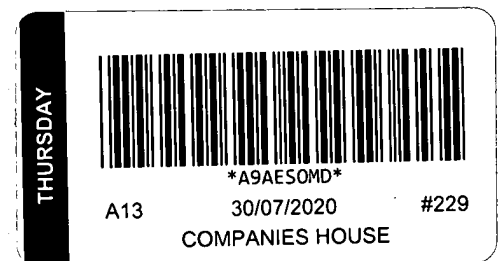




Creo Medical Group plc

Annual Report & Accounts 2019

Company registered number: 10371794



STRATEGIC REPORT

HIGHLIGHTS

Our focus.

We are focused on the development and commercialisation of minimally invasive electrosurgical devices, bringing advanced energy to endoscopy.

A YEAR OF ACHIEVEMENTS

- Increased commercial momentum with Creo's first products, Speedboat and the CROMA Advanced Energy Platform:
 - Successful roll-out of Creo's Clinical Education Programme (CEP) in the United States (US) and completion of the first Speedboat training course delivered by a US clinician trained as part of Creo's CEP
 - Procedures successfully carried out on patients by a number of US clinicians using Speedboat
 - First commercial orders for Speedboat and first revenue from US hospitals
 - Additional European Framework Distribution secured across France, Germany and Italy with first physicians trained and delivering procedures
 - Additional Asian Framework Distribution Agreement secured covering India with first physicians trained and publication of cases
 - Suite of devices launched at the United European Gastroenterology Week Congress in October 2019
- Advanced progress made in gaining regulatory approvals in the EU for a further four devices optimised for the core tissue effects of dissection, resection, haemostasis and ablation
- Post period end 510(k) clearance from the US Food and Drug Administration ('FDA') for Creo's HS1 Haemostasis device ('HS1') and on track to gain clearance with additional devices from the suite of products in the USA
- Strengthened IP portfolio, with 188 granted patents and 599 pending applications (as at 31 December 2019)
- Post period end, key appointments made including the addition of Iyonna Cantu as an independent Non-Executive Director

FINANCIAL HIGHLIGHTS

- Strengthened balance sheet following the successful raise of an additional £51.9m (before expenses) through a placing and open offer
- Cash and cash equivalents of £81.0m at 31 December 2019 (31 December 2018: £44.6m)
- R&D expenditure for 2019 was £8.1m (18 months to 31 December 2018: £7.8m) to expand the portfolio of products
- Operating loss of £18.9m (18 months to 31 December 2018: £17.7m) including £1.6m share-based payments, in line with management expectations
- Underlying operating loss of £14.0m (18 months to 31 December 2018: £12.6m) is in line with the anticipated spend profile and reflects increased commercial activities
- Net assets of £82.7m (31 December 2018: £47.7m)

COMPANY OVERVIEW

About us

Our CROMA Advanced Energy Platform, combined with our range of patented electrosurgical devices, is designed to provide clinicians with flexible, accurate and controlled clinical solutions.

We believe our technology can impact the landscape of surgery and endoscopy by providing a safer, less-invasive and more cost-efficient option for procedures, enabling procedures under sedation outside the operating theatre rather than under general anaesthetic in the operating room.

We focus on significant markets:

- Interventional Gastroenterology for the dissection, resection, ablation and haemostasis of diseased GI tissue
- Soft tissue ablation (including the liver, pancreas, kidney)
- Interventional Pulmonology for the resection and/or ablation of pre-cancerous and cancerous lesions.

Headquartered in Chepstow, UK, Creo Medical was founded in 2003 by Professor Chris Hancock, and was admitted to the AIM market of the London Stock Exchange on 9 December 2016.

Employees*

91

Granted patents

188

Patents pending

599

Our portfolio

Each of our patented electrosurgical devices is powered by our CROMA Advanced Energy Platform.

CROMA Advanced Energy Platform

The CROMA Platform delivers a combination of bi-polar radiofrequency and microwave energy for a range of surgical effects through a single accessory port. This advanced energy, enables single use, surgical accessories to be optimised for the dissection, resection, haemostasis and ablation of tissue in multiple areas of therapy.

Five patented electrosurgical devices at or close to commercialisation

We have developed a suite of multi and single modality, matched devices which are optimised around the core tissue effects of dissection, resection, haemostasis and ablation.

