Trinity Delta

ANGLE plc

Update

Building content to drive widespread adoption

30 January 2024

ANGLE's investment case rests on where Parsortix's position in mainstream cancer diagnostics eventually lands. The place of liquid biopsies is now established and, increasingly, the additional clinical value that CTC (circulating tumour cells) assays bring is becoming clear. Addressing the many, varied opportunities directly is challenging and time consuming, with numerous barriers to overcome. Management is creating industry awareness through its demonstration and acceleration activities, which should drive near- and medium-term revenues. Similarly, a progressively robust bank of clinical data across multiple common tumours is building credibility. We view the ability to perform ctDNA and CTC DNA analysis concurrently, from a single blood draw, on third-party NGS and PCR platforms as providing a major driver for adoption. Our updated valuation is £174m, equivalent to 67p per share.

Year-end: December 31	2021	2022	2023E	2024E
Revenues (£m)	1.0	1.0	2.2	6.3
Adj. PBT (£m)	(18.7)	(26.7)	(21.8)	(15.8)
Net income (£m)	(15.0)	(21.7)	(19.9)	(13.0)
Adj. EPS (p)	(7.2)	(9.6)	(7.8)	(5.6)
Cash (£m)	31.8	31.9	15.1	4.2
EBITDA (£m)	(15.7)	(21.4)	(19.3)	(12.3)

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals.

- **Focus on the commercial priorities** Parsortix commercialisation is at an early stage, with momentum building, and management is focused on progressing the potentially sizeable revenue streams through both Product and Service offerings. The reality of current market conditions has driven difficult decisions to streamline infrastructure whilst still enabling investment into developing protocols on third-party molecular systems, establishing products and services that are relevant to customers, and creating a robust body of supportive clinical data.
- **Third-party molecular platforms are key** It is increasingly recognised that CTCs provide invaluable additional clinical insights over current tumour diagnostics. The Parsortix system is uniquely placed, being proven, well validated, and, following FDA clearance, materially de-risked. However, addressing the myriad clinical opportunities will be a lengthy and costly process. Management focus has been on ensuring near-term revenues are optimised whilst reducing the barriers to widespread adoption. The ability to run concurrent ctDNA and CTC DNA analysis on third-party NGS and dPCR systems, such as Illumina's, is a major step forward.
- **Financials revised to reflect recent updates** We now forecast FY23e revenues of £2.2m, in-line with the most recent business update, growing to £6.3m in FY24e, just below the expected trebling of revenues. Cash is sufficient into H125.
- **Valuation now £174m, or 67p a share** We update our valuation to reflect the planned closure of the US clinical lab, which reduces potential internal capacity to perform revenue-generating tests, plus slightly slower near-term sales momentum. We have also incorporated H123 financials and rolled forwards in time. Our new valuation, based on a three-phase DCF model, is £174m (from our last published £253m prior to the business update), equivalent to 67p/share.

Price	16.0p
Market Cap	£41.7m
Enterprise Value	£26.6m
Shares in issue	260.6m
12 month range	9.07-37.4p
Free float	80.96%
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 clearance for its clinical use to guide precision cancer care should open up multiple commercial opportunities.

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ANGLE: focus on near-term commercial activities

The streamlining of ANGLE's operations sharpens the focus onto near-term commercialisation opportunities for Parsortix. This unique platform differs from other liquid biopsy approaches by capturing and harvesting CTCs (circulating tumour cells) for subsequent downstream analyses. Such CTC-driven diagnostics could provide invaluable clinical insights that current systems cannot deliver. However, achieving broad adoption across all potential uses requires a lengthy, complex, and costly, development programme. Pragmatically, management is concentrating its efforts into driving revenues from its Product and Services operations through developing market-relevant "content" (menus of assays), while continuing to generate robust clinical data to highlight its potential in multiple solid tumour treatment regimens. These "demonstration" and "acceleration" activities should provide near-term revenues and help drive wider industry recognition and partnering opportunities. Our updated DCF-based valuation is £174m ($209m), or 67p/share, which should rise as visibility on the commercialisation initiatives and Parsortix's positioning become clearer.

