

26 March 2020

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#### **Intelligent Ultrasound Group plc**

("Intelligent Ultrasound" or the "Group" or the "Company")

## **Unaudited Preliminary Results for the Year Ended 31 December 2019**

Intelligent Ultrasound Group plc (AIM: MED), the ultrasound artificial intelligence (AI) software and simulation company, announces its unaudited preliminary results for the year ended 31 December 2019, showing another excellent year of progress for the Group during which its Clinical AI Division signed its first AI software agreement with a major ultrasound manufacturer and its Simulation Division continued to grow sales.

## Financial highlights:

- Revenue from simulation sales grew 11% to £5.9m (2018: £5.3m)
- Gross profit up 22% to £3.5m (2018: £2.8m)
- R&D expenditure increased to £2.7m (2018: £1.9m)
- Strengthened the balance sheet in August 2019 with a placing and open offer which raised £5.8m after expenses
- Year-end cash plus investments (short term deposits), at £7.3m (2018: cash of £5.6m) and no debt<sup>1</sup>
- Current cash of £6.2m

<sup>1</sup>excluding IFRS 16 lease liabilities

### Operational highlights:

- Signed first long-term AI software licence and co-development agreement with one of the world's leading ultrasound equipment manufacturers
- Strong contribution from North America with revenue up 53% to £2.6m (2018: £1.7m)
- Signed marketing partnership with Fujifilm SonoSite, Inc. in North America for ultrasound training and services
- Commenced alliance with Mediscan Systems to use AI and simulation to improve patient care in India and enhance the Group's ultrasound scan image library to over 4 million images (2018: 1 million images)
- Commenced regulatory approval process and commercial discussions for ScanNav AnatomyGuide's Peripheral Nerve Block AI software

## Post year end:

- Received ISO13485:2016 medical device accreditation
- Launched COVID-19 simulation training system

## Commenting on the results, Riccardo Pigliucci, Chairman of Intelligent Ultrasound said:

"2019 has been another year of excellent progress by the Group and I would like to thank both our staff and our shareholders for enabling this to happen. The Clinical AI Division has performed particularly well, signing its first licensing agreement for ScanNav with a major OEM and progressing commercial discussions for its second AI software product. The reception for our products in development at trade shows is particularly encouraging. The Simulation Division has also worked hard to continue growing revenue.

However, it would be wrong to ignore the recent spread of the COVID-19 virus that is currently impacting all regions in which the Group operates, and we have therefore implemented a number of cost-saving measures that will enable the Group's EBITDA for FY2020 to remain in line with expectations. The outlook for the medium and long term remains unchanged, with the Group expected to have sufficient funds to continue its simulation and AI business activities for the next twelve months, when the revenues from its first AI software licence agreement are expected to be generated.

We remain an ambitious Group that is excited about bringing our first AI software products to market and continuing the growth of the business over the coming years."

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### About Intelligent Ultrasound Group (<u>www.intelligentultrasound.com</u>)

Intelligent Ultrasound (AIM: MED) develops artificial intelligence-based clinical image analysis software tools for the diagnostic medical ultrasound market and hi-fidelity virtual reality simulators for the ultrasound training market. Based in Cardiff and Oxford in the UK, Atlanta in the US and with representation in Beijing in Asia, the Group operates two divisions:

## Clinical AI Division

Focusses on developing deep learning-based algorithms to make ultrasound machines smarter and more accessible. Products in development include ScanNav which uses machine-learning based algorithms to automatically identify and grade ultrasound images to provide scan assessment and audit of protocol-based ultrasound scanning; and AnatomyGuide, which aims to simplify ultrasound-guided needling by providing the user with real-time Al-based needle guidance software for a range of medical procedures.

#### Simulation Division

Focusses on hi-fidelity ultrasound education and training through simulation. Its three main products are the ScanTrainer OBGYN training simulator, the HeartWorks echocardiography training simulator and the BodyWorks Eve Point of Care and Emergency Medicine training simulator. To date over 850 simulators have been sold to over 500 medical institutions around the world.

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

## Overview of the year

2019 was a pivotal year for the Group with the pre-revenue Clinical AI Division meeting all its commercial and development milestones for its first two AI-based software platforms. This included:

- signing our first long-term licence and co-development agreement in July 2019 with one of the world's leading ultrasound equipment manufacturers for our Al-based real-time ultrasound imaging software, a significant advance in validating our commercial model; and
- completing the pre-regulatory development of AnatomyGuide, the real-time anatomy highlighting software for nerve blocks and progressing both regulatory approval and commercial discussions

The Group's Simulation Division continued to show year-on-year growth and increased revenue by 11% to £5.9m, with particularly encouraging results in North America. The marketing partnership agreement signed with Fujifilm SonoSite, Inc. in the second half of the year, is a signal that our focus on high quality training remains important to the ultrasound market.

#### Strategy

Just over two years ago, the Group took the strategic decision to capitalise on our expertise in ultrasound image simulation and training by expanding the business into the development of real-time Al-based software for integration into ultrasound equipment used in the clinic. The expansion required both the successful acquisition and integration of The University of Oxford start-up company, Intelligent Ultrasound Limited, to augment our existing Al capability, as well as the support of shareholders to fund the subsequent research and development.

Two years on, I am impressed to see how much the executive team has achieved in such a short time, but I would also like to thank our existing and new shareholders for having the vision to back the Company through this strategic change.

A component of this strategy was to change the Company name from MedaPhor Group plc to Intelligent Ultrasound Group plc. The Board believes that the new name is reflective of our strategic change to being both a leading developer of artificial intelligence clinical software and a global leader in ultrasound training through simulation.

## **Board and governance**

The Board continues to recognise the importance of maintaining the highest standards of corporate governance and, as such, the Company has adopted the Quoted Companies Alliance Corporate Governance Code. Towards the end of the year we appointed an external advisor to conduct a full review of our board and its performance. The review is currently on-going and it is expected that its recommendations will be implemented during 2020.

