

#### 28 March 2019

## **Intelligent Ultrasound Group plc**

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

## **Unaudited Preliminary Results for the Year Ended 31 December 2018**

Intelligent Ultrasound Group plc (AIM: MED), the artificial intelligence (AI) software and simulation company, announces its unaudited preliminary results for the year ended 31 December 2018, an exciting year for the Group during which it piloted the lead AI obstetric product of its Clinical AI Division and continued to grow sales in its Simulation Division.

# Financial highlights:

- Group revenues (Simulation Division sales only) increased 27% to £5.3m (2017: £4.2m)
- Expenditure on R&D up 76% to £1.8m (2017: £1.1m) after significantly increased investment in Al
- Raised £4.8m net of costs by way of placing of shares and open offer
- Year-end cash at £5.6m (2017: £4.3m) and no debt

# **Operational highlights:**

#### **Simulation Division:**

- Successful launch of BodyWorks Eve, a new life-like manikin-based simulator for the Point of Care Ultrasound (PoCUS) market that combines ScanTrainer and HeartWorks technologies
- Now over 700 simulators sold to over 400 medical institutions in over 30 countries around the world

# Clinical Division (AI):

- Database used for training its AI products now exceeds 1 million obstetric ultrasound images
- First ScanNav real-time Al-based ultrasound image analysis software successfully piloted in two UK hospitals in advance of commercialisation
- Commenced a clinical study within the Aneurin Bevan University Health Board to capture data for its AnatomyGuide AI software for ultrasound-guided anaesthetic procedures such as peripheral nerve blocks

# Name change

 Post year-end completed the name change that was announced in November 2018 and changed the name of the Group from MedaPhor to Intelligent Ultrasound reflecting that, in addition to being a global leader in ultrasound training through simulation, the Group has expanded into the development of Al software to guide and support doctors and sonographers in clinical ultrasound scanning

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

"Despite the disappointing share price performance during the year, the Group made good progress in 2018 and I would like to thank all our shareholders for their continued support, as well as extending the Board's gratitude to all our staff and customers around the world. The Simulation Division demonstrated encouraging growth in the ultrasound simulation market and we expect broadly similar growth to continue in the coming years. The Clinical Division achieved all its development milestones in the year and is now focussed on signing commercial agreements with the ultrasound manufacturers and bringing our ScanNav and AnatomyGuide AI image analysis software through regulatory approval to market. The Group is currently trading in line with expectations and we look forward to the year ahead with considerable enthusiasm."

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 now considered to be in the public domain.

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# About Intelligent Ultrasound (www.investors.intelligentultrasound.com)

Intelligent Ultrasound (AIM: MED), the intelligent ultrasound software and simulation company, develops artificial intelligence-based clinical image analysis software tools, augmented reality-based needle guidance software and advanced hi-fidelity haptic and manikin-based training simulators for medical practitioners.

Based in Cardiff and Oxford in the UK, Atlanta in the US and with representation in Beijing in Asia, the Group operates two divisions:

Intelligent Ultrasound Simulation Division

Focusses on hi-fidelity ultrasound education and training through simulation. Its three main products are the ScanTrainer OBGYN training simulator, the HeartWorks echocardiography training simulator and the BodyWorks Eve Point of Care and Emergency Medicine training simulator. To date over 700 simulators have been sold to over 400 medical institutions in over 30 countries around the world.

Intelligent Ultrasound Clinical Division

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

Some products in the pipeline 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.

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

I am pleased to present Intelligent Ultrasound's results for the year ended 31 December 2018, during which we:

- increased turnover by 27% to £5.3m, all of which is currently derived from the Simulation Division;
- increased expenditure on R&D by 76% to £1.8m (2017: £1.1m);
- successfully piloted ScanNav, our first artificial intelligence (AI) based ultrasound image analysis software in two UK hospitals;
- commenced a clinical study within the Aneurin Bevan University Health Board to capture data for our AnatomyGuide AI software for ultrasound-guided anaesthetic procedures such as peripheral nerve blocks;
- expanded our AI imaging database for obstetrics to over one million images; and
- raised £4.8m net of costs by way of a share issue

In addition, post year-end, we changed the name of the Group from MedaPhor to Intelligent Ultrasound, to reflect that, in addition to being a global leader in ultrasound training through simulation, the Group has expanded into the development of AI software to guide and support doctors and sonographers in clinical ultrasound scanning.

## **Financial performance**

Summary financial results were:

	2018	2017
	£	£
Revenue	5,313,164	4,180,630
Gross profit	2,833,383	2,522,865
Gross margin	53%	60%
Other income	310,475	28,225
Administrative expenses excluding exceptional items	(7,120,434)	(5,228,211)
Operating loss before tax and exceptional items	(3,976,576)	(2,677,121)
Exceptional administrative items	362,718	(2,860,774)
Loss after exceptional items	(3,613,858)	(5,537,895)
Finance costs	(7,402)	(7,833)
Loss before tax	(3,621,260)	(5,545,728)
Income tax credit	203,796	127,609
Loss after tax	(3,417,464)	(5,418,119)
Cash at bank	5,607,052	4,250,198

During the year revenues increased by 27% to £5.3m (2017: £4.2m) and benefited from the launch of our new BodyWorks Eve training platform for doctors wishing to practise Point-of-Care Ultrasound (PoCUS) across emergency medicine and critical care.

The reduced gross margin in 2018 mainly reflects the higher proportion of distributor sales in 2018, at just under 50% (2017: 42%).

The loss for the year, before tax and exceptional items, was £4m (2017: £2.7m). Administrative expenses, excluding exceptional items, increased by £1.9m. £0.6m of this increase was attributable to consolidating a full year of overheads in respect of Intelligent Ultrasound Limited (IUL) which we acquired in October 2017.