Numerous commercial opportunities as both product supplier and service provider

The significant clinical information gleaned through the analysis of CTCs is increasingly recognised by KOLs (key opinion leaders) and industry interest is rising. The Parsortix platform is highly attractive and has already been significantly de-risked, most notably by the FDA's examination of the diagnostic data in mBC (metastatic breast cancer) and subsequent clearance. The opportunities are many and sizeable. Although addressing all these is beyond the scope, and means, of a small company, there are clear pathways to achieving meaningful revenues over the near-, medium-, and longer-term with the goal of building a sizeable business.

Liquid biopsies are becoming mainstream cancer assays

Liquid biopsies are emerging into the mainstream…

Over the past decade liquid biopsies, typically from minimally invasive blood draws, have finally emerged into mainstream clinical practice as viable alternatives to traditional invasive tissue biopsies. While improved convenience and tolerability are cited as a major boost for patients, clinicians, and payors, the bigger benefits arise from the ability to easily monitor a tumour's status with repeat testing.

…allowing repeat sampling and generating additional insights into tumour biology…

Repeated sampling allows not only appropriate real-time therapy selection, but identification of genetic mutations, spotting treatment resistance, and determining disease progression long before it would trigger clinical symptoms or appear on imaging scans. There are a wide array of tumour derived elements circulating in the peripheral blood, including circulating tumour DNA (ctDNA), extracellular vesicles (EVs), tumour educated platelets (TEPs), and circulating cell-free RNA (cfRNA). Although significantly better than previous testing methods, these analytes are known to provide only a partial picture of a tumour's evolution. In contrast, CTCs are intact, living cancer cells and the subsequent downstream analyses can provide a complete picture of a tumour's status and development.

…but progress with CTCs has been slower than ctDNA approaches

Academic and industry progress with CTCs (circulating tumour cells) has been slower than ctDNA approaches. CTCs are initially shed from the primary tumour but, in the later stages of disease, also from secondary and metastatic sites. Their existence has been known for over a century, but their relative infrequency and

difficulty in isolating them has held back their study. A number of enrichment techniques, broadly divided into antigen-dependent (targeting CTC-specific markers such as EpCAM) and antigen-agnostic (typically exploiting physical characteristics such as size, deformability, and charge) have been developed.

Exhibit 1 Comparison of CTCs, ctDNA, and mRNA

Characteristic	CTCs	ctDNA	mRNA
Origin	CTCs	Primary tumor, metastatic tumors, or CTCs	Primary tumor, metastatic tumors, or CTCs
Prognostic or predictive potential	Yes	Yes	Yes
Ability for genetic characterization	Yes	Yes	Yes
Ability for transcriptional characterization	Yes	No	Yes
Ability for molecular characterization	Yes	No	No
Unique features	Intact cells, closest representation to metastases	Ease of acquisition and durability of DNA	Ease of acquisition and scalability

Abbreviations: CTC, circulating tumor cells; ctDNA, circulating tumor DNA.

Source: : The Oncologist 21 (1); Circulating Tumor Cells, ctDNA, and mRNA: Potential for Clinical Utility

Parsortix system is a versatile technology...

Parsortix is an elegant and versatile technology that physically separates and captures intact, living CTCs through a microfluidic cascade chamber. Uniquely, it is the only CTC harvesting platform cleared for use by the FDA (May 2022). A simple blood draw, usually 10ml, can be taken as often as required to obtain timely and clinically relevant CTCs. These can then be examined through any selected downstream assay. Notably, the same blood draw can be used for both a ctDNA assay (or similar) and CTC enrichment for subsequent analysis of choice.

...with broad translational applicability from academic and research settings

Parsortix has been used extensively in academic and research settings, with over 90 peer-reviewed papers published in respected journals. These have shown consistent and reproducible enrichment and harvesting of high-quality CTCs. Importantly, they also demonstrate the breadth of potential applications, ranging from routine diagnosis and monitoring in common solid cancers, such as breast, lung, and prostate, to specific applications, such as predicting therapy responses and identifying likely treatment failures.

