# **ANGLE plc**

("ANGLE" or "the Company")

## **Preliminary Results for the year ended 31 December 2020**

#### FDA SUBSTANTIVE REVIEW PROGRESSING

## LAUNCH OF CLINICAL LABORATORY SERVICES

# FIRST LARGE-SCALE CONTRACT WITH PHARMA CUSTOMER USING THE PARSORTIX SYSTEM IN CLINICAL TRIALS

# PATIENT ENROLMENT COMPLETED IN OVARIAN CANCER CLINICAL VERIFICATION STUDY

ANGLE plc (AIM: AGL OTCQX: ANPCY), a world-leading liquid biopsy company, today announces audited preliminary results for the year ended 31 December 2020.

# **Operational Highlights**

- Full De Novo Submission made in September 2020 for US Food and Drug Administration (FDA) clearance of the Parsortix® system for capturing and harvesting circulating tumour cells from metastatic breast cancer patients
  - FDA Administrative Review complete and Substantive Review in progress
  - FDA Additional Information Request (AIR) received and response planned for submission in May 2021
- Ovarian cancer clinical verification study in progress with leading US cancer centre
  - patient enrolment completed after the year end
  - surgical procedures in progress and sample analysis in preparation
  - study expected to report headline results in Q4 2021
  - targeting launch as an LDT (laboratory developed test) around the end of the year
- Planning, recruitment and the development of facilities progressed during the year and, post year end, ANGLE launched clinical laboratories in the UK and United States and initiated a global pharma services business
- Post year end, first large-scale pharma services contract signed with an oncology focused pharma customer utilising the Parsortix system for longitudinal monitoring of patients in a Phase III drug trial with revenue potential of up to US\$1.2 million over 18 months
- Over 22,000 samples processed during the year and a further 11 peer-reviewed publications from internationally recognised cancer centres with key developments in breast, head and neck, melanoma, non-small cell lung, prostate and renal cancers

# **Financial Highlights**

Revenue £0.8 million (eight months ended 31 December 2019: £0.6 million)

- Loss for the year £11.6 million reflecting planned investment (eight months ended 31 December 2019 restated: loss £7.6 million)
- Fundraising from institutional investors, including existing and new US institutional investors, raising gross proceeds of £19.6 million (£18.5 million net of expenses)
- Cash and cash equivalents and short-term deposits combined balance at 31 December 2020 of £28.6 million (31 December 2019: £18.8 million)

# **Garth Selvey, Non-Executive Chairman of ANGLE plc, commented:**

"ANGLE adapted to COVID-19 related disruption and successfully completed the work required to make the full De Novo FDA Submission for the Parsortix system. This marked a watershed moment for ANGLE in its goal to achieve the first ever FDA clearance for a system to harvest cancer cells from patient blood for subsequent analysis, initially in metastatic breast cancer. It was encouraging that FDA's Additional Information Request was received without undue delay despite the ongoing pressure on FDA resources as a result of COVID-19. Whilst recent communication with FDA indicates a potential delay to their review processes, our response, which will be comprehensive, is expected to be submitted in May 2021, with a regulatory decision from FDA anticipated during H2 2021.

Towards the end of the year, we successfully raised further capital in a fundraising that was well supported by new and existing shareholders, particularly in the United States. As planned, the funds raised supported the launch of our clinical laboratories and pharma services business and I am delighted that, post year end, ANGLE has already announced its first large-scale contract with an oncology focused pharma customer.

ANGLE is making progress with the development of its ovarian cancer detection test, which in trials to date has shown the potential to outperform current standard of care by greatly reducing the level of false positives. Patient enrolment has been completed in the pivotal clinical verification study, and headline results are expected to be reported in Q4 2021, with the aim of supporting the establishment of a laboratory developed test for ovarian cancer around the end of the year, addressing a large unmet medical need.

ANGLE continues to gather momentum and, through its new services business, has begun to accelerate commercialisation of its unique liquid biopsy platform to support personalised cancer care. I look forward to the coming year with confidence."

## For further information:

**ANGLE plc** 

+44 (0) 1483 343434

Andrew Newland, Chief Executive Ian Griffiths, Finance Director Andrew Holder, Head of Investor Relations

## finnCap Ltd (NOMAD and Joint Broker)

Corporate Finance - Carl Holmes, Simon Hicks, Teddy +44 (0)20 7220 0500 Whiley

ECM - Alice Lane, Sunila de Silva

# **WG Partners (Joint Broker)**

Nigel Barnes, Nigel Birks, Andrew Craig +44 (0) 203 705 9330

# **FTI Consulting**

Simon Conway, Ciara Martin Matthew Ventimiglia (US) +44 (0) 203 727 1000 +1 (212) 850 5624

For Frequently Used Terms, please see the Company's website on https://angleplc.com/investor-relations/glossary/

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the EU Market Abuse Regulation (596/2014). Upon the publication of this announcement via a regulatory information service, this information is considered to be in the public domain.

These Preliminary Results may contain forward-looking statements. These statements reflect the Board's current view, are subject to a number of material risks and uncertainties and could change in the future. Factors that could cause or contribute to such changes include, but are not limited to, the impact of the COVID-19 pandemic, the general economic climate and market conditions, as well as specific factors including the success of the Group's research and development and commercialisation strategies, the uncertainties related to regulatory clearance and the acceptance of the Group's products by customers.

#### **CHAIRMAN'S STATEMENT**

As previously reported, restrictions enforced as a result of COVID-19 disrupted the Company's progress with both its key development programmes during the year, most notably through preventing the collection of blood samples for key studies, including healthy volunteer samples for our De Novo FDA Submission and patient samples for our ovarian cancer clinical verification study.