Our rich pipeline of technologies and devices

CROMA Platform

Our electrosurgical
products

Third party IP
and products

Conceptual IP
and products

Our advanced energy platform makes it possible to perform endoscopic surgery with precision FLEXIBLE instruments, with patients sedated in an outpatient setting rather than in the operation room under general anaesthetic.

OUR APPLICATIONS

Gastrointestinal endoscopy

Growing incidence of GI indications

- Poor diet, obesity, sedentary lifestyles and an aging population are leading to an increased prevalence of GI conditions.

Growing demand for screening

- Western governments and health organisations continue to expand endoscopic screening programmes, which is driving an increase in detection of a range of conditions requiring the resection or biopsy of tissue and the control of bleeding.

16m

screening colonoscopies are
performed per annum in the US¹

1.1m

find a lesion
requiring treatment²

c.50%

of those lesions
are removed surgically¹

Compelling improvements vs current options

- Current treatment is open or laparoscopic surgery, requiring up to 5-day hospital stays and with a mortality rate of up to 6% at 30 days³.
- Advanced therapeutic endoscopy allows procedures to be performed in outpatient clinics and the risk of complications and mortality are also reduced.

We are developing a range of devices to cover both upper and lower GI procedures.

1. US surgical procedures volumes 2010, Millennium Research, RPUS435SV10, Feb 2010.
2. Gastrointest Endosc 2014; 80:133-43.
3. Ann R Coll Surg Engl 2011; 96: 445-450.

Endoscopic accessible soft tissue ablation

Demand for new therapies:

- The GI tract allows access to close-by organs (for example, liver, pancreas and kidney). Cancers of these organs are among the highest causes of cancer-related deaths and are characterised by limited effective treatments and poor rates of survival.

Indications:

- Liver cancer combines high incidence and high mortality – it is the 4th biggest cause of cancer death worldwide, with 780,000 deaths annually, and has the second highest mortality rate (93%)¹.
- Pancreatic cancer has the highest mortality rate (94%) of all major cancers¹. It is expected to become the second largest cause of cancer-related deaths around 2020 in the USA² where it has a 5-year survival rate of 9%³ (7% in the UK⁴).
- Prevalence of incidental pancreatic cysts has been shown in studies to be c.9%⁵. Precancerous or cancerous potential of cysts is estimated to be 2%⁶. With a European and North American population of c.1.1bn, this could imply c.2m people with a potentially cancerous pancreatic cyst.
- Kidney cancer is increasing at one of the highest rates globally (est. 22% growth 2014–2020⁷) with over 400,000 incidences per year¹.

780,000

deaths annually from
liver cancer¹

94%

mortality rate for
pancreatic cancers¹

c.50%

of those lesions are
removed surgically¹

Therapeutic Endoscopy using an Endoscopic Ultrasound Scan combined with Creo's flexible microwave ablation probe could provide an alternative way to ablate soft tissue tumours and treat patients for whom there may be limited options for surgical intervention.

Creo's flexible microwave ablation probe is intended to navigate the GI tract to access adjacent organs using a fine gauge needle antenna, managing tumours and extending patient survival.

1. WHO, IARC Cancer Today Online Analysis 2018.
2. Lola Rahib, Benjamin D. Smith, Rhonda Aizenberg, Allison B. Rosenzweig, Julie M. Fleshman and Lynn M. Matrisian. Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States. DOI: 10.1158/0008-5472.CAN-14-0155 Published June 2014.
3. American Cancer Society, Cancer Facts and Figures 2019.
4. Pancreatic Cancer UK fact sheet.
5. Oliveira PBd, Puchnick A, Szejnfeld J, Goldman SM (2015). Prevalence of Incidental Pancreatic Cysts on 3 Tesla Magnetic Resonance. PLoS ONE 10(3): e0121317. doi:10.1371/journal.pone.0121317.
6. <https://www.roswellpark.org/cancertalk/201711/do-pancreatic-cysts-become-cancerous>
7. European Association of Urology, Scientific and Policy Briefing on Kidney Cancer.

