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Intelligent Ultrasound Group plc

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

Audited Results for the Year Ended 31 December 2022

Intelligent Ultrasound Group plc (AIM: IUG), the ultrasound artificial intelligence (AI) software and simulation company, announces its audited results for the year ended 31 December 2022, showing another year of significant progress.

Financial highlights:

- Group revenue grew by 33% to £10.1m (2021: £7.6m)
- Clinical AI-related revenue grew by over 200% to £0.7m (2021: £0.2m)
- Simulation related revenue grew by 28% to £9.4m (2021: £7.4m)
- Loss after tax reduced to £3.0m (2021: £3.6m)
- Year-end cash at £7.2m (31 December 2021: £5.0m) after a £4.8m placing (net of fees) and no debt (excluding IFRS 16 lease liabilities)

Operational highlights:

- GE HealthCare launched the SonoLyst technology, that utilises our ScanNav Assist AI software, on the Voluson Expert 22 ultrasound machine in July
- ScanNav Anatomy Peripheral Nerve Block (PNB), our second AI-driven product, received FDA *De Novo* clearance for sale in the US in October
- NeedleTrainer 2.0, our third AI-related product, to teach ultrasound-guided needling to medical professionals, was launched in September and now incorporates the GE HealthCare Vscan Air ultrasound device
- We began a charitable partnership with the World Federation for Ultrasound in Medicine and Biology ("WFUMB") to support their mission to bring sustainable ultrasound training programmes to the underserved areas of the world

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

"This has been another year of significant progress for the Group. We have increased Group revenue by over 30%, achieved the important milestone of FDA clearance for our second AI-driven product and continue to build an excellent partnership with the world's leading ultrasound company - GE HealthCare.

With a positive start in Q1 23, a growing range of AI and simulation related products, an established operational base, and year end cash of £7.2m, we expect to continue this growth during 2023 and remain excited about the long-term potential of our unique 'Classroom to Clinic' model".

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ABOUT INTELLIGENT ULTRASOUND GROUP

Intelligent Ultrasound (AIM: IUG) is one of the world's leading 'classroom to clinic' ultrasound companies, specialising in real-time hi-fidelity virtual reality simulation for the ultrasound training market ('classroom') and artificial intelligencebased clinical image analysis software tools for the diagnostic medical ultrasound market ('clinic'). Based in Cardiff in the UK and Atlanta in the USA, the Group has two revenue streams:

Simulation

Real-time hi-fidelity ultrasound education and training through simulation. Our main products are the ScanTrainer obstetrics and gynaecology training simulator, the HeartWorks echocardiography training simulator, the BodyWorks Eve Point of Care and Emergency Medicine training simulator with Covid-19 module and the new BabyWorks Neonate and Paediatric training simulator. To date c. 1500 simulators have been sold to over 750 medical institutions around the world.

Clinical AI software

Deep learning-based algorithms to make ultrasound machines smarter and more accessible using our proprietary ScanNav ultrasound image analysis technology. Current products on the market utilising this technology are GE HealthCare's SonoLyst software that is incorporated in their Voluson Expert 22 and SWIFT ultrasound machines; ScanNav Anatomy PNB that simplifies ultrasound image interpretation by providing the user with real-time AI-based anatomy highlighting for a range of ultrasound guided regional anaesthesia procedures; and NeedleTrainer that teaches real-time ultrasound-guided needling and incorporates ScanNav Anatomy PNB.

www.intelligentultrasound.com

CHAIRMAN'S STATEMENT

This has been another year of significant progress across the business. We have increased Group revenue by 33% to £10.1m (2021: £7.6m), achieved FDA *De Novo* clearance for our second Al-driven clinical product in the real-time ultrasound image analysis market and, with the launch of SonoLyst on the Voluson Expert 22 ultrasound machine, are building an excellent partnership with GE HealthCare - the world's leading ultrasound company.

Clinical AI:

- Revenue grew by over 200% to £0.7m in 2022 (2021: £0.2m)
- GE HealthCare launched the SonoLyst technology on the Voluson Expert 22 ultrasound machine in July. SonoLyst utilises our ScanNav Assist AI software technology and is the world's first fully integrated ultrasound AI tool that recognises the 21 views recommended by the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) mid-trimester practice guidelines for fetal imaging
- ScanNav Anatomy Peripheral Nerve Block (PNB), our second AI driven product, received FDA *De Novo* clearance in October for sale in the US
- NeedleTrainer 2.0, our third AI-related product, to teach ultrasound-guided needling to medical professionals, was launched in September and now incorporates the GE HealthCare Vscan Air handheld ultrasound device

Simulation:

- Revenue grew by 28% to £9.4m in 2022 (2021: £7.4m), primarily driven by UK direct sales that grew by 96% to £4.9m (2021: £2.5m)
- Direct sales revenue in the North American market was broadly flat due to the tighter than expected market in the second half of the year being positively offset by currency swings
- Sales in Europe and Asia, that are made through our reseller network, declined to £1.7m (2021: £2.1m), largely due to the restrictions of Covid-19 on the Chinese market

Group:

- Loss after tax reduced to £3.0m (2021: loss of £3.6m)
- Cash at bank at 31 December 2022 was £7.2m (2021: £5.0m) after an oversubscribed placing in November raised £4.8m (net of fees) from new and existing shareholders
- Agreed a charitable partnership with the World Federation for Ultrasound in Medicine and Biology ("WFUMB") to help support their mission to bring sustainable ultrasound training programmes to the underserved areas of the world

Strategy

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

- Growing the Group's 'Classroom' related revenues through increased sales from our existing simulator platforms sold through our direct sales operations in the UK and US, and our global reseller channels; and the continued expansion of our range of ultrasound training simulators into new medical market segments
- Building our 'Clinic' related AI revenues through increased revenue from royalty sales from GE HealthCare, who incorporate our ScanNav AI technology in their Voluson SWIFT and Expert 22 ultrasound systems; increased sales of our proprietary stand-alone AI-driven ScanNav Anatomy and NeedleTrainer systems, sold through our direct sales and reseller operations; and future new proprietary stand-alone AI-driven products aimed at new medical markets

We believe that our 'Classroom to Clinic' approach allows us to capture future clinical customers early in their medical careers, aiding brand recognition and product credibility as the ex-trainees progress their careers and increase their purchasing influence.

