Trinity Delta

ANGLE plc

Update

Poised to disrupt existing tumour assay protocols

1 October 2021

ANGLE's H121 results confirm progress of its proprietary Parsortix cancer diagnostic platform across multiple fronts. Whilst attention inevitably focusses on the expected upcoming FDA approval for use in metastatic breast cancer, important progress has been achieved with developing the ovarian cancer LDT (Laboratory Developed Test). UK and US clinical laboratories, created ahead of schedule, are anticipated to receive certification by year-end. This will drive nearer term revenues from pharma services, demonstrate the clinical value, and validate the proposition for larger commercial labs. Collectively these efforts will help shape Parsortix's positioning in the emerging, and dynamic, liquid biopsy market. We value ANGLE at £581m ($755m), 248p/share.

Year-end: December 31	2019*	2020	2021E	2022E
Revenue (£m)	0.6	0.8	2.3	5.4
Adj. PBT (£m)	(9.1)	(13.8)	(20.2)	(19.6)
Net Income (£m)	(7.9)	(11.6)	(17.9)	(17.6)
Adj. EPS (p)	(4.7)	(6.7)	(7.6)	(7.4)
Cash (£m)	18.8	28.6	27.3	10.3
EBITDA (£m)	(8.4)	(12.3)	(19.6)	(18.2)

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

- **UK and US clinical laboratories established** Creation of accredited clinical laboratories is a key element in translating the scientific promise of the Parsortix system into meaningful commercial traction. Parsortix's value as a liquid biopsy, especially its ability to provide longitudinal analysis in clinical trials and more relevant genomic insights, has been demonstrated by numerous independent studies by prestigious cancer research institutes. As well as generating near-term revenues, the laboratories essentially undertake pilot studies in many cases and act as demonstrators of clinical benefit and accelerators of market awareness.

- **Key LDTs are finalising development** Developing patient relevant and market ready Laboratory Developed Tests is an essential step in establishing attractive US reimbursement codes and confirming the clinical benefit and commercial demand. The ovarian cancer test, to differentiate between a benign pelvic mass and a tumour requiring specialist treatment, is completing a final verification trial. Results are due before end-2021 that, if positive, will lead to launch of this LDT. A prostate cancer LDT is planned, with the clinical programme at the early design stage.

- **FDA approval awaited** Parsortix was submitted for FDA approval under the De Novo regulatory pathway as a platform to harvest CTCs for downstream analysis in metastatic breast cancer. Parsortix's novelty means an inherently more uncertain process; likely outcomes and timings remain unclear, but indications suggest receipt of a response in H221. FDA clearance would be the first CTC harvesting system approval, and only the third product authorisation for any liquid biopsy.

- **248p/share DCF-based valuation** We value ANGLE using a three-phase DCF model based on the various forecast revenue streams netted against cash. Updating this for H121 results generates a valuation of £581m, or 248p/share vs £570m (244p/share) previously. Further upside would be unlocked by events such as FDA approval, additional pharma services contracts, and positive clinical outcomes.

Price	135.4p
Market Cap	£318.1m
Enterprise Value	£270.5m
Shares in issue	234.9m
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. FDA approval for its clinical use to guide precision cancer care will open up further multiple commercial opportunities.

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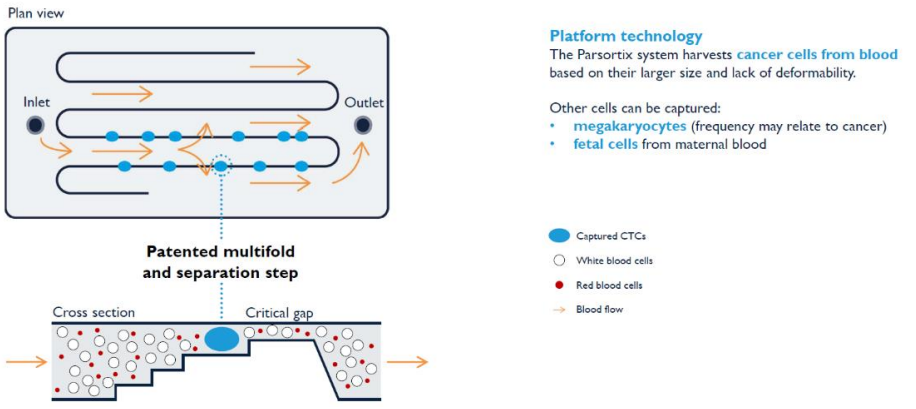
ANGLE: progressing towards major catalysts