IUL is the home of our Clinical Division. A number of specialist R&D staff who were previously within the Simulation Division moved across to the Clinical Division in 2018. The total overheads of the Clinical Division including these staff, but excluding depreciation, amortisation and exceptional items for the year was £1.2m compared to £0.2m in 2017 which related to IUL for the 3 months from the date of acquisition.

Staff costs, excluding those attributable to IUL, were up by £0.6m reflecting our increased investment in R&D, sales and support staff. Staff costs expensed were also higher by £0.1m because we capitalised less development

time. Marketing and travel costs were up £0.2m; depreciation and amortisation costs were also up by £0.2m and external development costs expensed and other costs were up by £0.2m.

Other income relates to grants received in the period.

The exceptional item for the year related to a credit in respect of a fair value adjustment on the settlement of deferred consideration in 2018 relating to the acquisition of IUL in the prior year.

#### **Key events**

The Group operates as two divisions:

#### Simulation Division

The Simulation Division, which is based in Cardiff and Alpharetta, Georgia (USA), is focussed on growing sales in the ultrasound training and simulation market. The successful launch of BodyWorks Eve, our new life-like manikin-based simulator was an important contributor to growing sales in the year. Eve is a combination of our ScanTrainer and HeartWorks simulation technologies and is aimed at the growing PoCUS market.

Over 700 Intelligent Ultrasound simulators have now been sold to over 400 medical institutions in over 30 countries around the world.

#### Clinical Division

The Clinical Division, which is based in Oxford, is developing the Group's new deep learning software for ultrasound image analysis (ScanNav) and ultrasound needle guidance (AnatomyGuide). During the year we completed two successful pilots of the ScanNav software in St George's Hospital NHS Trust in London and the Royal United Hospitals Bath. ScanNav has now completed its initial development and is ready to move to its commercialisation phase. It is believed to be the first CE marked artificial intelligence (AI) system to carry out an automated, real-time "peer review" of obstetric ultrasound images as the patient is scanned live in the clinic.

We also expanded our AI imaging database to over one million images and, post year-end, are working on establishing new collaborations to provide access to additional high-quality obstetric images for our simulation and AI products.

In November 2018 we commenced a clinical study within the Aneurin Bevan University Health Board to capture data for our AnatomyGuide AI software for Peripheral Nerve Block (PNB) ultrasound-guided anaesthesia. For many procedures, ultrasound-guided PNB is a safer and more cost-effective alternative to general anaesthesia, but not all anaesthetists have the specialist knowledge to recognise the necessary anatomy in the ultrasound image. AnatomyGuide aims to provide support and guidance to improve safety during the PNB procedure.

Finally, at the end of the year, we completed a placing and open offer and raised £4.8m of funds net of costs from new and existing shareholders with the placing of 59,750,331 new ordinary shares in the Company.

# Summary

Despite the disappointing share price performance during the period, the Group made good progress in 2018 and I would like to thank all our shareholders for their continued support, as well as extending the Board's gratitude to all our staff and customers around the world.

The Simulation Division demonstrated encouraging growth in the ultrasound simulation market and we expect broadly similar growth to continue in the near future. The Clinical Division achieved all its AI development milestones in the year and is aiming to sign commercial agreements with ultrasound manufacturers and bring our ScanNav and AnatomyGuide AI image analysis software through regulatory approval to market.

The Group is currently trading in line with expectations and we look forward to the year ahead with considerable enthusiasm.

Riccardo Pigliucci Chairman 28 March 2019

#### **STATEGIC REPORT - OPERATIONS**

2018 has seen considerable progress, with the Group taking significant steps in expanding our business from a purely ultrasound simulation-based training business, into the larger clinical ultrasound software market.

#### **Business model**

The Group's business model is to invest in R&D to develop and then commercialise software-based disruptive technologies in the ultrasound healthcare market. Our key strategy involves unlocking the potential of diagnostic ultrasound by (i) making it easier for medical professionals to learn how to use ultrasound through the development of advanced ultrasound training simulators and then (ii) making it easier for them to use ultrasound in the clinic by providing real-time AI assisted interpretation of the ultrasound images while scanning the patient.

Ultrasound is one the world's leading diagnostic modalities and although the increasing availability of low-cost handheld devices has the potential to dramatically change the professional ultrasound user base, we continue to believe that this alone is not sufficient to open up the potential for ultrasound to become a mass-market diagnostic tool that can also be used by medical practitioners who do not possess specialist ultrasound skills. To achieve this, ultrasound needs to become simpler to use by making ultrasound machines 'smarter', supporting users both in their scanning and with automated decision-making. This will involve integrating image analysis using AI into the ultrasound imaging machines including the new, smaller and cheaper handheld devices. This is an emerging market and, although competitive and fast moving, it's one we believe we have the skills and capabilities to compete in.

As such we aim to be not only a major global provider of hi-fidelity simulation-based ultrasound training, but also to follow the medical professional into the clinic and be a provider of AI based clinical ultrasound software that can support, guide and speed up ultrasound scanning to make ultrasound more accessible.

This model builds on the key strengths and resources of the Group by leveraging our knowledge and experience in medical ultrasound, simulation and machine learning to develop software that can increase the numbers of medical professionals who can use ultrasound, as well as increasing the speed and quality of the scanning itself.

In the long term, as the price of machines comes down and the performance of our AI enabled software increases, we aim to provide enabling software for mass market AI based 'do-it-yourself' health check scanning for the health-conscious consumer.

To achieve these aims the Group is organised under two divisions – Simulation and Clinical. The report below details the business models relevant to each division, the progress made over the year and the key challenges faced.