In the NeedleTrainer/Anatomy PNB example, there is a direct path from first learning basic skills with simulation in the classroom then, under supervision, learning on patients in clinical practice with the AI support tools and finally providing real-time AI-based support to practitioners' independent clinical practice.

We believe this unique 'classroom to clinic' approach to ultrasound will enable the Group to continue to grow in 2023 and reach profitability by the end of 2024.

People

Our people continue to have a pivotal role in our success and I would like to thank all our staff, in both the UK and the US, for working so hard and performing so well during a record year. Without their invaluable contribution we would not have achieved all the key milestones we set out to shareholders at the beginning of the year.

Shareholders

We are privileged to have such a supportive group of shareholders. During the second half of the year, we raised £5.2m (£4.8m net of fees) from new and existing shareholders and I would like to thank them for their continued support. It was pleasure to meet a number of our shareholders during our two technology open days that were held in London, and we will look to expand these events in 2023. As always, we maintain an open-door policy at our head office in Cardiff and welcome any visitors who wish to experience our cutting edge 'classroom to clinic' technology.

Board and governance

The Board aims to maintain the highest standards of corporate governance and is continuing to appoint new diverse, experienced and independent non-executive Directors, as some of our longest serving Directors retire.

- In August 2022 we were delighted to welcome Dr Christian Guttmann as a Non-executive Director to the Board. Christian is a recognised leader in shaping the global agenda on AI regulation and standards, as well as having outstanding AI research, development and commercialisation experience. He has edited and authored seven books, over 50 publications and has three patents in the field of AI
- At the 2022 AGM Prof Nazar Amso, one of the original founders of the company and David Baynes, representing the largest pre-listing investor, did not seek re-election and retired from the Board
- On 31 December 2022 Andrew Barker, who joined the Board after the acquisition in 2017 of Intelligent Ultrasound Ltd, retired.

I would like to thank all three retiring Directors for their outstanding contribution to the business. They have all worked tirelessly to support the Group and their input to the Board will be missed.

ESG

This is our second full year of ESG reporting and we have continued to make significant progress in all aspects of our reporting. For the first time we have provided a full calculation of our Scope 3 emissions and are delighted to be working with the World Federation for Ultrasound in Medicine and Biology ("WFUMB") in their mission to bring sustainable ultrasound training programmes to the underserved areas of the world. We continue to instigate new initiatives to promote better employee and local engagement and believe we continue to have a positive impact locally, nationally and globally. We look forward to continuing our ESG journey.

Outlook

This has been another year of significant progress for the Group. We have increased Group revenue by over 30%, achieved the important milestone of FDA clearance for our second Al-driven product and continue to build an excellent partnership with the world's leading ultrasound company - GE HealthCare. With a positive start in Q1 2023, a growing range of both AI and simulation related products, an established operational base, and year end cash of £7.2m, we expect to continue this growth during 2023 and remain excited about the long-term potential of our unique 'Classroom to Clinic' model.

Riccardo Pigliucci Non-executive Chairman

CEO REVIEW

Our vision is to make clinical diagnostic ultrasound easier to learn and simpler to use by providing clinicians around the world with real-time support from the classroom to the clinic. With the global market for artificial intelligence (AI) based ultrasound software expected to be \$1.3bn by 2028, AI remains a key element of our approach, as we expand both our simulation and clinical sales operations.

Based in Cardiff (UK), Alpharetta (US) and with representation in Beijing (China), the report below details the progress made in 2022 and the key challenges faced during the year.

SIMULATION (Classroom)

Training medical professionals in the specialist skills required to competently scan a patient using the diagnostic capabilities of ultrasound remains a key foundation stone of our business. We design, develop and sell some of the world's leading hi-fidelity ultrasound training systems and consider ourselves one of the world's leading companies in this growing market.

In 2022 simulation revenue increased by 28% to £9.4m (2021: £7.4m) and we now have four ultrasound simulation-only platform technologies focussed on the following markets:

- ScanTrainer obstetrics and gynaecology (OBGYN)
- HeartWorks echocardiography and anaesthesiology (ECHO)
- BodyWorks emergency medicine, critical care and point-of-care (PoCUS)
- BabyWorks (officially launched in the US in January 2022) neonate and paediatrics

During 2022, the majority of the simulation revenues came from our ScanTrainer, HeartWorks and BodyWorks platforms. In 2023 it is anticipated that BabyWorks will materially contribute to the simulation revenue stream, as we open up this new market.

The four ultrasound training platforms are, in the main, high value, capital equipment sold to the global medical institution market, through our direct sales forces in the US and UK and a network of 23 resellers covering 33 countries in the rest of the world. To date we have sold c. 1,500 simulators into over 750 medical institutions around the world.

Research & Development

During the year, the simulation R&D team focussed on four developments:

Launch of BodyWorks 4.0

In October we launched the latest version of our BodyWorks ultra-realistic female patient simulator for PoCUS scenario training with updated and enhanced images and an expanded range of modules to teach novice users how to develop ultrasound skills and competence in a non-clinical environment.

The first set of cardiac pathologies for the BabyWorks simulator

In November we launched the first suite of cardiac pathologies for the new BabyWorks augmented reality simulator which aims to aid medical trainees in the diagnosis and understanding of three important cardiac pathologies in the neonatal and paediatric intensive care settings. Further suites of pathologies are expected to be developed and launched during 2023.