H121 results highlight that ANGLE is maintaining its progress across the various elements of preparing its Parsortix platform for widespread commercialisation. Whilst the FDA clearance is rightly seen as a defining moment, there are multiple other initiatives also underway. These include the development of a pharma services business and the imminent launch of LDTs (Laboratory Developed Tests) from the newly established clinical services laboratories in the US and UK. Precise timing of the FDA approval remains uncertain, but before end-2021 remains probable. A positive decision would make Parsortix the first CTC harvesting system approved and only the third product authorisation for any liquid biopsy. These activities, collectively, are what will define Parsortix's place in the rapidly emerging liquid biopsy market. Given the clear clinical need, even a minor success would, in our view, be transformational for ANGLE. Our DCF-based valuation is £581m (248p/share), which should rise materially as visibility on commercialisation initiatives, Parsortix's positioning, and its market traction becomes clearer.

ANGLE is a low-risk play on the emerging field of targeted cancer treatments

ANGLE's Parsortix system is an elegantly simple automated system that can rapidly detect and harvest a whole range of circulating tumour cells (CTCs) from a patient blood sample, effectively a true liquid biopsy. The platform has been extensively validated by many renowned cancer research centres, with impressive results published in peer reviewed journals. The Parsortix microfluidic device (Exhibit 1) has been shown to physically capture CTCs consistently and reliably for analysis and, importantly, can complement other established liquid biopsy methods, such as ctDNA (circulating tumour DNA). The capture of viable CTCs allows valuable additional information of a tumour's status to be gathered, an apt example being the longitudinal monitoring of a tumour's evolving genetic status throughout treatment. Management's focus has been on translating this clear technical potential into viable commercial opportunities.

Exhibit 1: Parsortix platform overview

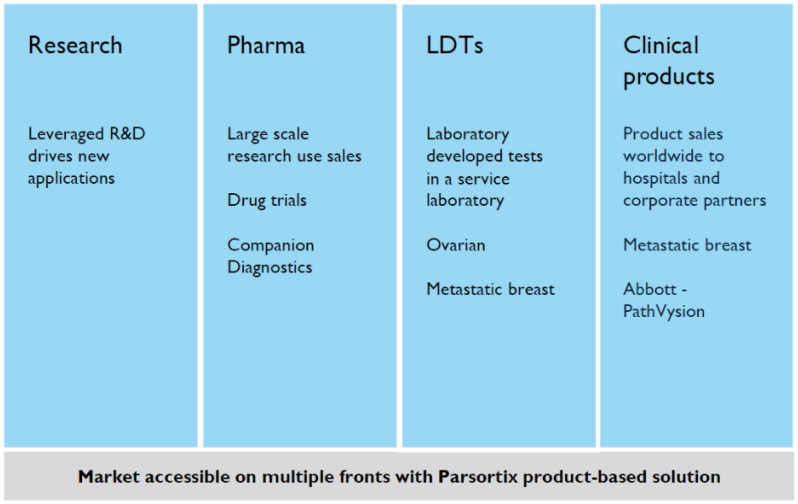


Source: ANGLE

FDA approval to unleash multiple commercial opportunities

Although the FDA approval of Parsortix would mark a defining moment in ANGLE's corporate development, and one which should drive growth across multiple revenue streams, this represents only one aspect of a multi-faceted approach to address the various opportunities. As shown in Exhibit 2, ANGLE is progressing four distinct, but complementary, commercial revenue streams: research use, pharma services, LDTs, and clinical products.