Rising to the challenge of gaining widespread acceptance

The challenge is now to capitalise on the commercial opportunity

Unlocking value from these myriad clinical opportunities in such a regulated and structured setting is neither straightforward nor rapid. ANGLE's focus since the pivotal FDA product clearance of its proprietary Parsortix cell capture system is to begin to deliver on Parsortix's commercial promise. The ultimate aim is to make Parsortix broadly available to the healthcare industry and for it to eventually form part of routine patient care in order to transform cancer treatment. However, such broad adoption of a novel medical device can require a paradigm shift in appreciation, understanding, behaviours, and processes, with sales subsequently taking time to materialise. Hence, the challenge will be for ANGLE to capture these opportunities in an effective and systematic manner.

The multi-layered strategy is focused on Products and Services

A comprehensive strategy, which should provide multiple layers of revenue growth over the near-, mid-, and longer-term, has been developed. The various elements can be grouped into two business areas: Product-led and Service-led.

These tend to have differing regulatory pathways, routes to market, speed of adoption, and near- and long-term revenue potential.

- **Product business:** the supply of equipment, separation cassettes, reagents and consumables to third-party clinical labs, for their use in research, pharmaceutical development, or clinical applications. These sales are made either directly (in the UK and US) or via a growing network of distributors in other key regions. Management is expanding the product offering through developing a menu of relevant assay kits and related protocols for the subsequent downstream analysis of the harvested CTCs. These are designed to be easily integrated with existing equipment and offer as seamless a workflow as possible.

- **Pharma services:** these are provided through a dedicated UK-based certified laboratory. In November 2023 it was decided improved sample stability and reliable logistics allowed the centralisation of all services onto one site, with the consequent closure of the US facility. The services are primarily for pharmaceutical and biotech companies undertaking clinical trials in oncology indications to help target appropriate patients and monitor treatment response.

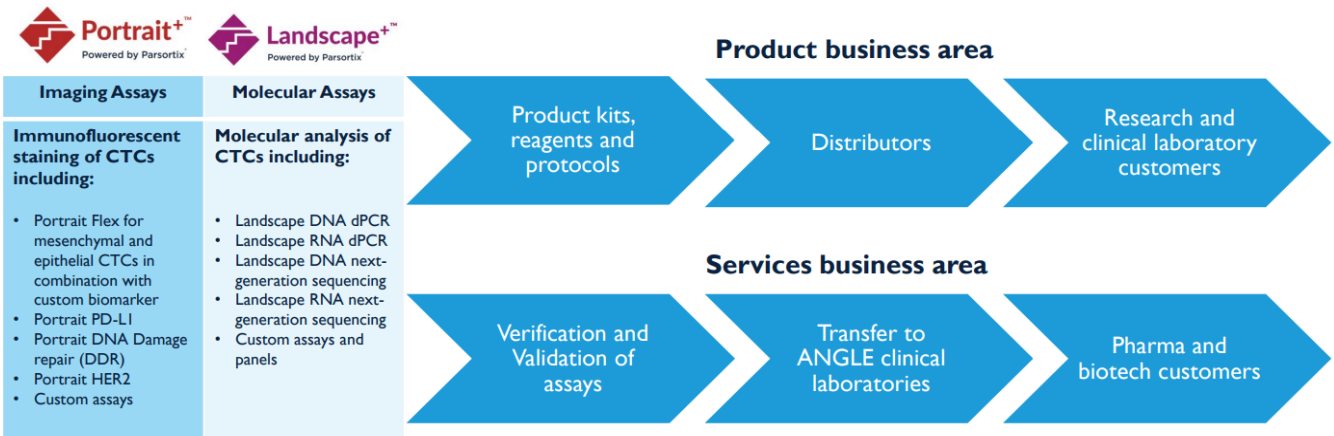
Pharma services could be a key revenue growth driver with the recent Eisai deal providing additional validation

Albeit from a currently small base, Pharma services is likely to be a key revenue growth driver over the near- and medium-term. The recently announced agreement with Eisai (January 2024) demonstrates how a pilot study, worth $0.25m, with HER2 CTC analysis for longitudinal patient monitoring in a Phase II study could provide valuable validation of CTCs as diagnostic tools and, over time, lead to a roll-out across major clinical trial programmes, both within Eisai and with other partners.

Developing a menu of clinically relevant assays

Management is creating a broad array of assays to support both Product and Service applications (Exhibit 2).

