH) is now in discovery.

Source: Avacta

Research and diagnostic reagents growth

Avacta's Affimer research and diagnostic reagents division revenue plus order intake grew 130% to £1.2m over the 12 months to 31 July 2019 compared with the previous 12-month period ending July 2018. Avacta also signed a deal with New England Biolabs (NEB) to commercialise a product for use in both life science research and diagnostic assays. NEB is currently field testing the product with customers.

Avacta continues to be involved in multiple paid-for technology evaluations and custom Affimer service projects that may lead to licensing deals, including:

- Seven diagnostic evaluations, four of which are with top 10 in vitro diagnostic companies.
- 14 projects with pharma/biotech, including four of the top 10 large pharmaceutical companies.
- Two evaluations with bioprocessing companies, one of which is a global leader in affinity purification.

To speed up the licensing deal timelines, Avacta is now developing an internal pipeline of Affimer diagnostic assays. It plans to have two assays complete by year end (D-dimer and estradiol assay).

Valuation: £47m (or 40p/share)

We value Avacta at £47m (or 40p/share) vs £51m (or 44p/share) previously. The reduction is due to lower net cash. In addition, we have rolled forward our model and updated for FX. Our valuation is based on a sum-of-the-parts model including risk-adjusted NPVs (rNPVs) of AVA021 (PD-L1/LAG-3 bispecific) of £24.8m and the LG Chem research partnership (£8.2m), and a peer valuation of both its reagents and animal health divisions (c £7.2m), in addition to adding net cash (£6.5m).

Exhibit 2: Avacta sum-of-the-parts valuation

	Therapeutics	Reagents/diagnostics	Animal health	Net cash	Total
Total (£m)	33.01	3.12	4.12	6.51	46.76
Per share (p)	28.42	2.69	3.55	5.60	40.25

Source: Edison Investment Research

We do not currently include in our valuation the proposed share issue of 59.8m shares at 15p/share, which is expected to raise gross proceeds of up to £9m. The proposed share issue will be voted on at the upcoming AGM on 4 November. For a detailed overview of our valuation, please see our initiation note, Affimer - potential best-in-class antibody mimetic.

Financials: Funding to be extended into 2021

We note that, as stated at the January 2019 interims, the financial year end is changing from 31 July to 31 December. While our forecasts are based on a December year end, our historic financials remain based on a July year end and we wait for Avacta to restate them.

Due to the change in year end, unless otherwise stated all numbers are for the 12-month period ending 31 July 2019. Revenue was £4.1m, a 49% increase (£2.8m) over the previous 12-month period ending 31 July 2018.This was mainly driven by a change in accounting policy (IFRS 15), which meant the LG Chem $2.5m (£1.96m) upfront – originally spread over three years – will be fully recognised upfront. While the deal was signed in December 2018, we currently assume in our forecasts that the upfront was received in early 2019. Life sciences revenue grew to £2.6m due to the $2.5m LG Chem upfront, while animal health revenue decreased slightly to £1.5m vs £1.6m previously.

Admin expenses remained essentially flat but continue to be one of the biggest contributors to the cost base at £8.5m. Admin expenses include costs associated with business development, operational delivery, administration, facilities, depreciation and share-based payment charges. R&D costs increased substantially to £5.9m (vs £3.8m previously) as a result of increased investment in the Affimer therapeutics programmes. COGS were flat at £0.9m. We forecast 2019 (December year-end) administrative costs of £8.6m, COGS of £0.9m and R&D of £6.2m. We forecast a 2019 net loss of £9.5m.

Net cash at 31 July 2019 was £6.5m. Avacta's proposed share issue (of 59.8m shares at 15p/share) should enable funding into early 2021. We do not currently include the capital raise in our financial forecasts (and retain our illustrative £10m debt raise in 2020) as we await its completion to confirm the total number of shares issued and capital raised. Avacta has suggested that £6.5m of the proposed funding will be used for the Phase I trial of AVA6000 (pro-doxorubicin) and to continue related business development activities. Avacta plans to invest the remaining £2.5m in the continued growth of the Affimer reagents business and development of the internal pipeline of Affimer-based diagnostic tests.