At the end of the year, Wilson Jennings, the Group's CFO stepped down from the Board and I would like to thank Wilson for his valuable contribution since joining the Group ahead of our IPO in 2014 and to wish him well for the future in his semi-retirement. Wilson has been an integral part of our team and he will be missed by the management and staff alike.

At the same time the Board is very much enjoying working with our new CFO, Helen Jones, who joined the Board on the 1 January 2020. She has a strong commercial and technical background that will benefit the Group going forward.

#### People

I would like to thank all the staff in the Group for working so hard in 2019 to grow the simulation business and to meet all the development and commercial milestones that we set for the new AI software products.

We operate in a highly competitive market and recruitment and retention of the best people remains a priority for the Group.

#### Outlook

The Clinical AI Division performed particularly well in 2019, meeting all its milestones including signing its first licensing agreement with a major Original Equipment Manufacturer ("OEM") and progressing development and commercial discussions for its second AI software product. The Simulation Division also worked hard to grow revenue, retain margins and keep its overheads in line with expectations.

However, it would be wrong to ignore the recent spread of the COVID-19 virus that is currently impacting all regions in which the Group operates and we have therefore implemented a number of cost-saving measures that will enable the Group's EBITDA for FY2020 to remain in line with expectations. The outlook for the medium and long term remains unchanged, with the Group expected to have sufficient funds to continue its simulation and AI business activities for the next twelve months , when the revenues from its first AI software licence agreement are also expected to be generated.

The Group is currently prioritising its resources on developing additional variants of its COVID-19 lung ultrasound training module, as the frontline fight against the virus continues (details of which are provided in the CEO's Report below); continuing to progress all internal milestones for its ScanNav range of AI products and accelerating proof of concept models for new AI product variants. This will give the Group the potential to bring additional AI products to market in 2021 and therefore be in a stronger position when the current restrictions end.

We remain an ambitious Group, that is successfully expanding into the new Al-based clinical software market and we are confident that, once we are through this period of uncertainty, we can continue to build upon this momentum.

Riccardo Pigliucci
Non-executive Chairman

#### **CEO REVIEW**

Artificial intelligence is expected to have a significant impact on medical imaging over the next decade and we aim to be at the forefront of that change as it happens, in ultrasound imaging.

To achieve this, we have organised the Group into two divisions — Clinical AI and Simulation, both of which are supported by a management and administrative resource. The report below details how each division operates, the progress made over the year and the key challenges that each division faced.

#### **CLINICAL AI DIVISION**

Our aim is to be a global leader in the provision of Al-based clinical ultrasound software that can boost scanning quality and streamline sonographer workflow in medical ultrasound specialties, such as anaesthesiology, obstetrics, gynaecology, radiology and primary care medicine, as well as making ultrasound accessible to more medical professionals.

The Division is built around the 2017 acquisition of The University of Oxford AI software company, Intelligent Ultrasound Limited that supplemented our in-house image analysis and ultrasound know-how and has enabled us to develop potentially ground-breaking AI image analysis tools for the professional ultrasound scanning market.

The algorithms are based on a growing database of over 4 million images that drive our machine learning; combined with sophisticated deep learning models originally developed by Professor Alison Noble FRS OBE (a founder of Intelligent Ultrasound Limited) and her team from The University of Oxford. This has enabled us to develop our ScanNav image analysis software and the first releases of the ScanNav family of products are in the process of being brought to market in 2020.

On 4 July 2019 the Group announced that it had signed its first long-term licence and co-development agreement for certain of its AI software products in development with one of the world's leading ultrasound equipment manufacturers. The long-term agreement will enable the integration of our real-time image analysis software onto a range of specialty specific ultrasound systems marketed in the global healthcare market. The first royalty per unit revenues are expected during 2021. Terms of the agreement remain confidential and undisclosed for commercial reasons.

Software products in development include:

#### ScanNav Audit

The ScanNav Audit software provides real-time support for ultrasound practitioners performing the 20-week fetal anomaly scan. ScanNav Audit aims to ensure that a complete set of scan images, that conform to the required global scanning protocols, are captured during the procedure. The ScanNav software acts as a live 'virtual' peer-review, ensuring that the scan is performed correctly by highlighting issues to the sonographer as he or she saves each image. The software will also provide a record of each sonographer's performance, allowing managers to monitor staff and form part of the record keeping and audit requirements of the clinic. ScanNav Audit requires regulatory approval prior to launch.

The Group expects to develop multiple obstetrics variants of ScanNav Audit to complement the 20-week protocol software described above.

#### ScanNav AutoCapture

The ScanNav AutoCapture software automatically captures and analyses all the ultrasound image planes in real-time, as the sonographer moves the ultrasound probe over the patient's abdomen during the 20-week fetal anomaly scan. The software then automatically selects and saves the key images required to meet the global protocols. The Directors believe that the ScanNav AutoCapture software has the potential to:

- speed up workflow as the software automatically captures the correct images, operators do not need to
  manually freeze and save each image required by the protocol allowing them to focus on their dynamic
  assessment of the fetus; and
- improve accuracy and consistency the use of AI software should reduce the operator variability from the procedure, which is expected to result in more accurate and consistent image capture.

ScanNav AutoCapture requires further development and regulatory approval prior to launch.

The Group also expects to develop multiple obstetrics variants of ScanNav AutoCapture to complement the 20-week protocol software described above.

#### ScanNav AnatomyGuide

ScanNav AnatomyGuide is an AI based ultrasound software product which can automatically and in real-time, identify anatomical structures on the live ultrasound scan image, highlighting structures such as arteries that must be avoided during a needling procedure. The software is currently being developed for use during Peripheral Nerve Block (PNB) procedures to support less experienced practitioners and its development has been partly funded by Innovate UK.

PNB is a form of anaesthesia using needling that can be used for certain surgical procedures as an alternative to general anaesthesia and as a form of pain relief (potentially reducing the need for opioid analgesia). The PNB procedure requires less time and resource and is safer than general anaesthetic. However, PNB requires significant skill to guide the needle safely through the patient's anatomical structures and AnatomyGuide aims to assist the anaesthetist during the procedure.