Exhibit 2: Four commercial streams targeted by Parsortix

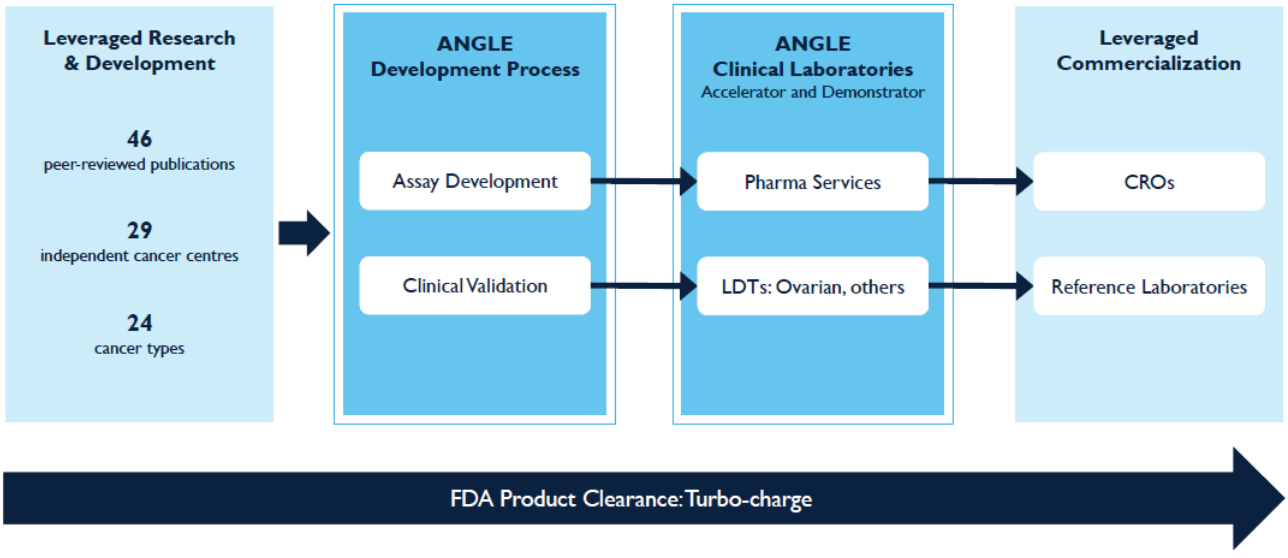


Source: ANGLE

Successful equity raise funds key strategic initiatives

The company successfully raised £20m in new equity in June (proceeds were received in early July) which will be deployed to current initiatives including PD-L1 status testing and other assay development for key target proteins, and liquid biopsy in prostate, ovarian, and breast cancer. An important element of ANGLE's commercialisation process (Exhibit 3) has been the creation of its own clinical laboratories in the US and UK; these are more than simple revenue streams, acting as valuable demonstrators of Parsortix's real-world utility and so seeking to accelerate uptake by the larger clinical laboratories and diagnostic and pharmaceutical companies.

Exhibit 3: ANGLE commercialisation process for Parsortix



Source: ANGLE

All eyes on FDA approval in metastatic breast cancer

De Novo regulatory pathway is inherently more uncertain

Parsortix is set to become the first system for harvesting intact CTCs from a blood sample for downstream analysis to be approved by the FDA. Its intended use is for CTC harvest and downstream analysis in metastatic breast cancer (mBC) but,

once the initial data package has been reviewed and approved, any subsequent utility will be more straightforward to process. The regulatory package for the De Novo Class II clearance was made in September 2020, with an Additional Information Request (AIR) received in March 2021 asking for some targeted additional analytical studies. These were completed as planned, with a comprehensive response announced in early June 2021. As there is no predicate device to benchmark, the De Novo approval pathway is inherently more uncertain. This, coupled with the FDA's documented COVID-19 related resource restraints, means the likely outcome and, importantly, its timing remains unclear. Management continues to anticipate that a response will be received from the FDA before end-2021.