Exhibit 2: Portrait and Landscape assay development



Source: ANGLE

Portrait+ assay range addresses imaging

The **Portrait+** range are imaging assays based on the immunofluorescent staining of CTCs. Recently introduced tests include Portrait Flex for mesenchymal and epithelial CTCs enumeration and offers the addition of a selected custom protein

biomarker. This is used in the Pharma Services contract with Crescendo Biologics for their Phase I prostate cancer clinical trial studying their CR307 bispecific. Other Portrait assays include a PD-L1 test for the evaluation of PD-L1 protein expression on CTCs, DNA Damage Response (DDR) tests that were developed initially for Artios Pharma, and a HER2 test developed with BioView for optimising treatment for low HER2 as well as HER2 positive patients.

Landscape+ covers molecular assays that can be run on third-party systems

Landscape+ are molecular assays that can be tailored to run on PCR systems or next-generation sequencers. These employ commercially available third-party cancer gene panels and can be run on commonly used instrumentation, such as the Illumina platforms. Assays are available for the detection of key mutations, such as EGFR, KRAS and PIK3CA, with additional tests, including custom panels, addressing multiple clinically relevant biomarkers are under development. These will initially be provided through ANGLE's clinical laboratory but will roll-out for use across all appropriate third-party laboratories.

ctDNA and CTC assays could be complementary…

ctDNA assays have become the most popular form of liquid biopsy profiling but, as mentioned earlier, no one approach can currently provide a complete picture of the tumour or its progression. ANGLE has examined how next-generation sequencing (NGS) DNA analysis of both ctDNA (fragments of DNA released mainly by dying cells) and CTCs (living cancer cells) across multiple solid cancer types (including breast, lung, prostate, and ovarian) compare.

…as shown by recent data from a pan-cancer assay on Illumina's standard NGS

Results from 47 patient samples (January 2024), analysed on a pan-cancer assay undertaken on an standard Illumina NGS, showed that in 60% to 70% of cases further clinically valuable mutations were identified through the addition of downstream CTC analysis. Importantly, management has developed a validated protocol that allows molecular profiling of CTC-DNA alongside ctDNA from the same patient 10ml blood sample within a straightforward workstream.

Compatibility with third-party platforms means Parsortix could benefit from a large existing installed base

Collectively these developments help position Parsortix within the still emerging liquid biopsy landscape. The breadth of additional actionable insights that are generated easily compensate for the increased workflows and costs involved. Although an internally developed complete "sample-to-answer" approach would arguably retain more value, we believe that in order to realise the commercial potential a meaningful installed base would need to be established, which would take time and require substantial additional investment. Encouraging compatibility with leading third-party platforms provides an existing large installed base that ANGLE can more rapidly leverage by providing truly value-adding content.

Creating robust clinical data for major applications

Several clinical trials to support broad Parsortix application

Compelling clinical data is a vital element of the various processes needed to establish the Parsortix system as a key tool in routine patient management. ANGLE is conducting various clinical studies, including ovarian cancer (EMBER), prostate cancer (DOMINO), and INFORM (1000 patients in four metastatic different cancers), with a pilot study (PRECISE) in lung cancer planned.

