

ANGLE plc

£20m placing to accelerate Parsortix opportunities

Update

28 June 2021

ANGLE has raised £20m (gross) to maintain momentum in consolidating its position as the leading player in CTC liquid biopsy. Its proprietary Parsortix microfluidic device captures circulating tumour cells (CTCs) for analysis and can complement ctDNA (circulating tumour DNA) liquid biopsies. New monies boost pro forma cash to c £47m supporting current initiatives (eg breast and ovarian cancer), new opportunities to expand Parsortix's utility, and expanding the commercial infrastructure. ANGLE has identified two specific, highly commercially attractive opportunities: an LDT to assess prostate cancer risk, and a PD-L1 pharma services assay for clinical trials. Both would be offered through its two clinical laboratories (UK and US), which in addition to accelerating Parsortix system adoption, also act as demonstrators of how it enables targeted treatments, response monitoring, and improved patient outcomes. Our updated DCF-based model generates a valuation of £570m (\$741m), or 244p/share.

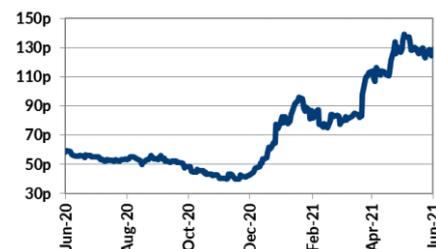
Year-end: December 31	2019*	2020	2021E	2022E
Revenue (£m)	0.6	0.8	2.3	5.5
Adj. PBT (£m)	(9.1)	(13.8)	(20.5)	(19.2)
Net Income (£m)	(7.9)	(11.6)	(18.2)	(17.3)
Adj. EPS (p)	(4.7)	(6.7)	(7.7)	(7.3)
Cash (£m)	18.8	28.6	26.9	10.2
EBITDA (£m)	(8.4)	(12.3)	(19.8)	(17.8)

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals * FY19 covers an eight-month period.

- £20m raised at 116p** ANGLE has raised £20m (gross) via a placing of 17.24m new shares with new and existing UK and US investors at a price of 116p/share (6.83% discount to the closing price on 23 June 2021). The new shares, representing 7.4% of the enlarged issued share capital, will be admitted to trading on 1 July.
- Proceeds to maintain Parsortix momentum** Pro forma cash of c £47.6m provides ANGLE with the resources to progress commercialisation of Parsortix, including in new clinical applications. Specifically, funds will be directed towards (1) pursuit of a major prostate cancer diagnostic opportunity (£7m); (2) building a US senior management team to support commercialisation (£3m); (3) assay development capability (£2m); and (4) ongoing operations for the breast and ovarian cancer opportunities and strengthening the balance sheet for pharma services (£8m).
- Addressing four priority markets** ANGLE has four commercial revenue streams (research use, pharma services, LDTs, clinical products) with an initial focus on four priority markets (PD-L1 status testing and other assay development for key target proteins, and liquid biopsy in prostate, ovarian, and breast cancer). In parallel with seeking FDA approval, ANGLE offers CTC analysis services to pharma companies and plans to launch LDTs that will be run in its own CLIA and ISO certified labs.
- New valuation of £570m or 244p/share** We value ANGLE using a three-phase DCF model based on the various forecast revenue streams netted against cash. Updating this for the raise generates a valuation of £570m, equivalent to 244p per share, vs £549m (255p/share) previously. Further upside would be unlocked by catalysts such as FDA approval, additional pharma services contracts, positive clinical data, and additional commercial partnerships.

Price	129.5p
Market Cap	£279.6m
Enterprise Value	£232.0m
Shares in issue	233.1m
12 month range	37.2-143.9p
Free float	62.5%
Primary exchange	AIM
Other exchanges	OTC QX
Sector	Healthcare
Company Code	AGL

Corporate client Yes



Company description

ANGLE is a specialist diagnostics company. Its proprietary Parsortix technology can capture and harvest very rare cells, including CTCs (circulating tumour cells), from a blood sample. The FDA approval for its clinical use to guide precision cancer care will open up further multiple commercial opportunities.