Range of e-learning modules

With medical professionals needing to continually build their learning and confidence, during the year we collaborated with a number of experts in their field to create five distance learning courses that provide high quality continuous education and improvement within ultrasound and healthcare. Sold as an integrated package or as an individual license, we expect to continue to roll out these modules on our simulator platforms during 2023.

New endometriosis module for ScanTrainer for launch in 2023

It is estimated that 10% of women worldwide have endometriosis. The ScanTrainer endometriosis augmented reality training module will support clinicians in learning how to locate and identify endometriotic disease in the ovaries, bowel and bladder using transvaginal ultrasound. The new module is expected to launch in May 2023.

Territory Review

Simulation revenues again grew strongly during the year, with revenue increasing by 28% to £9.4m (2021: £7.4m). However, there were significant variations in the performance across our three sales regions:

United Kingdom

Revenue increased by 96% to £4.9m (2021: £2.5m)

The UK had its second consecutive record year, with NHS spending on our simulators continuing to grow across all product lines. As indicated in our interim report in August 2022, we had a high number of one-off, individual orders from a UK NHS training initiative that totalled c.£1.9m over the full year. Although all our simulator sales are considered one-offs, if we exclude these exceptional orders, the UK like-for-like revenue would have been £3.0m, representing a growth of 15%. With a broad product portfolio, there remains good scope for growth within the UK and there continues to be strong purchasing interest in all our simulation products.

We therefore look forward to continuing the growth of the UK direct to market business in 2023.

North America

Revenue increased by 3% to £2.8m (2021: £2.7m)

Sales in North America grew to a record high of ± 2.8 m, but this was a disappointing performance relative to our expectations, as a high number of capital expenditure funding freezes were implemented by the larger teaching hospitals in the US, resulting in cancelled or delayed purchases of our simulators in the second half of the year. Although this loss of revenue was compensated for by a ± 0.3 m positive exchange rate variance, the like-for-like US dollar sales during the year were down 9% to \$3.4m (2021: \$3.8m).

However, North America is a key market for the Group and we have therefore continued to invest in growing the US based sales and marketing operation. We now have seven sales-related staff supported by a web-based clinical applications specialist plus an office-based support team in Alpharetta, Georgia. We believe we will see the benefit of this investment in 2023 and beyond.

2022 witnessed the beginnings of a post Covid-19 resurgence in major face-to-face trade exhibitions in the US and with an encouraging start to the year and a solid pipeline of opportunities, we look forward to a significant improvement in the North American direct to market business in 2023.

Rest of the World

Revenue declined by 19% to £1.7m (2021: £2.1m)

2022 was a difficult year for the 23 resellers that sell our simulators outside the UK and North America. Positive sales growth in countries such as Japan and Germany were offset by the continued Covid-19 restrictions in China, the loss of revenue from our decision to stop selling in Russia, and a disappointing market in France, that constrained our joint sales venture with Skills Meducation, where we are in the early stages of part-funding an Intelligent Ultrasound only sales team. Although this impacted sales in 2022, we see a more positive outlook for China with the Covid-19 restrictions lifting and the recruitment of a new, experienced French sales team is expected to improve sales in France in 2023.

With the increased range of products, a growing pipeline and anticipated sales growth from France and China, we look forward to a growing reseller market in 2023.

CLINICAL AI (Clinic)

Real-time clinical AI-driven software that makes ultrasound easier to use for medical professionals remains a key part of our 'Classroom to Clinic' vision, and although we are still in the early stages of commercialisation, clinical AI-related revenue for the year grew over 200% to £0.7m (2021: £0.2m).

Our products provide a range of real-time support to clinicians including real-time workflow enhancements that support faster, more standardised scanning, but importantly also support decision making, so that the stress of scanning is reduced and the 'burn-out' of operators being asked to increase productivity is minimised.

We now have three AI-driven software products available in the market:

- ScanNav Assist obstetric AI software that is utilised by GE HealthCare as SonoLyst on their ultrasound machines
- ScanNav Anatomy Peripheral Nerve Block (PNB) for real-time regional anaesthesia highlighting
- NeedleTrainer that incorporates the PNB software to teach ultrasound-guided needling skills

Two major milestones were achieved in the year:

- In July 2022, GE HealthCare launched the SonoLyst technology on the Voluson Expert 22 ultrasound machine, that utilises our ScanNav Assist AI software
- In October 2022, ScanNav Anatomy Peripheral Nerve Block (PNB), our second AI product, received FDA *De Novo* clearance for sale in the US

We expect 2023 to be a year of significant sales growth in our AI related sales.

ScanNav Assist

Our ScanNav Assist AI technology drives GE HealthCare's SonoLyst X/IR software, the world's first fully integrated ultrasound AI tool that automatically and in real-time recognises the 21 views recommended for fetal sonography imaging.

Currently available as an optional extra on GE HealthCare's Voluson SWIFT and Expert 22 ultrasound machines, the SonoLyst software augments a sonographer's scanning skills, helping faster and more standardised scanning. Acting as a virtual onboard expert, SonoLyst automatically identifies the fetal anatomy seen on standard views and can be used to compare the image or view acquired to a standard criteria, ensuring exam quality and consistency. By automatically and in real-time supporting the sonographer in their decision making, the software also helps reduce the often-considerable stress of obtaining the recommended views.

The issue of burnout in scanning centres is increasing around the world and it is hoped that the adoption of this technology will help reduce this burden.

Our long-term agreement with GE HealthCare was signed in 2019. GE HealthCare is the largest medical imaging company in the world, have the exclusive rights to our clinical AI technology in the field of women's healthcare and have now launched SonoLyst on two of its Voluson ultrasound machine ranges. The launch in July of SonoLyst on the Voluson Expert 22 was a key commercial milestone for Intelligent Ultrasound, as this is GE HealthCare's premium ultrasound machine in their women's health range.

Over 30,000 ultrasound machines are sold annually in the global obstetrics market and GE HealthCare is the dominant manufacturer. We therefore expect to see increased SonoLyst sales throughout 2023 and beyond as SonoLyst continues to be rolled out on the Expert 22 system.