In May 2019, we made the first live demonstration of the ScanNav AnatomyGuide software to clinicians at the Annual Scientific Meeting of Regional Anaesthesia United Kingdom (RA-UK).

The product development was substantially completed during 2019 for the first five nerve blocks and the regulatory and commercial partner process has started, with the aim of bringing the first variant of the product to market by the end of 2020.

#### Future ScanNav products

#### ScanNav Assist

The successful placing and open offer in August 2019 enabled the Group to start the process of building a third software development team that will look to begin the process of developing ScanNav Assist. ScanNav Assist aims to facilitate the automatic recognition of abnormalities within a general ultrasound scan confirming that a clinician has correctly scanned the anatomical area of interest and then flagging any areas of potential abnormality, so the patient can be triaged to the appropriate specialist. The Directors believe that ScanNav Assist will have the potential to allow more point-of-care medical practitioners to use ultrasound imaging for frontline diagnosis. The Directors believe that once developed such a device would be likely to support a broad range of medical professionals including GPs, midwives, paramedics and doctors working in Emergency Rooms.

#### ScanNav HealthCheck

In the longer term, we are investigating the potential development of AI software that could enable consumers to scan themselves at home. ScanNav HealthCheck aims to develop the current ScanNav technology to enable consumers to perform scans on themselves. When combined with the next generation of low-cost ultrasound devices, this software could have the potential to enable health conscious individuals to benefit from the ability to scan themselves at home.

## AI image database

In March 2019, we announced an alliance with Mediscan Systems, a premier fetal medicine and ultrasound research and training centre based in India, under which the Group provides ScanTrainer ultrasound training simulators in return for access to their large ultrasound image libraries. This has enabled us to significantly expand our Al image

database by over one million images and we are proud to support Mediscan in its goal of improving the quality of ultrasound practise in India and throughout the world.

The Division's AI image database currently has in excess of 4 million images acquired from several providers and we expect the growth in this database to continue in 2020 and beyond.

The curation and management of this data is of paramount importance to the Group and, as such, all externally sourced ultrasound imaging data is anonymised before it is sent to us. Patient consent and the right to use the data are obtained under a GDPR-compliant data sharing agreement for each image library. Ultrasound scans recorded by the Group from volunteers are also stored anonymously and always obtained with their consent and conform to the GDPR.

Notwithstanding the data anonymisation, all image data is stored securely, and its use is restricted to those who require access for development work. None of the source images are used in products sold to end-users as they are only used to train and create the deep-learning models of the product.

## Challenges to the Clinical Division

Al image analysis in ultrasound is a new area of medical innovation and we are attempting to open up markets in which the market size and the revenue models are unproven. We are also attempting to do this with relatively limited funds, compared to some of the Al based medical image analysis companies already operating in the US, China and Israel.

The threat from COVID-19 has resulted in very necessary restrictions being imposed on access to medical facilities, travel, conferences and face-to-face meetings to try to control the spread of the pandemic. This may compromise some aspects of our research and development projects; however, our Clinical Division currently still expects to meet its key milestone of first revenues in H1, 2021.

Our approach to these challenges is as follows:

- continue to progress all internal milestones for the ScanNav range of AI products;
- accelerate the development of any variants of these products;
- focus on developing AI software that has both a clinical need and a clear economic rationale for its purchase;
- partner the development of our first products with OEMs who can access the large ultrasound market more quickly with their existing product ranges and sales networks and facilitate faster regulatory approvals; and
- continue to build our AI image database to ensure we have high quality, curated images that will enable us
  to build AI algorithms in the field of anaesthesiology, obstetrics, gynaecology, radiology and primary care
  medicine.

The signing of our first agreement with one of the world's leading ultrasound machine manufacturers, combined with the encouraging reception to our products under development, has given us confidence that we can turn them into commercial products that can generate long-term revenue for the Division.

## SIMULATION DIVISION

Based in Cardiff (UK), Alpharetta (US) and with representation in Beijing (China), our Simulation Division designs, develops and sells some of the world's leading hi-fidelity ultrasound training systems for teaching ultrasound scanning to medical professionals in institutions and medical device companies.

This is the original business of the Group which was created out of Cardiff University Medical School and is the foundation of our expertise in ultrasound imaging and understanding of the clinical needs of the medical professionals who rely on ultrasound's growing diagnostic capabilities.

Our comprehensive range of ultrasound training simulators are, in the main, high value, cap-ex sales made to the

global medical institution market and sold through our direct sales forces in the US and UK and a network of almost 30 resellers in the rest of the world. The Division has continued to grow sales year-on-year, and it is recognised as one of the gold standard providers of ultrasound training simulators in the obstetrics/gynaecology (OBGYN), echocardiography/anaesthesiology (ECHO) and emergency medicine/point-of-care (PoCUS) markets.

During the year, the division reduced its net cash consumption impact on the Group.

## Research & Development

During 2019 the Simulation R&D team focussed much of its resource on the development of a new Compact version of the ScanTrainer for the OBGYN markets that aims to extend ScanTrainer's appeal to smaller hospitals and medical simulation centres in the US and around the world.

In addition, a new augmented reality (AR) app was developed, based on the HeartWorks software, aimed at broadening its appeal to the global cardiac and echocardiography teaching market and potentially to individual doctors who will benefit from access to the system's market leading 3D cardiac anatomy and ultrasound capabilities.

Post year end we launched a COVID-19 version of our BodyWorks Point-of-Care simulator, designed to train healthcare providers to use lung ultrasonography. Ultrasound has major utility for the management of respiratory related COVID-19 due to its safety, repeatability, absence of radiation, low cost, ease of disinfection and point of care use. This new training simulator, as well as the free COVID-19 upgrade training module for all our existing BodyWorks customers, includes a number of examples of lung ultrasound appearances typical of COVID-19 infection to enable frontline clinical staff to practise and train in the use of lung ultrasound. The module was made available to the market on 24 March 2020 and the first systems are already in use in the UK and US. We hope this initiative will help with the training of healthcare professionals working in the frontline of this global emergency.

