hardman&co

Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**AVCT**
Price (p)	32.0
12m High (p)	98.0
12m Low (p)	32.0
Shares (m)	69.0
Mkt Cap (£m)	22.1
EV (£m)	13.8
Free Float*	59%
Market	AIM

**As defined by AIM Rule 26*

Description

Avacta is a pre-clinical stage biotechnology company developing biotherapeutics based on its proprietary Affimer protein technology. It benefits from near-term revenues from research and diagnostic reagents.

Company information

CEO	Alastair Smith
CFO	Tony Gardiner
Chairman	Trevor Nicholls
	+44 1904 217 070
	www.avacta.com

Key shareholders

Directors	6.1%
IP Group	24.8%
Lombard Odier	10.8%
Aviva	9.6%
Ruffer LLP	7.1%
JO Hambro	6.7%

Diary

1H'18	Sloan Kettering feasibility
Oct-18	Finals
Jan-19	AGM

Analysts

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Avacta Group

Commendable rate of progress

Avacta (AVCT) is a pre-clinical biotechnology company and the proprietary owner of Affimer technology. Affimers represent a radical alternative to the established antibody technology, which continues to dominate the drug industry, despite its limitations. The significant technical and commercial benefits of Affimers is being recognised though increased corporate interest, on-going evaluations, and deal flow. Meanwhile, AVCT has made stunning progress in its strategic goal to enter first-in-man trials in 2020, which now looks likely to be with a valuable bi-specific Affimer immuno-oncology asset.

- **Strategy:** AVCT is aiming to commercialise its Affimer technology through bespoke research tools, collaborative deals and by identifying and developing its own proprietary therapeutic leads. AVCT has sufficient cash resources to identify an Affimer lead to be ready for first-in-man trials in 2019.

- **Interims:** Sales increased 16% to £1.47m (£1.26m), driven by a 50% rise in Life Sciences (custom service and reagent Affimers). Investment in personnel and US business development infrastructure generated an underlying EBIT loss a little ahead of forecasts at -£4.28m (-£3.71m). Net cash was £0.5m better at £8.3m.

- **2015 objectives:** In 2015, AVCT set out a number of objectives to advance the potential use of Affimer technology in both therapeutics and diagnostics. In just two years, the company has made incredible progress and looks set to enter the clinic with a potentially valuable and novel bi-specific Affimer asset in 2020.

- **Risks:** Affimers represent a new disruptive technology and the potential customer base might take time to recognise their advantages. While all new drug development carries a high risk, Avacta has hit a number of important milestones over the last two years which have reduced the risk profile.

- **Investment summary:** AVCT has made considerable progress towards its goal of having its own proprietary Affimer-based drugs and growing a profitable reagents business. By itself, the company has identified potential leads and completed both *in vitro* and *in vivo* pharmacokinetic pre-clinical, efficacy and immunogenicity tests. Awareness of the potential of Affimers is also being enhanced through the rising number of collaborative deals being signed.

Financial summary and valuation

Year-end July (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	1.81	2.17	2.74	3.15	3.60	5.49
R&D spend	-0.03	-1.50	-2.60	-3.40	-4.50	-5.50
EBITDA	-2.28	-4.79	-6.66	-8.13	-9.40	-9.25
Underlying EBIT	-2.85	-5.39	-7.60	-9.20	-10.47	-10.32
Reported EBIT	-5.51	-5.66	-7.98	-9.62	-10.94	-10.83
Underlying PBT	-2.83	-5.29	-7.51	-9.15	-10.48	-10.37
Statutory PBT	-5.48	-5.57	-7.89	-9.58	-10.94	-10.89
Underlying EPS (p)	-4.38	-6.46	-8.75	-11.74	-13.07	-12.55
Statutory EPS (p)	-9.72	-6.86	-9.31	-12.36	-13.74	-13.30
Net (debt)/cash	7.33	19.52	13.17	4.31	-6.22	-16.29
Capital increases	0.02	21.05	0.01	0.06	0.00	0.00
EV/sales (x)	17.7	14.8	11.7	10.2	8.9	5.8

Source: Hardman & Co Life Sciences Research

Interim results

Key features

Operational

- **Identification of clinical lead:** Although considerable progress has been made in progressing its PD-L1 programme, a second immuno-oncology programme (lymphocyte activation gene 3 protein (LAG3)) has made enormous strides, such that a bi-specific Affimer is the likely lead into the clinic.
- **Affimer XT platform:** This family of Affimers binds to human serum albumin with varying affinity, providing half-life in serum of up to two weeks. These have been deigned to extend the serum half-life of Affimer therapeutics but can also be licensed for use as a linker to carry small protein/peptide cytotoxic payloads.
- **Moderna:** The research partnership with Moderna Therapeutics investigating Affimer targeting of messenger RNA is due to complete in May 2018, which could lead to Moderna exercising an option to develop one of the Affimers in the pipeline, or to an extension of the research programme.
- **Partnerships:** The flexibility of Affimers is clearly being recognised with an increased number of partnerships, including Glythera, FIT Biotech and OncoSec.