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ANGLE: Demonstrating and accelerating progress

ANGLE's £20m (gross) raise provides additional funds to expand and accelerate its product-led commercialisation initiatives for its Parsortix circulating tumour cell (CTC) liquid biopsy platform. Potential FDA clearance in H221 for Parsortix as a medical device for harvesting of CTCs for subsequent analysis in metastatic breast cancer (mBC) would be a key milestone for the company. This would be the first approval for a CTC harvesting system and only the third product authorisation for any liquid biopsy. While many investors are focused on this catalyst, it is only one facet of ANGLE's myriad opportunities: the pharma services business is already generating strong interest and the first launch of an LDT (Laboratory Developed Test) from the newly established clinical services laboratories in the US and UK should happen in late-2021. The first pharma services contract was announced in April, and the PD-L1 assay (plus additional assays in development) will bolster this offering. LDT development for ovarian cancer is late-stage (data in Q421) and will shortly be underway for prostate cancer. Increasing visibility on ANGLE's commercial plans should unlock further material value. Updating our DCF-based model for the raise results in a £570m valuation, equivalent to 244p per share.

Deal structure and valuation impact

£20m gross raised at 116p per share (6.83% discount)

The equity raise boosts pro forma funds to c £47.6m providing ANGLE with the resources to maintain commercialisation momentum with the Parsortix system in existing, already planned, and new applications. The company raised £20m (gross) from new and existing UK and US investors via the placing of 17.24m new shares at a price of 116p/share (6.83% discount to mid-market close on 23 June 2021). The new shares will be admitted to trading on 1 July.

New valuation of £570m or 244p/share

Updating our valuation for the new funds raised and new shares issued generates a company valuation of £570m, equivalent to 244p per share, vs £549m or 255p per share previously. We continue to value ANGLE using a three-stage DCF based on comprehensive forecast cash flows to 2031, followed by a ten-year trending period, and a modest 2.5% terminal growth rate. We separately forecast cash flows for three business lines (research use, pharma services and LDTs, and clinical products) which are summed and netted against the central operating costs and current net cash/debt. Our [May 2021 Initiation](#) provides additional detail on our valuation methodology and outputs.

Use of proceeds

Supporting Pharma Services, LDT, and Clinical Products commercialisation

ANGLE is targeting four commercial revenue streams with the Parsortix system: research use; pharma services (CTC analysis in clinical trials); laboratory developed tests (LDTs) through its clinical laboratories; and clinical products (including through partners). New funds will address the latter three, providing additional resources for investment in R&D and into the sales and marketing infrastructure from H221 through FY22 and beyond.

Key US hires to drive adoption...

As the US is the largest market for liquid biopsy by potential value it will be the initial launch market for many of ANGLE's products. The company is therefore

...with Clinical Laboratories at the core of commercial plans

seeking to strengthen and develop its market position through several US key management hires. This larger experienced team is expected to have a significant impact on securing potential new pharma services contracts, corporate partners, and, once clearance is granted, driving adoption of LDTs and clinical products.

The establishment of its own CLIA and ISO-accredited clinical laboratories (accreditation expected in Q421) in the US and UK allows ANGLE to have direct control over several of its commercialisation activities. The two laboratories offer CTC analysis services to pharma companies and will, following relevant approvals, also launch LDTs (such as the triage LDTs for ovarian cancer and later for prostate cancer) that will be run at these locations. In addition to generating near-term revenues, these laboratories act as demonstrators of Parsortix's clinical utility and accelerators of market awareness and adoption.

Proceeds from the June fundraise has been earmarked as follows:

- £7m for the pursuit of a major prostate cancer opportunity;
- £3m to build a US senior commercial management team;
- £2m for assay development capability; and
- £8m to support ongoing operations for the breast and ovarian cancer opportunities and to strengthen the balance sheet for pharma services.

We have not yet adjusted our FY21 and FY22 forecasts to reflect additional spend associated with the fund raise but intend to do so following greater clarity on the specific development plans. We anticipate that this would be provided at H121 interim results.

Three priority addressable markets become four

Prostate cancer opportunity is being expedited

The Parsortix system has a broad potential clinical applicability and liquid biopsy is expected to be employed increasingly not only in initial diagnosis, but to monitor and guide treatment of cancer patients. It has numerous benefits over tissue biopsy, particularly when accessing primary or metastatic tumour sites is difficult, and in tracking changes of tumour status over time. A substantial portion of the equity raise - £7m - will be directed to pursuing a major new opportunity for Parsortix in prostate cancer screening.

Expediting plans for prostate cancer test development

Solid rationale for as biopsy triage for high PSA individuals

ANGLE is seeking to develop a prostate cancer triage test which would evaluate men with elevated PSA ([prostate-specific antigen](#)) to determine whether (a) they do have prostate cancer (PC) and if so (b) assess the aggressiveness of the disease (c 90% of cases are benign or indolent). This would reduce the need for expensive (typically c \$2k) and invasive core tissue biopsy which, despite being the current gold standard for diagnosis, detects cancer in only c 25% of biopsies reflecting 'overuse' (but also routinely missing some incidences of PC) and is associated with a high risk of complications.

