



29 April 2021

The information contained within this announcement is deemed by the Company to constitute inside information stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is considered to be in the public domain.

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

**Unaudited Preliminary Results for the Year Ended 31 December 2020**

Intelligent Ultrasound Group plc (AIM: IUG), the ultrasound artificial intelligence (AI) software and simulation company, announces its unaudited preliminary results for the year ended 31 December 2020, showing another positive year of progress, despite the restrictions of the pandemic.

**Financial highlights:**

- The simulation division worked extremely hard to minimise the negative impact of Covid-19 and as a result, Group revenue only declined by 13% to £5.2m (2019: £5.9m)
- Despite the reduction in revenue, operating loss improved by 2% to £4.5m (2019: £4.6m)
- The balance sheet was strengthened in May 2020 with a placing and open offer which raised £4.8m after expenses
- Year-end cash at £8.8m (2019: £7.3m) and no debt (excluding IFRS 16 lease liabilities)
- Current cash of £6.6m

**Operational highlights:**

- Launch of SonoLyst (incorporating ScanNav Assist AI technology) as an option on GE Healthcare's Voluson SWIFT ultrasound machine at the end of 2020
- SonoLyst is the world's first fully integrated AI tool that recognises the 20 views recommended by the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) for mid-trimester fetal images
- Commenced the CE and FDA regulatory approval process for ScanNav Anatomy Peripheral Nerve Block stand-alone device, with in-built AI software, that can be plugged into existing anaesthesiology ultrasound machines

**Post year end:**

- Reached the significant milestone of installing our 1000<sup>th</sup> ultrasound training simulator
- Received CE approval for ScanNav Anatomy Peripheral Nerve Block

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

*"This has been a positive year for the Group considering the impact of the Covid-19 lockdowns on our access to hospitals and the ability of our development teams to cope with the remoteness of home working.*

*We minimised the effect of the pandemic on simulation division sales and Group operating losses, launched our first AI software with GE Healthcare, the world's largest ultrasound manufacturer and raised £4.8m from existing shareholders in May to strengthen our balance sheet.*

*2021 has started well, with encouraging simulation sales as well as the recent announcement of CE approval for our second clinical AI software product. As such we remain confident that we can continue to build a successful 'Classroom to Clinic' ultrasound business and reach the profitability inflection point from a growing stream of simulation and clinical AI revenues. On behalf of the Board, I would like to thank our shareholders for their continued support, and we look forward to a successful 2021."*

**For further information, please contact:**

**Intelligent Ultrasound Group plc**  
Stuart Gall, CEO  
Helen Jones, CFO

www. [intelligentultrasound.com](http://intelligentultrasound.com)  
Tel: +44 (0)29 2075 6534

**Cenkos Securities - Nominated Advisor and Broker**

Giles Balleny / Max Gould (Corporate Finance)

Michael Johnson / Julian Morse (Sales)

Tel: +44 (0)20 7397 8900

**Walbrook PR**

Anna Dunphy / Paul McManus

Tel: +44 (0)20 7933 8780 or [intelligentultrasound@walbrookpr.com](mailto:intelligentultrasound@walbrookpr.com)

Mob: +44 (0)7876 741 001 / Mob: +44 (0)7980 541 893

**About Intelligent Ultrasound Group**

Intelligent Ultrasound (AIM: IUG) 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 in the UK and Atlanta in the US, 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 the market include:

*ScanNav Assist*

ScanNav Assist uses machine-learning based algorithms to automatically identify and grade ultrasound images. GE Healthcare's SonoLyst software on their Voluson SWIFT ultrasound machine incorporates the ScanNav Assist AI technology and has received CE approval and 510(k) clearance from the FDA. SonoLyst is the world's first fully integrated AI tool that recognises the 20 views recommended by the International Society of Ultrasound in Obstetrics and Gynaecology mid-trimester practice guidelines for fetal imaging.

*ScanNav Anatomy*

ScanNav Anatomy PNB uses machine-learning based algorithms to simplify ultrasound-guided needling by providing the user with real-time AI-based anatomy highlighting software for a range of medical procedures. ScanNav Anatomy has received CE approval and has also been submitted for FDA regulatory approval. ScanNav Anatomy PNB is therefore not available for sale in the US or any other territory requiring government approval for this type of product.

**Simulation Division**

Focusses on hi-fidelity ultrasound education and training through simulation. Its main products are the ScanTrainer OBGYN training simulator, the HeartWorks echocardiography training simulator, the BodyWorks Eye Point of Care and Emergency Medicine training simulator with Covid-19 module and the new AI-based Anatomy PNB training simulator. To date over 1,000 simulators have been sold to over 600 medical institutions around the world.

[www.intelligentultrasound.com](http://www.intelligentultrasound.com)

## CHAIRMAN'S STATEMENT

2020 has been another year of progress for the Group, with the clinical AI division announcing the successful launch of its ultrasound AI software in partnership with GE Healthcare, the global leader in women's health ultrasound and the simulation division working extremely hard to minimise the negative impact of Covid-19 on 2020 sales revenue, with the launch of the BodyWork's Covid-19 lung training simulator.