#### **Simulation Division**

Based in Cardiff (UK), Alpharetta (US) and with representation in Beijing (China), our Simulation Division designs, develops and sells some of the world's leading hi-fidelity ultrasound training systems for teaching ultrasound scanning to medical professionals. Our simulator systems are high value, cap-ex sales made to the global medical institution market and are sold through our direct sales forces in the US and UK and a network of over 30 resellers in the rest of the world. The Division has continued to grow sales year-on-year, as it has established itself as one of the gold standard providers of ultrasound training simulators in the obstetrics/gynaecology and echocardiography/anaesthesiology markets. With a growing range of training simulators that extend sales into new ultrasound training sectors of the medical market, the Division is expected to continue to grow and materially reduce its cash burn impact on the Group.

# Research & Development

During the year, the Simulation R&D team focussed on the launch and on-going development of BodyWorks Eve, our new life-like manikin-based simulator which is a combination of the ScanTrainer and HeartWorks technologies, but aimed at the new and growing Point of Care Ultrasound (PoCUS) market. BodyWorks Eve is the first female manikin-based simulator specifically developed to meet the educational needs of emergency medicine and critical care markets and combines the normal and pathological hearts from our HeartWorks simulator with the complete upper chest to pelvis real patient scans from our ScanTrainer platform. With over 100 real patient ultrasound cases and over 10,000 patient scenario combinations, BodyWorks Eve replicates

learning in a real-life emergency or critical care setting, allowing the tutor to control and change the severity and pathology of the patient in real time.

After its successful debut at the International Meeting on Simulation in Healthcare (IMSH) in Los Angeles in January 2018, the new simulator was launched to our resellers in February 2018 and proved to be an immediate success, with the majority purchasing demo systems. The first sales to end-user hospitals and medical schools were also made and included sales to a number of major institutions in the US.

#### Territory review

Our Simulation Division sales grew by 27% to £5.3m in 2018 (2017: £4.2m) and there are positive signs that the global ultrasound simulator market for hi-fidelity training simulators will continue this growth.

#### North America

Revenue in 2018 was flat at £1.7m (2017: £1.7m).

North America remains a key market for medical simulation and we continue to sell into North America through our direct sales operation based in Alpharetta, Georgia. With the US market actively supporting US based purchasing, all our US sales are now made through MedaPhor North America, Inc. and we expect the region to return to growth in 2019.

## **United Kingdom**

Revenue in 2018 increased by 39% to £1m (2017: £0.7m).

After a challenging 2017, UK sales bounced back in 2018, increasing by 39% to £1m. Although this is encouraging, UK sales growth in 2019 may depend on the outcome of Brexit related decisions.

#### Rest of the World

Revenue in 2018 increased to £2.6m (2017: £1.8m).

Revenue in the Rest of the World is mainly generated by over 30 resellers. During the year sales increased by 50% to £2.6m (2017: £1.8m), partly reflecting channel take up of the BodyWorks Eve demo simulators. There were encouraging sales made in the French and German markets although sales in 2019 in Europe may be affected by the outcome of Brexit related decisions. At the end of the year we also reorganised our reseller base in China, consolidating our sales representation in the region into a single distributor. Master Meditech has a proven track record of sales of our products in China over the last three years. We also moved our regional office from Hong Kong to Beijing.

### Challenges to the Simulation Division

High values sales in the medical training sector are affected by budgetary restraint in the healthcare sector. In addition, medical simulation has competitive product and pricing challenges, that can put pressure on margins.

The Division has responded well to these to date, by focussing on offering products that provide a gold standard in training ultrasound. When an end-user's career depends on their ability to scan and diagnose using ultrasound, the market has recognised that it needs to purchase the best simulators based on performance, not price. We continue to develop and bring to market new evolutionary products that target new areas of ultrasound training and our new BodyWorks Eve is a good example. Developed in-house from the ScanTrainer training platform, but incorporating a manikin, new training methods and images, it is focussed on the growing PoCUS market and is expected to make a major contribution to future revenues.

# **Clinical Division**

The Group's strategy is to become a provider of AI based clinical ultrasound software that can support, guide and speed up ultrasound scanning to make ultrasound accessible to more medical professionals. We acquired The University of Oxford AI software company, Intelligent Ultrasound Limited (IUL) in October 2017, to supplement our in-house image analysis and ultrasound know-how and enable us to develop potentially ground-breaking AI image analysis tools for the professional ultrasound scanning market. This integration was completed during 2018 and based on the work of world-renowned University of Oxford academic, Professor Alison Noble OBE FREng FRS, the Division has developed real-time image analysis software for ultrasound by utilising deep-learning techniques and sophisticated computer algorithms along with researched insights into patient, clinician and healthcare provider needs.

There are two key components to our algorithms: (i) an excellent, growing database of curated obstetric images to drive our machine learning and (ii) sophisticated deep learning models, developed by Professor Noble and her team. This has enabled us to develop our ScanNav image analysis software and pilot the first of these algorithms in two leading UK hospitals.

#### ScanNav Audit

In February 2018, the first pilot of the ScanNav real-time audit image analysis software was undertaken on a GE Voluson obstetrics ultrasound machine at the Fetal Medicine Department of St George's University Hospitals NHS Trust, London, UK. In July 2018, the pilot was extended to a second UK hospital on a Toshiba Aplio obstetrics ultrasound machine at the Princess Anne Wing Ultrasound Department of the Royal United Hospitals (RUH), Bath.

The ScanNav Audit software provides real-time support for obstetric ultrasound practitioners performing anomaly scans at 20 weeks gestation. ScanNav Audit aims to ensure that a complete set of scan images which are fit for purpose and conform to the required scanning protocol are captured during the procedure. The UK mandates the Fetal Anomaly Screening Programme or "FASP" protocol; other territories have their own related protocols. The ScanNav software acts as a live virtual peer review, ensuring that the scan is performed correctly by highlighting issues to the sonographer as he or she saves each image. The software will also provide a record of each sonographer's performance, allowing managers to monitor staff and form part of the record keeping requirements of the clinic. ScanNav Audit is currently a CE marked product in the UK only, and will require further development and regulatory approval to meet the US and global scanning protocols.

