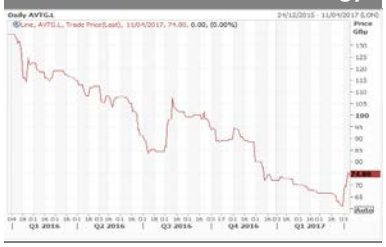
hardman&co

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	AVCT
Price (p)	74.5
12m High (p)	114.0
12m Low (p)	60.0
Shares (m)	68.4
Mkt Cap (£m)	51.0
EV (£m)	34.8
Free Float*	57%
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 which benefits from near-term revenues from research and diagnostic reagents

Company information	
CEO	Alastair Smith
CFO	Tony Gardiner
Chairman	Trevor Nicholls
	+44 1904 217 046
	www.avacta.com

Key shareholders	
Directors	4.2%
IP Group	24.8%
Lombard Odier	11.5%
Aviva	9.7%
Baillie Gifford	7.2%
Ruffer LLP	7.1%

Diary	
3Q-17	Affimer data
Oct-17	Finals
Jan-18	AGM

Analysts

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Avacta Group

Another important box ticked

Avacta is the proprietary owner of Affimer technology for the development of bio-therapeutics, diagnostic tests and research reagents. Affimers represent a radical alternative to established antibody technology which dominates the drug industry despite its limitations. During 2016, Avacta made considerable progress towards its strategic goal to have a first-in-man Affimer therapeutic by the end of 2019. In two years, management has hit several key milestones, moving Affimers from being an 'interesting concept' to one of 'real opportunity' and de-risking the technology as the next platform of biopharmaceutical drugs.

- **Strategy**: To commercialise its Affimer technology through a combination of bespoke research tools, collaborative deals and by identifying and developing its own proprietary therapeutic Affimer leads. The company has sufficient cash resource to identify an Affimer lead through to IND submission (end 2018).

- **Immunogenicity:** Results from the immunogenicity study were the very best that could be expected. High concentrations of three Affimer constructs were shown to have very low immunogenicity, comparable to Avastin, in a well-recognised industry-standard assay, hitting an important drug development milestone.

- **Interims:** The focus was more on the immunogenicity data than the numbers. However, the first-half has proceeded close to forecasts and the company ended the period with £0.6m more net cash than expected, at £16.1m. Sales increased +17% to £1.26m (£1.05m), the reported figure being boosted modestly by forex.

- **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 years which have considerably altered the risk profile.

- **Investment summary:** Avacta has made considerable progress towards its goal of having its own proprietary Affimer-based drugs. In just 18 months, it has completed a number of *in vitro* and *in vivo* pre-clinical tests. The next step will be to select its immuno-oncology lead candidate and file an Investigational New Drug (IND) in late 2018, as a prelude to beginning clinical testing in 2019. The market is starting to wake up to this interesting *de novo* technology platform.

Financial summary and valuation

Year end July (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	3.18	1.81	2.17	2.85	3.40	3.80
R&D spend	0.00	-0.03	-0.86	-1.98	-2.43	-2.88
EBITDA	-1.16	-2.28	-4.15	-5.94	-6.48	-7.00
Underlying EBIT	-1.69	-2.85	-4.75	-6.94	-7.48	-8.00
Reported EBIT	-2.07	-5.57	-5.66	-7.81	-8.44	-9.05
Underlying PBT	-1.66	-2.83	-4.65	-6.86	-7.44	-8.00
Statutory PBT	-2.04	-5.54	-5.57	-7.73	-8.40	-9.05
Underlying EPS (p)	-2.66	-4.38	-5.51	-8.75	-9.42	-10.05
Statutory EPS (p)	-3.57	-9.84	-6.86	-10.02	-10.82	-11.57
Net (debt)/cash	11.48	7.33	19.52	12.26	4.01	-4.86
Capital increases	14.54	0.02	21.05	0.00	0.00	0.00
EV/sales (x)	23.4	41.1	34.4	26.1	21.9	19.6