The Company responded by changing working patterns and introducing new protocols to enable blood collection for the remaining FDA analytical studies. Similarly, University of Rochester Medical Center Wilmot Cancer Institute resumed patient blood collection for the Company's ovarian cancer verification study, once protocols had been put in place, albeit with slower patient enrolment while hospital resources and facilities have been allocated to COVID-19 patients and urgent treatments.

During the year, ANGLE progressed clinical and analytical studies to support a De Novo FDA Submission for its Parsortix system for capturing and harvesting circulating tumour cells from metastatic breast cancer patients and successfully completed the FDA Submission in September 2020. FDA review progress has been encouraging and an Additional Information Request, as had been expected, has been received and is the focus of current work.

Patient enrolment for the Company's ovarian cancer assay clinical verification study resumed in June 2020 and has now completed. The study is expected to report headline results in Q4 2021. A laboratory developed test is scheduled for launch around the end of 2021, pending the results of the study and once the clinical laboratories have received accreditation.

Following a successful fundraise in November 2020, ANGLE has made excellent progress in establishing clinical laboratories in the US and UK, which were launched ahead of schedule. These laboratories are already offering pharma services and, once accredited, will be able to offer validated clinical tests. These will be used as accelerators and demonstrators in support of the Company's established plan for product sales of Parsortix instruments and cassettes and to provide services to pharmaceutical and biotech customers running drug trials. ANGLE has already signed a large-scale pharma services contract for the use of the Parsortix system in three separate global clinical trials.

ANGLE's collaborators and customers continue to demonstrate the Parsortix system's versatility in cancer translational research developing important new applications. This work generated 11 new publications during the year increasing the body of peer-reviewed evidence supporting the platform from independent cancer centres.

# **Overview of Financial Results**

Following a detailed review, a number of areas were identified for restatement or reclassification and the prior year numbers have been amended accordingly. These have no cash impact and are explained in Note 8 below. The restatement amendments relate to 1) a judgement that certain of the capitalised product development costs do not meet the IAS 38 criteria and should be expensed rather than capitalised and 2) exchange differences on certain overseas Group loans being recognised in the income statement rather than other comprehensive income resulting in a movement in reserves. The reclassification amendment relates to certain short-term deposits now shown separately from cash and cash equivalents.

Revenue of £0.8 million in the year (eight months ended 31 December 2019: £0.6 million) came mainly from research use of the Parsortix system, with sales impacted due to COVID-19 closures at customer sites. ANGLE continued its investment in studies to develop and validate the clinical application and commercial use of the Parsortix system and began the investment required in its new clinical laboratories and pharma services business, resulting in operating costs of £14.4 million (eight months ended 31 December 2019 restated: £9.5 million) and a loss for the year of £11.6 million (eight months ended 31 December 2019 restated: loss £7.6 million).

The cash and cash equivalents and short-term deposits combined balance was £28.6 million at 31 December 2020 (2019: £18.8 million) with R&D Tax Credits due at 31 December 2020 of £2.1 million (2019: £3.4 million). The cash position was strengthened in November 2020 with a successful placing of new shares with demand from new and existing US and UK institutional investors, which raised gross proceeds of £19.6 million. Proceeds net of expenses were £18.5 million.

# Strategy

ANGLE has continued with its sustained focus on its four-pronged strategy for achieving widespread adoption of its Parsortix system in the emerging multi-US\$ billion liquid biopsy market:

 Completion of rigorous large-scale clinical studies run by leading cancer centres, demonstrating the effectiveness of different applications of the system in cancer patient care

- 2) Securing regulatory approval of the system with the emphasis on FDA clearance as the *de facto* global gold standard. ANGLE is seeking to be the first company ever to gain FDA clearance for a system which harvests circulating tumour cells (CTCs) from the blood of patients (initially metastatic breast cancer patients) for subsequent analysis
- 3) Building a body of published evidence from leading cancer centres showing the utility of the system through peer-reviewed publications, scientific data and clinical research evidence, highlighting a wide range of potential applications
- 4) Establishing partnerships with large healthcare companies for market deployment and development of multiple other clinical applications incorporating the Parsortix system

ANGLE has also made excellent progress in establishing clinical laboratories in the United States and the UK that will have the capability of offering validated clinical tests. These will be used as accelerators and demonstrators in support of the Company's established plan for product sales of Parsortix instruments and cassettes and to provide services to pharmaceutical and biotech customers running drug trials.

# FDA De Novo application submitted and in substantive review

ANGLE is seeking to become the first ever company to receive FDA clearance for a medical device that harvests intact circulating tumour cells from the blood of metastatic breast cancer patients for subsequent analysis. US regulatory clearance by FDA is considered the global standard for approval of medical devices and diagnostics.

On 28 September 2020, ANGLE announced it had submitted a full De Novo FDA Submission for its Parsortix PC1 system seeking FDA clearance for use with metastatic breast cancer (MBC) patients. The Submission comprised over 400 technical reports and documents characterising the system. This included the assessment, *inter alia*, of performance with clinical samples, recovery, linearity, limit of detection, reproducibility, repeatability, blood volume, blood stability and interfering substances both exogenous and endogenous, requiring over 15,000 samples to be run on the Parsortix system in the UK and at clinical sites in the United States. This process, combined with the manufacture of the Parsortix system and associated consumables, has been completed and fully documented under ANGLE's ISO 13485 quality system and in compliance with numerous other technical and quality standards active in the United States and Europe. The Submission was also designed to meet the requirements for European CE Mark and, if granted clearance by FDA in the United States, ANGLE intends to register for European CE Mark clearance allowing clinical sales in both the United States and Europe for the intended use.

