EDISON

Angle

FY16 results

Progress with R&D and commercialisation

Pharma & biotech

Recent newsflow from Angle and the FY16 report released last week showed progress in developing and commercialising the liquid biopsy diagnostic system Parsortix. The R&D strategy is progressing, with the ovarian cancer trials recruiting first patients in the US and Europe and on track to deliver data around end-2016, while the first research use sales met our expectations and a new large client is on board. Our updated valuation of Angle is £129.6m (vs £95m previously).

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
04/15	0.00	(3.55)	(7.50)	0.0	N/A	N/A
04/16	0.36	(5.03)	(7.97)	0.0	N/A	N/A
04/17e	1.09	(7.72)	(10.26)	0.0	N/A	N/A
04/18e	3.62	(5.25)	(6.70)	0.0	N/A	N/A

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

Sales spot on, costs lower than expected

In FY16 Angle's revenues were £361k, in line with our estimate, while an operating loss of £5.4m came in better than our expected loss of £6.0m. While a small number in absolute terms, this was significant as it represented a commercial milestone for the first ever sale of Parsortix for research use. In line with the company's strategy, sales for research use are the near-term goal, while the largest potential is in clinical utility of Parsortix, currently being explored in clinical trials. Importantly, besides the economic benefit, research use sales mean that Parsortix will be increasingly used in cancer clinical trials run by third parties. This will drive the generation of additional data and thus the clinical credibility of Parsortix.

Progress on both fronts

The company indicated that the research use sales pipeline is developing with new customers and converting existing relationships with key opinion leaders (KOLs). Notably, the contract signed with Cancer Research UK (CRUK) Manchester Institute after the close of FY16 indicates a potential boost to research use sales in the near term, in our view. The R&D strategy is developing in Europe and the US, with three clinical applications now likely to be progressing.

Valuation: Upped to £129.6m or 173p/share

We have revised our valuation of Angle and now include metastatic breast cancer and prostate cancer applications in addition to our previous DCF-based valuation of Angle's core operations and ovarian cancer application. We calculate that the two new applications add £15m to Angle's valuation. Following strong newsflow in recent months, ramp-up of R&D activities and initial sales meeting our expectations, we increase our valuation to £129.6m or 173p/share from £95m or 161p/share.

1 August 2016

Price	**68.8p**
Market cap	**£51m**

Net cash (£m) at 30 April 2016, including net £9.6m raised in May	13.4
Shares in issue	74.8m
Free float	90%
Code	AGL
Primary exchange	AIM
Secondary exchange	OTC QX

Share price performance

%	1m	3m	12m
Abs	15.6	1.1	(22.8)
Rel (local)	8.8	(5.3)	(23.5)
52-week high/low		95.5p	54.5p

Business description

Angle is a pure-play specialist diagnostics company. The proprietary Parsortix cell separation platform can be used for detecting and harvesting very rare cells from a blood sample, including circulating tumour cells (CTCs). The resulting liquid biopsy enables the analysis of these cells for precision cancer care.

Next events

Results from KOL studies in other cancer indications	H216
Preliminary results from ovarian cancer clinical trial	End-2016/ early 2017
H117 results	January 2017

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Evolving R&D and commercialisation strategy

As previously, Angle aims to sell Parsortix for research use initially, followed by clinical sales for specific indications, with the most advanced one being ovarian cancer. Encouraging data from the investigator-initiated studies released this year indicate that the other likely clinical applications are metastatic breast cancer and prostate cancer.

Key commercial and strategy highlights from FY16 report

Research use sales in line with expectations

Initial research use sales were announced in December 2015 and Angle reported that the sales pipeline is developing with selected institutions. Research use sales came from existing relationships with KOLs, who were converted to paying customers, but new clients were established as well. Further growth of research use sales will depend on the number of clinical trials in which Parsortix will be used. In total there are now over 90 Parsortix instruments in active use, with over 17,000 blood samples processed, up from around 80 instruments and 12,000 separations at the beginning of this calendar year.

As announced previously one of the largest customers is CRUK Manchester Institute, with the contract signed after the end of FY16. CRUK Manchester Institute will adopt Parsortix in routine use in clinical trials and research. Currently it is being used in 10 clinical trials with an additional four planned. Notably, CRUK Manchester Institute is running around 620 clinical trials in cancer, so there is significant potential for Parsortix to be used in more studies.