#### Territory review

Our Simulation Division sales grew by 11% to £5.9m in 2019 (2018: £5.3m) and there are positive signs that the ultrasound simulator market for hi-fidelity training simulators will continue this growth once we are through the disruption currently being experienced as a result of the COVID-19 pandemic.

#### North America

Revenue in 2019 increased by over 50% to £2.6m (2018: £1.7m).

This was an excellent performance by the North America team and the region remains a key market for medical simulation. Based in Alpharetta, Georgia, the team are now able to provide full sales, marketing, shipping, technical support and small-scale local system build and we believe this capability was an important element in enabling us to enter into a marketing agreement with Fujifilm SonoSite, Inc. to deliver a training solution to the point-of-care ultrasound (PoCUS) market.

The agreement utilises Intelligent Ultrasound's BodyWorks Eve PoCUS training solution and the HeartWorks transthoracic echocardiography (TTE) and transoesophageal echocardiography (TEE) simulator training platforms to accelerate training for all Fujifilm SonoSite's PoCUS systems. Both companies will co-exhibit at numerous conferences, as well as providing hands-on workshops where clinician training is needed.

During the year sales of HeartWorks and BodyWorks on the new Eve manikin platform were particularly encouraging and we expect the Fujifilm SonoSite marketing agreement will generate increased awareness and therefore demand for these simulators.

## Rest of the World

Revenue in 2019 was steady at £2.6m (2018: £2.6m).

Revenue in the Rest of the World is mainly generated by our reseller network of just under 30 resellers and included simulation system sales of £0.5m (2018: £Nil) at fair value, which were exchanged for ultrasound images under the alliance with Mediscan referred to above. As well as a landmark sale of multiple systems to universities in Romania,

we were encouraged by good growth in the Iberian market. France however, proved to be a more challenging market in 2019, but a refreshment of the reseller parties is expected to strengthen our position in the region.

#### **United Kingdom**

Revenue in 2019 declined by 28% to £0.7m (2018: £1.0m).

The UK had a difficult year, which is believed to be in part due to the inertia in NHS non-essential spending caused by the continued delay in completing Brexit. Despite significant interest being shown by hospital departments wishing to buy our systems, many found their purchase requests being delayed or blocked by the hospital procurement departments. After a very challenging 2019, the Chancellor's budget on 11 March 2020 offered some comfort through his commitment to provide more funding for the NHS.

## Challenges to the Simulation Division

High values sales in the medical training sector remain affected by health budgets, which can be both hard to access and predict, especially during times of political upheaval or global pandemics, which can divert funds from training to frontline care. Like many markets, medical simulation is subject to competitive products and associated pricing and margin pressures.

The Division has historically responded well to these pressures by focussing on offering products that provide a gold standard in training ultrasound. This has traditionally been important to end-users whose careers depend on their ability to scan and diagnose using ultrasound and as a consequence, purchasing decisions tend to be based on quality of training and value for money rather than the lowest price solution.

Clearly the potential impact on sales from both the ongoing exit of the UK from the EU and COVID-19 are difficult to quantify at this time, but are being closely monitored by the Group to assess the impact on inventory, its supply chain and staff availability, as well as revenue. The development of a new simulation system aimed at training medical professionals working in response to the threat from COVID-19 is an example of the Division's agile response to unpredictable market conditions.

## **Quality Management System**

In 2018 the UK operation implemented a Quality Management System and I'm pleased to say that post year-end on 4 March 2020, we received ISO 13485:2016 certification following an audit of our systems by the certification body, LRQA.

ISO 13485:2016 is the internationally recognised quality standard to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes. The Group's Clinical AI Division is in the process of bringing a range of AI-based image analysis software products to market and obtaining ISO 13485:2016 certification is an essential step in taking these products through regulatory approval.

## Workplace environment

We recently merged our two UK sites into the Cardiff office but, in response to the threat from COVID-19, we have now implemented a working from home policy for the majority of our staff. In the longer term, we intend to move to larger, more modern and flexible office space in the centre of Cardiff, but until then, we will continue to host live demonstrations of all our latest technology at our current head office facility at the Cardiff Medicentre. We were recently proud to host a visit by the Chancellor of the Duchy of Lancaster, The Rt Hon Michael Gove MP and The Secretary of State for Wales, The Rt Hon Simon Hart MP, when they experienced first-hand the advances the Group has made over the last two years.

We would be delighted to welcome any shareholders or prospective investors should they also wish to visit us to see our technology for themselves.

## Looking ahead

Despite the understandable concerns over COVID-19, we aim to continue to be both ambitious and successful in our quest to train medical professionals in the use of ultrasound, which, more than ever, is a key medical diagnostic tool; as well as develop cutting-edge AI software technology that will generate long-term licence revenue for the Group over the coming years.

Stuart Gall

Chief Executive Officer

#### FINANCIAL REVIEW

## **Summary financial performance**

	2019	2018
Revenue (£m)	5.9	5.3
Gross profit (£m)	3.5	2.8
Gross profit margin (%)	58	53
R&D costs expensed (£m)	2.2	1.3
Administrative expenses (£m)	(8.2)	(7.1)
Adjusted EBITDA* (£m)	(3.1)	(2.7)
Loss after taxation (£m)	(4.2)	(3.4)
Cash and investments (short term deposits) (£m)	7.3	5.6

<sup>\*</sup>Non-GAAP measure reconciled below

#### Revenue

Revenues from the Simulation Division increased 11% to £5.9m (2018: £5.3m). The growth achieved this year was due to strong simulator sales in North America, up by £0.9m (53%) compared to 2018. However, this was partially offset by a fall in UK sales of £0.3m (28%) considered to be attributable to continued training budget cuts in the NHS and uncertainty surrounding the timing and impact of Brexit. Sales in the Rest of the World were in line with 2018.