In January 2022, we announced we had signed an extension to our GE HealthCare agreement to enable GE HealthCare to utilise the ScanNav Assist AI software in a new segment of automated ultrasound image analysis, that is outside the Group's original agreement. As with the main agreement, the terms, product sales and the timings of the related product launches are undisclosed.

Future variants of ScanNav Assist that will support additional protocol-based scanning are in advanced development.

ScanNav Anatomy Peripheral Nerve Block (PNB)

ScanNav Anatomy PNB simplifies ultrasound-guided needling by providing the user with real-time AI-driven anatomy highlighting for a range of medical procedures. The device supports the performance of healthcare professionals who are suitably qualified, but who perform ultrasound-guided local anaesthesia procedures on a less frequent basis.

ScanNav Anatomy PNB achieved a major milestone in October 2022 when it was cleared by the FDA as a *De Novo* device for sale in the US. The *De Novo* regulatory process provides a marketing pathway to classify novel medical devices with a low to medium risk for their intended use, where there is no existing legally marketed comparable device.

The device supports nine common peripheral nerve blocks and is sold as a stand-alone screen that is plugged into existing anaesthesiology ultrasound machines to provide clinicians with 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 now available for sale in the UK, France, Germany, Spain, Scandinavia and the US. With over 25,000 anaesthesiology machines in operation in these markets, and ultrasound-guided peripheral nerve blocks increasingly being used as a prudent alternative to general anaesthesia as well as a method of concurrent analgesia (potentially reducing opioid usage). Our aim is to support anaesthetists, who are competent but less confident in the specialist knowledge of ultrasound anatomy, to perform nerve blocks and as a result increase the number of ultrasound-guided nerve blocks that they can perform.

A number of studies were released during the year to support the adoption of the system and 2023 will continue this focus, as we aim to educate and grow the market for ScanNav Anatomy PNB.

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

NeedleTrainer

NeedleTrainer was relaunched to the market in September 2022 as a standalone needle training device incorporating the new GE HealthCare Vscan Air handheld ultrasound device. Developed by the clinical AI software team as a spin-off from the ScanNav Anatomy PNB research and development, NeedleTrainer is a portable, plug-in system that uses a retractable needle and real-time, virtual image overlays to simulate needling non-invasively on a live volunteer, using the live ultrasound scan. This enables medical professionals to develop hand-eye coordination, optimum positioning, and accuracy in ultrasound-guided interventional procedures in a safe, realistic, simulated-clinical environment.

The system is sold with the trainer version of our ScanNav Anatomy PNB AI-driven software integrated into the device and is being sold into major simulation centres, anaesthesiology departments, emergency and primary healthcare.

Future ScanNav AI products

During 2022 the focus of the division remained on developing the partnership with GE HealthCare, commercialising ScanNav Assist, achieving FDA *De Novo* clearance for ScanNav Anatomy PNB and relaunching NeedleTrainer with the GE HealthCare Vscan Air handheld ultrasound system. In addition, the development team continues to work on proof-of-concept AI software 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 patients can be triaged to a specialist.

Challenges to the 'Classroom to Clinic' Business

Ultrasound continues to be a growing medical diagnostic tool, with increasing demand for training tools that can enhance a medical practitioner's scanning skills and clinical products that can assist sonographers. However, there have historically always been capital expenditure limitations on medical training budgets for high value medical simulators and on the clinical side hospital funding can also be hard to access, with most purchases being made on a 6 to 18-month purchase cycle. This makes annual revenues harder to forecast, especially during times of government spending cutbacks, political upheaval, changes of government or pandemics when funds can be diverted to frontline care. The purchasing decisions made by medical institutions in the high value sector of the simulation market remain broadly based on the quality of training combined with value for money, rather than simply the lowest priced solution. During 2022, we continued to respond well to competitive products and pricing and margin pressures by offering a variety of purchase price points, expanding our product extensions and increasing our e-learning options that can work in tandem with our hands-on training simulators.

To counter clinical funding constraints our clinical AI products are competitively priced and aim to either provide improvements to the workflow, destress the scanning process or enable more clinicians to confidently complete a procedure that will save a hospital money.

Although we continued to experience supply chain pressure during the year, we were able to increase our key component stock holding in 2022, as well as switch a number of our tracking sensors to an alternative supplier. This enabled us to successfully avoid any disruption to sales in the year and we believe it has also minimised the component supply risk for 2023. It did however increase the amount of cash tied up in stock.

Simulation product cost of goods increased by approximately 6% during the year and as a result we had to increase the list price of many of our products. We continue to review supplier costs and overheads but expect the impact of price rises on our cost of goods in 2023 to be broadly similar to 2022, which we expect will result in a broadly similar impact on our end user pricing in the second half of 2023.

The Al-based ultrasound imaging software market is recognised as having significant global potential and as such there is considerable competition from both the existing ultrasound manufacturers and well-funded independent Al software vendors. With the revenue models for Al-driven software still in the early stages of commercialisation our two-pronged go-to market strategy aims to identify the most effective route to material revenues:

- Our ScanNav Assist software is being sold through a royalty-based, 'on-machine' licence with GE HealthCare, whose established sales network can provide faster roll-out of our technology in the new ultrasound machine market; and
- Our ScanNav Anatomy PNB software is being sold through our own sales network directly to the global pool of existing ultrasound machines via our own portable 'plug-in' real-time AI enabled device.

The challenge of recruiting high calibre AI software engineers eased in 2022 and we hope that the combination of attractive, flexible salary packages, and a flexible work environment in a vibrant university capital city will enable this to continue in 2023.

During 2023 we expect the restrictions caused by the pandemic to have fully receded in all our markets, but there remains a threat that the continued Russian invasion and occupation of Ukraine could escalate to the point where it impacts our other European markets.

The impact of inflation and interest rates on global healthcare spending is also of concern.