#### ScanNav AutoCapture

The ScanNav AutoCapture software automatically captures and analyses all the ultrasound image planes in real-time, as the sonographer moves the ultrasound probe over the patient's abodomen during the 20-week fetal anomaly scan. The current version of the software then automatically selects and saves the key images required to meet the FASP protocol in the UK. Further development will be required to integrate this software into OEM machines as well as expanding the image recognition to meet the American College of Radiology (ACR) protocol in the US and the International Society of Ultrasound in Obstetrics and Gynecology (ISOUG) global protocol. The Directors believe that the ScanNav AutoCapture software has the potential to:

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

The Directors also believe that ScanNav AutoCapture's ability to automatically capture protocol-adherent ultrasound images will have more commercial value to OEMs looking to enhance the performance of their ultrasound machines. Consequently, the Group is in discussions with a number of OEMs to bring ScanNav Audit and AutoCapture to market.

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

#### ScanNav AnatomyGuide

ScanNav AnatomyGuide is an AI based ultrasound software product which can identify and highlight anatomical structures on a live ultrasound image. The product is being developed for use during Peripheral Nerve Block (PNB) procedures to support less experienced practitioners. PNB is a form of local anaesthetic that can be used in certain surgical procedures as an alternative to general anaesthesia.

The Group is currently gathering data to assist in the development of the product through a clinical study in partnership with the Aneurin Bevan University Health Board in Newport, Wales. It is anticipated that the product will also be sold into hospitals through the ultrasound OEMs. The Directors expect that development of ScanNav AnatomyGuide will be substantially completed in 2019 and that the regulatory approval process for its sale in Europe and the United States will commence thereafter.

#### **Future ScanNav products**

The Group is looking to develop future products including:

#### ScanNav NeedleGuide

*NeedleGuide* aims to use commercially available augmented reality hardware, combined with AI needle guidance tools, to enable live tracking of a needle during procedures such as PNB, kidney biopsy and cyst aspiration. The initial research work for this project has been part funded by the award of an Innovate UK grant of £466,000. This is a long-term development project that will be reviewed at the end of the Innovate UK grant in 2019.

#### ScanNav Assist

Assist is the next logical development for the ScanNav technology and could facilitate the automatic recognition of abnormalities within a general ultrasound scan. ScanNav Assist aims to confirm that a clinician has correctly scanned the anatomical area of interest and then highlight any areas of abnormality. The Directors believe that ScanNav Assist has the potential to allow more point-of-care medical practitioners to use ultrasound imaging for front line diagnosis and that such a device could support a broad range of medical professionals including GPs, midwives, paramedics and doctors working in Emergency Rooms.

# ScanNav HealthCheck

HealthCheck aims to take the concept of the ScanNav Assist product to the next level by potentially enabling consumers to perform scans on themselves. When combined with the next generation of low-cost hand-held ultrasound devices, this software could have the potential to enable health conscious individuals to benefit from the ability to scan themselves at home.

### Challenges to the Clinical Division

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

Our approach to these challenges is as follows:

- focus on the growing area of ultrasound imaging, the fastest, safest and cheapest imaging modality.
   Although this is probably one of the hardest of the imaging modalities to develop AI based image analysis tools for (MRI, CT and X-Ray being the others), we believe we have a potentially world leading expertise in this technology, combining ten years' experience in developing simulation-based training tools with our AI development expertise from The University of Oxford;
- leverage the assets that the acquisition of IUL has given us and which have already enabled us to bring our first pilot products into clinic. We believe these are the first real-time obstetric ultrasound AI software tools that are working in a live operational environment;
- focus on developing AI software that has both a clinical need and a clear economic rationale for its purchase; and
- partner our first products with OEMs who can access the large ultrasound market more quickly with their existing product ranges and sales networks and facilitate faster regulatory approvals.

The reception to our pilot ScanNav products at RSNA in December 2018 has given us confidence that the approach above is the right one and that we are on track to turn these pilot products into commercial products that can generate long-term revenue for the Division.

#### Name Change

On 14 January 2019 Company announced that it had changed its name from MedaPhor Group plc to Intelligent Ultrasound Group plc. The name change will roll out across the Group during 2019. The Board believes that the new name reflects the Group's expansion into the development of AI related software to guide and support doctors and sonographers in clinical ultrasound scanning.

Trading in the Group's shares under the new name commenced on 15 January 2019 and the Group's ticker symbol has remained as "MED". The Group's website can now be found at <a href="https://www.intelligentultrasound.com">www.intelligentultrasound.com</a>.

#### Management of ultrasound image data

The Al-based products being developed by the Group use deep-learning models that are 'taught' by processing thousands of ultrasound images. The curation and management of this data is of paramount importance to the Group and, as such, all externally-sourced ultrasound imaging data is anonymised before it is sent to us. Patient consent and the right to use the data are obtained under a GDPR-compliant data sharing agreement for each image library. Ultrasound scans recorded by the Group from volunteers are also stored anonymously and always obtained with their consent and GDPR compliance.

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

#### **Quality Management System**

During the year we implemented a company-wide Quality Management System (QMS). Originally this was intended to aid the development of the Clinical Division's ScanNav software, as it progressed towards regulatory approval, but in September 2018, the decision was taken to implement the QMS across both divisions in the UK. We expect to obtain ISO13485 accreditation during 2019.

#### **STATEGIC REPORT – FINANCE**

#### Revenue

Revenues for the Group increased 27% to £5.3m (2017: £4.2m). The growth achieved this year was organic but was boosted by the launch of our new BodyWorks Eve training simulator. The first Eve sale was made in April 2018 and the simulator contributed £1.2m to sales during the year, of which £0.5m were demo systems sold to distributors.