### **Gross profit**

Gross margin increased from 53% in 2018 to 58% in 2019 and was helped by the higher proportion of direct sales representing 56% of total sales (2018: 50%), as well as a number of higher margin distribution sales.

#### **Administrative expenses**

Administrative expenses increased by £1.1m during the year to £8.2m (2018: £7.1m) as a result of our continued increased investment in R&D activity, particularly in the Clinical AI Division. We also increased the number of sales support staff employed in North America and the number of logistics staff in the UK.

#### Research and development costs and grants received

The Group expensed through the income statement £2.2m (2018: £1.3m) of R&D costs in 2019, largely in relation to earlier stage R&D activity in the Clinical AI Division, which had not yet met the criteria for capitalisation under IAS 38. A further £0.5m (2018: £0.5m) of costs relating to the continued ongoing development of products in the Simulation Division were capitalised within intangible assets.

The Group received an R&D grant from Innovate UK of £0.2m (2018: £0.3m) which has been included within Other Income.

## **Adjusted EBITDA**

	2019	2018
	£m	£m
Operating loss	(4.6)	(3.6)
Add back/(deduct):		
Depreciation & amortisation	1.4	1.2
Share option charges	0.1	0.1
Exceptional items	-	(0.4)
Adjusted EBITDA	(3.1)	(2.7)

The adjusted EBITDA loss increased by £0.4m in 2019 which was mainly attributable to the higher level of investment in R&D activity during in the year.

Adjusted EBITDA is not a measurement of financial performance under IFRS however it is considered that the presentation of adjusted EBITDA enhances the understanding of the Group's financial performance, in regard to understanding its ability to generate stable and predictable cash flows from operations.

## **Exceptional items in 2018**

The Exceptional item in the prior year related to a credit of £0.4m in respect of a fair value adjustment on the settlement of contingent consideration relating to the acquisition of Intelligent Ultrasound Limited ("IUL") in 2017.

#### **Taxation**

The Group claims each year for R&D tax credits and, since it is loss-making, elects to surrender these tax credits for a cash rebate. The amount included within the consolidated income statement in respect of amounts received and receivable for the surrender of R&D expenditure was £0.168m (2018: £0.214m). The 2019 tax credit also includes £0.08m credit in respect of a release of a provision made in 2018 for potential pre-acquisition over claims of R&D tax credits in IUL which HMRC confirmed in the period does not need to be repaid. The tax credit for the year also includes deferred tax of £0.09m (2018: £0.09m) on the fair value of intangible fixed assets acquired with Inventive Medical Limited ('IML') and IUL which is being recognised over the life of those assets.

As at 31 December 2019, the Group has cumulative gross UK tax losses of approximately £14.9m (2018: £11.4m) for which no deferred tax asset has been recognised.

#### Placing and open offer

On 28 August 2019 the Company issued 63,369,043 new ordinary shares of 1 pence each at a price of 10 pence per share which raised £6.3m before costs of the share issue and £5.8m after costs. The share issue costs of £0.5m have been netted off against the share premium arising on the new share issue.

#### **Balance sheet**

Consolidated net assets increased to £11.0m (2018: £9.3m). Intangible fixed assets at £2.3m were £0.6m lower than the carrying amount at 31 December 2018 of £2.9m. Additions to intangibles in the year were £0.5m (2018: £0.5m) relating to capitalised development costs; whereas, amortisation of all intangibles including IP and brands totalled £1.0m (2018: £1.0m).

The Group adopted the new leasing standard IFRS 16 in 2019 and recognised an additional £0.1m within property, plant and equipment and a corresponding lease liability in relation to leases of office space and company cars.

Trade and other receivables of £2.7m (2018: £1.9m) have increased largely due to the timing profile of the high level of sales in the last quarter of 2019. Trade and other payables of £1.8m (2018: £1.5m) include £0.2m of warrants issued as part of the consideration paid for IUL (2018: £0.2m).

#### **Cash and investments**

Cash and cash equivalents at 31 December 2019 stood at £1.8m (2018: £5.6m). The Group also had £5.5m of investments in the form of cash held in short term deposits that matured post year end on 6 January 2020.

Net cash used in operating activities was £3.3m (2018: £2.6m) and the net cash outflow arising from investment activities was £6.3m (2018: outflow of £0.9m) due to the cash held in short term deposits. Cash flow in the year was boosted by the placing of new ordinary shares in the Company which raised £5.8m net of costs (2018: placing raised £4.8m net of costs). The net proceeds have been, and will continue to be, used for the research and development to bring the ScanNav products to market and to continue the proof of concept research and development work on future ScanNav products and general working capital.

The Group continues to explore appropriate financing options that will fund its growth from 2021 onwards.

### Events since the end of the financial year

The recent spread of the COVID-19 virus and the resultant downturn in global business are well documented and impacting all regions in which the Group operates. There is also considerable uncertainty over the likely duration of the disruption. Consequently, in anticipation of a short term slow-down in global simulator sales, we have implemented a number of cost saving measures that will enable the Group's EBITDA to remain in line with expectation. The outlook for the medium and long term remains unchanged, with the Group expected to have sufficient funds to continue its simulation and AI business activities well into 2021, when the revenues from its first AI software licence agreement are expected to be generated.