Financial

- **Sales:** Underlying sales grew 16% to £1.47m (£1.26m), with all the growth coming from the Life Sciences division. 58% (54%) of sales are now derived outside the UK.
- **R&D:** Investment in R&D rose 16% to -£1.48m (-£1.28m), as forecast, given increased spend on its own proprietary therapeutic programme, which is being charged directly to the P&L account.
- **Administration:** SG&A costs increased 15% to -£3.81m (-£3.32m), reflecting the greater investment in personnel and the opening of US business development offices on both the east (Philadelphia) and west (San Diego) coasts.
- **Underlying EBIT:** Increased sales were offset by the higher than expected SG&A spend, such that the underling EBIT loss was ca.£0.25m higher than expected.
- **Net cash/(debt):** Overall cash burn was ca.£0.5m below expectations, such that the net cash position at the end of the reporting period was £8.3m, in contrast to our forecast of £7.3m.

Avacta interims – actual vs. forecasts

Half-year analysis £m	1H'17 actual	1H'18 actual	Growth %	1H'18 forecast	Delta Δ
Life Sciences	0.46	0.69	50.4%	0.55	+0.14
Animal Health	0.80	0.77	-3.5%	0.80	-0.03
Group sales	**1.26**	**1.47**	**16.2%**	**1.35**	**+0.12**
COGS	-0.38	-0.46	20.2%	-0.45	-0.01
R&D	-1.28	-1.48	15.7%	-1.50	+0.02
SG&A	-3.06	-3.81	14.8%	-3.45	-0.36
Underlying EBIT	**-3.71**	**-4.28**	**+15.2%**	**-4.05**	**-0.23**
Net cash/(debt)	**16.1**	**8.3**		**7.8**	**+0.5**

Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Affimer development update

In 2015, management set a number of goals to develop the concept of Affimers as therapeutic and diagnostic agents in order to realise the commercial potential. The aim was to prove that the theoretical technical advantages of Affimers could be translated into products with commercial benefits. In just two years, the company has made progress at a commendable rate with both its therapeutic and diagnostic programmes, through both in-house development and partnerships. AVCT remains very much on target to move into clinical development with at least one in-house therapeutic programme during 2020.

Avacta objectives set in 2015

	Objective	Progress
1.	Develop the first in-house Affimer therapeutic candidate for clinical development	✓
2.	Build a pipeline of therapeutic Affimers and enabling Affimer platform technologies for licensing or future in-house development	✓
3.	Secure further partnership deals to develop the Affimer platform for both therapeutics and diagnostics	✓
4.	Grow a custom Affimer revenue stream with the potential for long term royalties	✓

Source: Avacta, Hardman & Co Life Sciences Research

Affimer therapeutics

Following discussion with its scientific advisory board, management took the decision not to try and identify new drug targets, but to develop Affimers that could resolve problems associated with known and well-validated targets. The aim was to lower the risk and to minimise the time needed to identify a lead candidate to take into human trials. Consequently, the company focused on two areas, immuno-oncology (IO) and haematology.

Immuno-oncology

Throughout the development of in-house therapeutic Affimers, PD-L1 has been the main target and to date, in excess of 50 PD-L1 antagonists have been generated and characterised with the best having single and double digit nanomolar binding affinities. These Affimers have been generated with high lab-scale yield and have been shown to possess significant tumour growth reduction in animal models, similar to the PD-L1 antibody control.

However, at the company's capital markets day (7th February 2018), AVCT indicated that it had also made significant progress in developing Affimers for another surface receptor known to inhibit T-cell function, namely LAG3[1]. In its interim statement, management stated that progress has been sufficiently rapid and encouraging with its Affimer LAG3 antagonist Affimer, that it has decided to take a more ambitious approach to its clinical development options.