Quality Management System

Meeting the standards of ISO 13485:2016 remains a high priority for the Group, as we continue to ensure the consistent design, development, production, installation, and sale of medical devices that are safe for their intended purpose.

Workplace environment

One of the benefits of the pandemic was that it forced companies to operate remotely and enabled staff and companies to trial working on a more flexible basis. Once the full impact of the pandemic ended in 2022, we took the decision to continue to operate the company on a flexible basis, where appropriate. This has been well received by our staff and we believe it makes a significant contribution to the attractiveness of working for Intelligent Ultrasound. In our 2022 annual staff survey, over 90% of staff recommended the Group as a great place to work, with many citing that the Company has a great ethos and is doing rewarding work that is making a real difference to hospitals and patients around the world.

As ever, our staff have been tremendous throughout the year, and I would like to thank them for all their hard work in enabling us to achieve a record year.

Shareholders

I would also like to thank our shareholders for not just supporting the £5.2m placing, but also supporting our vision that a currently small UK company can be a major player in the \$1.3 billion AI related ultrasound imaging market and produce cutting edge AI software that will make ultrasound easier to use for medical professionals around the world.

Looking ahead

Five years ago, we embarked on our 'classroom to clinic' vision to specialise in providing medical professionals with realtime, hi-fidelity, augmented reality simulation for the ultrasound training market ('the classroom') and then follow them into clinical scanning and provide real-time, artificial intelligence-based, clinical image analysis software tools for the diagnostic medical ultrasound market ('the clinic').

With the important milestone of FDA *De Novo* clearance achieved for our second AI-driven product and an excellent partnership with GE HealthCare, we are well placed to turn our 'classroom to clinic' vision into commercial reality. A positive start in Q1 2023, a growing range of both AI and simulation related products, an established operational base, and a successful £5.2m placing increasing our cash to £7.2m, means we expect 2023 to be a year of continued commercial growth, as we drive the Group to our goal of profitability by the end of 2024.

Stuart Gall Chief Executive Officer

FINANCIAL REVIEW

Summary financial performance:

£m	2022	2021	Change
(unless otherwise stated)			
Revenue	10.10	7.60	+33%
Gross profit	6.33	4.66	+36%
Gross profit margin (%)	63%	61%	+2%
Total R&D spend	(3.20)	(3.23)	-1%
Administrative expenses (excluding expensed R&D)	(8.32)	(7.04)	+18%
Operating loss	(3.67)	(4.33)	-15%
Loss after taxation	(2.98)	(3.61)	-17%
Net cash used in operating activities	(0.68)	(1.82)	-62%
Cash and cash equivalents	7.17	4.95	+45%

Income statement

Revenue

The Group delivered strong growth in 2022 with revenues up 33% to a record high of £10.1m (2021: £7.6m) with growth in revenues achieved across both revenue streams. We continued to experience significant growth in the UK with revenue up 104% from 2021, however Covid-19 related challenges continued to impact reseller markets in Asia and Europe where revenues declined by 14% year on year.

Simulation

£m	2022	2021	Change
UK	4.91	2.51	+96%
North America	2.78	2.73	+3%
Rest of the World	1.74	2.15	-19%
	9.43	7.39	+28%

Simulation revenue grew 28% year-on-year largely driven by significant growth in sales in the UK which almost doubled in 2022, due in part to a NHS ultrasound training programme to standardise training in echocardiography across NHS England. Revenue from North America also increased by 3% due to positive exchange rate movements of £0.3m but on a like for like US dollar basis revenue had declined by 9% to \$3.4m (2021: \$3.8m).

It was also another difficult year for our resellers in the Rest of the World where sales were down 19% to £1.7m (2021: £2.15m) due to ongoing Covid-19 restrictions in China, the decision to prohibit sales to Russia and also a disappointing performance in France.

Clinical AI

£m	2022	2021	Change
UK	0.24	0.02	0.22
North America	0.16	-	0.16
Rest of the World	0.27	0.19	0.08
	0.67	0.21	0.46

Clinical AI revenues began to gain commercial traction in 2022 with revenues increasing to £0.67m (2021: £0.21m). AI royalty revenue in 2022 and 2021 is split based on the location of the country of invoicing rather than by end user geographical location.

Gross profit

Group gross profit increased by 36% to £6.33m (2021: £4.66m), the increase being higher than revenue growth due to a higher weighting of direct versus reseller sales as well as favourable USD exchange rate movements.

Simulation gross margin percentage went up 2% to 63% (2021: 61%) with 82% of revenue coming from direct sales in the UK and North America (2021: 71%) as well as favourable USD exchange rate movements. We were also able to pass on some inflationary raw material cost pressures where possible through sales price increases. Some supply chain disruption continued to present challenges during the year, but these were overcome by maintaining adequate buffer inventories.

Clinical AI gross margin declined to 60% (2021: 74%) due to the one-off cost of a component upgrade to the NeedleTrainer V2 demonstration units, which reduced gross margin by 14%. Excluding this one-off cost, the Clinical AI gross margin increased to 79% on a like-for-like basis.

Administrative expenses

£m	2022	2021	Change
Sales, marketing and distribution	3.08	2.44	+26%
Other general and administrative	3.48	2.86	+22%
Other non-cash costs:			
Share based payment charges	0.38	0.53	-28%
Depreciation and amortisation	1.38	1.19	+16%
	8.32	7.02	+18%

Administrative expenses, excluding expensed R&D costs, increased by 18% to £8.32m (2021: £7.02m). Despite some challenges affecting the US market in 2022, the long-term opportunity for commercial growth exists and to address this we have further invested in sales and marketing in this key region as well as in our UK marketing and product management teams to be able to maximise the potential from these growth opportunities. In addition, a lot of the sector conferences and exhibitions, key to sales lead generation, that were cancelled or held virtually in 2021 returned in 2022, resulting in an increase of marketing costs of £0.17m (+67%) in 2022. Sales travel also returned to pre-pandemic levels in 2022, increasing costs year on year by £0.15m.