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME for the year ended 31 December 2019

		Unaudited	Audited
	Note	2019	2018
		£	£
Continuing operations		_	_
REVENUE	2	5,915,671	5,313,164
Cost of sales		(2,462,207)	(2,479,781)
GROSS PROFIT		3,453,464	2,833,383
Other income		157,314	310,475
Administrative expenses excluding exceptional costs		(8,168,711)	(7,120,434)
Exceptional administrative items	3	_	362,718
Total administrative costs		(8,011,397)	(6,447,241)
OPERATING LOSS		(4,557,933)	(3,613,858)
Finance costs		(2,002)	(7,402)
LOSS BEFORE INCOME TAX		(4,559,935)	(3,621,260)
Income tax credit	4	337,517	203,796
LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT		(4,222,418)	(3,417,464)
OTHER COMPREHENSIVE INCOME			
Items that will or may be reclassified to profit or loss:			
Exchange (loss)/gain arising on translation of foreign operations		(33,453)	844
OTHER COMPREHENSIVE INCOME FOR THE YEAR		(33,453)	844
TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO THE EQUITY			_
SHAREHOLDERS OF THE PARENT		(4,255,871)	(3,416,620)
LOSS PER ORDINARY SHARE (PENCE) ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT			
Basic and diluted	5	(2.37)p	(3.59)p

## **CONSOLIDATED STATEMENT OF FINANCIAL POSITION** for the year ended 31 December 2019

	Note	Unaudited 2019 £	Audited 2018 £
NON-CURRENT ASSETS			
Intangible assets		2,331,779	2,886,562
Property, plant and equipment		544,775	417,732
		2,876,554	3,304,294
CURRENT ASSETS			·
Inventories		663,240	851,491
Trade and other receivables		2,699,608	1,912,975
Current tax assets		147,517	80,302
Investments (short term deposits)		5,500,000	-
Cash and cash equivalents		1,790,318	5,607,052
		10,800,683	8,451,820
TOTAL ASSETS		13,677,237	11,756,114
CURRENT LIABILITIES			
Trade and other payables	6	(1,795,698)	(1,467,865)
Deferred income		(325,177)	(311,496)
Lease liabilities		(53,095)	-
Current tax liabilities		-	(100,000)
Provisions		(94,776)	(68,972)
		(2,268,746)	(1,948,333)
NON-CURRENT LIABILITIES			
Deferred income		(108,680)	(160,074)
Deferred taxation		(287,994)	(377,994)
Lease liabilities		(20,340)	
		(417,014)	(538,068)
TOTAL LIABILITIES		(2,685,760)	(2,486,401)
NET ASSETS		10,991,477	9,269,713
EQUITY AND RESERVES			
Share capital	7	2,199,968	1,566,278
Share premium		21,653,273	16,437,213
Accumulated losses		(20,074,969)	(15,854,436)
Share-based payment reserve		687,600	561,600
Merger reserve		6,538,023	6,538,023
Foreign exchange reserve		(12,418)	21,035
TOTAL EQUITY	-	10,991,477	9,269,713
	=	10,001,177	3,203,713

# **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY** for the year ended 31 December 2019

	Share capital	Share premium	Accumulated losses	Share- based payment reserve	Merger Reserve	Foreign exchange reserve	Total equity attributable to shareholders
	£	£	£	£	£	£	£
BALANCE AS AT 1 JANUARY 2018	907,015	12,216,670	(12,436,972)	413,600	6,013,065	20,191	7,133,569
COMPREHENSIVE INCOME FOR THE YEAR Loss for the year and total							
comprehensive income TRANSACTIONS WITH OWNERS, RECORDED DIRECTLY IN EQUITY	-	-	(3,417,464)	-	-	844	(3,416,620)
Shares issued for cash	597,503	4,481,275	-	_	_	_	5,078,778
Cost of raising finance	, -	(260,732)	-	-	-	-	(260,732)
Retention shares issued							
further to acquisition of IUL	61,760	-	-	-	524,958	-	586,718
Cost of share-based awards		-	-	148,000	-	-	148,000
	659,263	4,220,543	-	148,000	524,958		5,552,764
BALANCE AS AT 31							
DECEMBER 2018 as							
previously stated (audited)	1,566,278	16,437,213	(15,854,436)	561,600	6,538,023	21,035	9,269,713
Impact of IFRS 16		-	1,885	-	-		1,885
BALANCE AS AT 1 JANUARY 2019 as restated COMPREHENSIVE INCOME FOR THE YEAR	1,566,278	16,437,213	(15,852,551)	561,600	6,538,023	21,035	9,271,598
Loss for the year and total comprehensive income TRANSACTIONS WITH OWNERS, RECORDED	-	-	(4,222,418)	-	-	(33,453)	(4,255,871)
DIRECTLY IN EQUITY	622.600	5 702 24 4					6 226 004
Shares issued for cash	633,690	5,703,214	-	-	-	-	6,336,904
Cost of raising finance	-	(487,154)	-	126,000	-	-	(487,154)
Cost of share-based awards	633,690	F 216 060	-	126,000	<u> </u>	-	126,000
BALANCE AT 31 DECEMBER	053,090	5,216,060	-	126,000	-	-	5,975,750
2019 (unaudited)	2,199,968	21,653,273	(20,074,969)	687,600	6,538,023	(12,418)	10,991,477

# CONSOLIDATED STATEMENT OF CASH FLOWS for the year ended 31 December 2019

	Unaudited	Audited
	2019	2018
	£	£
Cash flows from operating activities		
Loss before tax	(4,559,935)	(3,621,260)
Depreciation	334,209	244,957
Amortisation of intangible assets	1,040,032	992,586
Fair value adjustment on contingent consideration	-	(362,718)
Finance costs	2,002	7,402
Share-based payment charge	126,000	148,000
Operating cash flows before movement in working capital	(3,057,692)	(2,591,033)
Movement in inventories	188,251	(438,247)
Movement in trade and other receivables	(786,633)	(203,539)
Movement in trade and other payables	282,570	507,545
Cash used in operations	(3,373,504)	(2,725,274)
Income taxes received	80,302	133,495
NET CASH USED IN OPERATING ACTIVITIES	(3,293,202)	(2,591,779)
		_
Cash flows from investing activities		
Purchase of property, plant and equipment	(355,321)	(361,707)
Disposal of property, plant and equipment	12,194	11,523
Increase in short term deposits	(5,500,000)	-
Internally generated intangible assets	(485,249)	(512,671)
NET CASH USED IN INVESTING ACTIVITIES	(6,328,376)	(862,855)
Cash flows from financing activities		
Issue of new shares	6,336,904	5,078,778
Share issue costs	(487,154)	(260,732)
Principal elements of lease payments	(37,371)	-
Finance costs paid	(2,002)	(7,402)
NET CASH GENERATED FROM FINANCING ACTIVITIES	5,810,377	4,810,644
	, ,	· · · ·
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(3,811,201)	1,356,010
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	5,607,052	4,250,198
Exchange (losses)/gains on cash and cash equivalents	(5,533)	844
CASH AND CASH EQUIVALENTS AT END OF YEAR	1,790,318	5,607,052
2.2 2.2 2.2 2 2 2 2 2		5,557,552