Bronchoscopic accessible ablation

Demand for new therapies

1.8m

global cases of lung cancer each year¹

85%

of patients are inoperable², leaving radiotherapy and chemotherapy the only treatment options

17%

five-year survival rate³

- Therapeutic bronchoscopy allows treatment of pre-cancerous nodules in the lung as a first-line option, as well as treatment of patients not eligible for surgery.
- Lung cancer is not yet routinely screened for, however recent consolidation in the sector indicates investment and improvements in diagnostic accuracy.
- Population-based screening will become a part of life in the near future, resulting in earlier stage disease diagnosis.
- Earlier diagnosis requires less invasive and more precise treatment options.
- These requirements ideally suit the key features of our CROMA Advanced Energy Platform and tiny non-cooled flexible ablation devices.
- Creo's lung probe is intended to be able to navigate to see and treat lesions deep in the lung, ablating lesions safely without the complications associated with percutaneous ablation.

1. WHO, IARC Cancer Today Online Analysis 2018.
2. US surgical procedures volumes 2010, Millennium Research, RPUS435SV10, Feb 2010.
3. Gastrointest Endosc 2014; 80-133-43.

INVESTMENT PROPOSITION

A strong portfolio of IP.

Deep in-house expertise coupled with partnerships with trusted third parties creates a powerful combination.

CROMA Advanced Energy Platform and patented devices with compelling benefits

Our patented CROMA Advanced Energy Platform delivers microwave and bipolar radiofrequency energy through a single accessory port, delivering precise cut, coagulation and ablation for a range of electrosurgical devices bringing significant advantages in time, costs and outcomes.

Rich product pipeline and strong IP

We have a promising pipeline of products, from early concept development to in-human use, supported by an IP portfolio of 188 granted patents and 599 pending applications as at 31 December 2019.

Attractive market potential

Our devices are designed to enhance existing techniques and provide effective new therapies in high-value segments of large and growing global markets. Healthcare providers are expanding screening programs, driving increasing early stage detection rates for a range of conditions requiring tissue management and the control of bleeding.

Scalable business model

Our pioneering CROMA Advanced Energy Platform is designed to be scaled via the 'razorblade mode' with a suite of single-use devices that deliver superior outcomes for physicians and patients. Our business model – from R&D, through manufacture and sales and distribution – is designed to be resilient and scalable.

Experienced team

Our management team is drawn from the surgical instrumentation and technology market and has experience spanning R&D, quality, regulatory approval and commercialisation and we have strategic relationships with respected scientific advisers and Key Opinion Leaders.

Clear commercialisation strategy

We are pursuing a defined roadmap towards the launch of a suite of devices, initially focused on GI and ablation applications. We begin by building advocacy with Key Opinion Leaders, driving penetration through our Clinical Education Programme and the subsequent breadth of usage through stimulating increased generator utilisation and expanding into adjacent markets.

Framework distribution agreements with respected partners give us a route to market in multiple countries around the world.

CHAIRMAN'S STATEMENT

At IPO in December 2016, we set out our ambitious and challenging three-year plan.

We are therefore reporting on both the progress made by the Company in the twelve months ended 31 December 2019, and reviewing the key milestones achieved over those three years. Craig, Chris and Richard provide more detail in their reports and set out our vision and framework for Creo's development over the next three years.

Overview

Having achieved US FDA clearance and CE marking ahead of plan for CROMA, our Advanced Energy Platform, and Speedboat, the first in our suite of patented electrosurgical devices, we have introduced our products in key international markets. These are delivering clinical benefits in the UK, EU, US, South Africa and India, where we now have distributors appointed and leading surgeons and endoscopists using our devices daily. We are completing the regulatory clearance process for our wider suite of GI devices which will work alongside Speedboat, and are delighted to have received US FDA 510(k) clearance of our HS1 Haemostasis Device in March 2020.

We have received first commercial orders and revenue from US hospitals, a key milestone in our evolution from early clinical adoption to wider international commercialisation. With proprietary products at the core of the Company, we continue to focus on Research and Development and thereby strengthen our extensive IP portfolio, as detailed in Chris's report on page 16.

Management and staff

I would like to congratulate our executive team and staff on delivering on the three-year plan. They have made excellent progress against milestones, in particular our focused three-prong strategy of turning production into manufacturing; projects into products; and trainees into users.