As announced on 20 October 2020, ANGLE received an Acceptance Review Notification from FDA that the Submission was accepted. The administrative acceptance review is a formal process undertaken by FDA to determine that the Submission contains all of the necessary elements and information needed by FDA to proceed with substantive review.

Following substantive review, FDA has provided a written response in the form of an Additional Information Request (AIR). Receipt of an AIR was expected and is in line with typical De Novo clearance processes. Some of the technical information requested necessitates some targeted additional analytical studies. These additional analytical studies do not require patient samples and ANGLE anticipates that the necessary studies, which are currently in progress, can be completed and the response submitted in May 2021. FDA regulatory decision is anticipated during H2 2021.

As previously communicated, ANGLE is following a De Novo FDA process for the Parsortix system as there is no identified predicate device. Consequently, there is inherent uncertainty over the timing of the process and its ultimate success. The outcome and timing of any FDA regulatory decision is entirely dependent on FDA's review and response to the Company's Submission. Whilst there has not been a delay to date, in its communication with FDA, ANGLE has been advised that, due to unprecedented allocation of resources to COVID-19 priorities, it is currently unclear how quickly FDA will be able to review ANGLE's response to the AIR once it has been submitted.

# **Ovarian cancer clinical application**

ANGLE's ovarian cancer clinical verification study is in progress and is being undertaken by the University of Rochester Medical Center (URMC) Wilmot Cancer Institute, New York, USA to evaluate the use of ANGLE's combined Parsortix® and HyCEAD™ platforms as a simple blood test to detect the presence of ovarian cancer in women with an abnormal pelvic mass.

A positive outcome from the study will support ANGLE's plans to launch a clinical assay for the detection of ovarian cancer in women with an abnormal pelvic mass, with both high sensitivity (correctly detecting cancer) and high specificity (correctly detecting no cancer with a low false positive rate).

Post year end, patient enrolment for this pivotal study has completed and, following surgical procedures and analysis of the patient samples, headline results of the study are expected in Q4 2021.

Once the new performance data is available and assuming positive results, ANGLE intends to establish this test as a laboratory developed test (LDT) in an accredited clinical laboratory setting. The test has the potential to significantly improve patient outcomes whilst also reducing overall healthcare costs and is scheduled for launch around the end of 2021.

## **PD-L1** assessment capability

There are now several published studies demonstrating the use of the Parsortix system for enabling the molecular analysis of CTCs in solid tumours, including the investigation of PD-L1 (programmed death-ligand 1) expression, a key target for leading immunotherapy drugs.

During the year, ANGLE made significant progress in developing an immunofluorescence (IF) imaging assay for determination of PD-L1 expression levels in CTCs harvested by the Parsortix system. This work has been completed and we have a method for assessing the presence and number of PD-L1 positive and PD-L1 negative CTCs in patient blood samples. This approach examines actual cells (cytological analysis) as opposed to molecular analysis approaches, which work with cell lysates (nucleic contents of cells that have been broken open, analysed as a mixture). Currently the PD-L1 expression assay is Research Use Only, however we are examining options for clinical development.

The newly developed in-house cell-based approach will enable use of the Parsortix system to assess PD-L1 status using two complementary techniques, molecular analysis and cell imaging with IF. We believe this is a powerful combination, which, together with the key advantages of the Parsortix system to capture both epithelial and mesenchymal CTCs (traditional antibody-based systems fail to capture the clinically relevant mesenchymal CTCs) and to capture CTC clusters, may provide significant benefits to the pharma services market.

# Launch of clinical laboratories and pharma services

ANGLE has made excellent progress in establishing clinical laboratories in the United States and the UK that will have the capability of offering validated clinical tests. The laboratories, in Guildford, UK and Plymouth Meeting, Pennsylvania, United States were completed ahead of schedule in Q1 2021 and are now processing clinical samples for global clinical trials. The laboratories will be used as accelerators and demonstrators in support of the Company's established plan for product sales of Parsortix instruments and cassettes and to provide services to pharmaceutical and biotech customers running clinical trials.

In April 2021 ANGLE announced that it has secured its first large-scale pharma services contract. The customer, a pharma company with numerous cancer drugs under development and forecast revenues exceeding US\$1 billion per annum, selected ANGLE's Parsortix system to undertake longitudinal monitoring of patients in a Phase III global clinical trial in prostate cancer and two other smaller Phase I clinical trials. Longitudinal monitoring relates to assessing a patient's condition at multiple time points (i.e. before, during and after drug intervention), which cannot be achieved with tissue biopsy.

The contract is expected to be worth up to US\$1.2 million over 18 months. The Phase I studies, if successful, could progress to larger Phase II studies and, if successful, much larger Phase III studies.

The services cover the capture, harvest and analysis of CTCs and CTC clusters. Samples are being shipped from multiple study centres to ANGLE's clinical laboratories in the United States and the UK for analysis using the Parsortix system.

The contract represents the first large-scale adoption of the Parsortix system for processing patient blood samples to help inform decision making in cancer drug trials. Importantly, the customer recognises the advantage in capturing mesenchymal as well as epithelial cancer cells and the importance that CTC clusters as well as single CTCs may have in the progression of disease, metastasis, and drug resistance.