An approved and validated CTC liquid biopsy could alter clinical practice

FDA approval could be the catalyst for Parsortix partnerships with a wider and larger number of organisations, as well as permitting the sale of the platform as a product to support the development of clinical assays for patient management in mBC. An effective and validated liquid biopsy would make a significant difference to the outcomes of many women. The two main issues with current diagnostic approaches are that many metastatic sites are not suitable for routine (and regular) biopsy and that the biomarkers currently examined (eg oestrogen [ER], progesterone [PR], and HER2) may not provide a sufficiently complete picture of a tumour's current sensitivities to direct effective treatment. Availability of a proven, validated liquid biopsy could materially alter current practice, with insights gained having the potential to improve treatment outcomes significantly.

Clinical labs in place, accreditation progressing

Clinical laboratories provide invaluable real-world demonstration

The establishment of its own CLIA and ISO-accredited clinical laboratories in the US and UK allows ANGLE to have greater control over its commercialisation activities. The two laboratories offer CTC analysis services to pharma companies and will, following relevant accreditations, also launch LDTs (such as the triage LDTs for ovarian cancer and, in future, for prostate cancer) that will be offered at these locations. In addition to generating near-term revenues, these laboratories act as important demonstrators of Parsortix's clinical utility and accelerators of market awareness, reimbursement codes, and adoption among the target customer base.

Both sites completed ahead of schedule and on budget

The laboratories in Guildford, Surrey and Plymouth Meeting, Pennsylvania are well placed to provide these services. They were completed ahead of schedule, and within budget, in Q121 and are already processing patient samples as part of the clinical services offering for pharmaceutical trials. Processing samples for drug clinical trials can be undertaken without FDA approval and ahead of CLIA (Clinical Laboratory Improvement Amendments) and UKAS accreditation. The application for ISO15189 (Medical laboratories Requirements for quality and competence) has been submitted for both laboratories. The respective CLIA and UKAS recognitions are expected to be granted by end-2021, following which the broader range of clinical testing can be offered to all customers.

Pharmaceutical services for oncology clinical trials

Clinical trial services provide near-term revenues and longer-term opportunities

The provision of sample testing for oncology clinical trials could be a sizeable revenue stream. All pharmaceutical companies developing cancer therapies are seeking better biopsy tools for use in their clinical studies, notably for patient

targeting and monitoring. The growing understanding of how genetically targeted immunotherapies work means the appropriate selection of patients that are expected to respond to the drugs under evaluation is a critical determinant of a trial's likely success. For instance, knowing the PD-L1 status of a tumour is an increasingly common requirement that is typically established by tissue biopsy. But, as mentioned, accessing the primary tumour is often difficult and becomes even more so when dealing with metastatic disease. Importantly, the tumour's status often changes materially during the course of disease progression and solid biopsies seldom allow for the longitudinal monitoring that is increasingly required.

Longitudinal monitoring and bespoke assays prove to be real differentiators

During the H121 period, ANGLE has agreed pharma services contracts with three pharma and biotech companies. Given the importance of the service, the sales process requires extensive validation of the testing chain and evidence of the consistency and reproducibility of the diagnostic results. The contracts are varied; one includes the longitudinal monitoring of tumour progression in a large Phase III prostate cancer trial, whilst another involves development of bespoke immunofluorescence (IF) assays to detect specific target proteins implicated in DNA damage repair. The contracts include Phase I studies that, if successful, would also involve longitudinal monitoring in later Phase II and Phase III trials. A key factor in the customer's selection criteria was the ability to also capture mesenchymal cancer cells and CTC clusters, since these may have important roles in the progression of disease, metastasis, and emergence of drug resistance.