Exhibit 3: Financial summary

Accounts: IFRS, year-end: December, £000s	2017*	2018*	2019e**	2020e
INCOME STATEMENT				
Total revenues	2,735	2,763	4,480	4,531
Cost of sales	(941)	(893)	(896)	(906)
Gross profit	1,794	1,870	3,584	3,625
SG&A (expenses)	(7,178)	(8,518)	(8,603)	(8,689)
R&D costs	(2,597)	(3,783)	(6,158)	(7,630)
Other income/(expense)	0	0	0	0
Exceptionals and adjustments	0	0	0	0
Depreciation and amortisation	0	0	0	0
Reported EBIT	(7,981)	(10,431)	(11,177)	(12,694)
Finance income/(expense)	88	41	45	35
Other income/(expense)	0	0	0	0
Exceptionals and adjustments	0	0	0	0
Reported PBT	(7,893)	(10,390)	(11,133)	(12,659)
Income tax expense (includes exceptionals)	1,526	1,561	1,673	1,902
Reported net income	(6,367)	(8,829)	(9,460)	(10,757)
Basic average number of shares, m	65.2	65.4	116.2	116.2
Basic EPS (p)	(9.8)	(13.5)	(8.1)	(9.3)
BALANCE SHEET				
Property, plant and equipment	3,453	3,054	2,760	2,542
Goodwill	0	0	0	0
Intangible assets	12,299	12,204	12,256	12,301
Other non-current assets	0	0	0	0
Total non-current assets	15,752	15,258	15,016	14,843
Cash and equivalents	9,166	5,220	5,689	4,462
Inventories	158	187	188	190
Trade and other receivables	1,277	1,288	2,088	2,112
Other current assets	5,200	1,500	1,912	2,552
Total current assets	15,801	8,195	9,877	9,316
Non-current loans and borrowings	0	0	0	10,000
Other non-current liabilities	0	0	0	0
Total non-current liabilities	0	0	0	10,000
Trade and other payables	1,664	2,040	2,047	2,070
Current loans and borrowings	0	0	0	0
Other current liabilities	0	0	0	0
Total current liabilities	1,664	2,040	2,047	2,070
Equity attributable to company	29,889	21,413	22,846	12,089
Non-controlling interest	0	0	0	0
CASH FLOW STATEMENT				
Profit for the year	(6,367)	(8,829)	(9,460)	(10,757)
Taxation expenses	(1,526)	(1,561)	(1,673)	(1,902)
Profit before tax	(7,893)	(10,390)	(11,133)	(12,659)
Net finance expenses	(88)	(41)	(45)	(35)
EBIT	(7,981)	(10,431)	(11,177)	(12,694)
Depreciation and amortisation	1,583	2,856	2,771	2,708
Share based payments	386	308	0	0
Other adjustments	11	161	(1)	(1)
Movements in working capital	(73)	336	(794)	(3)
Interest paid / received	88	41	45	35
Income taxes paid	1,745	1,261	1,261	1,261
Cash from operations (CFO)	(4,241)	(5,468)	(7,896)	(8,693)
Capex	(658)	(578)	(584)	(590)
Acquisitions & disposals net	0	0	0	0
Other investing activities	4,530	2,055	(1,945)	(1,945)
Cash used in investing activities (CFIA)	3,872	1,477	(2,529)	(2,535)
Net proceeds from issue of shares	14	45	10,893	0
Movements in debt	0	0	0	10,000
Dividends paid	0	0	0	0
Other financing activities	0	0	0	0
Cash from financing activities (CFF)	14	45	10,893	10,000
Currency translation differences and other	0	0	0	0
Increase/(decrease) in cash and equivalents	(355)	(3,946)	469	(1,228)
Currency translation differences and other	0	0	0	0
Cash and equivalents at beginning of period	9,521	9,166	5,221	5,689
Cash and equivalents at end of period	9,166	5,221	5,689	4,462

Source: Company accounts, Edison Investment Research. Note: *July year end. Will be updated once restated. **12-month period ending 31 December 2019.

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