The Parsortix liquid biopsy has particular advantages in capturing intact cancer cells including mesenchymal cells and clusters and provides the opportunity for longitudinal testing in a clinical setting, which is not possible with tissue biopsy. ANGLE believes that longitudinal monitoring of CTCs will prove highly attractive to the pharma industry looking for new insights in cancer drug trials.

In a further initiative, ANGLE has identified numerous immunotherapy cancer drug trials in progress or planned where assessment of PD-L1 status on CTCs from patient blood samples may have a major bearing on whether the trial is successful. The new trials being planned are targets for adoption of the Parsortix system and ANGLE is developing a service capability to be able to process samples on a commercial basis as part of these trials. ANGLE has established a dialogue with prospective customers and collaborators for the deployment of PD-L1 analysis capabilities in pharma services cancer drug trials.

# **Building a body of published evidence**

The Company's strategy to secure research use adoption of the Parsortix system by leading cancer research centres, in order to get independent third parties driving development of new clinical applications, continues to build momentum.

Over 115,000 samples have been processed using the Parsortix system as at 31 December 2020, with over 22,000 samples in the year. There were 37 peer-reviewed publications as at 31 December 2020 with 11 new publications announced during the year (see <a href="https://angleplc.com/library/publications/">https://angleplc.com/library/publications/</a>):

- Edith Cowan University, Perth, Australia demonstrating prognostication and treatment response in melanoma with the Parsortix system out-performing competing systems in head-to-head comparisons
- University Medical Center Hamburg-Eppendorf, Germany with validated standardised Parsortix system protocols for use in future clinical trials in metastatic breast cancer including single cell analysis
- Istituto Nazionale Tumori di Milano, Milano, Italy showing the Parsortix system outperforming other CTC systems in renal cell carcinoma
- University Medical Center Hamburg-Eppendorf, Germany with breakthrough research showing the investigation of brain metastasis in non-small cell lung cancer and the potential for a Parsortix system blood test to replace a highly invasive tissue biopsy of the patient's brain
- University of Athens, Greece demonstrating molecular analysis in head and neck squamous cell carcinoma and key advantages of the Parsortix system over other CTC systems
- University of Southern California, USA developing a workflow for RNA gene expression in prostate cancer with key advantages compared to alternative approaches
- Liquid Biopsy Analysis Unit at the Health Research Institute of Santiago, Spain on the
  assessment of MET alterations on CTCs as a target for MET inhibitor drugs in head and
  neck cancer and non-small cell lung cancer opening an important new revenue opportunity
  for ANGLE with pharma services
- University of Southern California, USA compared the Parsortix system liquid biopsy to tissue biopsy of a metastatic site in metastatic breast cancer. Potential actionable therapeutic targets were found in the Parsortix system liquid biopsy that were missed in the tissue biopsy of a single metastatic site
- Laboratory of Translational Oncology, School of Medicine, University of Crete, Greece
  published breakthrough research using the Parsortix system to assess whether non-small
  cell lung cancer patients will respond to immunotherapy drugs. This potentially opens a
  new market for ANGLE for use in PD-L1 cancer drug trials worth an estimated US\$1 billion
  per annum globally
- University of Basel, using the Parsortix system to research the role of hypoxia (reduced oxygen levels) in promoting breast cancer metastasis
- University of Texas MD Anderson Cancer Center, United States showing CTCs harvesting by the Parsortix system can be analysed using multiple downstream molecular techniques.

Following the year end, there were four further publications of note:

- Western University and Lawson Health Research Institute, Ontario, Canada demonstrating the performance of the Parsortix system in a head-to-head comparison with the leading antibody-based CTC system
- CANCER-ID Consortium, the Europe-wide Public-Private-Partnership aimed at standardising protocols and driving wide adoption of liquid biopsy in clinical practice, establishing the performance and technical capabilities of five CTC isolation platforms, in which key advantages of the Parsortix system were identified
- National and Kapodistrian University of Athens, Greece demonstrating the utility of the Parsortix system for minimally invasive, longitudinal monitoring of changes in CTC gene expression in non-small cell lung cancer patients with an EGFR mutation being treated with the tyrosine kinase inhibitor (TKI), Osimertinib (AstraZeneca's Tagrisso®)
- University Medical Centre Hamburg-Eppendorf, Germany demonstrating the ability of the Parsortix system to harvest CTCs with a mesenchymal phenotype, which can be used to detect the metastatic biomarker cysteine-rich angiogenetic inducer 61 (Cyr61) in breast cancer patients.

To date, 26 separate cancer centres from around the world have published positive reports on their use of the Parsortix system. Leading independent cancer centres throughout Europe, North America and elsewhere using the Parsortix system are working on developments in 24 different cancer types.

# **Progressing partnerships with large healthcare companies**

Large-scale deployment of the Parsortix system across numerous cancer types and application areas requires ANGLE to partner with large, global healthcare companies to take advantage of their distribution and sales channels and economic resources. Discussions continue with companies in relevant fields: medtech companies, pharma companies, contract research organisations and reference laboratories (laboratories offering clinical tests). We expect to see our partnership programme accelerate once FDA clearance for the Parsortix system has been achieved.

## COVID-19

The Company has had some short-term negative impacts from government lockdowns associated with COVID-19. While this created an initial need to adapt the operating model, it has not had any significant long-term impact on the Company.