Progressing interactions with the FDA and breast cancer application update

Angle confirmed that the first FDA clearance in the US will be pursued for metastatic breast cancer and released more details about the clinical trial. The required patient number is 392, split equally between healthy volunteers and breast cancer patients. Angle believes the data could be obtained next year with subsequent filing with the FDA, although the timelines for eventual approval rest with the agency.

Angle has been in discussions with the FDA for the past two years as a result of the novelty of the emerging liquid biopsy field. Angle noted that the completed work on the system's analytical validation will not be needed for every clinical application, thus likely shortening the review timelines for other applications. Separate clinical trials will be needed for every application as planned previously. We also note the joint FDA workshop together with the American Association for Cancer Research (AACR) on liquid biopsies in oncology conducted on 19 July. In our view this indicates increased focus on clarifying regulatory pathways for the emerging liquid biopsy test.

First patients recruited to ovarian cancer studies

As announced in July, the first patients were recruited into two clinical studies that are running in parallel in the US and Europe and explore Parsortix efficacy in triaging women with ovarian masses before surgery (whether the tumour is benign or malignant). Both studies seek to recruit 200 patients. In Europe, blood samples from the first half of the patients will be used as "training" to optimise the use of biomarkers for malignancy, which were identified during the previous successful pilot trial with the Medical University of Vienna. The blood samples from the rest of the patients will be used for verification. Angle reiterated its goal of completing the trial by the end of 2016, but this will depend on the speed of the recruitment. The design of the US study is slightly different and will

also evaluate clinical information (eg demographics, imaging results, etc) for the estimation of the risk of malignancy.

In Europe, if the data from the ovarian cancer study is positive, Angle plans to start offering Parsortix to accredited European hospitals via a laboratory developed test (LDT) pathway, which means that the laboratories will be required to validate the test under their own quality control system. As this represents an additional hurdle for the customers and may limit the potential of Parsortix, Angle now plans to conduct a second prospective clinical study to validate the clinical utility of Parsortix, which would "upgrade" the existing CE mark for this specific indication, thus eliminating the need for internal validation at the hospitals. Angle aims to complete the study next year. A similar validation study will likely be needed in the US.

Valuation

During the past few months Angle has released headline data from KOL studies supporting Parsortix use in metastatic breast cancer and prostate cancer patients. While these were pilot studies and full results are yet to be published, the company is progressing with the plans for clinical trials; we therefore add these additional applications to our valuation model.

Metastatic breast cancer

As we discussed previously headline data from Angle's KOL partner University of Southern California (USC) Norris Comprehensive Cancer demonstrate that circulating cancer cells (CTCs) captured using Parsortix potentially have the same biology compared to invasive tissue biopsy and can be used to guide the treatment. At this still early stage precise positioning in the clinic is difficult to foresee, but if the efficacy is replicated in future clinical studies, Parsortix could potentially replace tissue biopsy. Non-invasive, blood-based tests offer many advantages over tissue biopsy with the most important being patient comfort, ability to follow up during the treatment and cost. In addition, it is not always possible to access a metastatic lesion, although recently updated American Society of Clinical Oncology (ASCO) guidelines recommend a biopsy of a metastatic site to guide the decision for treatment.

Initial data show that Parsortix could be an alternative to tissue biopsy of the metastatic tumour, which point to women with existing metastatic disease as the most likely primary population given current knowledge (c 160k in the US, Metastatic Breast Cancer Network; and extrapolated c 320k in Europe per year). For this indication, we forecast peak sales of c £60m in 2027-2028 with the expected launch date in 2019 in the US and Europe. As in ovarian cancer application, our sales forecasts are based on the assumption that Parsortix will be used in 20% of existing metastatic breast cancer patients, where a follow up with 2-4 tests a year seems likely. We also maintained a conservative uptake with peak sales reached over nine years due to the novelty of the technology. Our other assumptions are also in line with those for the lead ovarian cancer application as discussed in detail in our initiation report. Due to early stage of the plans for the design of the clinical trial and because only headline data is available we see a success probability between 5-10% as reasonable (7.5% applied in the model).

Prostate cancer

Headline data from Angle's KOL partner Barts Cancer Institute (BCI) indicate that Parsortix can potentially perform as well as or better than current standard of care in terms of detecting early-stage prostate cancer and assessing its severity, and can do so with a simple blood test. As with metastatic breast cancer precise clinical application is yet to be defined, but in particular the finding that Parsortix may be able to indicate the metastatic or localised status of the disease with a higher

level of accuracy than the Gleason score looks to be striking, but will still need to be repeated in larger-scale trials.