The company decided originally to focus on PD-L1, as a well understood and validated IO target, in order to get clinical data for the Affimer platform as quickly as possible. However, from a commercial perspective, a potential issue with PD-L1 inhibitors is that there are many such putative drugs in clinical development and that

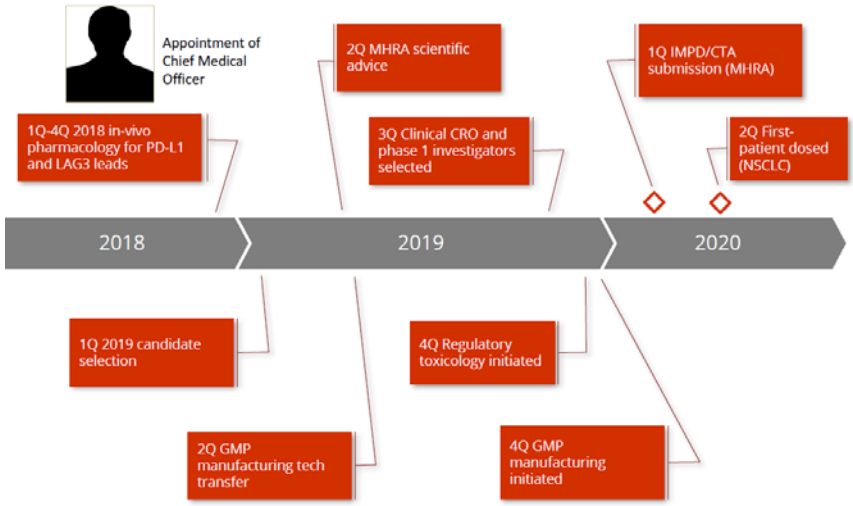
[1] Nguyen, LT and Ohashi, PS. Clinical blockade of PD1 and LAG3 — potential mechanisms of action. Nature Reviews Immunology, 2015, 15, 45-56.

it is a crowded market place. In addition, the clinical effectiveness of approved PD-L1 inhibitors has not been as great as expected when used in a broader population of patients. This is largely believed to be due to an effect called 'T-cell exhaustion', which can be reduced by blocking the interaction of LAG3.

Therefore, combining the two Affimer targets into a single bi-specific Affimer would take AVCT into a much less competitive field and be a more valuable asset. Of course, all the potentially competitive products are based on bi-specific antibodies, which will be very large molecules, and more difficult and expensive to make. Management believes that it will still be ready to have this bi-specific Affimer ready for first-in-man trials in 2020.

Although there remains a considerable amount of work to be done in readiness for a Phase I clinical trial, management has set out a clear schedule to achieve this goal.

Bi-specific pathway to clinic

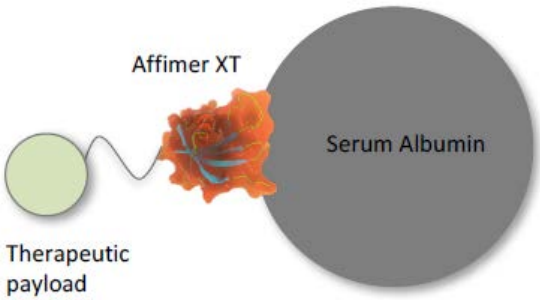


Source: Avacta

Affimer XT

In parallel, AVCT has been working to develop Affimers that bind to human serum albumin (HAS) to extend the serum half-life of Affimer drugs from hours to days or weeks. This technology can be applied to any other third party, small therapeutic payload, creating the possibility for licensing deals independent of other Affimer drugs.

Affimer XT – mechanism of action



Source: Avacta

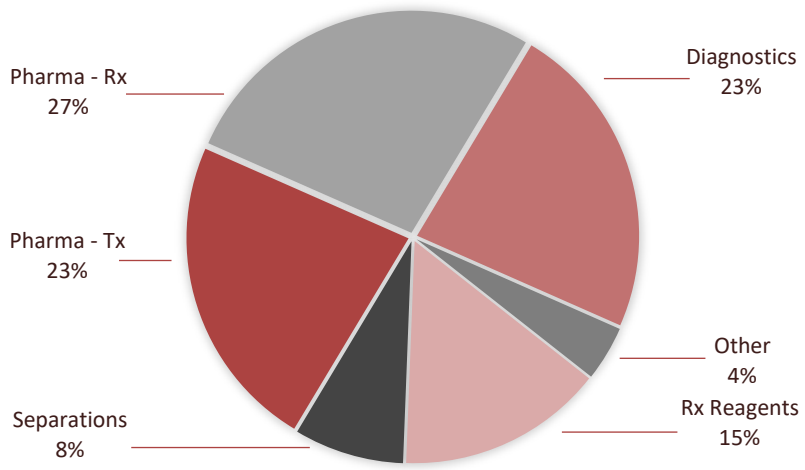
Given that peptide drugs have a short half-life in serum, which requires them to be administered regularly, AVCT sees clear potential to use Affimers as a 'linker' mechanism that will be recirculated along with the HSA, thereby extending the half-life of the payload. This could result in a significantly improved dosing regimen from daily to weekly or fortnightly.