During lockdowns, 'non-essential' screening, surgical and other procedures for cancer treatment have been postponed, delayed or cancelled by clinical institutions across the world. This extends to procedures such as tissue biopsies both of primary cancer sites for diagnosis and secondary cancer sites for treatment selection. The delay of these procedures may have significant adverse impacts on patients. This highlights the need for the regulatory approval of a CTC based liquid biopsy alternative to such invasive tissue biopsy procedures. Harvested cancer cells from a simple blood test that could be used to progress a patient's diagnosis and treatment while reducing the time to answer delays associated with the processing and pathological evaluation of tissue biopsies would be extremely valuable. The blood draw could be undertaken at the patient's home avoiding the need for the patient to visit the clinical institution for a surgical procedure.

#### Outlook

The Company adapted to COVID-19 related disruption and successfully completed the work required to make the full De Novo FDA Submission for the Parsortix system. This marked a watershed moment for ANGLE in its goal to achieve the first ever FDA clearance for a system to harvest cancer cells from patient blood for subsequent analysis, initially in metastatic breast cancer. It was encouraging that the Additional Information Request was received without undue delay despite the ongoing pressure on FDA resources as a result of COVID-19. Whilst recent communication with FDA indicates a potential delay to their review processes, we anticipate a regulatory decision during H2 2021. Approval for use of the Parsortix system with MBC patients would open up a market that ANGLE estimates is worth a potential US\$3.9 billion per annum in the United States alone.

Towards the end of the year, we successfully raised further capital in a fundraising that was well supported by new and existing shareholders, particularly in the United States. As planned, the funds raised supported the launch of our commercial laboratory and pharma services business. Post year end, ANGLE has announced its first large-scale contract with an oncology focused pharma customer. The signing of a commercial contract with its first pharma customer validates this strategy and ANGLE looks forward to announcing the further expansion of this business and additional customer agreements in due course.

ANGLE is making progress with the development of its ovarian cancer test, which in clinical studies to date has shown the potential to out-perform current standard of care by greatly reducing the level of false positives. Patient enrolment has been completed in the pivotal clinical verification study, and headline results are expected to be reported in Q4 2021, with the aim of supporting the establishment of a laboratory developed test for ovarian cancer around the end of the year, addressing a large unmet medical need.

In 2020, ANGLE made significant progress towards its strategic objectives and has set a solid foundation for the future. The start of 2021 has seen ANGLE continue to gather momentum and, through its new services business, has begun to accelerate commercialisation of its unique liquid biopsy platform to support personalised cancer care. The planned roll-out of its sample-to-answer solutions and expansion of pharma services business will further strengthen the ANGLE offering as we move through the year.

# ANGLE PLC CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2020

		Year ended	8 months ended
	31	December 2020	31 December 2019
			(Restated*)
	Note	£'000	£'000
Revenue		762	581
Cost of sales	_	(165)	(142)
Gross profit		597	439
Other operating income		79	61
Operating costs		(14,407)	(9,512)

Operating profit/(loss)		(13,731)	(9,012)
Finance income		78	40
Finance costs		(92)	(66)
Profit/(loss) before tax		(13,745)	(9,038)
Tax (charge)/credit	5	2,139	1,482
Profit/(loss) for the period		(11,606)	(7,556)
Other comprehensive income/(loss)			
Items that may be subsequently reclassified to profit of	or loss:		
Exchange differences on translating foreign operations		562	241
Other comprehensive income/(loss) Total comprehensive income/(loss) for the		562	241
period		(11,044)	(7,315)
Earnings/(loss) per share attributable to owners of the parent			
Basic and Diluted (pence per share)	6	(6.52)	(4.62)

All activity arose from continuing operations.

# ANGLE PLC CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2020

			31	
	311	December	December	30 April
		2020	2019	2019
			(Restated*)	(Restated*)
	Note	£'000	£'000	£'000
Assets				
Non-current assets				
Intangible assets		3,710	3,974	4,149
Property, plant and equipment		1,176	1,508	1,347
Right-of-use assets		1,233	1,514	<u> </u>
Total non-current assets		6,119	6,996	5,496
Current assets				
Inventories		742	788	988
Trade and other receivables		1,443	627	942
Taxation		2,127	3,398	1,900
Short-term deposits		16,538	15,009	-
Cash and cash equivalents		12,080	3,757	11,010
Total current assets		32,930	23,579	14,840
Total assets		39,049	30,575	20,336

 $<sup>\</sup>ensuremath{^{*}}$  The impact of the restatement is described in Note 8.

## Liabilities

Non-current liabilities				
Lease liabilities		(928)	(1,201)	
Total non-current liabilities		(928)	(1,201)	-
Current liabilities				
Lease liabilities		(434)	(352)	-
Trade and other payables		(3,343)	(2,425)	(3,684)
Total current liabilities		(3,777)	(2,777)	(3,684)
Total liabilities		(4,705)	(3,978)	(3,684)
Net assets		34,344	26,597	16,652
Equity		_		
Share capital	7	21,540	17,277	14,349
Share premium		81,532	67,272	53,273
Share-based payments reserve		1,745	1,518	1,266
Other reserve		2,553	2,553	2,553
Translation reserve		(3,785)	(4,347)	(4,588)
Accumulated losses		(69,139)	(57,574)	(50,099)
ESOT shares		(102)	(102)	(102)
Total equity		34,344	26,597	16,652

<sup>\*</sup> The impact of the restatement is described in Note 8. In addition the Group had classified short-term deposits within cash and cash equivalents in the Financial Statements at 31 December 2019. These deposits required a notice period of 95 days in order to access the cash and therefore do not strictly comply with the "readily convertible" requirements of IAS 7. These deposits have therefore been reclassified from cash and cash equivalents to short-term deposits and are shown as a separate line item in the Consolidated Statement of Financial Position.