Over the course of the year we welcomed twenty-two new recruits to the Creo team in key areas including sales and marketing, clinical training, and corporate development. Together, this has taken the Company's permanent headcount to 91, more than trebling since the IPO.

Shareholders and corporate finance

None of this is possible without the enthusiasm and support of our shareholders. A key milestone was the equity fundraising, completed in December, which raised £51.9 million. This follows the £48.5 million raised in August 2018 and the £20.0 million at the IPO. Each fundraising has been priced at a premium to previous equity issues, both strengthening the balance sheet and building shareholder value. These have allowed Creo to progress energetically over the three years, and our strong balance sheet puts us in an excellent position to execute on the next phase of our development.

We welcome all new shareholders to the Company and thank them, and our existing shareholders, for their continued encouragement.

Board and governance

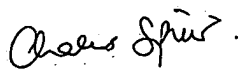
We welcome Ivonne Cantu to the Board as our third independent Non-Executive Director and chair of the Remuneration Committee and member of the Audit Committee. Ivonne brings deep experience of corporate finance, M&A and investor relations from her twenty-year career in the City and subsequent executive roles in the quoted sector.

Coronavirus (COVID-19)

We are continually monitoring the development of COVID-19 and the impact it is having on our business. We have a cogent plan to manage the business during these uncertain times, in particular during the measures announced by the UK Government. The Board want to thank our colleagues, our customers, and our suppliers for all their support and, of course, wish them and their families the best of health. We will support them and the wider medical technology community in any way we can.

Outlook

With a strong balance sheet, supportive shareholders and further additions to our team, we are confident we can build on this progress for the next stage of Creo's development. Notwithstanding delays that may arise outside our control from COVID-19 globally, our focus remains to complete the regulatory clearance for our suite of GI devices, accelerate the commercial rollout of our products in the US along with our global distribution partners, explore potential strategic acquisition opportunities, and continue research and development of new devices, energy modalities and applications for CROMA based on our extensive intellectual property.



Charles Spicer

Chairman
6 May 2020

A solid record of achievement.

And a rich pipeline of opportunity.

We have made enormous strides since Creo was admitted to AIM three years ago, achieving all of the goals set out in the three-year plan we articulated at IPO.

Below I set out progress we have made against the three pillars of our strategy.

Projects to products

I am delighted to report that 2019 saw our first commercial orders, generating revenues for the first time from our CROMA Advanced Energy Platform and Speedboat product, the first of a unique range of electrosurgical devices for GI and other applications.

Progress in gaining regulatory approvals for a further four devices optimised around the core tissue effects of dissection, resection, haemostasis and ablation is well advanced. Technical files are complete and, with revised arrangements with the Company's Notified Body, all four products will be CE marked in Europe simultaneously on receipt of Creo's new EC certificate, which is expected in the near term. In addition, alongside the FDA clearances received so far for the CROMA Advanced Energy Platform and the Speedboat device, we remain on track to gain US clearance for the remaining products with US FDA 510(k) clearance of our HS1 Haemostasis Device being issued in March 2020, the first device to use our unique non-stick haemostasis technology.

Having launched the range of devices to the market at the United European Gastroenterology Week Congress in October 2019, plans are in place to introduce the devices into clinical practice as we gear up for commercialisation.

All of our existing and future devices will be powered by CROMA's broad spectrum, adaptive technology, encompassing radio frequency ("RF"), microwave and other future modalities such as plasma or millimetre (mm) wave. Creo's talented team of developers is continuing to work on creating pioneering devices and energy modalities, with some exciting programmes in the pipeline that Chris outlines from page 16.

Production to manufacturing

In anticipation of seeing significant growth in orders for Speedboat, during the year we signed heads of agreement with an outsource contract manufacturer to facilitate the larger scale production of our devices and are in the final stages of formalising that contract. We have validated the process for Speedboat in the first instance, and our partner is poised to initiate production once orders reach a specified volume threshold. For other devices, we intend to retain early production in-house to optimise processes for newly launched products ahead of outsourcing.

Trainees to users

In collaboration with our distribution partners, our Clinical Education Programme (CEP) for our Speedboat device now operates through multiple training centres of excellence spanning the UK, US, Europe, India and South Africa.