Source: Hardman & Co Life Sciences Research

Interim results

Key features

Operational

- **Immunogenicity data:** Positive outcomes from the independent studies on the immunogenic effect of Affimers were reported along with the results (see later)
- **Therapeutic Affimers:** Considerable progress has been made over the last 12 months with its proprietary therapeutic Affimer programmes, with the target to enter human in 2019 very much on schedule
- **Moderna:** The research partnership with Moderna Therapeutics on Affimers targeted at messenger RNA continues to make progress and has been expanded to cover more targets
- **Order book:** Reflecting the increasing awareness and potential of Affimer technology, Avacta's Life Sciences order book for customised Affimers and evaluations is 70% higher than it was a year ago

Financial

- **Sales:** Underlying sales grew +17% to £1.26m (£1.05m), with a modest currency gain on translation
- **R&D:** Investment in R&D rose substantially, as forecast, given increased spend on its own proprietary therapeutic programme, which is being charged directly to the P&L account
- **Administration:** Underlying SG&A costs rose 47% to -£3.06m (-£2.08m), broadly in-line with forecasts, reflecting the increased investment in senior personnel that has taken place during the last 12 months
- **Underlying EBIT:** Differences in the sales and costs between actual and forecasts negated each other, such that EBIT was in line with expectations
- **Net cash/(debt):** Overall cash burn was below expectations, such that the net cash position at the end of the reporting period was +£0.6m better than forecast at £16.1m

Interim analysis

Half-year analysis £m	1H'16 actual	1H'17 actual	Growth %	1H'17 forecast	Delta £m
Life Sciences	0.34	0.46	+35%	0.40	+0.06
Animal Health	0.71	0.80	+13%	0.75	+0.05
Group sales	**1.05**	**1.26**	**+20%**	**1.15**	**+0.11**
COGS	-0.44	-0.38	-14%	-0.45	+0.07
R&D	-0.45	-1.28		-1.15	-0.13
SG&A	-2.08	-3.06	+47%	-3.00	-0.06
Underlying EBIT	**-1.91**	**-3.45**	**+81%**	**-3.45**	**-0.01**
Underlying PBT	-1.87	-3.39		-3.40	+0.01
Underlying EPS (p)	-2.42	-4.53		-4.50	-0.03
Statutory EPS (p)	-2.61	-5.01			
Net cash/(debt)	**25.0**	**16.1**		**15.5**	**+0.6**

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

Immunogenicity results

Background

Importance of immunogenicity testing highlighted by specific FDA guidelines on the subject

Given the large number of biotherapeutics and personalised medicines currently in development, immunogenicity represents an increasing concern for the drug regulators, such as EMA and FDA, that request evaluation of anti-drug antibodies (ADA). Measurement of the immunogenic effect of biotherapeutics is required by the regulatory bodies because these agents run the risk of being recognised as a foreign agent by a host immune system, and may increase the potential and the scale of any adverse event. In this regard, the FDA has published detailed industry guidance on the subject with a view to speeding up the process of measuring and assessing immunogenicity.

The relevance of the immunogenicity study was highlighted in our research report dated 21st March 2017 – "*Low response would be positive!*" available on our website: http://www.hardmanandco.com/docs/default-source/company-docs/avacta-documents/21.03.17-low-response-would-be-positive!.pdf Results from this immunogenicity trial were published concomitant with the release of interim results. Overall the data were excellent and represent a major step forward in the development of therapeutic Affimers both by Avacta and through out-licensing of the technology.

The PBMC test

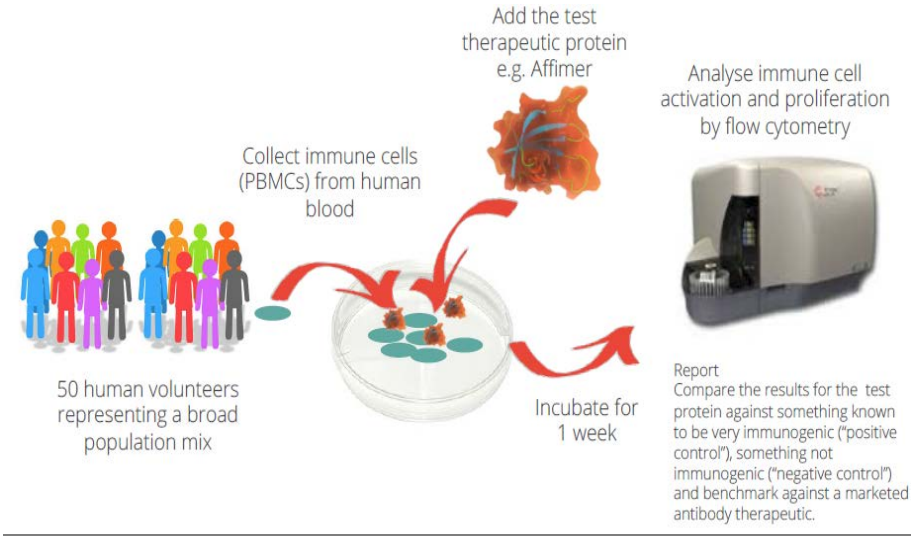
PBMC test correlates with outcomes in the clinic…