# **ANGLE PLC**

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 DECEMBER 2020

	Year ended	8 months ended
	31 December 2020	31 December 2019 (Restated*)
	£'000	£'000
Operating activities		
Profit/(loss) before tax	(13,745)	(9,038)
Adjustments for:		
Depreciation of property, plant and equipment	661	432
Depreciation and impairment of right-of-use assets	421	219
(Profit)/loss on disposal of property, plant and equipment	2	13
Amortisation and impairment of intangible assets	337	240
Share-based payments	268	333
Exchange differences	565	235
Net finance (income)/costs	14	26
Operating cash flows before movements in working capital	(11,477)	(7,540)
(Increase)/decrease in inventories	14	90

(Increase)/decrease in trade and other receivables	(658)	314
Increase/(decrease) in trade and other payables	872	(1,171)
Operating cash flows	(11,249)	(8,307)
Research and development tax credits received	3,410	-
Overseas tax payments	<u>(9)</u>	(59)
Net cash from/(used in) operating activities	(7,848)	(8,366)
Investing activities		
Purchase of property, plant and equipment	(412)	(529)
Purchase of intangible assets	(94)	(66)
Transfer to short-term deposits	(1,530)	(15,009)
Interest received	70	40
Net cash from/(used in) investing activities	(1,966)	(15,564)
Financing activities		
Net proceeds from issue of share capital	18,650	16,921
Interest paid	-	(2)
Principal elements of lease payments	(463)	(231)
Interest elements of lease payments	(44)	(13)
Net cash from/(used in) financing activities	18,143	16,675
Net increase/(decrease) in cash and cash equivalents	8,329	(7,255)
Cash and cash equivalents at start of period	3,757	11,010
Effect of exchange rate fluctuations	(6)	2
Cash and cash equivalents at end of period	12,080	3,757
Cash at bank - immediate access	4,074	1,556
Cash at bank - restricted access (35 day notice)	8,006	2,201
Cash and cash equivalents at end of period	12,080	3,757

# **ANGLE PLC**

# **CONSOLIDATED STATEMENT OF CASH FLOWS (Continued)**FOR THE YEAR ENDED 31 DECEMBER 2020

	Year ended 31 December 2020	8 months ended 31 December 2019 (Restated*) £'000
	£'000	2
Cash and cash equivalents at end of period	12,080	3,757
Short-term deposits	16,538	15,009
Cash and cash equivalents and short-term deposits	28,618	18,766

<sup>\*</sup> The impact of the restatement is described in Note 8. In addition the Group had classified short-term deposits within cash and cash equivalents in the Financial Statements at 31 December 2019. These deposits required a notice period of 95 days in order to access the cash and therefore do not strictly comply with the "readily convertible" requirements of IAS 7. These deposits have therefore been reclassified from cash and cash equivalents to short-term deposits and are shown as a separate line item in the Consolidated Statement of Financial Position.

# **ANGLE PLC**

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2020

			Equity at Share- based	tributable t	o owners of the	e parent		
	Share capital	Share premium	payments reserve	Other reserve	Translation reserve (Restated*)	Accumulated losses (Restated*)	ESOT shares	Total equity (Restated*)
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
At I May 2019 as originally reported Restatement - IAS 38 adjustment Restatement -	14,349	53,273	1,266	2,553	106	<b>(52,109)</b> (2,675)	(102)	1 <b>9,336</b> (2,684)
retranslation of Group balances					(4,685)	4,685		-
At I May 2019 restated	14,349	53,273	1,266	2,553	(4,588)	(50,099)	(102)	16,652
For the 8 months to 31 December 2019 Consolidated profit/(loss) as	,	,	,	,	,	, , ,		,
originally reported						(6,248)		(6,248)
Restatement - IAS 38 adjustment Restatement - retranslation of Group						(1,046)		(1,046)
balances Other comprehensive income/(loss): Exchange differences on translating foreign						(262)		(262)
operations as originally reported					(24)			(24)
Restatement - IAS 38 adjustment Restatement -					3			3
retranslation of Group balances					262			262
Total comprehensive income/(loss) restated Issue of shares (net of					241	(7,556)		(7,315)
costs)	2,928	13,999	222					16,927
Share-based payments  Released on forfeiture			333 (78)			78		333
Released on exercise			(3)			3		-
At 31 December 2019 restated	17,277	67,272	1,518	2,553	(4,347)	(57,574)	(102)	26,597
At 31 December 2019 as originally reported Restatement - IAS 38	17,277	67,272	1,518	2,553	82	(58,276)	(102)	30,324
adjustment Restatement -					(6)	(3,721)		(3,727)
retranslation of Group balances At 31 December					(4,423)	4,423		-
2019 restated	17,277	67,272	1,518	2,553	(4,347)	(57,574)	(102)	26,597

For the year to 3 I December 2020 Consolidated profit/(loss) Other comprehensive income/(loss): Exchange differences on translating foreign						(11,606)		(11,606)
operations					562			562
Total comprehensive income/(loss) lssue of shares (net of costs)	4,263	14,260			562	(11,606)		(11,044) 18,523
Share-based payments			268					268
Released on forfeiture			(37)			37		-
Released on exercise			(4)			4		-
At 31 December 2020	21,540	81,532	1,745	2,553	(3,785)	(69,139)	(102)	34,344

<sup>\*</sup> The impact of the restatement is described in Note 8.