Other general and administrative costs increased by 22% due partly to headcount increases in central functions combined with salary increases, as well as higher general travel costs and legal and professional costs.

Operating loss

The operating loss reduced by 15% to £3.67m (2021: £4.33m) due to the 36% improvement in gross profit, partly offset by a 18% increase in administrative expenses (detailed above).

Research and development (R&D) costs

£m	2022	2021	Change
Expensed	1.69	1.96	
Capitalised	1.51	1.27	
Total R&D	3.20	3.23	-1%
Simulation	1.24	1.15	+8%
Clinical Al	1.96	2.08	-6%

The Group incurred R&D expenditure of £3.20m (2021: £3.23m). The Simulation R&D team was largely focused on increasing the BabyWorks functionality as well as development of the new version of BodyWorks. The Clinical AI R&D team continued the development of the ScanNav Anatomy PNB product, in particular in relation to progressing the product through US FDA regulatory clearance, achieved in October 2022, as well as further improvements to NeedleTrainer and the development of other variants of ScanNav Assist. With significant costs of taking ScanNav Anatomy PNB through US FDA clearance incurred in 2021, Clinical AI R&D costs were lower in 2022.

Taxation

The total tax credit in 2022 was £0.72m (2021: £0.76m). 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.

As at 31 December 2021, the Group had cumulative gross UK tax losses of approximately £19.2m (31 December 2021: £17.3m) for which the Group continues to hold a cautious view, and consequently the Group has chosen not to recognise those losses fully as a deferred tax asset.

Balance sheet

The balance sheet was strengthened in December following a successful share placing and subscription of a net £4.81m after costs. This contributed significantly to net assets increasing to £12.16m at the year end (31 December 2021: £9.72m).

Included within trade and other receivables of £2.03m (31 December 2021: £2.65m) are trade receivables of £1.36m (31 December 2021: £1.89m), lower than the previous year end due to timing of invoicing and customer payments in the last quarter.

Inventory of £1.60m (31 December 2021: £1.20m) increased by £0.40m due to timing of receipt of certain high value bulk stock items as well as an adequate amount of buffer stock in the event of any supply chain disruption.

Included within current assets is the R&D tax credit receivable of ± 0.71 m (31 December 2021: ± 0.95 m). This is ± 0.24 m lower than as at 31 December 2021 due to the balance in 2021 including ± 0.2 m of the 2020 receivable, which was received at the start of 2022.

During the year £1.49m (2021: £1.27m) of product development costs were capitalised within intangible assets with more development costs meeting the criteria for capitalisation in 2022 compared to the prior year.

Current liabilities were to £3.28m (31 December 2021: £3.21m), with trade payables of £1.36m (31 December 2021: £1.35m) and accruals of £0.97m (31 December 2021: £1.23m) largely relating to sales-based royalties payable, sales commissions and annual bonuses. Lease liabilities of £0.49m (31 December 2021: £0.67m), relating to offices, the warehouse facility and company cars, reduced by £0.18m in 2022 with ongoing lease payments. New leases in the year related to the US office lease renewal.

Deferred income at 31 December 2022 was £0.55m (31 December 2021: £0.53m) which relates to extended warranties and technical support. These amounts are deferred and released to the income statement over the life of the extended warranty and support period.

The share based payment reserve increased by £0.38m to £1.75m (31 December 2021: £1.37m) due to the share based payment charge for the year.

Cash flow

The Group reported cash and cash equivalents of £7.17m at 31 December 2022 (31 December 2021: £4.95m).

Operating cash outflows before working capital movements of £1.91m (2021: £2.61m) improved by £0.70m in 2022 due to the higher trading levels in the year offset partly by increases in administrative expenses. Movements in working capital of £0.26m (2021: £0.31m) and higher R&D tax credits received in the year of £0.96m (2021: £0.48m) resulted in the net cash used in operating activities reducing by 62% to £0.68m (2021: £1.82m).

The net cash outflow arising from investing activities was £1.82m (2021: £1.78m) relating to capitalised R&D expenditure of £1.47m (2021: £1.28m) and £0.36m (2021: £0.50m) of property, plant and equipment, the majority of which relates to the capitalisation of sales demonstration equipment.

The net cash inflow from financing activities was £4.55m (2021: £0.22m outflow) as a result of the gross proceeds from the share placing of £5.2m reduced by issue costs of £0.39m. We also paid £0.23m (2021: £0.20m) in lease payments.

Going concern

In undertaking a going concern review, the Directors have reviewed two financial projections to 31 December 2024 based on the existing base budget and a flexed, more conservative version of the base budget; both of which include estimates and assumptions regarding the product development projects, sales pipeline, future revenues and costs and timing and quantum of investments in the R&D programmes. Both forecasts indicate that the Group should be able to operate within the limits of its existing resources and therefore the Directors have a reasonable expectation that the Company and the Group can continue in operational existence for at least twelve months from the date of approval of the financial statements. Therefore, the Company and Group continues to adopt the going concern basis in preparing its financial statements.

CONSOLIDATED STATEMENT OF PROFIT AND LOSS AND OTHER COMPREHENSIVE INCOME for the year ended 31 December 2022

Continuing operations	Note	2022	2021
		£'000	£'000
Revenue	2	10,100	7,596
Cost of sales		(3,766)	(2,937)
Gross profit		6,334	4,659
Other income	3	8	2
Administrative expenses		(10,014)	(8,993)
Operating loss		(3 <i>,</i> 672)	(4,332)
Finance income		1	1
Finance costs		(31)	(37)
Loss before taxation		(3,702)	(4,368)
Taxation	4	718	758
Loss attributable to the equity shareholders of the Parent		(2,984)	(3,610)
Other comprehensive income			
Items that may be reclassified to profit or loss:			
Exchange gain arising on translation of foreign operations		238	33
Other comprehensive gain for the period		238	33
Total comprehensive loss attributable to the equity shareholders of the Parent		(2,746)	(3,577)
Loss per ordinary share attributable to the equity shareholders of the Parent			
Basic and diluted (pence)		(1.08)	(1.34)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION as at 31 December 2022