The year not only brought the first clinical use of Speedboat in the US, it was also satisfying to see the first of our trainees training other GI endoscopists who are now keen advocates and users of Speedboat, with the expertise now cascading through an expanding network of training centres in this important market.

We are working with our distribution partners to launch our range of GI and general ablation products, where the first cases had been expected in the first half of 2020 (prior to the outbreak of COVID-19). Our additional GI devices will be commercialised through the same channels as Speedboat, a model that we will work with distributors to replicate for the ablation product which will target pulmonary/bronchoscopy applications in particular.

To accelerate our route to market capabilities we have identified a cadre of high-quality prospective acquisition candidates to help us build a direct presence in the US and be better positioned to collaborate with distribution partners in other territories. Key appointments have brought extensive expertise in M&A from previous roles at Ernst & Young and Deloitte, and our strengthened balance sheet following our recent fundraising gives us the capabilities and firepower to execute on corporate development activity in a timely manner.

Growing the pie

Conscious that our ground-breaking products and energy platform have valuable application in much broader therapies than we have the resources to target, in 2021 we intend to run the first of a series of developer conferences. The aim is to stimulate third party device manufacturers and innovators to develop products powered by our full spectrum kamaptive technology and the CROMA Advanced Energy Platform (see page 22 for more details on our Kamaptive technology). As well as increasing the overall size of the market for devices based on advanced energy in multiple applications and geographies, we envisage that this open platform approach will also be a source of royalty income for Creo.

Favourable market context

Our experience of working with clinicians and key opinion leaders around the world indicates latent demand for flexible endoscopic surgery devices to allow minimally invasive procedures. We believe that the advantages relative to more established laparoscopic or open procedures are compelling for physicians, patients and healthcare providers, in terms of outcomes and cost.

Detection of cancer has continued to increase as diagnostic capability improves and screening programmes have been extended in key markets (read more on page 4). Growing numbers of cases are being diagnosed at an earlier stage of progression, with smaller tumours particularly suited to endoscopic surgery.

An entrepreneurial team

Our talented team has been enhanced by the appointment of several high-calibre recruits to help Creo in the next stage of its development. We boosted our commercial team with the appointment of three former Olympus employees with commercial leadership roles to help drive our commercial expansion across EMEA, UK and the US. Post period, we have appointed our first US employee who has joined us from PENTAX Medical, bringing extensive sales experience and knowledge.

We are also delighted to benefit from the expertise of our new Chief Scientific Advisor, Joe Amaral, who held leadership positions within the surgical advanced energy division at Johnson & Johnson. Prior to this, a surgeon for many years, Joe co-developed the harmonic scalpel as well as becoming CEO of a major NY hospital. His experience of running a hospital and a surgical department are invaluable commercial and clinical

insights. Our clinical evaluation capabilities have also been strengthened with the appointment of Professor Paul Sibbons, one of the world's leading histopathologists. Paul founded and for many years led the Northwick Park Institute of Medical Research, a pioneering research centre recognised worldwide.

As the business has grown we have been mindful to preserve our innovative, agile and outcome-oriented spirit and 'thinking out of the box' culture, and I am grateful and humbled by the hard work, determination and talent we have in team Creo; we are one tribe.

COVID-19

As 2019 drew to a close we were poised to capitalise on momentum built during the year, whilst the COVID-19 pandemic was gathering force to impact on our lives in ways we could not have imagined just a few short weeks later.

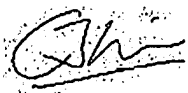
We went into the pandemic slow down with a full calendar of clinical education and mentoring via centres in all our developing markets. At the time, this was with our first and only product cleared in the US and EU – Speedboat. Whilst the front line clinical focus worldwide has rightly focused on caring for patients with COVID-19 and related conditions, procedures utilising our products have, for the right reasons, been delayed as routine diagnostics have been stopped to free up resources for other use.