…and helps with selection of drug candidates

Avacta used the services of ImmunXperts, an independent service partner that specialises in immunology assessment projects. The gold standard *in vitro* test is a "T-cell activation/proliferation assay using human peripheral blood mononuclear cells", or PBMC, which are a critical component in the immune system. Outcomes from this test correlate well with those observed with drugs in clinical use.

This well validated test involves incubating the desired biotherapeutic agent with samples of PBMCs from 50 diverse human donors, meaning that each Affimer construct was tested against all 50 donors, individually, at high concentration. The volunteers were selected on the basis of their human leukocyte antigen (HLA) type, in order to get a representative sample of the world population.

PBMC assay procedure



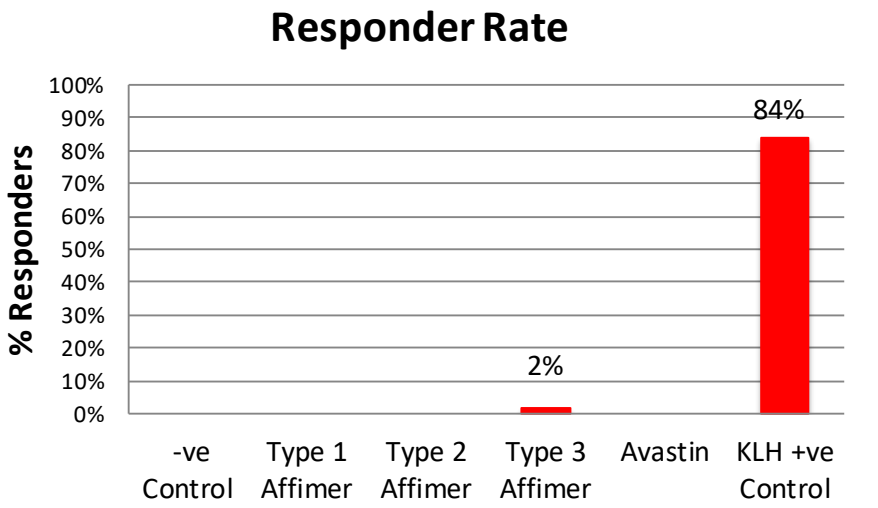
Source: Avacta

Affimers versus controls

The test was designed carefully so that results with Affimers could be compared to those obtained with both positive and negative controls. Avacta requested tests on three different Affimer scaffolds, which were compared to results with the marketed antibody drug, Avastin, keyhole limpet haemocyanin (KLH; positive control), and buffer solution (negative control).

- **Affimer Type 1:** Human Affimer scaffold
- **Affimer Type 2:** Plant consensus sequence Affimer protein
- **Affimer Type 3:** Next generation human Affimer scaffold