### Clinical AI:

- GE Healthcare's SonoLyst technology on the Voluson SWIFT ultrasound machine, that utilises our ScanNav Assist AI software, received CE approval for sale in Europe and 510(k) clearance from the FDA for sale in the USA at the end of 2020. SonoLyst is the world's first fully integrated ultrasound AI tool that recognises the 20 views recommended by the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) mid-trimester practice guidelines for fetal imaging
- Our ScanNav Anatomy Peripheral Nerve Block (PNB) AI software was submitted for both CE and FDA approval during the year, with CE approval announced post year-end on 12 April 2021

### Simulation:

- Revenue of £5.2m (2019: £5.9m), the decline of 13% being mainly due to the impact of the global pandemic during the year in the territories where we do not have a direct sales organization.
- Sales in the UK and USA grew by over 13% to £3.7m (2019: £3.3m)
- Sales in Europe and Asia, that are made through our reseller network, were impacted by global Covid-19 restrictions and declined to £1.4m (2019: £2.6m)

### Group:

- Operating loss was lower at £4.5m (2019: loss of £4.6m) with selling and marketing cost reductions helping to minimise the Covid-19 impact of lower revenues
- Cash at bank at 31 December 2020 was £8.8m (2019: £7.3m) after receiving £4.8m net of costs in May 2020 from the successful placing and open offer

## Strategy

We continue to progress our 'Classroom to Clinic' ultrasound strategy based on:

- Growing simulation revenues from our direct UK and US operations and global reseller channels, by expanding our range of ultrasound training simulators into new medical market sectors; and
- Building on our partnership with GE Healthcare, that incorporates our ScanNav AI technology in their latest ultrasound systems, to grow clinical AI revenues through royalty-based licences with ultrasound machine manufacturers; and
- Marketing, through our direct sales organisation, proprietary stand-alone AI systems that target the large pool of existing ultrasound machines.

Three years on from our strategic 'Classroom to Clinic' expansion, we believe the successful progress of all parts of the business is reaffirming the wisdom of this decision and we look forward to continuing to build on this momentum.

## Board and governance

The Board continues to recognise the importance of maintaining the highest standards of corporate governance and is fully aware that the Group is in transition from a typical founders and venture driven company to a more mature public entity.

At the end of 2019 we therefore appointed an external advisor to conduct a full review of our Board and its performance and also held meetings with a number of our major shareholders during 2020, to allow us to fully align the Group's corporate governance with stakeholder expectations.

The key actions enacted from this review were:

- The establishment of a Nomination Committee of the Board with the task to reconfigure our Board to comply with both the independence, as well as the seniority requirement of today's public companies
- The goal to reduce, by 2022, the size of the board from the current nine directors to seven while maintaining a majority of independent non-executive directors (NEDs)
- The goal to increase board diversity and the relevant experience of the directors in the ultrasound equipment market and in the evolving AI sector

2021 and 2022 will therefore be transition years with newly appointed NEDs overlapping with current directors, some of whom will not stand for re-election the following year.

### **People**

2020 has been a difficult year for many companies, as we have all had to learn how to cope with the unpredictable impact of Covid-19 and I would like to thank all our staff for working so hard and performing so well in such difficult circumstances.

The move of our head office to larger premises in the centre of Cardiff was well timed, giving us the ability to continue key research in a Covid-secure environment, as well as building new web-based demo facilities that have enabled product sales demonstrations to continue in these restricted times.

### **Outlook**

This has been a positive year for the Group considering the impact of the Covid-19 lockdowns on our access to hospitals and the ability of our development teams to cope with the remoteness of home working.

We minimised the effect of the pandemic on simulation division sales and Group operating losses, launched our first AI software with GE Healthcare, the world's largest ultrasound manufacturer and raised a net £4.8m from existing shareholders in May to strengthen our balance sheet.

2021 has started well, with encouraging simulation sales, as well as the recent announcement of CE approval for our second clinical AI software product. As such we remain confident that we can continue to build a successful 'Classroom to Clinic' ultrasound business and reach the profitability inflection point from a growing stream of simulation and clinical AI revenues.

Riccardo Pigliucci  
*Non-executive chairman*

## **CEO REVIEW**

Intelligent Ultrasound is harnessing the power of the new generation of artificial intelligence (AI) algorithms to make ultrasound simpler to use and easier to learn, by providing guidance and support to medical professionals whilst they are scanning.

AI is a key element of our 'Classroom to Clinic' approach to ultrasound as we expand both our simulation and clinical AI divisions. The report below details how each division operates, the progress made in 2020 and the key challenges faced during the year.

## **CLINICAL AI DIVISION**

Our clinical AI division continues to build on the original work of Professor Alison Noble FRS OBE, and Professor Aris Papageorgiou FRCOG from The University of Oxford. Alison and Aris still work with us today, keeping us informed of the latest advances in the machine learning field, to ensure that we can develop products that meet real clinical needs.

In under three years the AI development team has grown to over 30 software engineers, image segmenters and medical and regulatory advisors. Their leading-edge development work is underpinned by a well-curated and growing database of over five million ultrasound images that we have used to develop our range of AI-based ScanNav real-time image analysis software products. These products are focused on moving AI into the clinic to give real-time support to clinicians whilst they are scanning.

### ***ScanNav Assist***

For obstetricians, our ScanNav Assist AI technology acts like a personal scanning assistant, by comparing the image or view acquired to specific criteria on standard views within a fetal scan, to ensure they contain the required anatomy for the imaging plane.

In 2019, we entered a long-term partnership agreement for our ScanNav Assist AI software with GE Healthcare, one of the world's leading ultrasound manufacturers. At the end of September 2020 GE Healthcare announced the launch of the Voluson SWIFT, which is the first GE ultrasound system to feature SonoLyst, the new software that utilises our ScanNav Assist real-time image analysis software to enhance workflow and improved consistency by reducing variability between operators. SonoLyst is the world's first fully integrated AI tool that recognises the 20 views recommended by the ISUOG mid-trimester practice guidelines for fetal sonography imaging:

#### ***SonoLystIR***

Utilises ScanNav Assist to perform automated detection of the key scanning views and automated selection of the relevant Voluson SonoBiometry measurement tools. SonoLystIR automatically detects anatomy then selects all applicable annotations and measurements, enhancing workflow and reducing variability between operators for improved consistency.