With our financial strength, we have been able to deploy our staff remotely with almost all the resources they need to continue with our technology development unabated with a skeleton staff operating within the production side of the business where needed. With this clarity of focus, we hope to emerge from the lock-down poised and ready to go with multiple devices cleared for use in the EU and the US. We are continuing to work hard behind the scenes to keep our clinical education and mentoring calendar full for the next 2 quarters ahead and utilising technology to continue with remote mentoring, case reviews and clinical studies with our customers who use this as much needed relief from COVID-19 wards.

We challenged staff to find ways to be productive at home during the lock-down, focusing on the things we can do and not what we can't, whether this is Creo related work or, if their Creo work can not be done from home, work to help in the community or the NHS. I have been humbled by and am very proud to be part of Team Creo, which has not only kept pace with key business objectives, but has managed to deliver some amazing charitable initiatives:

- We have secured over 300 ventilators to help our local hospitals
- A disperse team have acquired over 20 3D printers and laser cutters to set up their own production lines printing PPE masks which they have delivered to local care homes, hospitals, pharmacies and other care workers
- We have delivered an initiative with 100 bicycles donated to front line staff at local hospitals to help with travel to shifts and between hospitals avoiding complicated and lengthy commutes
- Our innovation team have worked day and night to enhance our plasma sterilisation technology to optimise it against the COVID-19 virus with testing of rapidly produced prototypes in the coming weeks

We continue to monitor the COVID-19 situation globally and we are poised with a range of devices ready to relaunch into our key markets. This time is allowing us to strengthen our approach and adapt to what will inevitably be a different world and I am confident Creo will re-emerge from the lock-down, stronger, and with more game-changing products to drive through our global CEP and through our network of distributors and direct sales teams.



Craig Gulliford
Chief Executive Officer
6 May 2020

OUR MARKET OPPORTUNITY

Our solutions will enable transformational procedures that blur the lines between surgery and endoscopy, addressing unmet needs in large and growing applications.

What is electrosurgical surgery?

Electrosurgery is the application of electrical current to biological tissue as a means to cut, coagulate and ablate. Electrosurgical devices were first commercialised in the 1920s for use in open surgical applications. Over time, advancing technology drove innovation into laparoscopy (i.e. keyhole surgery), a field in which there are now a considerable number of devices. In contrast, therapeutic endoscopy or endoscopic surgery has comparatively few surgical tools available.

Endoscopes are effective screening and diagnostic instruments that allow physicians to visualise the internal structures of organs such as the gastrointestinal tract, lungs and bladder via naturally occurring orifices. Endoscopes are not equipped to perform a surgical intervention in most situations. Insertion of the endoscope is surgically non-invasive, avoiding the need for surgical incisions, which, however small, increase the risk to the patient and increase the cost of the procedure.

Endoscope diameter is limited by the size of the entry orifice. For example, a colonoscope will typically be 12mm in diameter, while an orally inserted gastroscope will typically have a diameter of 10mm. Within these confines the endoscope must carry a video camera lens, light source, air/water/suction channel and guide wires to control the insertion. There is very limited space left in an endoscope for instruments, although all endoscopes have a working instrument channel offering approximately 3mm of space through which devices can be introduced. As such, and with the limited device options currently available, while a patient can be diagnosed endoscopically, the majority of interventions still require a minimally invasive surgical procedure at best, or open surgery at worse.

A minimally invasive procedure, such as laparoscopy, improves on open surgery as it can be performed through a few small incisions rather than a single large one. Laparoscopic surgical procedures are versatile as multiple instruments can be placed at the surgical site through multiple bore insertion tubes with short lengths, allowing fast insertion and removal of instruments. Our technologies are designed to enable certain surgical procedures to be effected through the insertion of devices through the working channel of an endoscope, circumventing the need to make abdominal incisions with the associated general anaesthetic.

Endoscopy has been a rapidly expanding practice due to the advent of colorectal cancer screening in most healthcare systems. This has driven growth in equipment and devices to enhance the ability to screen and detect early stage and pre-cancerous lesions in the GI tract.

Why are we targeting particular segments?

There are unmet needs

Advanced therapeutic endoscopy has the potential to reduce the risk of complications, with mortality rates improved to negligible levels. Current mortality rates from upper GI bleeding are up to 15%¹, and traditional colorectal surgery is associated with a 6% mortality rate at 30 days² because of the risks associated with partial or complete removal of the colon when using traditional surgical blades. In contrast to the need for a long hospital stay, endoscopy procedures can be performed in an outpatient clinic.