Affimer reagents

Although most of the focus is on the Affimer therapeutics opportunity, AVCT continues to progress the potential use of Affimers as diagnostics reagents. Initially, products were generated for use as research tools, allowing scientists to provide independent external validation of Affimers and increase awareness via publications in peer-reviewed journals. However, this business has also developed considerably over the last two years.

Avacta has focused its business development and production activities on providing a custom service to generate Affimer reagents on demand, with a view to getting these into third parties' future products, and generating royalty payments. It currently has work-in-progress for over 40 projects. Earlier work on such projects has led to over 25 evaluations being undertaken by external customers. One of the more advanced has led to AVCT granting the first product development license to a top-three global diagnostics company in 1H'18. Given the level evaluation activity being undertaken, management expects more license deals to be signed in 2018 and beyond.

Ongoing Affimer evaluations (>25)



Source: Avacta

One of the first customers to publicly talk about its experience of Affimers is Covance, part of Lab Corp, one of the world's largest CROs. Avacta has been working closely with Covance to develop reagent Affimers that resolve a critical step in the manufacture of antibodies, called "anti-idiotypic" binders. Development of anti-idiotypic antibodies can be a long and potentially difficult process, which can result in delays to therapeutic programmes. AVCT has helped to resolve this issue with an elegant, reliable, and fast solution that has been adopted by Covance. With thousands on new monoclonal antibodies in development around the world, and each one benefiting potentially from an anti-idiotypic reagent, this has the potential to become a solid high margin business in coming years. For 2018, Hardman & Co is forecasting reagent revenues of around £1.5m.

Financial forecasts

Profit & Loss

- **Sales:** Although 1H'18 sales were modestly better than expected, the difficulty in predicting timing of sales, coupled with the increased level of activity outside the UK, has led us to tweak our full-year sales down £0.1m to £3.1m.
- **R&D spend:** The reported R&D number refers only to the spend on therapeutic Affimers *plus* the amortisation charge. Capitalised R&D on the reagents business is not included in this figure and can be found in the cashflow statement.
- **SG&A:** Increased US infrastructure with offices on both the east and west coast, coupled with the employment on additional headcount has led us to increase full-year SG&A by £0.5m to ca.£8.0m.

Profit & Loss account

Year-end July (£m)	2015	2016	2017	2018E	2018E	2020E
Life Sciences	0.44	0.70	1.15	1.55	1.90	3.69
Animal Health	1.37	1.46	1.59	1.60	1.70	1.80
Sales	**1.81**	**2.17**	**2.74**	**3.15**	**3.60**	**5.49**
COGS	-0.53	-0.90	-0.94	-0.97	-1.07	-1.25
Gross profit	**1.29**	**1.27**	**1.79**	**2.18**	**2.53**	**4.25**
Gross margin	**71%**	**59%**	**66%**	**69%**	**70%**	**77%**
SG&A	-4.11	-5.16	-6.79	-7.98	-8.50	-9.06
R&D	-0.03	-1.50	-2.60	-3.40	-4.50	-5.50
EBITDA	-2.28	-4.79	-6.66	-8.13	-9.40	-9.25
Depreciation	-0.52	-0.60	-0.93	-1.07	-1.07	-1.07
Amortisation	-0.06	-0.64	-0.65	-0.80	-0.95	-1.00
Licensing/royalties	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-2.85**	**-5.39**	**-7.60**	**-9.20**	**-10.47**	**-10.32**
Share-based costs	-0.25	-0.27	-0.39	-0.42	-0.47	-0.51
Exceptional items	-2.41	0.00	0.00	0.00	0.00	0.00
Statutory EBIT	-5.51	-5.66	-7.98	-9.62	-10.94	-10.83
Net financials	0.03	0.10	0.09	0.04	0.00	-0.06
U/L Pre-tax profit	**-2.83**	**-5.29**	**-7.51**	**-9.15**	**-10.48**	**-10.37**
Reported pre-tax	-5.48	-5.57	-7.89	-9.58	-10.94	-10.89
Tax payable/credit	0.65	0.92	1.53	1.09	1.46	1.69
Tax rate	-12%	-16%	-19%	-11%	-13%	-16%
Underlying net income	**-2.18**	**-4.38**	**-5.98**	**-8.07**	**-9.02**	**-8.68**
Statutory net income	-4.84	-4.65	-6.37	-8.49	-9.49	-9.19
Ordinary 10p shares:						
Period-end (m)	49.80	68.38	68.39	68.98	69.08	69.18
Weighted average (m)	49.73	67.71	68.39	68.69	69.03	69.13
Fully diluted (m)	42.85	51.91	70.39	73.21	73.50	73.85
Underlying Basic EPS (p)	**-4.38**	**-6.46**	**-8.75**	**-11.74**	**-13.07**	**-12.55**
Statutory Basic EPS (p)	-9.72	-6.86	-9.31	-12.36	-13.74	-13.30
U/l Fully-diluted EPS (p)	**-4.20**	**-6.22**	**-8.17**	**-10.97**	**-12.22**	**-11.74**
Stat. Fully-diluted EPS (p)	-9.31	-6.60	-8.70	-11.55	-12.85	-12.43
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash:** Avacta had £8.3m of cash on its balance sheet at 31st January 2017, and no debt. This was about £0.5m higher than forecast.
- **Tax credit:** The tax credit in relation to R&D spend on the balance sheet at the end of January was £1.7m, of which £1.2m is likely to be received during 2H'18.
- **Cash balance:** Based on current forecasts, and in the absence of any up-fronts associated with licensing deals, our forecasts suggest that Avacta will have a capital increase before reporting fully-year 2018 numbers in order to have sufficient working capital to get auditor sign-off.