Barts pilot study provides supporting evidence

A pilot study run by Barts Cancer Institute, published in [Clinical Cancer Research](#), has shown supportive evidence that CTCs can be used to detect the presence of

Familiar development pathway to ovarian cancer LDT

PC and also risk stratify patients for intervention or further surveillance. The Barts study in 81 prostate cancer patients (34 with castrate-resistant PC and 38 localised PC) found CTCs in all CRPC cases and in 79% of localised patients.

Given the parallels with the ovarian cancer triage test, we expect that the PC development pathway could take a similar route as an LDT. The initial step would be an assay development study in a relatively small number of patients (c 200), which could support LDT launch in 2023. Pursuit of an approval as a clinical product would require a larger clinical verification study. We anticipate that management will provide future details and guidance on the timing and design of the PC development pathway, which would determine the phasing of R&D investment and potential launch timings.

Sizeable and accessible commercial opportunities

The commercial opportunity is sizeable, with similar application characteristics to those in other difficult to biopsy solid tumours. These can be classified as high-risk screening, active surveillance, therapeutic decision making, and remission monitoring. Management estimates the addressable markets in the US alone as being worth \$1.20bn, \$1.47bn, \$3.07bn, and \$0.99bn respectively. The first of these tests could be ready for commercial launch as soon as end-2022, with further roll-outs through to 2024.

PD-L1, ovarian, and breast cancer tests closer to market

Prostate cancer joins tests for PD-L1 status, mBC, and ovarian cancer

Prostate cancer adds a fourth dimension to the three priority addressable markets previously highlighted by ANGLE. Each of these has new funds directed towards supporting future marketing plans, and are covered in more detail, along with their markets, in our [May 2021 Initiation](#). To recap, these are:

- **PD-L1 testing for immunotherapy clinical trials:**

PD-L1 is one of two pharma services assays currently offered

The PD-L1 assay, known as Portrait Plus PD-L1, is the second pharma services test offered by ANGLE, the first being the Epithelial/Mesenchymal Transition (EMT) enumeration and CTC cluster assay, known as Portrait Plus. Tumour PD-L1 status is critical to determining the appropriate immunotherapy regimen and, for clinical trials it offers key information for the assessment of drug effectiveness and may enable the development of companion diagnostics to select patients likely to respond to the drugs under evaluation. Use of ANGLE's Portrait Plus PD-L1 assay in Phase I studies by pharmaceutical development companies or CROs is a precursor to involvement in the later clinical stages where patient numbers are larger and trials longer.

ANGLE has a significant opportunity in developing additional assays for harvested CTCs, and £2m of new funds will be invested in this. As well as bespoke assay development for customers, new biomarker-based tests – including those where ctDNA-based liquid biopsies are not applicable as the biomarker is protein – could contribute to an expanded menu of assays that can be offered direct to pharma clients or used in LDTs.

- **Clinical testing for breast cancer:**

FDA clearance in mBC could open many doors for ANGLE

FDA device clearance of Parsortix for harvesting of CTCs for subsequent analysis in mBC will provide major validation for ANGLE. The *de novo* submission was filed in September 2020, provision of the response to a subsequent AIR (Additional Information Request) was announced in June 2021 and, assuming no delays,

clearance is possible in H221. This could be the catalyst for Parsortix partnerships with a wider and larger number of organisations, as well as permitting sale of the mBC test as a clinical product to guide treatment decisions.

Liquid biopsy has an important role to play in mBC, particularly as many metastatic sites are not suitable for routine (and regular) biopsy and that the biomarkers currently examined (eg oestrogen, progesterone, and HER2) may alter during disease progression/treatment, and thus not provide a sufficiently complete picture of a tumour's current sensitivities to direct effective treatment.

- **Ovarian cancer testing:**

Ovarian cancer LDT to launch late-2021, post clinical verification study read out

A LDT to triage abnormal pelvic masses is the initial Parsortix application in ovarian cancer. It has the potential to be a best-in-class test for discriminating between benign pelvic masses and ovarian cancer and informing next surgical steps. ANGLE plans to launch an ovarian cancer LDT in late-2021 following release of Q421 top line clinical verification study data.