	Note	2022	2021
		£'000	£'000
Non-current assets			
Intangible assets		3,272	2,558
Property, plant and equipment		1,174	1,400
Trade and other receivables		61	61
		4,507	4,019
Current assets			
Inventories		1,603	1,196
Trade and other receivables		2,025	2,650
Current tax assets		713	954
Cash and cash equivalents		7,166	4,950
		11,507	9,750
Total assets		16,014	13,769
Current liabilities			
Trade and other payables		(2,732)	(2,767)
Deferred income		(337)	(206)
Lease liabilities		(188)	(213)
Provisions		(22)	(22)
		(3,279)	(3,208)
Non-current liabilities			
Deferred income		(209)	(320)
Lease liabilities		(298)	(457)
Other payables		(65)	(65)
		(572)	(842)
Total liabilities		(3,851)	(4,050)
Net assets		12,163	9,719
Fauity			
Equity Share capital	6	3,269	2,707
· · ·	0	30,207	25,959
Share premium Accumulated losses		(29,951)	(26,967)
Share-based payment reserve		1,753	(26,967) 1,373
• •			6,538
Merger reserve		6,538 182	(56)
Foreign exchange reserve		182	()
Other reserves			165
Total equity		12,163	9,719

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY for the year ended 31 December 2022

	Share	Share	Share	Accumulate	Share-	Merger	Foreign	Other	
	capital	premium	warrant	d losses	based	reserve	exchang	reserv	Total
	£'000	£'000	S	£'000	paymen	£'000	e	es	equity
	L 000	1 000	£'000	1 000	t	1 000	reserve	£'000	£'000
			2 000		reserve		£'000	2000	2000
					£'000				
As at 31 December	2,694	25,959	126	(23,381)	842	6,538	(89)	_	12,689
2020	,	,		. , ,		,	. ,		,
Loss for the year	_	_	-	(3,610)	_	-	-	-	(3,610)
Other	_	_	-	_	_	-	33	-	33
comprehensive loss									
Total	_	_	-	(3,610)	-	_	33	-	(3,577)
comprehensive loss									
for the year									
Transactions with own	ners, recor	ded directly	in equity						
Issue of share	13	_		_	-	-	-	-	13
capital									
Exercise of share	-	-	(126)	24	-	-	-	165	63
warrants									
Cost of share-based	-	-	-	-	531	-	-	-	531
awards									
As at 31 December	2,707	25,959	-	(26,967)	1,373	6,538	(56)	165	9,719
2021									
Loss for the year	-	—	-	(2,984)	-	-	-	-	(2,984)
Other			-						
comprehensive	-	-		—	-	-	238	-	238
income									
Total			-						
comprehensive loss	-	-		(2,984)	-	-	238	-	(2,746)
for the year									
Transactions with own	ners, recor	ded directly	in equity		[r	[1	
Issue of share	562	4,248	-	_	_	_	_	_	4,810
capital		.,=							.,
Cost of share-based awards	-	-	-	-	380				380
As at 31 December 2022	3,269	30,207	-	(29,951)	1,753	6,538	182	165	12,163

CONSOLIDATED STATEMENT OF CASH FLOWS for the year ended 31 December 2022

	2022	2021
	£'000	£'000
Cash flows from operating activities		
Loss before taxation	(3,702)	(4,368)
Depreciation	604	508
Amortisation of intangible assets	780	680
Fair value adjustment to share warrants	-	3
Net finance costs	30	36
Share-based payment charge	380	530
Operating cash flows before movement in working capital	(1,908)	(2,611)
Movement in inventories	(404)	(149)
Movement in trade and other receivables	739	(592)
Movement in trade and other payables	(70)	1,045
Movement in provisions	-	12
Cash used in operations	(1,643)	(2,295)
Income taxes received	959	476
Net cash used in operating activities	(684)	(1,819)
Cash flows from investing activities		
Purchase of property, plant and equipment	(357)	(503)
Internally generated intangible assets	(1,467)	(1,275)
Interest received	1	1
Net cash (used in) investing activities	(1,823)	(1,777)
Cash flows from financing activities		
Proceeds from issue of new shares	5,200	13
Share issue costs	(390)	_
Principal elements of lease payments	(231)	(195)
Interest paid	(31)	(37)
Net cash generated by/(used in) financing activities	4,548	(219)
Net increase/(decrease) in cash and cash equivalents	2,041	(3,815)
Cash and cash equivalents at beginning of year	4,950	8,774
Exchange losses on cash and cash equivalents	175	(9)
Cash and cash equivalents at end of year	7,166	4,950

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 Floor 6A Hodge House, 114-116 St Mary Street, Cardiff, CF10 1DY.

These results do not constitute the Group's statutory accounts for the year ended 31 December 2022 but are derived from those accounts. Statutory accounts for 2021 have been delivered to Companies House and those for 2022 will be delivered following the Company's Annual General Meeting. The external auditors have reported on those accounts; its report was unqualified and did not contain any statements under section 498 of the Companies Act 2006.

Going concern

In undertaking a going concern review, the Directors have reviewed two financial projections to 31 December 2024 based on the existing base budget and a flexed, more conservative version of the base budget; both of which include estimates and assumptions regarding the product development projects, sales pipeline, future revenues and costs and timing and quantum of investments in the R&D programmes. Both forecasts indicate that the Group should be able to operate within the limits of its existing resources and therefore the Directors have a reasonable expectation that the Company and the Group can continue in operational existence for at least twelve months from the date of approval of the financial statements. Therefore, the Company and Group continues to adopt the going concern basis in preparing its financial statements.

The Directors continue to explore additional sources of income and finance available to the Group to continue the development of its 'classroom to clinic' business.