## NOTES TO THE PRELIMINARY RESULTS for the year ended 31 December 2019

#### 1. GENERAL INFORMATION

Intelligent Ultrasound Group plc ("the Company") is a publicly limited liability company incorporated and domiciled in the United Kingdom whose shares are traded on AIM, a market operated by the London Stock Exchange. The Company's registration number is 09028611 and its registered office address is Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ.

The financial information for the year ended 31 December 2019 set out in this announcement does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2018 have been delivered to the Registrar of Companies and those for 2019 will be delivered following the Company's Annual General Meeting ('AGM').

#### **BASIS OF PREPARATION**

The financial information has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards ('IFRS') adopted for use in the European Union (EU) and in accordance with the AIM rules and the Companies Act 2006. However, this announcement does not itself contain sufficient information to comply with IFRS. The Company will publish full financial statements that comply with EU adopted IFRS in April 2020.

The consolidated preliminary results incorporate the results of the Company and its subsidiary undertakings (together the 'Group').

The accounting policies applied in these consolidated preliminary results are consistent with those of the annual financial statements for the year ended 31 December 2018, as described in those annual financial statements, except for the adoption of IFRS 16 'Leases'.

#### **GOING CONCERN**

The unaudited consolidated preliminary results have been prepared on a going concern basis. The Group meets its day-to-day working capital requirements from its cash reserves. The Group expects that it will need to raise additional funds through either equity-based investor funding or debt finance within the next 12 to 15 months. Subject to this, the directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future and therefore continue to adopt the going concern basis of accounting in preparing the annual financial statements. However, in the absence of binding agreements combined with the current uncertain global economic outlook due to the COVID-19 pandemic, there can be no guarantee that additional funds will be made available as required. The Group is currently monitoring the COVID-19 situation on a daily basis with cash preservation a primary concern and as a result has revised its forecasts and subsequent sensitivity analysis to reflect certain cost cutting measures implemented to mitigate any potential impact on short term revenues and loss after tax. Current conditions therefore indicate the existence of a material uncertainty which may cast significant doubt about the ability of the Company and the Group to continue as going concerns. These financial statements do not include any adjustments that would result from the going concern basis of preparation being inappropriate.

#### IFRS 16 'Leases'

The Group has adopted IFRS 16 'Leases' from 1 January 2019. The nature and effect of the changes as a result of adoption of this new accounting standard are described below. Several other amendments and interpretations apply for the first time in 2019, but do not have an impact on the consolidated financial statements of the Group. The

Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

The Group has not restated comparatives for the 2018 reporting period, as permitted under the specific transition provisions in the standard. The Group adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of 1 January 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognised at the date of initial application. The Group elected to use the transition practical expedient to not reassess whether a contract is, or contains a lease at 1 January 2019. The Group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 'Leases'. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of 1 January 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 4%.

## i) Practical expedients applied

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- accounting for operating leases with a remaining lease term of less than 12 months as at 1 January 2019 as short-term leases;
- excluding initial direct costs for the measurement of the right-of-use asset at the date of initial application; and
- The Group has also elected not to reassess whether a contract is or contains a lease at the date of initial application. Instead, for contracts entered before the transition date the group relied on its assessment made applying IAS 17 and IFRIC 4 'Determining whether an Arrangement contains a Lease'.

## ii) Impact of adoption

The effect of adoption of IFRS 16 as at 1 January 2019 (increase/(decrease)) is, as follows:

	£
ASSETS	
Property, plant and equipment	32,561
LIABILITIES	
Lease liabilities	(30,676)
OPENING ADJUSTMENT TO EQUITY	(1,885)
iii) Measurement of lease liabilities	
	£
Operating lease commitments disclosed as at 31 December 2018	38,237
Discounted using incremental borrowing rate as at 1 January 2019	(1,388)
Discounted operating lease commitments as at 1 January 2019	36,849
Less: commitments relating to short term leases	(6,173)
LEASE LIABILITIES AS AT 1 JANUARY 2019	30,676
iv) Impact on 2019	
Increase in depreciation expense due to increase in right-of-use assets	39,284
Decrease in administrative expenses due to lower operating lease rental costs	(40,387)
Increase in finance costs relating to the interest expense on additional lease liabilities	3,016
Increase in loss on disposal of property, plant and equipment	2,927
NET INCREASE IN LOSS AFTER TAXATION	4,840
Decrease in cash outflows from operating activities	(37,301)
Increase in cash outflows from financing activities	37,301

#### 2. REVENUE ANALYSIS

The chief operating decision maker ('CODM') is defined as the Board. The format of revenue reporting is based on the Group's management and internal reporting (including reports to the CODM) of the Divisions below which carry different risks and rewards and are used to make strategic decisions. Distribution is the sale of products through the Group's resellers. Direct Sales represents the sale of the products and services direct to customers. The Group's Clinical AI Division which develops image analysis software for ultrasound through the development of deep-learning software was established in October 2017 with the acquisition of IUL and has not made any material sales to date.

The Board review the revenue and gross margin by division and channel (Distribution/Direct) and are not reporting segments under IFRS 8. All revenue is generated from external customers.