Given the fact that only around 10% (cancer.gov) of men, who undergo prostate tissue biopsy because of the elevated PSA level, need further active treatment and around 80% are considered disease-free, the incentive to add a non-invasive test with sufficient sensitivity/specificity seem high. We assume total number of biopsies carried out in the US (c 1m, cancer.gov) and Europe (c 2m, extrapolated). We forecast peak sales of c £140m in 2029-2030 with the expected launch date in 2020 in the US and Europe with same 20% market penetration. This indication is somewhat earlier that metastatic breast cancer, we therefore apply a lower success probability of 5%.

Looking at the cost side of the model, we forecast c £9-13m in R&D spend over the next two to three fiscal years in order to secure EU and US approval for clinical sales and to fund clinical trials in other applications. We assume that Angle will bear the full cost of the ovarian clinical study, leaving room for upside should funding be available under various European research programmes. Our valuation assumes that Angle will market Parsortix directly, and that manufacturing costs remain as projected, driving an effective product mix margin to 80%. Exhibit 1 details the risk-adjusted NPV approach for the two new applications. Notably, while prostate cancer application is in earlier stages, the rNPV is higher than metastatic breast cancer application indicating a larger potential.

Exhibit 1: rNPV-based valuation of early-stage projects for Parsortix

Indication	Launch	Peak sales (£m)	Value (£m)	Probability	rNPV (£m)	NPV/share
Metastatic breast cancer	2019	60	106.6	7.5%	7.0	24.8
Prostate cancer	2020	140	177.4	5.0%	8.1	28.5

Source: Edison Investment Research

We value Angle at £129.6m or 173p/share (up from £95m or 161p/share), based on sum-of-the parts approach. This includes our previous DCF model (rolled forward and updated for net cash) for Angle's core operations running the organisation, research use sales and ovarian cancer application, assuming a discount rate of 10%, terminal growth of 2%. We also now add risk-adjusted NPVs for metastatic breast cancer and prostate cancer as above, assuming our standard discount rate of 12.5% for earlier stage projects. The breakdown of our valuation is shown in Exhibit 2.

Exhibit 2: Sum-of-the parts valuation of Angle

Key assumptions	NPV (£m)
DCF valuation (core operations, research use sales and ovarian cancer application)	
Free cash flow model FY17-25e	23.4
Tapering growth free cash flows FY26-35e	39.6
Terminal value (2% growth rate assumed)	38.1
Discount rate	10%
Tax rate	20%
NPV	101.0
rNPV valuation	
Metastatic breast cancer	7.0
Prostate cancer	8.1
Discount rate	12.5%
Net cash (FY16 + private placement)	13.4
Valuation (£m)	**129.6**
Valuation/share (p)	**173.2**

Source: Edison Investment Research

Financials

Research use sales of £361k were in line with our estimate and we therefore leave our forecasts unchanged. However, recent news about the CRUK Manchester Institute adopting Parsortix for

routine use in clinical trials may provide upside given that the contract was signed after the close of FY16. We keep our expected long-term peak sales forecast of c £10m for research use, to be reached in 2022/23 (more details in our previous report).

We slightly reduce our clinical sales expectations in the near term from the ovarian cancer application, with a slower uptake after Angle provided more details about its development strategy in ovarian cancer (the validation study). Nevertheless we maintain our previous long term peak sales estimate for this indication, which slightly increased to £18m from £16m due to currency effect. Angle reiterated its aim to complete the ovarian cancer study in 2016, although this depends on the recruitment speed, which is difficult to forecast. Given the need for the LDT pathway, we can still see a limited launch in Europe in FY2018, with sales accelerating after the validation study. Our previous expectation of US launch in 2019 also seems feasible.

Exhibit 3: Key changes to our financial forecasts and introduction of 2018 forecasts

£m	2016			2017e			2018e
	Estimate	Actual	Change (%)	Old	New	Change (%)	New
Revenue	0.341	0.361	+6%	2.186	1.085	-50%	3.620
Gross profit	0.238	0.254	+7%	1.537	0.762	-50%	2.545
Operating profit (rep.)	(5.963)	(5.449)	N/M	(4.112)	(8.493)	N/M	(6.057)
Profit before tax (rep.)	(5.929)	(5.427)	N/M	(4.097)	(8.478)	N/M	(6.057)
Profit after tax (rep.)	(5.729)	(5.086)	N/M	(3.897)	(8.278)	N/M	(5.857)
EPS rep. (p)	(9.69)	(8.64)	N/M	(6.57)	(11.29)	N/M	(7.77)

