Avacta Group plc

Interim results comment

Avacta’s interim results provide further evidence that the company is delivering against its core objectives set out in 2015. In particular, the key objective of generating clinical data for the group’s lead Affimer immuno-oncology (I-O) therapeutic programme is gathering momentum and Avacta is targeting Phase I clinical data in the financial year 2020/21.

Avacta’s Affimer Therapeutics business continues to make solid progress in its lead I-O programme; the PD-L1 inhibitor. The company has generated over 50 Affimer inhibitors of PD-L1 and has now selected its lead molecule for clinical development. Of particular interest is that Avacta has also made strong progress with a second I-O programme focused on a LAG-3 blockade. Consequently, the company has decided to clearly differentiate itself and combine PD-L1 with LAG-3 for improved efficacy and take a PD-L1/LAG-3 bispecific combination into the clinic.

Affimer Therapeutics has a strong developmental pipeline of Affimers that can bind to other important I-O targets and widen the scope of the technology platform. The group has established ten pipeline programmes in addition to those associated with third party collaborations. However, Avacta will be focusing its core efforts on the PD-L1/LAD-3 project and the human serum albumin (Affimer XT™) half-life extension with the intention of generating partner-able assets as quickly as possible.

Avacta has made progress with its collaborations with Glythera in the UK and Memorial Sloan Kettering Cancer Center in the US. The company also established two further collaborations with NASDAQ listed OncoSec in the US and Finnish company, FIT Biotech Oy, during the interim period. Of immediate interest is Avacta’s research partnership with Moderna Therapeutics which has a natural termination date in May 2018 by which time, Avacta expects that Moderna will select Affimers to take into its pre-clinical/clinical development pipeline.

Avacta’s Research and Diagnostic Division has reported over 25 evaluations of Affimer technology ongoing under its auspices which have the potential to lead to long term revenue generating licensing arrangements. To expedite ongoing international growth, the company has also established a business development team on the east and west coasts of the US to accelerate growth in this key global market.

On the financial side, revenue increased by 16% from £1.26m in H1 2017 to £1.47m in H1 2018. This growth was driven by the Life Sciences business where revenue increased by 50% from £0.46m in H1 2017 to £0.69m in H1 2018. The group loss after tax was £3.9m in H1 2017 compared to £3.4m due to continued investment in the operations of Avacta Life Sciences and the expansion of the US business. Cash at the end of January 2018 was £8.3m compared to £13.2m at the end of July 2017.

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Avacta reported revenue of £1.47m for the six months ended January 2018, an increase of 16% compared to the same period in the previous year. Revenue generated by the company’s Affimer business, Avacta Life Sciences, increased by 50% to £0.69 whilst revenue from Animal Health decreased marginally by 3.5% from £0.80m in H1 2017 to £0.78m in H1 2018.

### Income statement summary, six month period to January (£000)

<table>
<thead>
<tr>
<th>Income statement (Six months ended January)</th>
<th>2017A</th>
<th>2018A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Sciences revenue</td>
<td>460</td>
<td>692</td>
</tr>
<tr>
<td>Animal Health revenue</td>
<td>802</td>
<td>774</td>
</tr>
<tr>
<td><strong>Total revenue</strong></td>
<td>1,262</td>
<td>1,466</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-381</td>
<td>-458</td>
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<tr>
<td>Gross profit</td>
<td>881</td>
<td>1,008</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>-1,277</td>
<td>-1,477</td>
</tr>
<tr>
<td>Admin</td>
<td>-3,495</td>
<td>-4,003</td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>-3,891</td>
<td>-4,472</td>
</tr>
<tr>
<td>Finance income</td>
<td>64</td>
<td>0</td>
</tr>
<tr>
<td><strong>Profit before tax</strong></td>
<td>-3,827</td>
<td>-4,472</td>
</tr>
<tr>
<td>Taxation</td>
<td>400</td>
<td>500</td>
</tr>
<tr>
<td><strong>Profit after tax</strong></td>
<td>-3,427</td>
<td>-3,949</td>
</tr>
</tbody>
</table>

Source: Avacta, RNS

### Costs

Avacta expensed £1.48m of research and development (R&D) costs in the interim period as the company continues to invest in its Affimer therapeutics programme. The company capitalised £0.9m of development costs in the interim period of 2018 compared to £0.7m in the interim period in 2017.