Interest shown suggests a pipeline of demand

Management has confirmed discussions are progressing with multiple additional potential customers, including several global pharmaceutical companies. The creation of bespoke assays appears to be a particularly attractive proposition, with the opportunity to select the protein targets on a CTC to correspond with their drug's mechanism of action being a valuable differentiator for ANGLE's offering. Importantly, any such bespoke assays that are developed remain ANGLE's intellectual property and can be added to the test menus that are being developed for routine use.

Laboratory Developed Tests progressing well

LDTs should be as important as FDA approval for commercial traction

If Parsortix is to become adopted widely for the treatment and management of patients then, in our view, it must crack the US. At the risk of over-simplifying, for the Parsortix system to become recognised as a liquid biopsy of choice in the US, two critical steps need to be addressed. The first is the establishment of economically attractive US reimbursement codes; the second is demonstration of commercial demand. Both are best dealt with by developing and providing tests that are patient-relevant and market-ready. Once CLIA accredited, the clinical laboratories should act as demonstrators of the services that can be offered, including complete workflows, and help accelerate the development and uptake of integrated diagnostic testing. This will act as an important proof of concept for the larger CLIA laboratory networks.

Attractive reimbursement codes are an important element

Development of in-house Laboratory Developed Tests (LDT) will allow dialogue with US clinical payors to establish dedicated reimbursement codes (CPT codes), which are an essential step in driving widespread adoption and becoming established clinical practice. Assays for several of the more common diagnostic procedures are being developed; first as part of the pharma services offering above and, once clinical studies have been successfully completed, as LDTs. These initially include enumeration of epithelial and mesenchymal CTCs and CTC

clusters (features that antibody-based approaches cannot perform), monitoring PD-L1 status, and, when employed with ANGLE's proprietary HyCEAD technology, multiplex expression profiling of up to 100 genes.

High profile assays will showcase Parsortix's clinical value

However, it will be high-profile programmes (such as a pelvic mass assay to differentiate between a benign mass and ovarian cancer, or an assay that reduces the need for invasive biopsies in prostate cancer) that should generate momentum. The ovarian cancer test in development to triage women set to undergo surgery for an abnormal pelvic mass is the most advanced. This aims to distinguish between a benign and malignant growth ahead of surgery and so direct the patient to the appropriate treatment option.

Ovarian cancer triage is a clear medical need

Most women have benign masses and can be treated in local non-specialist units with conservative surgery (typically laparoscopy, since this is associated with lower morbidities and shorter hospital stays). However, for ovarian cancer patients the most important prognostic factors are accurate surgical staging, cytoreductive surgery, and the expertise of the gynaecological oncologist who performs the operation. Hence, these women should be referred directly to a specialist centre. The difficulty of an accurate pre-operative assessment means that many with ovarian cancer end up in non-specialist centres, resulting in a poorer prognosis, or, conversely, many women with benign masses are operated on unnecessarily in a specialist centre, with longer recoveries, wasted resources, and higher costs.

Pivotal clinical data expected before end-2021

ANGLE has developed a test that is undergoing a 200-patient clinical verification study at the University of Rochester Wilmot Cancer Center. This is expected to show both high sensitivity (correctly detecting cancer) and high specificity (correctly detecting no cancer with a low false positive rate). Patient enrolment has completed, and patient status will remain blinded until the analysis is concluded. Headline results are expected during Q421. The test will be developed as an LDT that can be performed in an accredited laboratory, using the HyCEAD platform at ANGLE laboratories or, in third-party laboratories. If the study delivers as expected, management hopes to launch an LDT as soon as practicable.

Prostate cancer assay being assessed for development

Based on published experience with Parsortix by independent researchers, management is also looking to develop a prostate cancer triage test which would evaluate men with elevated PSA (prostate-specific antigen) to determine whether they do have prostate cancer (PC) and, if so, 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 and is associated with a high risk of complications.