#### **ANGLE PLC**

# NOTES TO THE PRELIMINARY ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2020

# I Preliminary announcement

The preliminary results for the year ended 31 December 2020 were approved by the Board of Directors on 29 April 2021.

The preliminary announcement set out above does not constitute ANGLE plc's statutory Financial Statements for the year ended 31 December 2020 or the eight months ended 31 December 2019 (as restated) within the meaning of section 434 of the Companies Act 2006 but is derived from those audited Financial Statements (as restated).

The auditor's report on the Consolidated Financial Statements for the periods ended 31 December 2020 and 31 December 2019 is unqualified and does not contain statements under s498(2) or (3) of the Companies Act 2006. PricewaterhouseCoopers were appointed as the Group's new auditor for the year ended 31 December 2020.

The accounting policies used for the year ended 31 December 2020 are unchanged from those used for the statutory Financial Statements for the period ended 31 December 2019. The December 2020 statutory accounts will be delivered to the Registrar of Companies following the Company's Annual General Meeting.

# 2 Compliance with accounting standards

While the financial information included in this preliminary announcement has been computed in accordance with the measurement principles of International Financial Reporting Standards (IFRS), this announcement does not itself contain sufficient information to comply with IFRS.

# Accounting standards adopted in the year

No new accounting standards that have become effective and adopted in the year have had a significant effect on the Group's Financial Statements.

## Accounting standards issued but not yet effective

At the date of authorisation of the Financial Statements, there were a number of other Standards and Interpretations (International Financial Reporting Interpretation Committee - IFRIC) which were in issue but not yet effective, and therefore have not been applied in these Financial Statements. The Directors have not yet assessed the impact of the adoption of these standards and interpretations for future periods.

## **3** Going concern

The Group's business activities, together with the factors likely to affect its future development, performance and financial position are set out in the Chairman's Statement.

The Directors have considered the uncertainties, risks and potential impact on the business associated with Brexit, COVID-19 impacts and potential FDA delays and are carefully managing the discretionary expenditure in line with available cash resources.

The Directors have prepared and reviewed the financial projections for the 12 month period from the date of approval of these Financial Statements with discretionary expenditure carefully controlled. Based on the level of existing cash and expected R&D tax credits, the projected income and expenditure (the timing of some of which is at the Group's discretion) and other potential sources of funding, the Directors have a reasonable expectation that the Company and Group have adequate resources to continue in business for the foreseeable future. Accordingly the going concern basis has been used in preparing the Financial Statements.

# 4 Critical accounting estimates and judgements

The preparation of the Financial Statements requires the use of estimates, assumptions and judgements that affect the reported amounts of assets and liabilities at the date of the Financial Statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates, assumptions and judgements are based on the Directors' best knowledge of the amounts, events or actions, and are believed to be reasonable, actual results ultimately may differ from those estimates.

The estimates, assumptions and judgements that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities are described below.

Valuation and amortisation of internally-generated intangible assets (Note 8)

IAS 38 Intangible Assets contains specific criteria that if met mean development expenditure must be capitalised as an internally generated intangible asset. Judgements are required in both assessing whether the criteria are met, (for example, differentiating between enhancements and maintenance) and then in applying the rules (for example, determining an estimated useful life). Intangible assets are amortised over their useful lives.

IAS 38 criteria are reviewed at the end of each accounting period. The Group assessed the cumulative capitalised product development expenditure and determined that some of these costs did not fully meet the required IAS 38 criteria as it is now considered that the technical feasibility of a product in development is not proven until regulatory clearance is achieved. This approach is consistent with other companies in the sector. A prior year adjustment has been made to restate the previously capitalised costs not meeting IAS 38's recognition criteria on technical feasibility. Restated intangible assets had a carrying value of £4.0 million at 31 December 2019 and £4.1 million at 30 April 2019.

## Share-based payments

In calculating the fair value of equity-settled share-based payments the Group uses options pricing models. The Directors are required to exercise their judgement in choosing an

appropriate options pricing model and determining input parameters that may have a material effect on the fair value calculated. These key input parameters are expected volatility, expected life of the options and the number of options expected to vest.

Leases - extension and/or termination options

The Group has three lease contracts that include extension and/or termination options. The Directors exercise significant judgement in determining whether these extension and/or termination options are reasonably certain to be exercised, and agreed that it was reasonable to assume that these lease contracts would be extended beyond the termination option/notice period due to significant fit-out and renovations to create specialist laboratories and the prohibitive cost of finding equivalent alternative accommodation. The impact of including the extension and/or termination options is to increase both the carrying value of the right-of-use assets and the non-current lease liability at the reporting date by £0.8 million (2019: £0.9 million).

#### 5 Tax

The Group undertakes R&D activities. In the UK these activities qualify for tax relief and result in R&D tax credits.

# 6 Earnings/(loss) per share

The basic and diluted earnings/(loss) per share is calculated by dividing the after tax loss for the year attributable to the owners of the parent of £11.6 million (eight months ended 31 December 2019 restated: £7.6 million) by the weighted average number of shares in the year.

In accordance with IAS 33 Earnings per share, I) the "basic" weighted average number of Ordinary shares calculation excludes shares held by the Employee Share Ownership Trust (ESOT) as these are treated as treasury shares and 2) the "diluted" weighted average number of Ordinary shares calculation considers potentially dilutive Ordinary shares from instruments that could be converted. Share options are potentially dilutive where the exercise price is less than the average market price during the period. Due to losses in the 2020 and 2019 reporting periods, share options are non-dilutive for those periods as adding them would have the effect of reducing the loss per share and therefore the diluted loss per share is equal to the basic loss per share.