# **Gross profit**

The gross margin in the year was 53% compared to 60% in 2017. The reduced margin mainly reflects the higher proportion of distributor sales in 2018, at just under 50% (2017: 42%), but there has also been some discounting in both direct and distribution pricing to win new business and an increase in sales of a lower margin third party owned product for whom the Group acts as reseller has also had some impact.

# **Administrative expenses**

Administrative expenses, excluding exceptional costs, increased by £1.9m during the year to £7.1m (2017: £5.2m) as we absorbed the first full year of overheads relating to Intelligent Ultrasound Limited (IUL) acquired in 2017, compared to 3 months post-acquisition overheads which were consolidated in 2017. Staff costs, excluding those relating to IUL, were up by £0.6m reflecting our increased investment in sales, R&D and support staff.

Increase in administrative expenses excluding exceptional items:

	£III
IUL (Clinical Division) overheads for the full year (acquired 6 October 2017)	0.6
Staff costs, excluding those included in IUL above	0.6
Lower staff costs transferred to internally generated development costs	0.1
Marketing and travel	0.2
Depreciation and amortisation	0.2
External development costs expensed	0.1
Other	0.1
Total increase in administrative overheads excluding exceptional costs	1.9

Investment in the Clinical Division was also increased in 2018 by the transfer of specialist R&D staff from the Simulation Division, which added a further £0.5m to Clinical Division overheads.

#### Research and development costs and grants received

During the year the Group expensed through the income statement £1.3m (2017: £0.6m) in relation to research and development costs. In addition, development costs amounting to £0.5m (2017: £0.5m) were capitalised within intangible assets and an amortisation charge of £0.5m (2017: £0.4m) has been recognised against cumulative capitalised development costs.

The Group received an R&D grant of £0.3m (2017: £0.03m) which has been included as Other Income in the Statement of Consolidated Income.

#### **EBITDA**

The loss for the year (including £0.8m additional expensed R&D) before tax, exceptional items, depreciation and amortisation was £2.7m (2017, loss £1.7m).

#### **Exceptional items**

The Exceptional Item in the year related to a credit of £0.4m in respect of a fair value adjustment on the settlement of contingent consideration relating to the acquisition of IUL in the prior year (see note 4 below).

### Exceptional items in the prior year

Goodwill of £3.3m arose on the acquisition of Inventive Medical Limited (IML) and IUL and the Company is required under International Accounting Standard 36 – Impairment of Assets (IAS 36) to test the carrying value of this goodwill for impairment annually, using base cash flow projections that should not extend beyond five years and must exclude net revenues from pipeline products. As the majority of the Group's projected net revenues arise from its on-going research and development activities which are forecast to contribute more to revenue in later years, the directors concluded that, while they believe the investments in both IML and IUL will be monetised and yield returns in future years, the goodwill arising on these acquisitions should be treated as impaired under the strict requirements of IAS 36. Consequently, an impairment charge equal to the total goodwill which arose on these acquisitions of £3.3m was made to the Income Statement and included in Exceptional Items in 2017.

Exceptional Items in 2017 also included acquisition costs relating to the purchase of IUL of £0.2m and a credit of £0.6m in respect of a fair value adjustment on the settlement of contingent consideration relating to the acquisition of IML in the prior year (see note 4 below).

#### **Taxation**

The Group claims each year for research and development 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 research and development expenditure was £113,796 (2017: £55,310) which was net of R&D tax credit over-claims of £100,000 relating to prior periods. The tax credit for the year also includes deferred tax of £90,000 (2017: £72,299) on the fair value of intangible fixed assets acquired with IML and IUL which is being recognised over the life of those assets.

As at 31 December 2018, the Group has cumulative tax losses of approximately £9.8m (2017: £8.8m).

#### Placing and open offer

On 13 December 2018 the Company issued 59,750,331 new ordinary shares of 1 pence each in the capital of the Company at a price of 8.5 pence per share which raised £5,078,778 before costs of the share issue and £4,818,046 after costs. The share issue costs of £260,732 have been netted off against the share premium arising on the new share issue.

# **Balance sheet**

Consolidated net assets increased to £9.3m (2017: £7.1m). Inventories at £0.85m at the year-end were double the level of the previous year (2017 £0.41m) and we continue to hold higher than normal stock levels to mitigate supply chain risks during the Brexit transition period. Cash at £5.6m was up £1.3m on the prior year (2017: £4.3m). Trade and other payables of £1.9m at 31 December 2018 (2017: £2.4m) include £0.2m of warrants issued as part of the consideration paid for IUL (2017, retained consideration and warrants relating to the acquisition of IUL: £1.1m).

#### **Cash flow**

Cash at 31 December 2018 stood at £5.6m (2017: £4.3m), with cash flow in the year boosted by the placing of new ordinary shares in the Company which raised £4.8m net of costs (2017: placing raised £5.4m net of costs). Net cash used in operating activities was £2.6m (2017: £2.2m) and the net cash outflow arising from investment activities was £0.9m (2017: £0.7m, excluding cash used or acquired on the acquisition of IUL).

In early 2020 the Company will commence the process to secure a further round of funds to take the Group through the next stage of growth.

#### **Contingent liability**

The Board has been made aware of a potential over-claim of R&D tax credits made by IUL in periods prior to its acquisition by the Company arising from an omission to file certain tax elections with HMRC on a timely basis. IUL has made full disclosure of this matter to HMRC and requested that they accept retrospective elections for the accounting periods concerned. The Company has estimated that the potential amount that IUL could be asked to repay if the retrospective elections are not permitted is approximately £434,000 including interest and possible penalties, but considers that the likelihood of HMRC demanding repayment is possible rather than probable and consequently no provision has been made for this contingent liability.

#### Events since the end of the financial year

Other than as disclosed above, there are no events to report that have occurred since the end of the financial year.