Administration costs increased from £3.5m in H1 2017 to £4.0m in H1 2018 as the scale of the Affimer business operations increased over the period. This increase primarily reflects the growth in operations of Avacta Life Sciences, in particular the US business development team as it scales up its resources to deliver growth.

A loss of £3.95m was reported in H1 2018 compared to a loss of £3.4m in H1 2017. Avacta claims each year for R&D tax credits which, since it is loss making, it elects to surrender for a cash rebate. The rebate in H1 2018 was £0.5m compared to £0.4m in H1 2017.

### Cash flow and balance sheet

Cash outflow from operations was £3.6m in H1 2018 compared to an outflow of £3.0m in H1 2017. At the end of January 2018, the company reported cash of £8.275m compared to cash and short term deposits totalling £13.2m at the end of July 2017 and £16.1m at the end of January 2017. During the interim period, Avacta transferred £4.0m of funds from short term deposits in order to fund ongoing group operations.

Net assets as of 31 January 2018 were £26.2m, down from £29.9m at the end of July 2017 predominantly as a function of the reduced cash balances. The group remains debt free.
Five year financial summary

<table>
<thead>
<tr>
<th>Item</th>
<th>FY 2013 £’000</th>
<th>FY 2014 £’000</th>
<th>FY 2015 £’000</th>
<th>FY 2016 £’000</th>
<th>FY 2017 £’000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>2,700</td>
<td>3,180</td>
<td>1,813</td>
<td>2,165</td>
<td>2,735</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>-1,852</td>
<td>-2,043</td>
<td>-5,541</td>
<td>-5,565</td>
<td>-7,893</td>
</tr>
<tr>
<td>Profit after tax</td>
<td>-1,521</td>
<td>-1,492</td>
<td>-4,893</td>
<td>-4,647</td>
<td>-6,367</td>
</tr>
<tr>
<td>EPS (p)</td>
<td>-0.05</td>
<td>-0.04</td>
<td>-20.09</td>
<td>-6.86</td>
<td>-9.31</td>
</tr>
<tr>
<td>Net cash (debt)</td>
<td>582</td>
<td>11,480</td>
<td>7,330</td>
<td>19,521</td>
<td>13,166</td>
</tr>
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</table>

Source: Company

Operational review

Affimer Therapeutics – Clinical progress

Avacta’s therapeutic programme is focused on applying Affimer therapeutics in the field of immunoncology (I-O) (therapies that harness the body’s immune system to help fight cancer) and the company has selected an inhibitor of PD-L1 as its lead programme. PD-L1 (Programmed Death Ligand 1) is an immune checkpoint protein which appears on the surface of a tumour cell and ‘fools’ the body’s immune system into thinking that the tumour cell is actually healthy and should be left alone. By using Affimers to block PD-L1, the cell can no longer ‘hide’ from the immune system which can then attack the tumour.

The company notes that an Affimer inhibitor of PD-L1 as a therapy on its own has relatively limited commercial value given that there are numerous antibody inhibitors of PD-L1 already approved or in the clinic. PD-L1 is a relatively well understood I-O target and was selected to minimise the risks in acquiring first time human data quickly.

In light of this, Avacta has now generated and characterised over 50 Affimer inhibitors of PD-L1 and has selected its lead molecule for clinical development. However, the company notes that it has also made strong progress towards generating Affimer inhibitors of a second immune checkpoint called LAG-3 and has now decided to take a PD-L1/LAG-3 bispecific (can simultaneously bind to two different types of antigen) combination into the clinic. The company believes that an Affimer bispecific could have significant potential for partnering prospects as well.