PBMC responder analysis



Source: Avacta

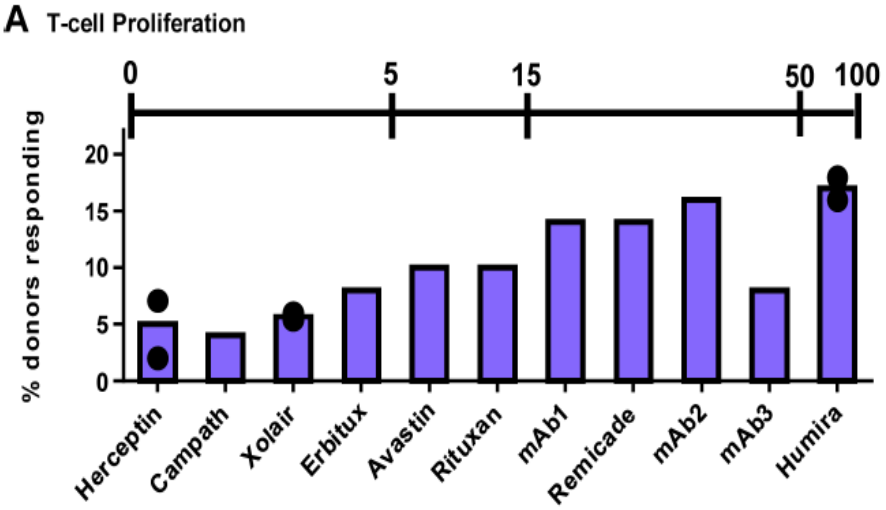
- **Negative control** (buffer): No response
- **Positive control** (KLH): High (84%) immunogenic response generated
- **Antibody control** (Avastin): No response
- **Affimers:** Within the 50 donors population, there were no responders to Type 1 and Type 2 Affimers, and only one responder (2%) to Type 3

These results represent the best possible outcome and allay any fears that the Affimer technology may be immunogenic. The results are even more impressive when you take into account that the Avastin used was the commercial product which has been manufactured under GMP conditions, whereas the Affimer constructs were 'home made' being produced in-house under non-GMP conditions and without significant purification. In addition, being much smaller than antibodies, the effective concentration of the Affimers was five times greater than the concentration of Avastin being tested.

Antibody results

Although Avastin was chosen as the antibody control in this study, response rates for a series of antibodies using the same test are readily available in the literature. Typical response rates are usually in the range 3-15%, as shown in the following diagram. The scale bar shows the incidence (in %) of immunogenicity seen in the clinic caused by these marketed antibody-derived drugs.

Published PBMC results for marketed antibody-derived drugs



Source: PLOS ONE DOI:10.1371/journal.pone.0159328 August 5, 2016

Conclusion

- The three Affimer protein constructs tested have been shown to produce low/no immunogenicity and results were at least as good as those obtained for the marketed antibody drug, Avastin
- The data show that there are no immunogenicity issues with the Affimer technology platform. Moreover, they show that there is no need for any further protein engineering to remove any part of the construct that might be causing immunogenicity
- These data tick an important box with respect to major pharma/biotech looking to licence the technology platform and further de-risk the Affimer therapeutic programme

Possible advantages of Affimers vs Antibodies

Characteristic	Comment	Potential effect on immunogenicity*
Size	Affimers are 10 times smaller compared to antibodies	↓
Source	Affimers used as a therapeutic, derive from human source, the Stefin A protein	↓
Specificity	Highly and controllable specificity, easy to modulate	↓
Manufacturing process	Affimers easy to express, leading to higher purity products	↓

**when compared to an antibody*
Source: Hardman & Co Life Sciences Research

Technology overview

Over the last two years, Avacta has made enormous progress. The potential of Affimers has moved from an 'interesting concept' to a 'real opportunity'. Avacta no longer faces the question: "Do Affimers work?" The company has established a number of collaborations/partnerships, many with the top 10 global pharmaceutical and biotech companies, and with every set of data that Avacta generates, this number looks set to explode in coming years. The immunogenicity results represent another box ticked in the evolution of Affimers towards a new class of drugs.

Reagents

While the market focus has, understandably, been on therapeutics over the last 12-18 months, Avacta has made considerable progress in the development of its reagents business too. During 2015, Avacta began commercialising the Affimer reagent business opportunity.

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. Avacta is building a small catalogue of Affimers to make the technology widely available at a lower price point in order to drive awareness, adoption and publications.

To date, in customer projects and evaluations, and in-house projects, Avacta has generated over 300 new Affimers.

Affimer reagents

Source: Avacta

Affimer reagents – Commercial progress

Characteristic	Progress to date
Customers/partners	>50
Target classes/application	>10
New Affimers generated to date	>300
Speed of generation	7-12 weeks
Stability	pH 2-13; up to 90°C
Typical affinity	5-50nM

Source: Hardman & Co Life Sciences Research

These activities have demonstrated to customers that the theoretical advantages of Affimers over antibodies are genuine and that they have the potential to provide solutions to problems in a way that antibodies cannot.