#### ***SonoLystX***

Utilises ScanNav Assist to compare the acquired image to standardised criteria, to ensure that it meets clinical standards. SonoLystX is a virtual onboard ultrasound expert that can help enhance accuracy and quality and is ideal for teaching, training, and quality assurance to ensure quality image standards and consistency.

SonoLyst is an optional add-on to the Voluson SWIFT and is the first AI software to be launched under the Group's long-term agreement with GE Healthcare, that provides for the integration of Intelligent Ultrasound's real-time AI image analysis software into GE Healthcare's Voluson women's health ultrasound portfolio.

Although the terms of the agreement are confidential and undisclosed for commercial reasons, the Voluson SWIFT received CE approval for sale in Europe and 510(k) clearance from the FDA for sale in the USA at the end of 2020 and we would therefore look to be able to report more fully on clinical AI division revenues in our 2021 half year results.

Initial user feedback has been encouraging and with pandemic related restrictions on hospital capital expenditure expected to ease in the second half of 2021, combined with the full global roll-out of the Voluson SWIFT, this should result in a growth of our clinical sales through the second half of the year. However, we would expect 2022 to be a truer indication of the royalty generation potential of this first product in our AI range.

Intelligent Ultrasound's aim is to develop future variants of ScanNav Assist that will support additional protocol-based scanning in both obstetrics and general radiology.

### **ScanNav Anatomy**

ScanNav Anatomy uses the latest AI technology to automatically highlight the live ultrasound image to enhance the accuracy and standardisation of ultrasound image interpretation, by making it easier to identify key anatomical structures. This supports the performance of healthcare professionals who are suitably qualified, but who perform ultrasound-guided procedures on a less frequent basis.

Our first version of the product, ScanNav Anatomy PNB, received CE approval in April 2021 and supports nine common peripheral nerve blocks (a form of local anaesthesia). It will be sold as a stand-alone screen mounted on a portable stand that can be plugged into existing anaesthesiology ultrasound machines. The device will provide clinicians with continuous feedback from real-time highlighting of their live ultrasound. Users can also re-familiarise themselves with blocks that are carried out less frequently using the system's integrated 3D animations.

ScanNav Anatomy PNB is also available as a training simulator for medical learning on volunteers, prior to patient contact.

Increasingly, ultrasound-guided peripheral nerve blocks are being used as a prudent alternative to general anaesthesia, but not all anaesthetists have the specialist knowledge of ultrasound anatomy to perform them. Through the adoption of ScanNav PNB, it is hoped that hospitals will be able to increase the number of ultrasound-guided nerve blocks that they can perform.

We intend to sell the cart-based system to the UK market using our existing in-house sales resources, with an expected launch in Q2 2021. In addition, we continue to progress the product's FDA regulatory filing to enable a version of the product to be sold in the US<sup>1</sup>, as well as seeking to licence an integrated version of the product to the major ultrasound manufacturers.

Intelligent Ultrasound's aim is to develop further variants of ScanNav Anatomy that can be added to the existing ScanNav IPU hardware platform and support scanning in both interventional radiology and general radiology, as appropriate.

### **Future ScanNav AI products<sup>1</sup>**

The Group has the following additional products in various early stages of development.

#### **ScanNav Detect**

ScanNav Detect aims to facilitate the automatic recognition of abnormalities within a general medical 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 a specialist.

<sup>1</sup> AI products in development may require US FDA or other regulatory approval, as such this material should be considered informational only and does not constitute an offer to sell or infer claims or benefits.

We expect ScanNav Detect to allow more point-of-care medical practitioners to use ultrasound imaging for frontline medical diagnostic sonography. 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.

Developments include:

- Lung/Covid-19
- Prostate
- Liver

### **ScanNav HealthCheck**

ScanNav HealthCheck is a proof-of-concept development area that aims to build on our current ScanNav medical practitioner AI technology, to enable consumers to perform ultrasound scanning on themselves.

In the long term, as the price of ultrasound hardware decreases to a point, such that consumers can plug devices into their smartphones; and the performance of our AI software advances, we aim to provide enabling software for mass market AI-based ultrasound scanning at home, for the health-conscious consumer.

### **Challenges to the Clinical AI Division**

The medical imaging AI software market remains immensely exciting, potentially hugely significant, yet still unproven. In addition, there is considerable competition from both existing ultrasound manufacturers and new AI start-ups and many of these are extremely well funded.

To respond to these challenges, we remain focussed on developing AI software that has both a clinical need and a clear economic rationale for its purchase; and we will continue to build our AI image database to ensure we have high quality, curated images that are relevant to building AI algorithms in the field of anaesthesiology, obstetrics, gynaecology, radiology and primary care medicine.

In addition, we will deploy a two-pronged marketing strategy to:

- Sign royalty-based, 'on-machine' licences for the provision of real-time AI for the next generation of ultrasound machines with the major manufacturers, whose established sales networks can provide faster access to our technology in the new ultrasound machine market
- Sell our own proprietary stand-alone, real-time AI enabled devices to the global pool of existing ultrasound machines, through our own sales network

In summary, to date, we have signed our first partnership agreement with GE Healthcare, and they have launched SonoLyst, their first product to incorporate our ScanNav Assist technology. In April 2021 we received CE regulatory approval for ScanNav Anatomy PNB, our first direct to market proprietary stand-alone device and will launch this into the UK market in Q2 2021.

These successes are enabling us to focus on rolling these first products out to market, working with key opinion leaders to build compelling study data, such that we can convert early-stage interest into long-term sales and demonstrate the revenue potential of AI in ultrasound from 2022 onwards.