#### STRATEGIC REPORT - SUMMARY

The Group has made good progress this year. Sales in the Simulation Division continue to grow and after a well-received showcasing of ScanNav at RSNA in Chicago, the world's largest radiology exhibition, we believe there is considerable interest in our AI software algorithms from both manufacturers and end users.

The potential of the new ScanNav AI real-time image analysis software combined with our existing revenue generating simulation business enables us to look forward with considerable confidence.

This Strategic Report was approved by the Board on 28 March 2019 and signed on its behalf by:

Stuart Gall
Chief Executive

# Intelligent Ultrasound Group plc CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

for the year ended 31 December 2018

	Note	Unaudited 2018	Audited 2017
		£	£
REVENUE Cost of sales Gross profit	3	5,313,164 (2,479,781) 2,833,383	4,180,630 (1,657,765) 2,522,865
Other income Administrative expenses excluding exceptional costs Exceptional administrative costs Total administrative costs	4	310,475 (7,120,434) 362,718 (6,447,241)	28,225 (5,228,211) (2,860,774) (8,060,760)
OPERATING LOSS		(3,613,858)	(5,537,895)
Finance costs LOSS BEFORE INCOME TAX		(7,402) (3,621,260)	(7,833) (5,545,728)
Income tax credit	5	203,796	127,609
LOSS ATTRIBUTABLE TO THE EQUITY SHAREHOLDERS OF THE PA	ARENT	(3,417,464)	(5,418,119)
OTHER COMPREHENSIVE INCOME Items that will or may be reclassified to profit or loss:			
Exchange gain/(loss) arising on translation of foreign operation OTHER COMPREHENSIVE INCOME FOR THE YEAR	S	844	31,171
TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO THE EQUI-	TY	(3,416,620)	31,171 (5,386,948)
LOSS PER ORDINARY SHARE (PENCE) ATTRIBUTABLE TO THE EQ SHAREHOLDERS OF THE PARENT	ŲUITY		
Basic and diluted	6	(3.59)p	(11.70)p

# Intelligent Ultrasound Group plc

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY for the year ended 31 December 2018

	Ordinary share capital	Share premium	Accumulated losses	Share- based payment reserve	Merger Reserve	Foreign exchange reserve	Total equity attributable to shareholders
	£	£	£	£	£	£	£
BALANCE AS AT 1 JANUARY 2017	318,986	7,267,139	(7,005,812)	321,600	3,943,675	(10,980)	4,834,608
COMPREHENSIVE INCOME FOR THE YEAR Loss for the year and total comprehensive income							
	-	-	(5,418,119)	-	-	31,171	(5,386,948)
CONTRIBUTIONS BY AND DISTRIBUTIONS TO OWNERS							
Shares issued for cash	441,253	5,074,412	-	-	-	-	5,515,665
Cost of raising finance	-	(124,881)	-	-	-	-	(124,881)
Retention shares issued further to	22.256				240.446		262 272
acquisition of IML Shares issued on acquisition of IUL	23,256 123,520	-	-	-	340,116 1,729,274	-	363,372 1,852,794
Cost of share-based awards	123,320	-	-	92,000	1,729,274	-	92,000
Total contributions by and distributions to				32,000			32,000
owners	588,029	4,949,531	-	92,000	2,069,390	-	7,698,950
BALANCE AS AT 31 DECEMBER 2017 as previously stated Prior year adjustment – IFRS 15 Revenue from Contracts with Customers	907,015	12,216,670	(12,423,931)	413,600	6,013,065	20,191	7,146,610
nom contracts with customers	_	_	(13,041)	_	_	_	(13,041)
At 1 January 2018 as restated	907,015	12,216,670	(12,436,972)	413,600	6,013,065	20,191	7,133,569
COMPREHENSIVE INCOME FOR THE YEAR Loss for the year and total comprehensive income	·		, , , ,	,	, ,	,	, ,
CONTRIBUTIONS BY AND DISTRIBUTIONS	-	-	(3,417,464)	-	-	844	(3,416,620)
TO OWNERS							
Shares issued for cash	597,503	4,481,275	-	-	-	-	5,078,778
Cost of raising finance Retention shares issued further to	-	(260,732)	-	-	-	-	(260,732)
acquisition of IUL	61,760	_	_	_	524,958	_	586,718
Cost of share-based awards	-	_	-	148,000	-	-	148,000
Total contributions by and distributions to	659,263	4,220,543		148,000	524,958		5,552,764
owners	033,203	4,220,343	<u> </u>	140,000	324,338		3,332,704
BALANCE AT 31 DECEMBER 2018	1,566,278	16,437,213	(15,854,436)	561,600	6,538,023	21,035	9,269,713

# Intelligent Ultrasound Group plc CONSOLIDATED STATEMENT OF FINANCIAL POSITION

as at 31 December 2018

Not	Unaudited 2018 e £	Audited 2017 £
NON CURRENT ASSETS		
Intangible assets	2,886,562	3,366,477
Property, plant and equipment	417,732	312,506
	3,304,294	3,678,983
CURRENT ASSETS		
Inventories	851,491	413,244
Trade and other receivables	1,912,975	1,709,436
Current tax assets	80,302	-
Cash and cash equivalents	5,607,052	4,250,198
	8,451,820	6,372,878
TOTAL ASSETS	11,756,114	10,051,861
CURRENT LIABILITIES		
Trade and other payables 7	(1,939,435)	(2,369,743)
Income tax	(100,000)	-
Provisions	(68,972)	(80,555)
	(2,108,407)	(2,450,298)
NON CURRENT LIABILITIES		
Deferred taxation	(377,994)	(467,994)
TOTAL LIABILITIES	(2,486,401)	(2,918,292)
NET ASSETS	9,269,713	7,133,569
EQUITY CAPITAL AND RESERVES ATTRIBUTABLE TO EQUITY HOLDERS OF TH	HE COMPANY	
Ordinary share capital 8	1,566,278	907,015
Share premium	16,437,213	12,216,670
Accumulated losses	(15,854,436)	(12,436,972)
Share-based payment reserve	561,600	413,600
Merger reserve	6,538,023	6,013,065
Foreign exchange reserve	21,035	20,191
TOTAL EQUITY	9,269,713	7,133,569