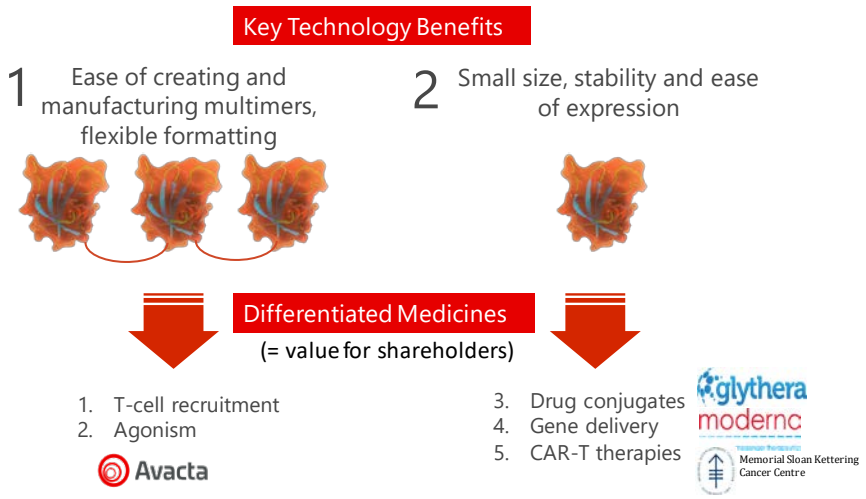
- Affimers have been generated for partners for a number of different activities
- Affimers has been functionalised with a number of different chemistries
- Affimer reagents are being used by partners for a range of different assays and processes

Consequently, Avacta's order book for customer Affimers is running at its highest level to date with the company engaged with many research, diagnostic and pharmaceutical companies. Given the multiple ongoing technology evaluations underway at the present time, management is confident that its first licensing deal for the reagents business will be signed during 2017.

Therapeutic Affimers

The strategy is to build a pipeline of Affimer drug candidates in immuno-oncology for partnering/licensing to major pharma. The aim is to generate highly differentiated medicines that build on the key benefits of Affimers.

Affimers – competitive advantages

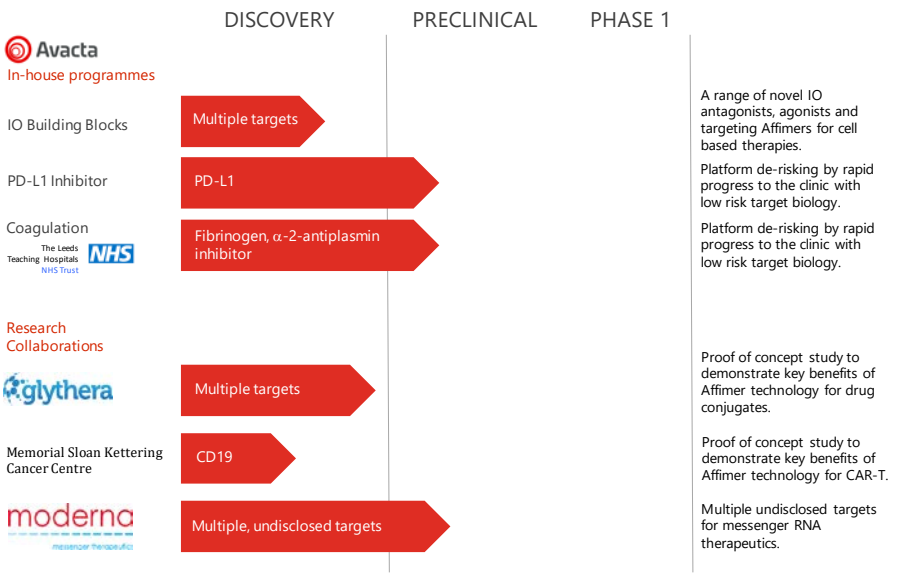


Source: Avacta

Avacta is working on the development of drugs that target T-cell recruitment and will focus also on those that act as agonists of the target, whereas it is working with partners in other areas including Affimer drug conjugates, gene delivery (DNA rather than recombinant protein) and CAR-T therapies.