The ovarian cancer triage LDT will initially be available to private payers via clinicians. Data generated will be leveraged to obtain reimbursement codes for Parsortix clinical applications. Subject to supportive clinical verification studies, this LDT could also be applied to monitoring in watchful waiting (of pre-surgical pelvic masses) or for disease remission monitoring.

Exhibit 1: Summary of financials

Year-end: Dec 31	£'000s	2018*	2019**	2020	2021E	2022E
INCOME STATEMENT						
Revenues		628	581	762	2,315	5,469
Cost of goods sold		(169)	(142)	(165)	(651)	(1,547)
Gross Profit		459	439	597	1,664	3,922
Operating expenses		(9,444)	(9,512)	(14,407)	(21,993)	(22,932)
Underlying operating profit		(8,985)	(9,073)	(13,810)	(20,328)	(19,010)
Share-based payments		(324)	(333)	0	(375)	(383)
Exceptionals		0	0	0	0	0
Other revenue/expenses		52	61	79	87	96
EBITDA		(8,467)	(8,441)	(12,310)	(19,843)	(17,792)
Operating Profit		(9,257)	(9,345)	(13,731)	(20,617)	(19,297)
Financing costs/income		8	(26)	(14)	(124)	(235)
Profit Before Taxes		(9,249)	(9,371)	(13,745)	(20,741)	(19,532)
Adj. PBT		(8,977)	(9,099)	(13,824)	(20,452)	(19,245)
Current tax income		1,387	1,482	2,139	2,574	2,188
Net Income		(7,862)	(7,889)	(11,606)	(18,167)	(17,344)
EPS (p)		(8.2)	(4.8)	(6.5)	(7.8)	(7.4)
Adj. EPS		(8.0)	(4.7)	(6.7)	(7.7)	(7.3)
DPS (p)		0.0	0.0	0.0	0.0	0.0
Average no. of shares (m)		95.5	163.7	178.0	233.1	233.1
BALANCE SHEET						
Current assets		11,219	23,579	32,930	31,344	14,405
Cash and short-term deposits		7,645	18,766	28,618	26,901	10,183
Trade and other receivables		828	627	1,443	1,078	1,199
Inventories		599	788	742	802	848
Other current assets		2,147	3,398	2,127	2,562	2,176
Non-current assets		7,063	6,996	6,119	8,008	7,573
Property, plant & equipment		1,475	1,508	1,176	2,648	1,839
Intangible assets		5,588	3,974	3,710	3,620	3,487
Other non-current assets		0	1,514	1,233	1,740	2,247
Current liabilities		(2,398)	(2,777)	(3,777)	(2,872)	(2,459)
Short-term debt		0	0	0	0	0
Trade payables		(2,398)	(2,425)	(3,343)	(2,574)	(2,407)
Other current liabilities		0	(352)	(434)	(298)	(53)
Non-current liabilities		0	(1,201)	(928)	(928)	(928)
Long-term debt		0	0	0	0	0
Other non-current liabilities		0	(1,201)	(928)	(928)	(928)
Equity		15,884	26,597	34,344	35,552	18,591
CASH FLOW STATEMENTS						
Operating cash flow		(7,136)	(8,699)	(7,848)	(18,054)	(15,649)
Profit before tax		(9,249)	(9,371)	(13,745)	(20,741)	(19,532)
Non-cash adjustments		1,074	1,498	2,268	1,273	2,123
Change in working capital		538	(767)	228	(601)	(578)
Interest paid		0	0	0	(124)	(235)
Taxes paid		501	(59)	3,401	2,139	2,574
Investing cash flow		(5,466)	(15,564)	(1,966)	(2,156)	(563)
CAPEX on tangible assets		(1,861)	(595)	(506)	(2,156)	(563)
Acquisitions/disposals		(3,613)	0	0	0	0
Other investing cash flows		8	(14,969)	(1,460)	0	0
Financing cash flow		14,391	16,675	18,143	18,493	(507)
Proceeds from equity		14,391	16,921	18,650	19,000	0
Increase in loans		0	0	0	0	0
Other financing cash flow		0	(246)	(507)	(507)	(507)
Net increase in cash		1,789	(7,588)	8,329	(1,717)	(16,719)
Cash at start of year		5,536	11,010	3,757	12,080	10,363
Cash at end of year		7,321	18,766	28,618	26,901	10,183
Net cash at end of year		7,645	18,766	28,618	26,901	10,183

Source: ANGLE, Trinity Delta. Note: Adjusted numbers exclude exceptionals. * FY18 relates to 12 month period ending 30 April 2018, ** FY19 relates to 8 month period ending 31 December 2019.

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