Year ended 31 December 2019		Simulation Division	Clinical AI Division	Total
	Distribution	Direct Sales		
	£	£	£	£
Revenue	2,616,178	3,299,493	-	5,915,671
Gross profit	1,435,987	2,017,477	-	3,453,464
Year ended 31 December 2018		Simulation Division	Clinical AI Division	Total
	Distribution	Direct Sales		
	£	£	£	£
Revenue	2,630,116	2,683,048	-	5,313,164
Gross profit	1,237,938	1,595,445	-	2,833,383

The following table provides an analysis of the Group's revenue by geography based upon the location of the Group's customers.

Year ended 31 December 2019 Simulation Clin Division Al Division		Total
Distribution Direct Sales		
£ £	£	£
United Kingdom - 720,355	-	720,355
North America - 2,579,138	-	2,579,138
Rest of World 2,616,178 -	-	2,616,178
2,616,178 3,299,493	-	5,915,671

Rest of World sales in the year to 31 December 2019 included £455,339 of ScanTrainer simulation system sales at fair value which were exchanged for ultrasound images under the alliance with Mediscan, details of which are provided in the CEO Review above (2018: £Nil).

Year ended 31 December 2018		Simulation Division	Clinical Al Division	Total
	Distribution	<b>Direct Sales</b>		
	£	£	£	£
United Kingdom	-	994,080	-	994,080
North America	-	1,688,968	-	1,688,968
Rest of World	2,630,116	-	-	2,630,116
	2,630,116	2,683,048	-	5,313,164

Included within non-UK revenues are sales to the following countries which accounted for more than 10% of the Group's total revenue for the year:

	2019	2018
	£	£
USA	2,203,585	1,560,624
China	597,695	710,689

The Group had no customers who accounted for more than 10% of the Group revenue for the year ended 31 December 2019 or the year ended 31 December 2018.

## 3. EXCEPTIONAL ITEMS

	2019	2018
	£	£
Fair value adjustments on contingent consideration	-	(362,718)
	-	(362,718)

The fair value adjustment on contingent consideration in 2018 arose on the settlement during that year of the retained consideration on the acquisition of IUL. The difference between the original fair value of the Deferred Consideration and the fair value of the Deferred Consideration at the settlement date of £362,718 was recognised in the 2018 Consolidated Statement of Comprehensive Income as a fair value adjustment on deferred consideration and included within exceptional items.

#### 4. INCOME TAX

Analysis of credit in the year

	2019	2018
	£	£
R&D tax credit	(167,517)	(213,796)
Adjustment for over-claim of R&D tax credit in prior periods	(80,000)	100,000
Deferred tax credit	(90,000)	(90,000)
	(337,517)	(203,796)

#### 5. LOSS PER ORDINARY SHARE

The earnings per ordinary share has been calculated using the loss for the year and the weighted average number of ordinary shares in issue during the year as follows:

	2019	2018
	£	£
Loss for the year after taxation	(4,222,418)	(3,417,464)
	2019	2018
Number of ordinary shares of 1p each	No.	No.
Basic and diluted weighted average number of ordinary		
shares	178,503,090	95,233,054
Basic loss pence per share	(2.37)p	(3.59)p

At 31 December 2019 and 2018 there were share options outstanding which could potentially have a dilutive impact but were anti-dilutive in both years.

## 6. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	2019	2018
	£	£
Trade payables	715,828	665,040
Taxation and social security	81,326	88,870
Accruals	763,703	507,568
Warrants	165,464	165,464
Other	69,377	40,923
	1,795,698	1,467,865

### 7. SHARE CAPITAL

	2019			2018	
	No.			2010 £	
	INO.	L	No.	L	
Allotted, issued and fully paid					
Ordinary shares of 1p each					
Balance at 1 January	156,627,749	1,566,278	90,701,443	907,015	
Shares issued for cash	63,369,043	633,690	59,750,331	597,503	
Shares issued on acquisition of IUL	-	-	6,175,975	61,760	
Balance at 31 December	219,996,792	2,199,968	156,627,749	1,566,278	

The fair values and premium arising on shares issued during the year are as follows:

Date	Description	Shares	Fair value	Premium
		number	£	£
28 August 2019	Shares issued in connection with capital raising	63,369,043	633,690	5,703,214

On 28 August 2019 the Company placed 63,369,043 newly issued shares of 1 pence each in the capital of the Company at a price of 10 pence per share. Share issue costs of £487,154 have been netted off against the share premium arising on the new share issue.

One third of the consideration payable in respect of the acquisition of IUL in 2017 was deferred for 12 months from completion with the actual number of deferred shares and warrants to be issued dependent on any vendor warranty

or indemnity breaches (as specified in the Sale and Purchase Agreement) arising during that 12 month period. The Company was not aware of any vendor warranty or indemnity breaches and so the 6,175,975 deferred consideration shares (with a fair value of £586,718 at 9.5 pence per share) were admitted to trading on 9 October 2018 and 418,897 deferred consideration warrants were issued at their fair value.

The share premium arising was subject to merger relief and has been taken to merger reserve.

On 13 December 2018 the Company placed 59,750,331 newly issued shares of 1 pence each in the capital of the Company at a price of 8.5 pence per share. Share issue costs of £260,732 were netted off against the share premium arising on the new share issue.

## 8. SUBSEQUENT EVENTS

Any potential impact of the COVID-19 viral pandemic is a non-adjusting post balance sheet event in accordance with IAS 10 'Events after the Reporting Period' on the basis that the significant development and spread of the virus did not take place until January 2020. The downturn in global business resulting from the pandemic are impacting all regions in which the Group operates. There is also considerable uncertainty over the likely duration of the disruption. To counter any short term slow-down in revenue a number of cost reduction measures have been implemented to mitigate the impact. As such the current expectation is for the outlook in the medium and long term to remain in line with expectations.

#### 9. PUBLICATION OF FINANCIAL STATEMENTS

It is anticipated that the full Annual Report and Financial Statements will be published in April 2020. Copies will be available from this date at the Company's head office; Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ and on the Company's website (<a href="https://www.intelligentultrasoundgroup.com">www.intelligentultrasoundgroup.com</a>).