Source: Angle accounts, Edison Investment Research

Expected acceleration of R&D activities, however, caused a reduction in forecasted earnings for 2017 and 2018. We now include costs to run the additional validation study for ovarian cancer and include additional expenses for the two other applications. Our model suggests break-even on operating profit could be reached in 2021, yet this depends on the timing of the initiation of clinical trials for other applications. Notably, the cash position of £3.8m at end of FY16 (30 April) was boosted with net proceeds of £9.6m from the private placement in May. This provides a comfortable safety margin likely sufficient to develop Parsortix for all three clinical applications in our base scenario.

Exhibit 4: Financial summary

£'000s	2014	2015	2016	2017e	2018e
Year end April	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	0	0	361	1,085	3,620
Cost of Sales	0	0	(107)	(322)	(1,075)
Gross Profit	0	0	254	762	2,545
Research and development	(900)	(1,600)	(2,470)	(4,750)	(4,125)
EBITDA	(1,994)	(3,452)	(4,858)	(7,445)	(4,889)
Operating Profit (before amort. and except.)	(2,051)	(3,563)	(5,056)	(7,734)	(5,250)
Intangible Amortisation	(99)	(204)	(187)	(279)	(326)
Share-based payments	(61)	(111)	(238)	(480)	(480)
Other	0	0	32	0	0
Operating Profit	(2,211)	(3,878)	(5,449)	(8,493)	(6,057)
Net Interest	13	9	22	15	0
Profit Before Tax (norm)	(2,038)	(3,554)	(5,034)	(7,719)	(5,250)
Profit Before Tax (FRS 3)	(2,198)	(3,869)	(5,427)	(8,478)	(6,057)
Tax	0	0	309	200	200
Discontinued operations	960	(18)	32		
Net Income (norm)	(1,078)	(3,572)	(4,693)	(7,519)	(5,050)
Net Income (FRS 3)	(1,238)	(3,887)	(5,086)	(8,278)	(5,857)
Average Number of Shares Outstanding (m)	45.1	47.6	58.9	73.3	75.4
EPS - normalised (p)	(2.39)	(7.50)	(7.97)	(10.26)	(6.70)
EPS - normalised and fully diluted (p)	(2.39)	(7.50)	(7.97)	(10.26)	(6.70)
EPS - (IFRS) (p)	(2.74)	(8.16)	(8.64)	(11.29)	(7.77)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	n/a	n/a	70.4	70.3	70.3
EBITDA Margin (%)	n/a	n/a	n/a	n/a	n/a
Operating Margin (before GW and except.) (%)	n/a	n/a	n/a	n/a	n/a
BALANCE SHEET					
Fixed Assets	1,882	1,572	1,801	1,895	1,789
Intangible Assets	1,142	1,149	1,346	1,399	1,405
Tangible Assets	139	423	455	496	385
Investments	601	0	0	0	0
Current Assets	4,278	9,648	4,938	7,053	1,932
Stocks	52	197	376	353	442
Debtors	328	1,008	489	446	496
Cash	3,898	8,443	3,764	5,945	685
Other	0	0	309	309	309
Current Liabilities	(645)	(1,131)	(1,504)	(1,911)	(2,060)
Creditors	(645)	(1,131)	(1,504)	(1,911)	(2,060)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	0	0	0
Long term borrowings	0	0	0	0	0
Other long term liabilities	0	0	0	0	0
Net Assets	5,515	10,089	5,235	7,037	1,661
CASH FLOW					
Operating Cash Flow	(1,899)	(3,413)	(4,762)	(6,999)	(4,878)
Net Interest	(4)	5	23	15	0
Tax	0	0	0	227	200
Capex	(83)	(325)	(186)	(330)	(250)
Acquisitions/disposals	4,326	126	577	0	0
Financing	0	8,257	1	9,600	0
Other	(270)	(105)	(332)	(332)	(332)
Dividends	0	0	0	0	0
Net Cash Flow	2,070	4,545	(4,679)	2,181	(5,260)
Opening net debt/(cash)	(1,828)	(3,898)	(8,443)	(3,764)	(5,945)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(3,898)	(8,443)	(3,764)	(5,945)	(685)

Source: Angle accounts, Edison Investment Research. Note: Historic reported revenues relate to the legacy business, which has now been divested. FY14 has been restated to exclude discontinued operations.

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