An attractive commercial opportunity

The plan is to work alongside a US chain of urology clinics to outline an appropriate clinical trial which, if the outcomes are positive (and given the parallels with the ovarian cancer triage test), would be developed into an LDT. The commercial opportunity is sizeable, with similar application characteristics to those in other difficult to biopsy solid tumours.

Valuation and Finances

Our DCF model values ANGLE at £581m, equivalent to 248p per share

As ANGLE transitions from development of the Parsortix platform to execution of its commercial strategy so our preferred valuation methodology shifts from an rNPV approach to a DCF model. We employ 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) to reflect the differing markets, revenue potential, growth profiles, and R&D investment requirements that these represent. These are summed and netted against the central costs of running the business and current net cash/debt. Using conservative assumptions throughout, our model generates a valuation of £581m, equivalent to 248p per share (Exhibit 4).

Exhibit 4: Three-phase DCF valuation of ANGLE

Business line	NPV (£m)	NPV ($m)	rNPV (£m)	rNPV ($m)	rNPV/ share (p)	Notes
Research use	19.4	25.3	19.4	25.3	8.3	
Pharma services & LDTs	156.4	203.3	132.9	172.8	56.7	Includes priority LDT applications for PD-L1 and ovarian cancer triage. Overall 85% risk adjustment to reflect development and commercialisation risks.
Clinical Products	493.5	641.5	394.8	513.2	168.5	First meaningful sales FY23, following launch in FY22; 90% risk adjustment for mBC programme.
Operating costs	(13.7)	(17.8)	(13.7)	(17.8)	(5.8)	
Net cash at H121	47.6	61.9	47.6	61.9	20.3	
Total	**703.2**	**914.1**	**581.0**	**755.3**	**247.9**	

Source: Trinity Delta Note: 12.5% discount rate, 2.5% terminal growth rate, 20% tax rate, and $1.3/£ FX rate. mBC = metastatic breast cancer

Parsortix is an acknowledged leader in CTC capture

CTC-based diagnostics are likely to be employed across multiple clinical segments including as non-invasive assays for early detection of cancer; as prognostic tools for cancer survival and the prediction and monitoring of response to therapies; and in the development of new drugs for cancer. These are broad indications and large market opportunities but, as discussed earlier, the field is still immature, crowded, and no industry standard has yet emerged. As the clear leader, Parsortix is well placed to capture meaningful share of these indications, however, in line with our conservative philosophy, we employ modest assumptions in our modelling.

Our forecasts based on visible programmes only, with remainder leaving upside

For instance, we base our revenue assumptions on the three target areas detailed by management: PD-L1 testing as a service for immunotherapy clinical trials; liquid biopsy clinical testing for breast cancer, initially for the presence of metastatic disease then rolling out increasingly into monitoring and therapy selection; and ovarian cancer clinical testing, with the initial focus on pelvic mass triage and expanding into monitoring of the various resulting groups. Sales from RUO (Research Use Only) are also included but, as previously detailed, we do not assume these to be substantial in the context of the clinical revenue potentials.

Whilst we are arguably being overly cautious, it does leave scope for significant potential upside in our valuation as visibility increases with the execution of the commercialisation and partnering strategy.

Strong cash balance funds key clinical programmes

Continued investment in technology platforms and infrastructure

H121 revenues of £0.3m (H120: £0.2m) consisted mainly of Research Use Only sales (Parsortix systems and consumables). Operating costs of £8.9m (H120: £4.6m restated) reflect the continuing spend on the development and validation of Parsortix's clinical application and commercial uses as well as the investment required to complete ANGLE's new clinical laboratories. Net loss for H121 was £7.7m (H120: £3.4m loss restated). The restatement of H120 and FY20 reported numbers relates mainly to the treatment of certain capitalized product development costs, and the exchange differences allocated to some inter-group overseas loans. These restatements had no cash impact.