### **SIMULATION DIVISION**

Training clinicians through hi-fidelity simulation is a cornerstone of our business and has been the foundation of our expertise in understanding the clinical needs of medical professionals who rely on ultrasound imaging and its growing diagnostic capabilities in medicine.

Based in Cardiff (UK), Alpharetta (US) and with representation in Beijing (China), our simulation division continues to design, develop and sell some of the world's leading hi-fidelity training systems for teaching ultrasound scanning to medical professionals in institutions and medical device companies.

During the year we continued to focus on three key markets

- Obstetrics/gynaecology (OBGYN)
- Echocardiography/anaesthesiology (ECHO)
- Emergency medicine/point-of-care (PoCUS) markets

This will continue in 2021 and is expected to be supplemented with the in-house development of new simulator platforms that, when combined with the existing products ranges, should accelerate our growth from 2022 onwards.

Highlighting the synergy between our two divisions, one of the new simulation platforms is a spin-off from the clinical AI development team and represents a new area of joint development for the Group, whereby some of our new AI developments may also have training simulator potential.

Our ultrasound training simulators are, in the main, high value, capital equipment 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. In March 2021, we were delighted to announce the significant sales milestone of installing our 1000<sup>th</sup> ultrasound simulation system, a BodyWorks Eve PoCUS and Covid-19 training simulator, at the Ohio State University College of Medicine, one of the leading medical institutions in North America.

### **Research & Development**

At the start of the pandemic in early 2020, the simulation R&D team resources were diverted to focus on the development of a Covid-19 version of our BodyWorks Point-of-Care simulator, designed to train frontline healthcare providers to use lung ultrasonography.

Ultrasound has major utility for patient monitoring of respiratory-related Covid-19 due to its safety, repeatability, absence of radiation, low cost and point of care use. Our Covid-19 upgrade module was made available globally and free of charge, to all our existing customers and enabled rapid and effective training of many healthcare professionals working in the front line. Examples include the UK Nightingale hospitals, New York's Harbour Healthcare hospitals and Ohio State University system, to name but a few.

During the year we also continued to release new products, including a new version of the HeartWorks Augmented Reality tablet with its exceptional 3D cardiac anatomy, and a comprehensive module upgrade for ScanTrainer to add new training modules to its teaching material.

At the beginning of 2021 we released in the UK, the first AI-enabled training simulator for peripheral nerve blocks. As highlighted above, this represents a new area of joint development opportunity for the Group, whereby new AI developments may also have training simulator sales potential.

We also are in the process of releasing a significant number of remote learning options for our simulators to help with the flexible and hybrid learning requirements that training needs to provide in the current environment.

### **Territory Review**

Sales in a Covid-19 impacted year declined by 13% to £5.2m (2019: £5.9m), but there are positive signs that 2021 will see a return to growth and that the expansion of our hi-fidelity simulator range will continue this growth in the longer term.

#### ***United Kingdom***

Revenue increased by 95% to £1.4m (2019: £0.7m)



The UK rebounded well after a difficult 2019. The relaxing of NHS spending limitations by the UK government opened up the backlog of interest in our simulator range from UK universities and teaching hospitals. Importantly, the development of our free Covid-19 training module aimed at training medical professionals working on the pandemic frontline, increased sales of our BodyWorks simulator. The successful training of the Nightingale hospitals' staff, at such short notice, was particularly rewarding for the team.

We continue to have significant purchasing interest in all our simulation products in the UK and look forward to continuing this growth in 2021.

### ***North America***

Revenue decreased by 10% to £2.3m (2019: £2.6m)

Sales in North America recovered well in the year, to finish only 10% down on 2019, despite the on/off effect of Covid-19 and its subsequent restrictions on access to teaching institutions and hospitals.

In a number of major US states, including New York, Ohio and California, our free Covid-19 training module achieved significant success in training frontline staff responding to the pandemic.

With almost every major face-to-face trade exhibition event in the US cancelled during the year, we were able to adapt our sales processes by building a new virtual demonstration room in Alpharetta (Atlanta) for potential customers. This enabled sales demos to continue, even during total state lockdowns. As such, even with hospital visits severely restricted, the US team was able to recover from the initial sales downturn in the first half of the year and is confident that this recovery will continue in 2021.

### ***Rest of the World (ROW)***

Revenue decreased by 46% to £1.4m (2019: £2.6m)

Although our combined direct sales force in the UK and North America was able to mitigate the effect of the pandemic and grow sales by a combined 15% to £3.8m (2019: £3.3m), many of our resellers, who are one step removed from us in the sales process, were unable to mitigate the impact and in some cases, were closed for virtually the whole year.

However, there were signs of a recovery in sales in Germany, Scandinavia and China during the second half of the year and sales in 2021 have started encouragingly, with training and product sales support being provided to our resellers from our new, state-of-the-art web demonstration room in our head office in Cardiff.

### ***Challenges to the Simulation Division***

Training budgets for high value simulators within the global healthcare markets remain affected by restricted health budgets, which can be both hard to access and predict, especially during times of political upheaval or global pandemics, when funds are diverted from training to frontline care.

We continue to respond well to competitive products and associated pricing and margin pressures, by offering a range of simulators that provide the highest standard of ultrasound training, at a variety of price points. Purchasing decisions in our sector of the market continue to be based on quality of training and value for money, rather than simply the lowest priced solution.

However, we have also recognised that eLearning is an important element of the training mix and are developing a range of online training solutions that work in tandem with our hands-on training simulators.

The impact of Covid-19 in reducing the ability to demo in hospitals, meet potential customers at trade shows and train our resellers has been met by an increase in online marketing, combined with the development of new web demo rooms with on-site training resource in Atlanta and Cardiff.