Each step adds to the de-risking of the Affimer technology as the next generation biotherapeutic platform. A key strategic objective for the company is to have a therapeutic drug candidate ready for early clinical trials during 2019.

Avacta therapeutics programme

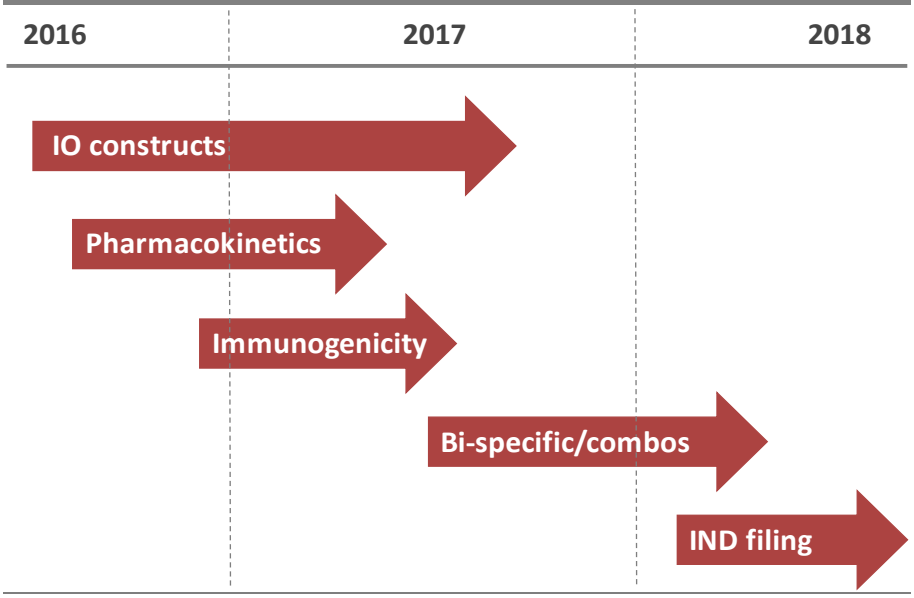


Source: Avacta

Progress to date

- Identification of a number of potential Affimer candidate leads that bind with high affinity to the Programmed Death Ligand 1' (PD-L1) checkpoint protein
- Successful manufacturing of multimeric Affimer constructs with high production yield, suggesting leads can be produced in commercial quantities
- Successful completion of *in vivo* pre-clinical pharmacokinetic studies showing that Avacta's PD-L1 Affimer inhibitors had good half-life in serum and were well tolerated at clinically relevant doses
- Early evidence of efficacy in a mouse model which showed that the PD-L1 Affimer lead produces a reduction in tumour growth indicating bioavailability and functionality
- Successful outcomes from the independent immunogenicity testing of Affimers demonstrating that there are no immunogenicity issues with this technology platform

Avacta PD-L1 development timelines



IO = immuno-oncology

Source: Adapted from Avacta by Hardman & Co Life Sciences Research

Avacta is targeting late 2018 for making its IND filing to start clinical trials, by which time the company should know whether this will be with a bi-specific or tri-specific Affimer, or an Affimer in combination with another oncology drug. It could also be with an Affimer that modulated blood clotting.

Newsflow

Expected newsflow

Timing	Event
Mid-2017	Continued development of PD-L1 leads, candidate selection, pre-clinical testing
Mid-2017	Details on Affimer Drug Conjugate progress from partner Glythera
3Q 2017	Details on CAR-T cell therapy progress from partner Sloan Kettering
4Q 2017	Detailed *in vitro* data from blood coagulation programme
End 2017	Potential update from Moderna Therapeutics, notwithstanding restrictions
2018	Selection of immune-oncology lead candidate for pre-clinical development

Source: Hardman & Co Life Sciences Research

Financials

Profit & Loss

- **Sales:** Slight rebalancing of the sales following the interim results, with more coming from Animal Health and less from Life Sciences. Overall forecast reduced by £0.15m to £2.85m
- **R&D spend:** Care needs to be taken with R&D numbers. The figure reported by the company is for the actual spend on therapeutic Affimers *plus* the amortisation charge. Capitalised R&D on the reagents business is not included in this figure. Our R&D spend is for the actual spend on therapeutics only and excludes the non-cash amortisation charge (figures shown separately in table)
- Underlying versus statutory: The differences between the two figures are share based costs (excluded from SG&A) and amortisation costs (excluded from R&D)