EMBER covered pelvic mass triage to determine presence of ovarian cancer…

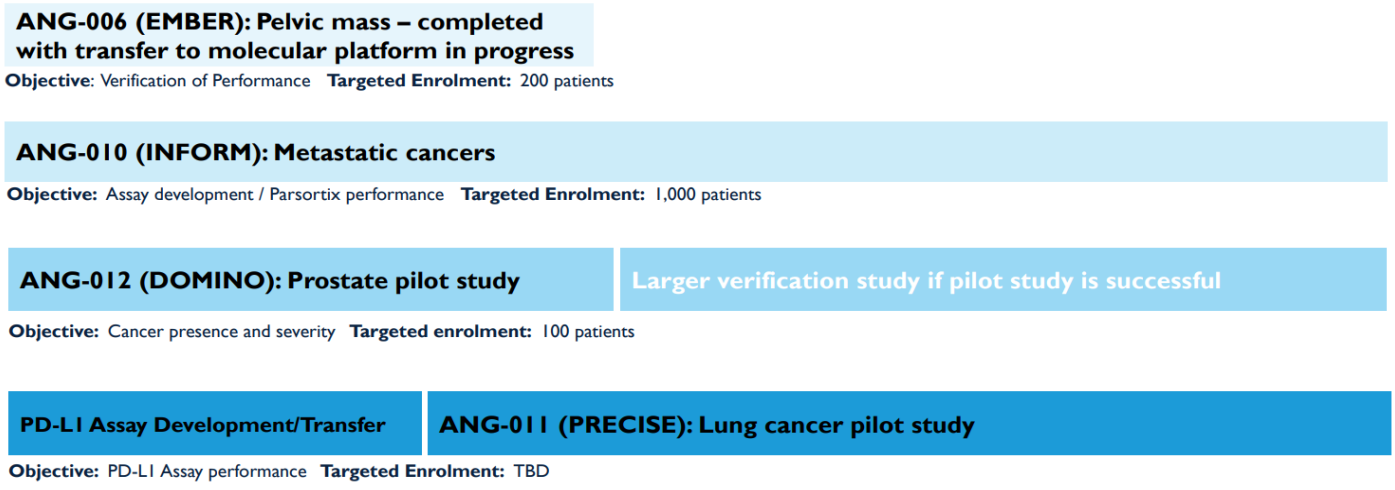
The EMBER trial, performed with the Wilmot Cancer Institute, saw 200 women with a diagnosed pelvic mass and scheduled to undergo a pathological evaluation of the mass (imaging guided biopsy, surgical biopsy, or surgical excision) have a blood sample sent to ANGLE for processing and evaluation. Cells were harvested with Parsortix, which then underwent multiplexed gene expression analysis using

ANGLE's in-house molecular ovarian assay. This was combined with clinical information, including the physician's initial cancer risk assessment and the patient's age, into an algorithm for the prediction of benign vs malignant disease.

...where Parsortix demonstrated high sensitivity and specificity

The results showed the Parsortix assay has a high sensitivity and high specificity, and a 95.4% ROC-AUC (area under the receiver operating characteristic curve, a measure of accuracy) which is classified as "Excellent". This is in-line with the prior study of 95.1%. The test was more accurate than physician assessment, reducing both the false positive and false negative rate by at least 50%. A follow-on study, EMBER2, has enrolled a further 200 women and over 1,000 samples are stored. These samples will be analysed with a third-party molecular platform once the optimal assay has been identified.

Exhibit 3: Portrait and Landscape assay development



Source: ANGLE

DOMINO is investigating detection of prostate cancer

The DOMINO study, partnered with MidLantic Urology, investigates Parsortix in the detection of prostate cancer and to predict severity. MidLantic Urology is an affiliate of Solaris Health Partners, one of the largest urology providers in the US. The aim is to assess 100 males scheduled for a prostate biopsy to predict the presence of a clinically significant prostate cancer and to correlate assessed disease severity with the Gleason score (the generally accepted grading for prostate cancer). The partnership with MidLantic Urology offers the potential for Solaris Health's network of clinics to be a rapid first route to market. Solaris Health is a national healthcare platform that offers access to specialty healthcare through 600+ providers that treat >850,000 patients annually. In the longer-term, pursuit of an approval as a clinical product would require a larger clinical verification study.

While the longitudinal INFORM study covers four different cancers

ANGLE's largest study is the INFORM study, which targets c 1,000 patients with advanced disease over a five-year period in four different cancers (breast, prostate, ovarian and lung) involving six NHS Trusts. This longitudinal study will follow patients over up to six different points over the course of their treatments. Over 300 patients have been enrolled and over 2,000 blood samples taken.

FDA clearance in mBC supported by HOMING study data

A key element of the FDA clearance for use in metastatic breast cancer (mBC) was a 400-subject (200 mBC and 200 healthy patients) blinded clinical study (HOMING). The primary objective was demonstrating the capture and harvesting of CTCs from mBC patient blood and demonstration of downstream analysis of

the CTCs using cytopathological evaluations, FISH testing for HER-2 status, and RT-qPCR and cDNA libraries for RNA-seq assays.