Finally, the development and launch of our first AI-based training simulator for PNB, demonstrates the potential for clinical AI developments to result in training simulator spin-offs, that could provide future incremental revenue to the Group.

### **Quality Management System (QMS)**

The Group continues to meet the standards of ISO 13485:2016 to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purpose. Post year-end, the Group has changed its Notified Body to Dare!! Services B.V.

### **Workplace environment**

During the year, the Group moved to a larger, more modern and flexible head office space in the centre of Cardiff, and also moved the Group's warehouse and technical support operation to new premises in Caerphilly. The combined effect of these moves was to significantly improve the Group's ability to operate effectively during the pandemic restrictions, as well as providing the facilities for post-pandemic growth of both divisions.

Our staff have been tremendous in this very difficult working year, mixing at-home and office work to minimise the impact of the pandemic on the business. Safety of employees has been of key importance and we quickly acted to ensure all employees, where possible, had the resources to be able to work effectively from home.

I would like to convey my thanks to all staff, for being so supportive during the year.

### **Brexit**

Sales to European resellers in 2020 were relatively small and as such, the impact of Brexit on the business has been minimal to date.

### **Looking ahead**

Despite the understandable concerns over Covid-19 and its potential ongoing negative impact on revenue in 2021, we are encouraged by the start to the year.

For the simulation division, 2021 is expected to be a year of new product launches and revenue growth and our simulator sales have started well.

For the clinical AI division, we have our first AI product on GE Healthcare's Voluson SWIFT and we have just received CE approval for our second AI product, ScanNav Anatomy PNB. We are, however, conscious that the pandemic is still restricting hospital access and budgets and that our new AI products are launching into new markets that need time to accept the product and time to build significant sales. 2021 is therefore expected to be a year where we will continue to invest heavily in R&D, but also focus on generating the compelling key opinion leader study data that will enable the longer-term acceptance and subsequent sales potential of AI in ultrasound to be realised from 2022 onwards.

The directors continue to believe that the current cash position will be sufficient to enable the Group to meet its anticipated profitability inflection point from expected future revenues from the clinical AI division. We remain optimistic about the opportunities for the Group in this exciting sector of the market and would like to thank our shareholders and investors for their continued support.

Finally, with our move to new offices in Cardiff, we would be delighted to welcome any shareholders or prospective investors should they wish to visit us to see our technology for themselves.

Stuart Gall  
*Chief executive officer*

## FINANCIAL REVIEW

### Summary financial performance

£m (unless otherwise stated)	2020	2019
Revenue	5.2	5.9
Gross profit	3.2	3.5
Gross profit margin (%)	61	58
Administrative expenses	(7.9)	(8.2)
Operating loss	(4.5)	(4.6)
Net cash used in operating activities	(2.3)	(3.3)
Loss after taxation	(3.3)	(4.2)
Cash and investments (short term deposits)	8.8	7.3

#### Revenue

Revenues from the simulation division declined by 13% in 2020 to £5.2m (2019: £5.9m), mainly caused by a significant downturn in revenue due to the impact of Covid-19 on our reseller network in Europe and Asia, where sales year on year were down by £1.2m (46%). This was offset however by an increase in sales in the UK and US combined of £0.5m (13%).

#### Simulation division revenue

£m	2020	2019
UK	1.4	0.7
North America	2.4	2.6
Rest of World	1.4	2.6
	5.2	5.9

#### Clinical AI division revenue

First revenue from our clinical AI division was generated at the end of the year and totalled £17k (2019: £0k).

#### Gross profit

Gross margin increased from 58% in 2019 to 61% in 2020, due largely to the higher proportion of direct sales representing 73% of total sales (2019: 56%).

#### Operating costs

The operating loss improved by £0.1m to £4.5m (2019: £4.6m), despite gross profits decreasing by £0.3m to £3.2m (2019: £3.5m). This reduction in gross profits was offset by a £0.4m saving in administrative expenses, down to £7.8m (2019: £8.2m), due to a significant decrease in travel and marketing costs, with lockdown restrictions preventing our sales teams from providing live on-site demonstrations of our products and the majority of exhibitions and conferences being cancelled in the year.

#### Research and development (R&D) costs

£m	2020	2019
R&D		
- Expensed	2.0	2.2
- Capitalised	0.6	0.5
	2.6	2.7
Simulation division	0.9	1.2
Clinical AI division	1.7	1.5

Total R&D spend in 2020, including both expensed and capitalised costs, was £2.6m which is £0.1m lower than in 2019. Expensed R&D costs of £2.0m in 2020 largely relate to activity in the clinical AI division, which had not yet met the criteria for capitalisation under IAS 38. A further £0.6m (2019: £0.5m) of costs relating to the continued ongoing development of products in the simulation division were capitalised within intangible assets, which are being amortised over three years.

### **Other income**

Other income includes an advance of £0.12m (\$0.16m) relating to the US Government's Paycheck Protection Program which allowed US small businesses to apply for forgivable loans to pay for their payroll and certain other costs during the pandemic.

RDEC to the amount of £0.83m was received in relation to R&D projects which have been previously in receipt of grant funding which cannot be claimed under the R&D SME regime. RDEC is recognised as taxable income within other income.

### **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 £0.9m (2019: £0.2m), this includes a £0.2m credit following a change in accounting policy to recognise R&D tax credits on an accruals basis.

Included within the tax credit of £1.2m is a deferred tax credit of £0.3m, which represents the movement in the consolidated deferred tax liability as well as the recognition at the year end of an equivalent deferred tax asset in relation to the intangible fixed assets acquired on acquisition of IUL and IML representing the view that the intangible fixed assets have value which will lead to the accumulated trading losses being utilised in the future.