Profit & Loss account

Year end July (£m)	2014	2015	2016	2017E	2018E	2019E
Avacta Life Sciences	0.03	0.44	0.70	1.25	1.70	2.05
Avacta Animal Health	1.59	1.37	1.46	1.60	1.71	1.75
Sales	**3.18**	**1.81**	**2.17**	**2.85**	**3.40**	**3.80**
COGS	-1.14	-0.53	-0.90	-1.00	-1.10	-1.20
Gross profit	**2.04**	**1.29**	**1.27**	**1.85**	**2.30**	**2.60**
Gross margin	**64%**	**71%**	**59%**	**65%**	**68%**	**68%**
SG&A	-3.73	-4.11	-5.16	-6.80	-7.35	-7.72
R&D	0.00	-0.03	-0.86	-1.98	-2.43	-2.88
EBITDA	-1.16	-2.28	-4.15	-5.94	-6.48	-7.00
Depreciation	-0.36	-0.52	-0.60	-1.00	-1.00	-1.00
Amortisation	-0.17	-0.06	-0.64	-0.52	-0.57	-0.62
Licensing/Royalties	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-1.69**	**-2.85**	**-4.75**	**-6.94**	**-7.48**	**-8.00**
Share based costs	-0.21	-0.25	-0.27	-0.35	-0.39	-0.43
Exceptional items	0.00	-2.41	0.00	0.00	0.00	0.00
Statutory EBIT	-2.07	-5.57	-5.66	-7.81	-8.44	-9.05
Net financials	0.02	0.03	0.10	0.08	0.04	0.00
U/L Pre-tax profit	**-1.66**	**-2.83**	**-4.65**	**-6.86**	**-7.44**	**-8.00**
Reported pre-tax	-2.04	-5.54	-5.57	-7.73	-8.40	-9.05
Tax payable/credit	0.55	0.65	0.92	0.87	0.99	1.11
Tax rate	-27%	-12%	-16%	-11%	-12%	-12%
Underlying net income	**-1.11**	**-2.18**	**-3.73**	**-5.99**	**-6.46**	**-6.90**
Statutory net income	-1.49	-4.89	-4.65	-6.86	-7.41	-7.94
Ordinary shares (m):						
Period-end	49.68	49.80	68.38	68.48	68.58	68.68
Weighted average	41.82	49.73	67.71	68.43	68.53	68.63
Fully diluted	39.95	42.85	51.91	70.39	71.10	71.20
Underlying Basic EPS (p)	**-2.66**	**-4.38**	**-5.51**	**-8.75**	**-9.42**	**-10.05**
Statutory Basic EPS (p)	-3.57	-9.84	-6.86	-10.02	-10.82	-11.57
U/l Fully-diluted EPS (p)	**-2.60**	**-4.20**	**-5.30**	**-8.42**	**-9.07**	**-9.67**
Stat. Fully-diluted EPS (p)	-3.48	-9.43	-6.60	-9.64	-10.41	-11.14
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 £16.1m of cash and deposits on its balance sheet at 31st January 2017, and no debt. This was about £0.6m higher than forecast
- **Tax credit** – The tax credit in relation to R&D spend on the balance sheet at the end of July was £1.42m, of which £0.72m has been paid and a further £0.3m has been accrued on current spend
- **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 £12.3m of cash at the end of fiscal 2017 which will be sufficient until at least the end of fiscal 2018