Balance sheet

@31st July (£m)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	19.13	35.86	29.89	21.40	11.91	2.72
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	19.13	35.86	29.89	21.40	11.91	2.72
Share capital	5.06	6.92	6.92	6.92	6.92	6.92
Reserves	14.08	28.94	22.97	14.48	4.99	-4.20
Provisions/liabilities	0.86	0.34	0.34	0.34	0.34	0.34
Deferred tax	0.00	0.00	0.00	0.00	0.00	0.00
Long-term loans	0.00	0.00	0.00	0.00	0.00	0.00
Short-term loans	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash	7.33	9.52	9.17	4.31	-6.22	-16.29
less: Deposits	0.00	10.00	4.00	0.00	0.00	0.00
Invested capital	**12.67**	**16.68**	**17.06**	**17.42**	**18.47**	**19.35**
Fixed assets	1.55	3.74	3.45	3.18	3.05	3.06
Intangible assets	10.36	11.48	12.30	14.10	16.01	17.70
Inventories	0.33	0.27	0.16	0.18	0.21	0.32
Trade debtors	*0.21*	*0.16*	*0.25*	*0.25*	*0.25*	*0.25*
Other debtors	*0.55*	*0.97*	*1.03*	*1.04*	*1.19*	*1.81*
Tax liability/credit	*1.07*	*1.42*	*1.20*	*1.09*	*1.46*	*1.69*
Trade creditors	*-0.66*	*-0.40*	*-0.65*	*-0.85*	*-1.15*	*-1.55*
Other creditors	*-0.74*	*-0.95*	*-0.68*	*-1.57*	*-2.54*	*-3.93*
Debtors less creditors	0.43	1.19	1.15	-0.04	-0.79	-1.73
Invested capital	**12.67**	**16.68**	**17.06**	**17.42**	**18.47**	**19.35**
Net cash/(debt)	7.33	19.52	13.17	4.31	-6.22	-16.29

Source: Hardman & Co Life Sciences Research

Cashflow

- **1H'18 cashflow:** Operating cashflow was about £0.5m better than forecast, largely because of higher non-cash items – depreciation and amortisation.
- **Cap-ex:** Investment in cap-ex has reverted to normalised levels in fiscal 2018, with -£0.43m being spent in 1H'18.
- **Tax received:** No R&D-related tax refund was received from HMRC in 1H'18, although forecasts assume that £1.2m will be received before the fiscal year end.
- **Cash balance:** Forecasts suggest that Avacta will have ca.£4.3m cash at 31st July. As the company continues to deliver on its clearly-stated objectives, we believe that the company will have an equity issue prior to the announcement of full year results and in the absence of any significant up-fronts from licensing deals.