Despite the rise in incidence rates due to increases in underlying causes and through increased screening, the endoscopist has very few 'tools' to work with. Our Horizon Group of Key Opinion Leaders quantified 76 specific unmet or underserved clinical needs in the GI where advanced energy could be applied.

The markets we address are large

We focus on significant markets where we can bring products to market that serve poorly met needs. Our initial focus is in the GI tract, GI tract accessible soft tissue (liver, pancreas, kidney) and lung interventions.

Colorectal cancer is the third most common cancer worldwide and the second leading cause of death with over 880,000³ related deaths. Obesity, sedentary lifestyles, poor diet and aging populations are key drivers, but increasing screening programmes, earlier detection and improvements in treatment (including at pre-cancerous stages) are reducing incidence and mortality particularly in developed countries⁴.

Soft tissue cancers of the liver and pancreas, whilst lower in terms of incidence have the two highest mortality/incidence rates, exceeding 90% and jointly account for some 1.3 million incidences and 1.2m causes of death⁵. Both cancers are characterised by late stage detection, thereby being mostly inoperable (for pancreatic cancer, less than 20% of patients are candidates for surgery⁶) and have very low 5-year survival rates.

Known as the silent killer, pancreatic cancer is expected to become the second leading cause of cancer-related death in the United States by 2020⁵ with a current 5-year survival rate of 9%⁴. During 2020, more than 57,000 Americans will be diagnosed with pancreatic cancer, and some 47,050 are expected to die⁴. In the UK it is the 5th biggest cancer killer, where the survival rate is only 7%⁶. Approximately three-quarters of patients die within the first year of diagnosis⁶.

The incidence of liver cancer is increasing, driven not only by poor lifestyles, but also as a result of Hepatitis B (HBV) and Hepatitis C (HCV) viruses. Hepatitis is more prevalent in developing countries, though in the US three-quarters of the HCV-infected population are aging baby-boomers (born 1945–65) for whom recommended testing uptake is low (1 in 8)⁴.

Lung cancer is the most common cancer worldwide with the highest incidence and mortality rates (exceeding 1.7m deaths annually)³. There were 46,700 new cases of lung cancer in the UK in 2015, three-quarters of which were diagnosed at later stages⁷. There are no nationwide population-based screening programmes in the US or UK, although the NELSON Study recently recommended that routine screening be introduced for high-risk patients. Approximately 150,000 screenings in the US involve a pulmonary nodule⁸.

In cases of lung cancer, 85% of patients are currently inoperable⁹ and have to rely on radiotherapy and chemotherapy, with the 5-year survival rate only 17%¹⁰. Surgery involves removal of large sections of the lung and even the entire lung. Challenges with existing treatment include difficulties with access for interventional treatment via bronchoscope, since this is limited by the size of the airway (<2mm in the periphery of the lung), poor navigation, and safety considerations, as percutaneous ablation is associated with skin burns, pain, infection and pneumothorax. Technology is developing fast to improve early diagnosis, with an end goal of screening for lung cancer.

The addressable markets are large and growing. The global market for endoscopic devices is estimated to be worth \$30bn, and growing at a compound annual growth rate of 6.3%¹¹. Within this, the global market for energy systems and instruments is valued at \$4.9bn¹. In the UK alone, there were 508 endoscopy units in 2017 and more than 4,000 endoscopists.

In terms of specific applications, the GI endoscopy market, which has seen limited innovation in recent years but a growing volume of interventional techniques, has an addressable market of \$3–4bn, and estimated annual average growth of 4–6%^{13–14}. For example, in the field of colorectal cancer, 16m screening colonoscopies are performed in the US per annum, of which 1.1m identify a lesion requiring treatment¹⁵, of which 50% are surgically removed¹⁶. There are moves to reduce the screening age in the UK and US, for example, as incidence has grown among a younger demographic.

For liver, pancreas and kidney treatment, endoscopically delivered fine needle microwave ablation provides minimally invasive treatment to manage tumours, and extend and improve quality of life where limited alternative surgical intervention options exist.