Impairment assessment of Clinical AI intangible assets

For the intangible assets that have a finite life, the Directors considered the need to impair the carrying value of intangible assets by performing a review for indicators of impairment by assessing the performance of the assets against qualitative and quantitative factors. If any of these factors are present a detailed impairment review is undertaken. A detailed impairment assessment is performed by assessing the assets value in use which requires management to make a number of estimates. The most sensitive estimate is in relation to management's estimates of future revenues on the basis that these are new products which have no extensive history of sales upon which to base the forecasts.

During the period ended 31 December 2022, the Clinical AI related assets of £1.5m were tested for impairment. The calculations use five-year cash flow projections based on financial budgets approved by management covering a twoyear period. Cash flows for periods three to five are extrapolated using estimated growth rates and growth rates beyond five years are consistent with forecasts specific to the sector in which the CGU operates.

Reasonable sensitivities applied to the cashflow projections indicate that there is significant headroom before any impairment would be required. A 69% reduction in the budgeted revenue used in the value-in-use calculation for the IUL acquired intangible assets would result in full impairment of the carrying value of the asset by £1.5m.

2. OPERATING SEGMENTS

Operating segments reflect the way in which information is presented to and reviewed by the CODM for the purposes of making strategic decisions and assessing Group-wide performance. The Group's Board of Directors ('the Board') is the Group's CODM. The Group evaluates performance of the operational segments on the basis of revenue and gross profit. Apart from Intangible assets and Property plant & equipment, all other assets and liabilities are reported to the Board at Group level and are not separated segmentally.

The format of revenue reporting is based on the Group's management and internal reporting (including reports to the CODM). The Group has two operating segments: Simulation and Clinical AI.

- Simulation: sales of ultrasound simulation systems and related services
- Clinical AI: sales of AI-related ultrasound image analysis software products

2022	Simulation £'000	Clinical AI £'000	Total £'000
Revenue	9,432	668	10,100
Cost of sales	(3,502)	(264)	(3,766)
Gross profit	5,930	404	6,334
2021	Simulation	Clinical AI	Total
	£'000	£'000	£'000
Revenue	7,390	206	7,596
Cost of sales	(2,883)	(54)	(2,937)
Gross profit	4,507	152	4,659

Revenue by destination of external customer

	2022	2021
	£'000	£'000
United Kingdom	5,145	2,553
North America (USA & Canada)	2,943	2,733
Rest of the World	2,012	2,310
	10,100	7,596
Timing of revenue recognition:		
At a point in time	9,591	7,284
Over time	509	312

Clinical AI royalty income is included within Rest of the World based on the external customer's invoicing country rather than the destination of the end customer.

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

	2022	2021
	£'000	£'000
USA	2,808	2,426

The Group had no customers who accounted for more than 10% of the Group revenue for the year ended 31 December 2022 or 2021.

Other segment information

	Depreciation and amortisation		Additions to non-current assets	
	2022	2021 £'000	2022	2021
Simulation	£'000 942	£ 000 843	£'000 1,258	£'000 1,334
Clinical Al	299	202	605	535
Central	143	143	-	-
	1,384	1,188	1,863	1,869

Non-current assets based outside the UK

Right-of-use assets include leased offices for Intelligent Ultrasound North America Inc (IUNA), based in Georgia. The net book value as of 31 December 2022 was £0.03m (2021: £0.07m).

3. OTHER INCOME

	2022	2021
	£'000	£'000
UK grant income	8	2

4. TAXATION

	2022	2021
	£'000	£'000
Current tax		
R&D tax credit	(711)	(769)
R&D tax credit relating to prior periods	(7)	11
	(718)	(758)
Deferred tax		
Origination and reversal of timing differences	-	-
Effect of tax rate change on opening balance	-	-
	-	-
Income tax credit	(718)	(758)

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:

	2022	2021
	£'000	£'000
Loss after taxation	(2,984)	(3,610)
Number of Ordinary shares of 1p each	2022	2021
	No.	No.
Basic and diluted weighted average number of Ordinary shares	275,274,014	269,964,886
Basic and diluted loss pence per share	(1.08)	(1.34)

At 31 December 2022 and 2021 there were share options outstanding which could potentially have a dilutive impact but were anti-dilutive in both years.

6. SHARE CAPITAL

Authorised, allotted, issued and fully	2022		2021		
paid	Number	£'000	Number	£'000	
Ordinary shares of 1p each					
Balance at 1 January	270,653,485	2,707	269,396,792	2,694	
Shares issued for cash	56,216,436	562	1,256,693	13	
At 31 December	326,869,921	3,269	270,653,485	2,707	

The nominal values and the premium arising on shares issued in 2022 and 2021 are as follows:

Date	Number of shares	Nominal value £'000	Premium £'000
19 July 2021	1,256,693	13	-
1 and 2 December 2022	56,216,436	562	4,638

On 1 December 2022 the Company placed 56,216,436 newly issued shares of 1 pence each in the capital of the Company at a price of 9.25 pence per share. Share issue costs of £0.39m have been netted off against share premium arising on the new share issue.

On 7 July 2021 pursuant to a receipt of notice for the exercise of warrants, the Company issued 1,256,693 new Ordinary shares with a nominal value of £0.01 each at a subscription price of £0.01 per Ordinary share. The Company has received gross proceeds of £12,566.93.

Ordinary shares have a par value of 1 pence. They entitle the holder to participate in dividends, and to share in the proceeds of winding up the company in proportion to the number of and amounts paid on the shares held. On a show of hands, every holder of ordinary shares present at a meeting, in person or by proxy, is entitled to one vote; and, on a poll, each share is entitled to one vote. Ordinary shares have equal rights, preferences and no restrictions on distributions of dividends nor the repayment of capital.

The Company does not have a limited amount of authorised capital.

7. PUBLICATION OF ANNUAL REPORT

It is anticipated that the full Annual Report will be published in May 2022. 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 website(www.intelligentultrasound.com).