Balance sheet						
@31st July (£m)	**2014**	**2015**	**2016**	**2017E**	**2018E**	**2019E**
Shareholders' funds	28.84	19.13	35.86	29.00	21.59	13.65
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	28.84	19.13	35.86	29.00	21.59	13.65
Share capital	5.05	5.06	6.92	6.92	6.92	6.92
Reserves	23.79	14.08	28.94	22.08	14.67	6.73
Provisions/liabilities	0.82	0.86	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	11.48	7.33	9.52	2.26	4.01	-4.86
less: Deposits	0.00	0.00	10.00	10.00	0.00	0.00
Invested capital	**18.18**	**12.67**	**16.68**	**17.08**	**17.92**	**18.84**
Fixed assets	1.40	1.55	3.74	3.68	3.44	3.31
Intangible assets	16.29	10.36	11.48	13.28	15.13	17.05
Inventories	0.47	0.33	0.27	0.35	0.42	0.47
Trade debtors	*0.47*	*0.21*	*0.16*	*0.16*	*0.16*	*0.16*
Other debtors	*0.51*	*0.55*	*0.97*	*1.27*	*1.52*	*1.70*
Tax liability/credit	*0.43*	*1.07*	*1.42*	*0.87*	*0.99*	*1.11*
Trade creditors	*-0.98*	*-0.66*	*-0.40*	*-0.40*	*-0.40*	*-0.40*
Other creditors	*-0.42*	*-0.74*	*-0.95*	*-2.13*	*-3.33*	*-4.55*
Debtors less creditors	0.02	0.43	1.19	-0.23	-1.07	-1.99
Invested capital	**18.18**	**12.67**	**16.68**	**17.08**	**17.92**	**18.84**
Net cash/(debt)	**11.48**	**7.33**	**19.52**	**12.26**	**4.01**	**-4.86**

Source: Hardman & Co Life Sciences Research

Cashflow

- **1H'17 cashflow** – Operating cashflow was largely as forecast, the tax credit boosting period end cash balances
- **Cap-ex** – Investment has returned to normalised levels following the fitting out of the new facilities at Wetherby and Cambridge
- **Tax received** – Out of the £1.42m in the balance sheet, £0.72m was received early in the reporting period. A further receipt of £0.8-0.9m is anticipated before the end of July
- **Cash balance** –Forecasts suggest that Avacta has sufficient cash until at least the end of fiscal 2018 excluding any up-fronts from licensing deals

Cashflow

Year end July (£m)	2014	2015	2016	2017E	2018E	2019E
Trading profit	-1.69	-2.85	-4.75	-6.94	-7.48	-8.00
Depreciation	0.36	0.52	0.60	1.00	1.00	1.00
Amortisation	0.17	0.06	0.64	0.52	0.57	0.62
Inventories	*-0.09*	*-0.21*	*0.07*	*-0.09*	*-0.07*	*-0.05*
Receivables	*0.10*	*0.20*	*-0.36*	*0.00*	*0.00*	*0.00*
Payables	*0.04*	*0.06*	*-0.08*	*0.00*	*0.00*	*0.00*
Change in working capital	0.05	0.04	-0.38	-0.09	-0.07	-0.05
Exceptionals/provisions	0.00	0.00	-0.44	0.00	0.00	0.00
Other	0.04	-0.29	0.00	0.00	0.00	0.00
Company op cashflow	**-1.24**	**-2.55**	**-4.90**	**-6.02**	**-6.55**	**-7.05**
Net interest	0.02	0.03	0.10	0.08	0.04	0.00
Tax paid/received	0.42	0.01	0.57	1.42	0.87	0.99
Operational cashflow	-0.80	-2.52	-4.23	-4.52	-5.64	-6.07
Capital expenditure	-0.92	-0.81	-2.86	-0.94	-0.76	-0.87
Capitalised R&D	-1.86	-3.06	-1.76	-1.80	-1.85	-1.93
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-3.58**	**-6.38**	**-8.86**	**-7.27**	**-8.25**	**-8.86**
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	-0.06	0.00	0.00	0.00	0.00	0.00
Disposals	0.00	2.21	0.00	0.00	0.00	0.00
Cashflow after invests.	**-3.64**	**-4.17**	**-8.86**	**-7.27**	**-8.25**	**-8.86**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	14.54	0.02	21.05	0.00	0.00	0.00
Cash/(debt) acquired	0.00	0.00	0.00	0.00	0.00	0.00
Change in net debt	**10.90**	**-4.15**	**12.19**	**-7.27**	**-8.25**	**-8.86**
Hardman FCF/share (p)	-1.9	-5.1	-6.3	-6.6	-8.2	-8.8
Opening net cash	0.58	11.48	7.33	19.52	12.26	4.01
Closing net cash	**11.48**	**7.33**	**19.52**	**12.26**	**4.01**	**-4.86**

Source: Hardman & Co Life Sciences Research

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