As at 31 December 2020, the Group has cumulative gross UK tax losses of approximately £15.7m (2019: £14.3m) for which no deferred tax asset has been recognised.

### **Share placing**

On 4 May 2020 the Company issued a further 49,400,000 new ordinary shares of 1 pence each at a price of 10.5 pence per share which raised £5.2m before costs, and £4.8m after costs.

The proceeds have been and will continue to be used for the research and development costs of bringing clinical AI products to market, to continue the development of our simulation products and general working capital.

### **Statement of financial position**

Consolidated net assets increased to £12.7m (2019: £11.1m). Intangible fixed assets of £2.0m were £0.3m lower than the carrying amount at 31 December 2019 of £2.3m. Additions to intangibles in the year were £0.6m (2019: £0.5m) relating to capitalised development costs; whereas amortisation of all intangibles including IP and brands totalled £0.9m (2019: £1.0m). Property, plant equipment of £1.3m (2019: £0.5m) includes £0.9m of new right of use assets in relation to the leases of the new head office in Cardiff and the new manufacturing and technical support operation warehouse in Caerphilly. This much larger warehouse has enabled the Group to hold higher inventory levels in anticipation of any Covid-19 related delays resulting in inventory at year end totalling £1.0m (2019: £0.7m).

### **Cash and short-term deposits**

Cash and cash equivalents at 31 December 2020 was £8.8m (2019: £1.8m), an increase of £7.0m.

Net cash used in operating activities was £2.3m, £1.0m lower than in 2019 (2019: £3.3m). This decrease was due to the lower operating loss combined with improvements in the management of net working capital as well as higher R&D tax credits of £0.36m (2019: £0.1m).

The net cash inflow arising from investing activities was £4.6m (2019: outflow £6.3m), largely relating to the maturity of the £5.5m that was held on short term deposit offset by capitalised internally generated intangible assets of £0.6m (2019: £0.5m).

The net cash inflow from financing activities of £4.7m (2019: £5.8m) included £4.8m raised from the share placing less lease payments of £0.1m.

**CONSOLIDATED STATEMENT OF PROFIT AND LOSS AND OTHER COMPREHENSIVE INCOME**  
**for the year ended 31 December 2020**

	Note	Unaudited 2020 £'000	Audited 2019 £'000
<i>Continuing operations</i>			
REVENUE	2	5,170	5,916
Cost of sales		(1,999)	(2,462)
GROSS PROFIT		3,171	3,454
Other income	3	207	157
Administrative expenses		(7,859)	(8,169)
OPERATING LOSS		(4,481)	(4,558)
Finance income		17	1
Finance costs		(17)	(3)
LOSS BEFORE TAXATION		(4,481)	(4,560)
Taxation	4	1,175	338
LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT		(3,306)	(4,222)
OTHER COMPREHENSIVE INCOME			
<i>Items that may be reclassified to profit or loss:</i>			
Exchange loss arising on translation of foreign operations		(77)	(33)
OTHER COMPREHENSIVE LOSS FOR THE PERIOD		(77)	(33)
TOTAL COMPREHENSIVE LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT		(3,383)	(4,255)
LOSS PER ORDINARY SHARE ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT			
Basic and diluted (pence)	5	(1.30)	(2.37)

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**as at 31 December 2020**

	Note	Unaudited 2020 £'000	Audited 2019 £'000
<b>NON-CURRENT ASSETS</b>			
Intangible assets		1,963	2,332
Property, plant and equipment		1,313	545
Trade and other receivables		61	-
		<b>3,337</b>	<b>2,877</b>
<b>CURRENT ASSETS</b>			
Inventories		1,048	663
Trade and other receivables		2,025	2,700
Current tax assets		671	148
Investments (short term deposits)		-	5,500
Cash and cash equivalents		8,774	1,790
		<b>12,518</b>	<b>10,801</b>
<b>TOTAL ASSETS</b>		<b>15,855</b>	<b>13,678</b>
<b>CURRENT LIABILITIES</b>			
Trade and other payables	6	(1,901)	(1,670)
Deferred income		(142)	(325)
Lease liabilities		(170)	(53)
Provisions		(10)	(95)
		<b>(2,223)</b>	<b>(2,143)</b>
<b>NON-CURRENT LIABILITIES</b>			
Deferred income		(275)	(109)
Deferred taxation		-	(288)
Lease liabilities		(603)	(20)
Other payables		(65)	-
		<b>(943)</b>	<b>(417)</b>
<b>TOTAL LIABILITIES</b>		<b>(3,166)</b>	<b>(2,560)</b>
<b>NET ASSETS</b>		<b>12,689</b>	<b>11,118</b>
<b>EQUITY</b>			
Share capital		2,694	2,200
Share premium		25,959	21,653
Share warrants		126	126
Accumulated losses		(23,381)	(20,075)
Share-based payment reserve		842	688
Merger reserve		6,538	6,538
Foreign exchange reserve		(89)	(12)
<b>TOTAL EQUITY</b>		<b>12,689</b>	<b>11,118</b>

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**  
**for the year ended 31 December 2020**