Successful equity placing to supportive UK and US investors

ANGLE's cash and short-term deposits stood at £21.0m at end-June 2021 (end-December 2020: £28.6m) and were subsequently strengthened by the £20.0m gross (£18.9m net) share placing to new and existing US and UK institutional investors which closed in July. R&D tax credits at end-June 2021 of £3.2m (end-December 2020: £2.1m) are due to be received in FY21.

Our forecasts are sensitive to Parsortix's FDA approval

Looking ahead to FY21, our forecasts are sensitive to the timing of FDA approval (assuming a positive recommendation). Any meaningful delay would see a corresponding shift in the timings of our expected revenue streams, but it should be noted there would be an equivalent delay in a number of related costs, with the effects likely to essentially balance out. A similar effect would flow through into FY22 but here the impact of, say, a three-month delay would be attenuated over a 12-month period rather than over the six months of H221. In cash terms, we believe the impact to be minimal and not material to our investment case. Hence, we will wait until there is greater clarity to review our forecasts.

Exhibit 5: Summary of financials

Year-end: Dec 31	£'000s	2018*	2019**	2020	2021E	2022E
INCOME STATEMENT						
Revenues		**628**	**581**	**762**	**2,295**	**5,419**
Cost of goods sold		(169)	(142)	(165)	(644)	(1,530)
Gross Profit		**459**	**439**	**597**	**1,651**	**3,889**
Operating expenses		(9,444)	(9,512)	(14,407)	(21,756)	(23,279)
Underlying operating profit		**(8,985)**	**(9,073)**	**(13,810)**	**(20,104)**	**(19,390)**
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)**	**(19,619)**	**(18,172)**
Operating Profit		**(9,257)**	**(9,345)**	**(13,731)**	**(20,393)**	**(19,677)**
Financing costs/income		8	(26)	(14)	(124)	(245)
Profit Before Taxes		**(9,249)**	**(9,371)**	**(13,745)**	**(20,517)**	**(19,921)**
Adj. PBT		**(8,977)**	**(9,099)**	**(13,824)**	**(20,228)**	**(19,634)**
Current tax income		1,387	1,482	2,139	2,574	2,317
Net Income		**(7,862)**	**(7,889)**	**(11,606)**	**(17,943)**	**(17,605)**
EPS (p)		**(8.2)**	**(4.8)**	**(6.5)**	**(7.7)**	**(7.5)**
Adj. EPS		**(8.0)**	**(4.7)**	**(6.7)**	**(7.6)**	**(7.4)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		95.5	163.7	178.0	233.8	234.3
BALANCE SHEET						
Current assets		**11,219**	**23,579**	**32,930**	**31,692**	**14,624**
Cash and short-term deposits		7,645	18,766	28,618	27,267	10,293
Trade and other receivables		828	627	1,443	1,069	1,188
Inventories		599	788	742	794	838
Other current assets		2,147	3,398	2,127	2,562	2,305
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)**	**(2,591)**
Short-term debt		0	0	0	0	0
Trade payables		(2,398)	(2,425)	(3,343)	(2,574)	(2,548)
Other current liabilities		0	(352)	(434)	(298)	(43)
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**	**35,901**	**18,678**
CASH FLOW STATEMENTS						
Operating cash flow		**(7,136)**	**(8,699)**	**(7,848)**	**(17,812)**	**(15,904)**
Profit before tax		(9,249)	(9,371)	(13,745)	(20,517)	(19,921)
Non-cash adjustments		1,074	1,498	2,268	1,273	2,132
Change in working capital		538	(767)	228	(583)	(444)
Interest paid		0	0	0	(124)	(245)
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**	**18,617**	**(507)**
Proceeds from equity		14,391	16,921	18,650	19,124	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**	**(1,351)**	**(16,974)**
Cash at start of year		5,536	11,010	3,757	12,080	10,729
Cash at end of year		**7,321**	**18,766**	**28,618**	**27,267**	**10,293**
Net cash at end of year		**7,645**	**18,766**	**28,618**	**27,267**	**10,293**

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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