Cashflow

Year-end July (£m)	2015	2016	2017	2018E	2019E	2020E
Trading profit	-2.85	-5.39	-7.60	-9.20	-10.47	-10.32
Depreciation	0.52	0.60	0.93	1.07	1.07	1.07
Amortisation	0.06	0.64	0.65	0.80	0.95	1.00
Inventories	*-0.21*	*0.07*	*0.11*	*-0.02*	*-0.03*	*-0.11*
Receivables	*0.20*	*-0.36*	*-0.13*	*0.00*	*0.00*	*0.00*
Payables	*0.06*	*-0.08*	*-0.06*	*-0.20*	*-0.30*	*-0.40*
Change in working capital	0.04	-0.38	-0.07	-0.22	-0.33	-0.51
Exceptionals/provisions	0.00	-0.44	0.00	0.00	0.00	0.00
Other	-0.29	0.00	0.00	0.00	0.00	0.00
Company op cashflow	**-2.55**	**-4.90**	**-6.07**	**-7.55**	**-8.78**	**-8.75**
Net interest	0.03	0.10	0.09	0.03	0.00	0.00
Tax paid/received	0.01	0.57	1.75	1.20	1.09	1.46
Operational cashflow	**-2.52**	**-4.23**	**-4.24**	**-6.32**	**-7.69**	**-7.30**
Capital expenditure	-0.81	-2.86	-0.66	-0.80	-0.94	-1.09
Capitalised R&D	-3.06	-1.76	-1.47	-1.80	-1.91	-1.69
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-6.38**	**-8.86**	**-6.37**	**-8.92**	**-10.53**	**-10.07**
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	0.00	0.00	0.00	0.00	0.00	0.00
Disposals	2.21	0.00	0.00	0.00	0.00	0.00
Cashflow after invests.	**-4.17**	**-8.86**	**-6.37**	**-8.92**	**-10.53**	**-10.07**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	0.02	21.05	0.01	0.06	0.00	0.00
Cash/(debt) acquired	0.00	0.00	0.00	0.00	0.00	0.00
Change in net debt	**-4.15**	**12.19**	**-6.36**	**-8.85**	**-10.53**	**-10.07**
Hardman FCF/share (p)	-5.1	-6.3	-6.2	-9.2	-11.1	-10.6
Opening net cash	11.48	7.33	19.52	13.17	4.31	-6.22
Closing net cash	7.33	19.52	13.17	4.31	-6.22	-16.29

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number: 04748597

Registered Office
Unit 20, Ash Way
Thorp Arch Estate
Wetherby
LS23 7FA

+44 1904 217 070
www.avacta.com

Board of Directors

Board of Directors

Position	Name	Remuneration	Audit
Chairman	Trevor Nicholls	C	M
Chief Executive Officer	Alastair Smith		
Chief Financial Officer	Tony Gardiner		
Non-executive director	Alan Aubrey	M	C
Non-executive director	Mike Owen	M	

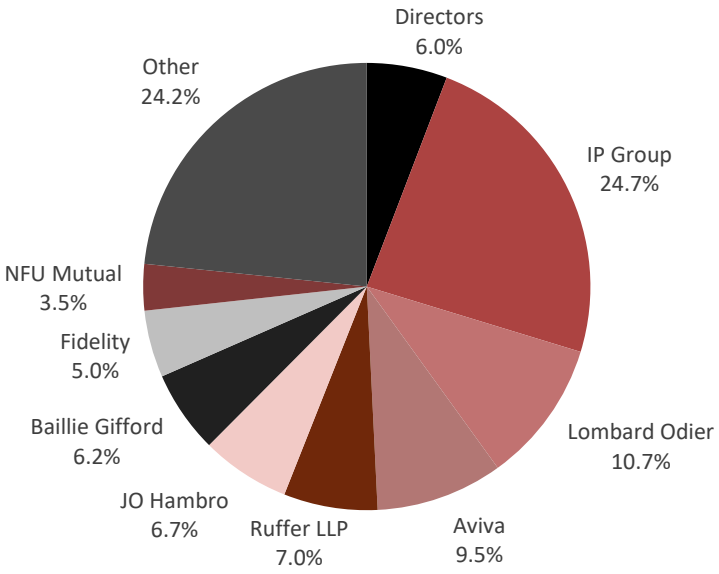
M = member; C = chair
Source: Company reports

The Nominations committee is convened on an 'as required' basis and chaired by the Chairman.

Share capital

At the date of this report, there were 68,989,487 Ordinary shares of 10p in issue. In addition, there are 4.8m share options outstanding.

Shareholders



Source: Hardman and Co Life Sciences Research

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