	Share capital	Share premium	Share warrants	Accumulated losses	Share-based payment reserve	Merger reserve	Foreign exchange reserve	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
AS AT 1 JANUARY	1,566	16,437	126	(15,853)	562	6,538	21	9,397
<b>COMPREHENSIVE INCOME FOR THE YEAR</b>								
Loss for the year	-	-	-	(4,222)	-	-	-	(4,222)
Other comprehensive loss	-	-	-	-	-	-	(33)	(33)
<b>TRANSACTIONS WITH OWNERS, RECORDED DIRECTLY IN EQUITY</b>								
Issue of share capital	634	5,703	-	-	-	-	-	6,337
Cost of raising finance	-	(487)	-	-	-	-	-	(487)
Cost of share-based awards	-	-	-	-	126	-	-	126
	<b>634</b>	<b>5,216</b>	<b>-</b>	<b>-</b>	<b>126</b>	<b>-</b>	<b>-</b>	<b>5,976</b>
AS AT 31 DECEMBER 2019	2,200	21,653	126	(20,075)	688	6,538	(12)	11,118
<b>COMPREHENSIVE INCOME FOR THE YEAR</b>								
Loss for the year	-	-	-	(3,306)	-	-	-	(3,306)
Other comprehensive loss	-	-	-	-	-	-	(77)	(77)
<b>TRANSACTIONS WITH OWNERS, RECORDED DIRECTLY IN EQUITY</b>								
Issue of share capital	494	4,693	-	-	-	-	-	5,187
Cost of raising finance	-	(387)	-	-	-	-	-	(387)
Cost of share-based awards	-	-	-	-	154	-	-	154
	<b>494</b>	<b>4,306</b>	<b>-</b>	<b>-</b>	<b>154</b>	<b>-</b>	<b>-</b>	<b>4,954</b>
<b>AS AT 31 DECEMBER 2020 (unaudited)</b>	<b>2,694</b>	<b>25,959</b>	<b>126</b>	<b>(23,381)</b>	<b>842</b>	<b>6,538</b>	<b>(89)</b>	<b>12,689</b>

**CONSOLIDATED STATEMENT OF CASH FLOWS**  
**for the year ended 31 December 2020**

	<b>Unaudited</b>	Audited
	<b>2020</b>	2019
	<b>£'000</b>	£'000
<i>Cash flows from operating activities</i>		
Loss before tax	(4,481)	(4,560)
Depreciation	406	334
Amortisation of intangible assets	937	1,040
Fair value adjustment on share warrants	21	-
Loss on disposal of property, plant and equipment	26	-
Finance costs	-	2
Share-based payment charge	154	126
Operating cash flows before movement in working capital	(2,937)	(3,058)
Movement in inventories	(389)	188
Movement in trade and other receivables	590	(786)
Movement in trade and other payables	198	283
Movement in provisions	(84)	-
Cash used in operations	(2,622)	(3,373)
Income taxes received	362	80
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,260)</b>	<b>(3,293)</b>
<i>Cash flows from investing activities</i>		
Purchase of property, plant and equipment	(371)	(355)
Disposal of property, plant and equipment	-	12
Decrease/(increase) in short term deposits	5,500	(5,500)
Internally generated intangible assets	(568)	(485)
Interest received	17	-
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>4,578</b>	<b>(6,328)</b>
<i>Cash flows from financing activities</i>		
Issue of new shares	5,187	6,337
Share issue costs	(387)	(487)
Principal elements of lease payments	(62)	(37)
Finance costs paid	(17)	(2)
<b>NET CASH GENERATED FROM FINANCING ACTIVITIES</b>	<b>4,721</b>	<b>5,811</b>
NET INCREASE IN CASH AND CASH EQUIVALENTS	7,039	(3,811)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	1,790	5,607
Exchange losses on cash and cash equivalents	(55)	(6)
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<b>8,774</b>	<b>1,790</b>



## 1. GENERAL INFORMATION

Intelligent Ultrasound Group plc (“the Company”) is a public 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 Floor 6A Hodge House, 114-116 St Mary Street, Cardiff, CF10 1DY.

The financial information set out in the announcement does not constitute the company’s statutory accounts for the years ended 31 December 2020 or 2019. The financial information for the year ended 31 December 2019 is derived from the statutory accounts for that year which have been delivered to the Registrar of Companies. The auditors reported on those accounts: their report was unqualified, did not draw attention to any matters by way of emphasis and did not contain a statement under s498(2) or (3) of the Companies Act 2006. The audit of the statutory accounts for the year ended 31 December 2020 is not yet complete. These accounts will be finalised on the basis of the financial information presented by the directors in this preliminary announcement and will be delivered to the Registrar of Companies following the company’s annual general meeting.

### 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 May 2021.

The unaudited consolidated preliminary results have been prepared on a going concern basis and has been approved by the Board of Directors.

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

The accounting policies applied in these unaudited consolidated preliminary results are consistent with those of the annual financial statements for the year ended 31 December 2019.

## 2. SEGMENTAL OPERATIONS

The Group identifies reportable operating segments based on internal management reporting that is regularly reviewed by the chief operating decision maker (CODM). The CODM is the Board of Directors.

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. The Group has two operating segments:

i) Simulation division

Revenue arises from sales of ultrasound training simulation systems and related services.

ii) Clinical AI division

Revenue arises from sales of regulatory approved AI-based ultrasound image analysis software products.

## 2. SEGMENTAL OPERATIONS (continued)

<b>2020</b>	Simulation	Clinical AI	Corporate	<b>Total</b>
	£'000	£'000	£'000	£'000
REVENUE	5,153	17	-	<b>5,170</b>
Cost of sales	(1,999)	-	-	<b>(1,999)</b>
GROSS PROFIT	3,154	17	-	<b>3,171</b>
Other income	207	-	-	<b>207</b>
Administrative expenses	(4,703)	(2,239)	(917)	<b>(7,859)</b>
OPERATING LOSS	(1,342)	(2,222)	(917)	<b>(4,481)</b>
Finance income	-	-	17	<b>17</b>
Finance costs	(6)	-	(11)	<b>(17)</b>
LOSS BEFORE TAXATION	(1,348)	(2,222)	(911)	<b>(4,481)</b>
Taxation	488	687	-	<b>1,175</b>
LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT	(860)	(1,535)	(911)	<b>(3,306)</b>