# Intelligent Ultrasound Group plc CONSOLIDATED STATEMENT OF CASH FLOWS

for the year ended 31 December 2018

	Unaudited 2018 £	Audited 2017 £
CASH FLOW FROM CONTINUING OPERATING ACTIVITIES		
Loss before tax	(3,621,260)	(5,545,728)
Depreciation	244,957	232,369
Amortisation of intangible assets	992,586	793,543
Impairment of goodwill	(262.710)	3,328,166
Fair value adjustment on contingent consideration Finance costs/(income)	(362,718) 7,402	(636,628) 7,833
Share-based payments	148,000	92,000
Operating cash flows before movement in working capital	(2,591,033)	(1,728,445)
operating cash nows before movement in working capital	(2,331,033)	(1,720,443)
Movement in inventories	(438,247)	69,094
Movement in trade and other receivables	(203,539)	(61,351)
Movement in trade and other payables	507,545	(575,798)
		_
Cash used in operations	(2,725,274)	(2,296,500)
Income taxes received	133,495	100,844
NET CASH USED IN OPERATING ACTIVITIES	(2,591,779)	(2,195,656)
NET CASH OSED IN OF ENATING ACTIVITIES	(2,331,773)	(2,133,030)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(361,707)	(183,012)
Disposal of property, plant and equipment	11,523	11,440
Internally generated intangible assets	(512,671)	(492,118)
Cash used on acquisition of subsidiaries	-	(72,000)
Cash acquired on acquisition of subsidiaries		1,559
NET CASH USED IN INVESTING ACTIVITIES	(862,855)	(734,131)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issue of new shares	5,078,778	5,515,665
Share issue costs	(260,732)	(124,881)
Finance (costs paid)/income received	(7,402)	(7,833)
NET CASH GENERATED FROM FINANCING ACTIVITIES	4,810,644	5,382,951
Exchange gains/(losses) on cash and cash equivalents	844	31,171
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,356,854	2,484,335
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	4,250,198	1,765,863
CASH AND CASH EQUIVALENTS AT END OF YEAR	5,607,052	4,250,198

# **Intelligent Ultrasound Group plc**

NOTES TO THE PRELIMINARY RESULTS

for the year ended 31 December 2018

#### BASIS OF PREPARATION AND ACCOUNTING POLICIES

The Group's financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union, IFRIC interpretations, the AIM Rules, and the Companies Act 2006.

The financial statements have been prepared on the going concern basis. The Group meets its day-to-day working capital requirements from its cash reserves. The Board receives rolling cash flow projections on a monthly basis and monitors these against the Group's long-term projections. These projections indicate that the Group will have sufficient funds to continue to trade for the next 15 months.

Therefore, the directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future and therefore continue to adopt the going concern basis of accounting in preparing the annual financial statements.

While the financial information included in this preliminary announcement has been computed in accordance with IFRS, this announcement does not itself contain sufficient information to comply with IFRS. The accounting policies used in the preparation of this preliminary announcement have been applied consistently to all periods presented. They are also consistent with those in the Group's statutory financial statements for the year ended 31 December 2018 which have yet to be published. The preliminary results for the year ended 31 December 2018 were approved by the Board of Directors on 28 March 2019.

The financial information for the year ended 31 December 2018 and the year ended 31 December 2017 does not constitute the company's statutory accounts for those years. Statutory accounts for the year ended 31 December 2017 have been delivered to the Registrar of Companies. The auditors' report on those accounts was unqualified, did include a material uncertainty in respect of going concern, and did not contain a statement under 498(2) or 498(3) of the Companies Act 2006. The financial information for the year ended 31 December 2018 is unaudited. The statutory accounts for that year will be delivered to the Registrar of Companies in due course.

The Company is a limited liability company incorporated and domiciled in England & Wales and whose shares are quoted on AIM, a market operated by The London Stock Exchange. The Group financial statements are presented in pounds Sterling.

# 2. BASIS OF CONSOLIDATION

The consolidated preliminary results incorporate the results of the Company and its subsidiary undertakings.

#### 3. REVENUE ANALYSIS

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

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

Year ended 31 December 2017		Simulation Division	Clinical Division	Total
	Distribution	Direct Sales		
	£	£	£	£
United Kingdom	-	715,531	-	715,531
North America	-	1,708,984	-	1,708,984
Rest of World	1,756,115	-	-	1,756,115
	1,756,115	2,424,515	-	4,180,630

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:

	2018 £	2017 f
USA	1,560,624	_
China	710,689	766,147
4. EXCEPTIONAL ITEMS		
	2018	2017
	£	£
Goodwill impairment	-	3,328,166
Fair value adjustments on contingent consideration	(362,718)	(636,628)
Acquisition costs		169,236
	(362,718)	2,860,774