Stored patient samples available for validating future molecular analyses

Patient samples from the various clinical trials that were processed with Parsortix have been stored and are available for establishing and validating future molecular analyses via existing and well-characterised third-party systems. The data generated by these study samples should be able to demonstrate and support the value of Parsortix in identifying key genetic mutations to guide therapy choices, the monitoring and evaluating of treatments, and screening for and establishing the severity of disease in currently undiagnosed patients.

Valuation and Financials

Our DCF-approach values ANGLE at £174m, equivalent to 67p per share

Our ANGLE valuation is based on a three-stage DCF, including revenues for the main business lines to reflect the differing markets, revenue potential and growth profiles. These are summed and netted against the central costs of running the business in terms of R&D and S&M spend, and in turn netted against current net cash/debt. Our valuation has been updated to reflect closure of the US clinical lab, which has reduced potential internal capacity to perform revenue-generating tests, plus slightly slower near-term sales momentum. This, together with incorporation of H123 financials and revised forecasts, plus rolling forwards in time, leads to an updated valuation of £174m, or 67p per share (Exhibit 4).

Exhibit 4: Three-phase DCF valuation of ANGLE

DCF Phase	£m	$m	p/share	Notes
PV of Forecast FCF	48.0	57.6	18.4	Based on forecasts to 2032
PV of Trending FCF	79.2	95.1	30.4	Five-year trending period 2033-2037
PV of Terminal	31.7	38.0	12.1	
Enterprise Value	**158.9**	**190.7**	**61.0**	
Net cash/(debt)	15.1	18.2	5.8	FY23e
Total	**174.1**	**208.9**	**66.8**	

Source: Trinity Delta Note: PV = present value, 10% discount rate, 2% terminal growth rate, 20% tax rate, and $1.2/£ FX rate

Revenue growth is emerging

ANGLE's H123 revenues trebled YoY to £1.2m (H122: £0.4m), with growth in both pharma services and in product sales. The order book was solid, with £2.5m of future revenues already sold, and at the time, revenues were seen as on-track to meet FY23 expectations (which were c £3.0m). Operating costs increased slightly to £11.4m (H122: £10.6m). Together, these led to a net loss of £9.8m (H122: £9.2m). End-June 2023 cash was £22.2m (31 December 2022: £31.9m). The cash runway at this time (September 2023) was extended into Q125 (from H224) through deferral of some spend and some cost cutting, which was expected to save c £5m by end-2024, without impacting near-term revenue opportunities.

Traction in Pharma Services, although sales cycles have lengthened due to a slowdown in biopharma spending

In November 2023 a trading and business update provided revised FY23 revenue expectations of c £2.2m, which although doubling year-on-year were below market consensus (at the time) of c £3.0m. This was due to some of the c £3.3m in sales secured in 2023 being recognised in FY24. Revenues in FY24 are anticipated to treble vs FY23, driven by growth in sales from the newly established distributor network, and planned launches of new Parsortix-based products and services. Our updated revenue forecasts are for £2.2m in FY23e, in-line with the trading update, but a slightly more conservative £6.3m in FY24e.

Services business being streamlined through closure of the US clinical lab

The Services business is being streamlined through closure of the US clinical laboratory. This is in response to the ongoing investment required in molecular capabilities across multiple platforms and the current adverse market conditions. Customers across multiple geographies will now be serviced from the single UK-based centre of excellence. The financial impact of this is an expected c £0.7m of non-recurring cash costs and c £0.5m of non-cash impairments, translating into an Operating Loss for FY23 of c £21m (updated TD FY23e £21.3m). The closure will contribute to cost savings of c £3m per annum from 2024. Year-end cash is expected to be c £15m (TD FY23e £15.1m), providing a runway into Q2 2025.