<b>2019</b>	Simulation	Clinical AI	Corporate	Total
	£'000	£'000	£'000	£'000
REVENUE	5,916	-	-	5,916
Cost of sales	(2,462)	-	-	(2,462)
GROSS PROFIT	3,454	-	-	3,454
Other income	157	-	-	157
Administrative expenses	(5,197)	(2,125)	(847)	(8,169)
OPERATING LOSS	(1,586)	(2,125)	(847)	(4,558)
Finance income	-	-	1	1
Finance costs	(3)	-	-	(3)
LOSS BEFORE TAXATION	(1,589)	(2,125)	(846)	(4,560)
Taxation	152	186	-	338
LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PARENT	(1,437)	(1,939)	(846)	(4,222)

### Revenue by destination of external customer

<i>Year ended 31 December 2020</i>	Simulation division	Clinical AI division	<b>Total</b>
	£'000	£'000	£'000
United Kingdom	1,419	-	<b>1,419</b>
North America	2,324	-	<b>2,324</b>
Rest of World	1,410	17	<b>1,427</b>
	5,153	17	<b>5,170</b>
Goods transferred at a point in time	4,907	17	<b>4,924</b>
Services transferred over time	246	-	<b>246</b>

## 2. SEGMENTAL OPERATIONS (continued)

<i>Year ended 31 December 2019</i>	Simulation Division	Clinical AI Division	Total
	£'000	£'000	£'000
United Kingdom	720	-	720
North America	2,580	-	2,580
Rest of World	2,616	-	2,616
	<u>5,916</u>	<u>-</u>	<u>5,916</u>
Goods transferred at a point in time	5,597	-	5,597
Services transferred over time	<u>319</u>	<u>-</u>	<u>319</u>

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:

	2020 £'000	2019 £'000
USA	2,036	2,204
China	<u>421</u>	<u>598</u>

The Group had no customers who accounted for more than 10% of the Group revenue for the year ended 31 December 2020 or the year ended 31 December 2019.

### Net operating assets/(liabilities) by division:

	2020 £'000	2019 £'000
Simulation division	(10,689)	(9,707)
Clinical AI division	(3,124)	(1,714)
Group	<u>26,502</u>	<u>22,539</u>
	<u>12,689</u>	<u>11,118</u>

## 3. OTHER INCOME

	2020 £'000	2019 £'000
US Government grant income	124	-
UK grant income	-	157
R&D expenditure credit (RDEC)	83	-
	<u>207</u>	<u>157</u>

#### 4. TAXATION

	2020 £'000	2019 £'000
<i>Current tax</i>		
R&D tax credit	(673)	(168)
R&D tax credit relating to prior periods	(214)	(80)
	(887)	(248)
<i>Deferred tax</i>		
Origination and reversal of timing differences	(289)	(90)
Effect of tax rate change on opening balance	1	-
	(288)	(90)
Income tax credit	(1,157)	(338)

#### 5. LOSS PER ORDINARY SHARE

The loss 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:

	2020 £'000	2019 £'000
Loss for the year after taxation	(3,306)	(4,222)

	2020 Number	2019 Number
<i>Number of ordinary shares of 1p each:</i>		
Basic and diluted weighted average numbers of ordinary shares	254,915,148	178,503,090
Basic and diluted loss per share (pence)	(1.30)	(2.37)

At 31 December 2020 and 2019 there were share options outstanding which could potentially have a dilutive impact but were anti-dilutive in both years.

#### 6. TRADE AND OTHER PAYABLES

	2020 £'000	2019 £'000
<i>Current liabilities</i>		
Trade payables	842	716
Taxation and social security	169	81
Accruals	829	764
Share warrants	61	40
Other	-	69
	1,901	1,670
<i>Non-current liabilities</i>		
Other payables	65	-
	1,966	1,670

## 7. SHARE CAPITAL

	2020		2019	
	Number	£'000	Number	£'000
<i>Allotted, issued and fully paid</i>				
Ordinary shares of 1p each				
Balance at 1 January	219,996,792	2,200	156,627,749	1,566
Shares issued for cash	49,400,000	494	63,369,043	634
Balance at 31 December	269,396,792	2,694	219,996,792	2,200

The fair values and premium arising on shares issued in 2020 and 2019 are as follows:

Date	Number of shares	Fair value £	Premium £
4 May 2020	49,400,000	494,000	4,493,000
28 August 2019	63,369,043	633,690	5,703,214

On 4 May 2020 the Company placed 49,400,000 newly issued shares of 1 pence each in the capital of the Company at a price of 10.5 pence per share. Share issue costs of £0.39m have been netted off against the share premium arising on the new share issue.

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 £0.49m have been netted off against the share premium arising on the new share issue.

### *Share warrants*

The consideration for the acquisition of IUL on 6 October 2017 included 837,795 share warrants with a fair value of £125,669 which were issued on completion. The terms of the warrant instrument agreement allow the holder to subscribe for a fixed number of shares in the Company for a fixed subscription price. In accordance with IAS 32 'Financial Instruments: Presentation', a contract that will be settled by the entity delivering a fixed number of its own equity instruments in exchange for a fixed amount of cash or another financial asset is an equity instrument.

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 418,897 deferred consideration warrants were issued at their fair value. These warrants remain as a financial liability and are measured at fair value through the income statement.

The share warrants expire on 10 July 2021.

## 8. PUBLICATION OF FINANCIAL STATEMENTS

It is anticipated that the full Annual Report will be published in May 2021. Copies will be available at the Company's head office; Floor 6A Hodge House, 114-116 St Mary Street, Cardiff, CF10 1DY and on the Company's website ([www.intelligentultrasound.com](http://www.intelligentultrasound.com)).