While Avacta acknowledges that there could be greater technical and timescale related challenges in developing a bispecific compared to a simple PD-L1 inhibitor, the management is confident that the same broad timeline can be achieved for the bispecific solution leading to Phase I clinical data in 2020/21.

The pipeline

Avacta continues to generate data that supports the Affimer platform and in vivo (performed or taking place in a living organism) data is also seen as a crucial de-risking step by Avacta’s potential partners. In particular, the company intends to generate more essential in vivo pharmacology data for the PD-L1/LAG-3 bispecific programme during 2018/19.
In order to build a strong pipeline of assets for partnering agreements and in-house development, Avacta has now established 10 pipeline programmes in addition to programmes associated with collaborations and partnerships. As the company does not now possess the resources to generate detailed in vivo data for all of its pipeline programmes, Avacta will be focusing existing resources on the PD-L1/LAD-3 project and also human serum albumin (Affimer XT™) half-life extension with the intention of generating partner-able assets as quickly as possible.

Drug development partnerships

Avacta’s collaborations with larger pharmaceutical and drug development companies provide it with the ability to accelerate the generation of proof of concept data. Avacta’s research partnership with Moderna Therapeutics is working on a number of targets to provide Affimer molecules for mRNA (gene) delivery for at least one of these targets during 2018. The initial research phase of the collaboration has a natural termination date in late May 2018 by which time, Avacta expects that Moderna will either select Affimers to take into the pre-clinical/clinical development pipeline or both companies will elect to extend the research element of the collaboration.

During the interim period, Avacta established two additional collaborations in the area of gene delivery with NASDAQ listed OncoSec and Finnish company FIT Biotech Oy. The collaboration with OncoSec is expected to yield the first significant data in late 2018 and the initial proof of concept study with FIT is anticipated to yield results within the next few weeks. In particular, Avacta is keen to see sustained production of Affimer molecules over a period of week in animals ‘injected’ with the Affimer DNA code.

Avacta is also collaborating with Glythera Ltd to generate in vitro and in vivo data packages for a drug conjugate using Glythera’s linkers and toxins and Avacta’s Affimers to target an undisclosed tumour marker. A recent proof of concept study established that Affimers could be efficiently conjugated with Glythera’s novel linkers without loss of function and the two partners anticipate reporting further progress towards the end of 2018.

Affimer Research and Diagnostics Reagents

Avacta is advancing the Affimer platform in non-therapeutic markets, with lower regulatory hurdles, in order to develop a licensing business model based on paid-for evaluations of bespoke Affimer reagents. These evaluations are intended to lead into licencing of Affimers for third party product development and ultimately long term royalty streams for the company.

There are currently over 25 evaluations of Affimer technology ongoing and the company anticipates an increasing number of these to lead to revenue generating commercial agreements over 2018 and 2019. To facilitate this strategy, the company has expanded its business development resources in the US and Avacta now has a presence on both the US east and west coasts that targets therapeutic and non-therapeutic partners.

This process has been supported by strong growth in public third-party validation of Affimer technology with the company noting a record period for publications of third party peer reviewed scientific papers including Nature, Molecular Cell and the Proceedings of the National Academy of Sciences in the USA. Complimentary to this, two existing commercial users of Affimers, Covance and Heptares, have provided both data and public testimonials supporting the use of Affimers in their ongoing research activities.
Avacta Animal Health

During the interim period, the Animal Health division extended its allergy offering providing a more comprehensive allergy service to support vets. Work has also commenced with the Life Sciences division to review the use of antibodies with Avacta’s existing diagnostic tests and assess where Affimers can be used to improve performance and reduce costs in these tests.

Although trading over the interim period was flat on the comparable period in 2017, the company anticipates a stronger performance from the allergy business in H2 2018 given that the Pet Allergy Week and the British Small Animal Veterinary Association meeting in early April 2018 represent key marketing phases in the second half of the year.

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