Exhibit 5: Summary of financials

Year-end: Dec 31	£'000s	2020	2021	2022	2023E	2024E
INCOME STATEMENT						
Revenues		**762**	**1,013**	**1,041**	**2,161**	**6,344**
Cost of goods sold		(165)	(302)	(428)	(702)	(2,049)
Gross Profit		**597**	**711**	**613**	**1,459**	**4,295**
Operating expenses		(14,407)	(17,987)	(22,721)	(21,567)	(18,229)
Underlying operating profit		**(13,810)**	**(17,276)**	**(22,108)**	**(20,108)**	**(13,934)**
Share-based payments		(268)	(1,325)	(4,386)	(1,754)	(1,789)
Exceptionals		0	0	(2,100)	(1,200)	0
Other revenue/expenses		79	41	1	0	0
EBITDA		**(12,312)**	**(15,748)**	**(21,369)**	**(19,305)**	**(12,335)**
Operating Profit		**(13,731)**	**(17,235)**	**(24,207)**	**(21,308)**	**(13,934)**
Financing costs/income		(14)	(128)	(232)	109	(108)
Profit Before Taxes		**(13,745)**	**(17,363)**	**(24,439)**	**(21,199)**	**(14,042)**
Adj. PBT		**(14,092)**	**(18,729)**	**(26,726)**	**(21,753)**	**(15,832)**
Current tax income		2,139	2,351	2,753	1,323	1,000
Net Income		**(11,606)**	**(15,012)**	**(21,686)**	**(19,876)**	**(13,043)**
EPS (p)		**(6.5)**	**(6.7)**	**(8.8)**	**(7.6)**	**(5.0)**
Adj. EPS		**(6.7)**	**(7.2)**	**(9.6)**	**(7.8)**	**(5.6)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		178.0	225.1	246.6	260.6	260.6
BALANCE SHEET						
Current assets		**32,930**	**39,366**	**38,628**	**20,125**	**9,494**
Cash and short-term deposits		28,618	31,839	31,896	15,128	4,209
Trade and other receivables		1,443	1,269	1,797	1,036	1,304
Inventories		742	1,748	2,059	1,442	1,544
Other current assets		2,127	4,510	2,876	2,519	2,438
Non-current assets		**6,119**	**7,949**	**11,240**	**10,093**	**8,938**
Property, plant & equipment		2,409	4,376	8,476	7,298	6,114
Intangible assets		3,710	3,573	2,764	2,795	2,824
Other non-current assets		0	0	0	0	0
Current liabilities		**(3,777)**	**(4,912)**	**(5,250)**	**(3,722)**	**(3,188)**
Short-term debt		0	0	0	0	0
Trade payables		(3,343)	(4,390)	(3,978)	(2,450)	(1,916)
Other current liabilities		(434)	(522)	(1,272)	(1,272)	(1,272)
Non-current liabilities		**(928)**	**(2,073)**	**(4,555)**	**(4,555)**	**(4,555)**
Long-term debt		0	0	0	0	0
Other non-current liabilities		(928)	(2,073)	(4,555)	(4,555)	(4,555)
Equity		**34,344**	**40,330**	**40,063**	**21,941**	**10,688**
CASH FLOW STATEMENTS						
Operating cash flow		**(7,848)**	**(14,010)**	**(16,050)**	**(15,911)**	**(10,476)**
Profit before tax		(13,745)	(17,363)	(24,439)	(21,199)	(14,042)
Non-cash adjustments		2,268	2,774	5,556	3,648	3,497
Change in working capital		228	606	(1,614)	(150)	(903)
Interest paid		0	0	0	109	(108)
Taxes paid		3,401	(27)	4,447	1,681	1,080
Investing cash flow		**(1,966)**	**14,774**	**(1,751)**	**(856)**	**(444)**
CAPEX on tangible assets		(506)	(1,788)	(1,887)	(856)	(444)
Acquisitions/disposals		0	0	0	0	0
Other investing cash flows		(1,460)	16,562	136	0	0
Financing cash flow		**18,143**	**18,991**	**18,096**	**0**	**0**
Proceeds from equity		18,650	19,690	19,045	0	0
Increase in loans		0	0	0	0	0
Other financing cash flow		(507)	(699)	(949)	0	0
Net increase in cash		**8,329**	**19,755**	**295**	**(16,768)**	**(10,920)**
Cash at start of year		3,757	12,080	31,839	31,896	15,128
Cash at end of year		**28,618**	**31,839**	**31,896**	**15,128**	**4,209**
Net cash at end of year		**28,618**	**31,839**	**31,896**	**15,128**	**4,209**

Source: ANGLE, Trinity Delta. Note: Adjusted numbers exclude exceptionals.

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