The fair value adjustment on contingent consideration arose on the settlement during the year of the retained consideration on the acquisition of IUL. The consideration was satisfied by the payment of cash of £72,000 plus the issue of 18,527,936 new Ordinary Shares ("the Consideration Shares") and 1,256,692 warrants ("the Consideration Warrants") in Intelligent Ultrasound Group plc with a combined fair value of £2,967,694 based on the market price of the shares at the time of the completion of the transaction. Two thirds of the Consideration Shares (12,351,961 shares) were admitted to trading and two thirds of the warrants (837,795 warrants) were issued upon completion. The issue of the remaining third of the Consideration Shares and Consideration Warrants (together "the Deferred Consideration") was deferred for 12 months from completion as the issue of these shares and warrants was contingent on no seller warranty or indemnity breaches (as specified in the Sale and Purchase Agreement) arising during that 12 month period. The issued warrants at their fair value of £125,669 along with the Deferred Consideration (retained shares at their original fair value of £926,396 and the retained warrants at their original fair value of £62,835), were included in creditors due within one year at 31 December 2017. The Company was not aware of any seller warranty or indemnity breaches and so the 6,175,975 deferred Consideration Shares were admitted to trading on 9 October 2018 and the 418,897 deferred Consideration Warrants were issued at the same time. The difference between the original fair value of the Deferred Consideration and the fair value of the Deferred Consideration at the settlement date of £362,718 has been recognised in the Consolidated Statement of Comprehensive Income as a fair value adjustment on deferred consideration and included within exceptional items.

At the end of 2017 the directors reviewed the carrying amount of goodwill arising on the acquisition of Inventive Medical Limited (IML) in 2016 and Intelligent Ultrasound limited (IUL) in 2017 for impairment. The conclusion of that review was that, there was an impairment of goodwill if the base cash projections were not extended beyond a five-year time horizon and cash flows from pipeline products were excluded. The directors concluded that the goodwill arising on the acquisition of IML and IUL should be treated as impaired under IAS 36 and consequently an impairment charge of £3,328,166 was been made to the 2017 Consolidated Statement of Comprehensive Income.

The fair value adjustment on contingent consideration in 2017 arose on the settlement of the retained consideration on the acquisition of IML. The issue of these ordinary shares in the Company was contingent on there being no vendor warranty or indemnity breaches arising in the 12-month period following the acquisition of IML in August 2016. This contingent consideration was included in creditors due within one year at 31 December 2016 at its original fair value of £1,000,000 being 2,325,582 shares at 43 pence per share which was the market price of the shares at the time of completion. There were no vendor warranty or indemnity breaches that the directors were aware of and so all the contingent consideration shares were issued in August 2017 when the fair value of the contingent consideration was £363,372 based on the market price of the shares of 15.625p on the day the shares were admitted to trading. The difference between the original fair value of the contingent consideration and the fair value of the contingent consideration at the settlement date was transferred to the Consolidated Statement of Comprehensive Income as a fair value adjustment on contingent consideration and included within exceptional items in 2017 above.

The acquisition costs in 2017 related to the purchase of Intelligent Ultrasound Limited (IUL) in October 2017.

#### 5. TAXATION ON ORDINARY ACTIVITIES

Analysis of credit in year:

	2018	2017
	£	£
R&D tax credit	(213,796)	(55,310)
Adjustment for over-claim of R&D tax credit in prior periods	100,000	-
Deferred tax credit	(90,000)	(72,299)
	(203,796)	(127,609)

### 6. LOSS PER SHARE

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

	Unaudited 2018	Audited 2017
	£	£
Loss for the year after taxation	(3,417,464)	(5,418,119)
Number of ordinary shares of 1p each Basic and diluted weighted average number of	2018 No.	2017 No.
ordinary shares	95,233,054	46,290,518
Basic loss pence per share	(3.59)p	(11.70)p

At 31 December 2018 and 2017 there were share options outstanding which could potentially have a dilutive impact but were anti-dilutive in both years.

#### 7. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	2018	2017
	£	£
Trade payables	665,040	389,911
Taxation and social security	88,870	80,319
Accruals	507,568	454,490
Deferred income	471,570	311,106
Warrants	165,464	125,669
Retention consideration shares	-	926,396
Retention consideration warrants	-	62,835
Other	40,923	19,017
	1,939,435	2,369,743

#### 8. SHARE CAPITAL

		2018		2017
	No.	£	No.	£
Authorised	Unlimited	Unlimited	Unlimited	Unlimited
Allotted, issued and fully paid				
Ordinary shares of 1p each Balance at 1 January	90,701,443	•	31,898,576	318,986
Shares issued for cash Shares issued on acquisition of IML	59,750,331 -	597,503	44,125,324 2,325,582	441,253 23,256
Shares issued on acquisition of IUL	6,175,975	61,760	12,351,961	123,520
Balance at 31 December	156,627,749	1,566,278	90,701,443	907,015

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

Date	Description	Shares	Fair value	Premium
		number	£	£
09/10/18	Retention shares issued to the vendors			
	of IUL	6,175,975	586,718	524,958
13/12/18	Shares issued in connection with			
	capital raising	59,750,331	597,503	4,481,275
		65,926,306	1,184,221	5,006,233

One third of the consideration payable in respect of the acquisition of IUL in 2017 was deferred for 12 months from completion with the actual number of deferred shares and warrants to be issued dependent on any vendor warranty or indemnity breaches (as specified in the Sale and Purchase Agreement) arising during that 12 month period. The Company was not aware of any vendor warranty or indemnity breaches and so the 6,175,975 deferred consideration shares (with a fair value of £586,718 at 9.5 pence per share) were admitted to trading on 9 October 2018 and 418,897 deferred consideration warrants were issued at their fair value. The share premium arising was subject to merger relief and has been taken to merger reserve.

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

#### 9. CONTINGENT LIABILITY

The Company has been made aware of a potential over-claim of R&D tax credits made by IUL in periods prior to its acquisition by the Company arising from an omission to file certain tax elections with HMRC on a timely basis. IUL has made full disclosure of this matter to HMRC and requested that they accept retrospective elections for the accounting periods concerned. The Company has estimated that the potential amount that IUL could be asked to repay if the retrospective elections are not permitted is approximately £434,000 including interest and possible penalties, but considers that the likelihood of HMRC demanding repayment is possible rather than probable and consequently no provision has been made for this contingent liability.