The basic and diluted earnings/(loss) per share are based on 178,036,093 weighted average ordinary £0.10 shares for the year (eight months ended 31 December 2019: 163,682,011).

# 7 Share capital

The Company has one class of Ordinary shares which carry no right to fixed income and at 31 December 2020 had 215,405,178 ordinary shares of £0.10 each allotted, called up and fully paid (31 December 2019: 172,771,483).

The Company issued 42,608,695 new Ordinary shares with a nominal value of £0.10 at an issue price of £0.46 per share in a subscription of shares realising gross proceeds of £19.6 million (£18.5 million net of expenses of £1.1 million). Shares were admitted to trading on AIM in November 2020.

The Company issued 25,000 new Ordinary shares with a nominal value of £0.10 at an exercise price of £0.645 per share as a result of the exercise of share options by an employee. Shares were admitted to trading on AIM in February 2020.

#### 8 Restatement

The Group has restated its Financial Statements as detailed below. These restatement amendments have no cash impact.

# IAS 38 Capitalisation of product development expenditure

The Group has restated its Financial Statements at 31 December 2019 and 30 April 2019 following a detailed review of its policy for the capitalisation of product development costs. "Product development" relates to internally generated intangible assets that are capitalised in accordance with IAS 38 Intangible Assets. IAS 38 criteria are reviewed at the end of each accounting period. The Group assessed the cumulative capitalised product development expenditure and determined that some of these costs did not fully meet the required IAS 38 criteria as it is now considered that the technical feasibility of a product in development is not proven until regulatory clearance is achieved. This approach is consistent with other companies in the sector. A prior year adjustment has been made to restate the previously capitalised costs not meeting IAS 38's recognition criteria on technical feasibility. Restated intangible assets had a carrying value of £4.0 million at 31 December 2019 and £4.1 million at 30 April 2019.

# Retranslation of Group loans

The Group has restated its Financial Statements at 31 December 2019 and 30 April 2019 to not treat historic Group loans with US subsidiaries as part of the Group's net investment in those foreign operations. As a result, exchange differences previously recognised in other comprehensive income on consolidation have been reclassified to the income statement. The restatement resulted in a reserve movement decreasing accumulated losses and increasing translation reserve in the Consolidated Statement of Financial Position by £4.4 million at 31 December 2019 and by £4.7 million at 30 April 2019.

The restatement movements are shown below:

# **Consolidated Statement of Comprehensive Income (extract)**

	8 months ended 31 December 2019 as originally reported	Restatement IAS 38	Restatement translation of Group balances	8 months ended 31 December 2019 Restated
	£'000	£'000	£'000	£'000
Operating costs	(8,204)	(1,046)	(262)	(9,512)
Profit/(loss) before tax	(7,730)	(1,046)	(262)	(9,038)
Other comprehensive income/(loss)	(24)	3	262	241
Total comprehensive income/(loss)	(6,272)	(1,043)	-	(7,315)
Earnings/(loss) per share Basic and diluted (pence per share)	(3.82)	(0.64)	(0.16)	(4.62)

## **Consolidated Statement of Financial Position (extract)**

	Year ended	Restatemen	Restatemen	Year	8 months	Restatemen	Restatemen	8 months
30	April 2019	t	t	ended	ended 31	t	t	ended 31
	as originally	IAS 38	translation	30 April	Decembe	IAS 38	translation	Decembe
	reported		of Group	2019	r 2019 as		of Group	r 2019
	•		balances	Restate	originally		balances	Restated
				d	reported			
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Intangible								
assets	6,833	(2,684)	-	4,149	7,701	(3,727)	-	3,974
Translation								
reserves	106	(9)	(4,685)	(4,588)	82	(6)	(4,423)	(4,347)
Accumulate								
d losses	(52,109	(2,675)	4,685	(50,099)	(58,276)	(3,721)	4,423	(57,574)
	)							

**Consolidated Statement of Cash Flows (extract)** 

	8 months ended 31 December 2019 as originally reported	Restatement IAS 38	Restatement translation of Group balances	8 months ended 31 December 2019 Restated
	£'000	£'000	£'000	£'000
Operating cash flows before movements in working capital	(6,494)	(1,046)	-	(7,540)
Operating cash flows	(6,942)	(1,365)	-	(8,307)
Purchase of intangible assets	(1,431)	1,365	-	(66)

#### 9 Shareholder communications

Copies of this announcement are posted on the Company's website www.ANGLEplc.com.

The Annual General Meeting (AGM) of the Company will be held at 2:00 pm on Wednesday 30 June 2021 at ANGLE plc, 10 Nugent Road, Surrey Research Park, Guildford, Surrey GU2 7AF. In line with the UK Government's current COVID-19 requirements to maintain social distancing this will be a closed meeting and Shareholders will not be permitted to attend the AGM in person. Shareholders will be able to join the AGM remotely with questions invited to be submitted before the meeting. Details will be included in the notice of AGM. The Company will continue to monitor the ongoing situation with regard to COVID-19 and any changes to the format of the meeting, including the ability for Shareholders to attend in person, will be notified through a regulatory news service ("RNS").

Notice of the meeting will be enclosed with the audited Statutory Financial Statements.

The audited Statutory Financial Statements for the year ended 31 December 2020 are expected to be distributed to shareholders by 4 June 2021 and will subsequently be available on the Company's website or from the registered office, 10 Nugent Road, Surrey Research Park, Guildford, GU2 7AF.

This preliminary announcement was approved by the Board of Directors on 29 April 2021.