In bronchoscopy, there is demand for new therapies and growth is driven by screening, but, as mentioned above, no interventional options are currently available. Worldwide, there are 1.7m³ cases of lung cancer related deaths each year.

Longer-term opportunities include laparoscopy applications, with an estimated addressable market of \$8bn¹⁷.

Drivers of growth in demand for minimally invasive surgery include:

- emerging applications and technological innovations, bringing compelling benefits that are recognised by patients, clinicians and healthcare providers;
- aging population and incidence of life-threatening diseases; and
- increasing patient awareness and influence over their treatment.

Why do we believe in the market opportunity?

There is a precedent: similar paradigm shifts have previously taken place in other fields of medicine. The transition from open surgery to laparoscopic surgery from the early 1990s is the obvious example. In recent years, advances in single-port laparoscopy, robotic surgery, natural orifice transluminal endoscopic surgery and flexible endoluminal endoscopy have heralded a new era of healthcare.

Thought leaders are advocating our solutions, and promoting the 'Anything is possible with the right approach' mindset to educate and engender confidence among endoscopists, blurring the lines between these practitioners who have typically specialised in investigative work, and surgeons. This is revolutionary: procedures that previously took place in the operating room can now be undertaken in an endoscopy room, with material advantages in cost, time and patient outcomes.

1. Annals of Hepatology, Vol. 10 No.3, 2011: 287-295.
2. Ann R Coll Surg Engl 2011; 93: 445–450.
3. WHO, IARC Cancer Today Online Analysis 2018.
4. American Cancer Society, Cancer Facts and Figures 2020.
5. Lola Rahib, Benjamin D. Smith, Rhonda Aizenberg, Allison B. Rosenzweig, Julie M. Fleshman and Lynn M. Matrisian. Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States. DOI: 10.1158/0008-5472.CAN-14-0155 Published June 2014.
6. Pancreatic Cancer UK fact sheet.
7. Cancer Research UK (<https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/lung-cancer#heading-Zero>, accessed March 2019).
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OUR BUSINESS MODEL

Resilient and scalable.

We have established a resilient and scalable model that combines the strengths of our pioneering products with the reach of our strategic partners for the benefit of our stakeholders.

INPUTS

We will create value through our unique resources and relationships

Expertise and IP

Our talented team of world-class developers is drawn from diverse related disciplines, spanning military radar to medical devices.

Our IP portfolio comprises 188 granted patents and 599 pending applications (as at 31 December 2019), all in the area of electrosurgical energy generation and control, together with a range of applicator structures for advanced tissue management.

Strategic relationships

We establish and nurture relationships with eminent clinicians and Key Opinion Leaders practicing in our fields of interest around the world. These relationships help us to hone our devices, generate clinical data and develop a network of influential advocates who help drive adoption of our CROMA Advanced Energy Platform and electrosurgical devices.

Our framework distribution agreements to provide clinical training and market seeding will allow us to scale our presence and provide a platform for the distribution of our products – once commercialised – in key markets around the world.

Long-term investors

During 2019 we significantly strengthened our balance sheet following the successful raise of an additional £51.9m (before expenses).

Sizeable shareholdings are held by key members of our team, as well as strategic partners, and our status as a public company gives us access to capital to achieve our vision.

KEY DIFFERENTIATORS

We will grow value through our resilient and scalable model

RESILIENCE

Recurring revenues from 'razorblade model'

The CROMA Advanced Energy Platform has a single accessory port compatible with the suite of single-use devices that use microwave and RF energy for cutting, coagulating and ablating in various procedures.

Platform technology

The CROMA Advanced Energy Platform has valuable application in much broader therapies than we have the resources to target. As we grow, we intend to stimulate third party device manufacturers and innovators to develop products that utilise the adaptive technology of the CROMA Advanced Energy Platform. As well as increasing the overall size of the market for devices based on advanced energy in multiple applications and geographies, we expect that this open platform approach will also be a source of royalty income for Creo.

Diversified applications

The precise cut, coagulation and ablation capabilities of the CROMA Advanced Energy Platform have application in a range of electrosurgical procedures where tissue resection with haemostasis (control of bleeding) and/or the ablation of tissue is required. The ability to bring precision and control to long, flexible devices opens up opportunities in minimally invasive surgery.

Our strategy is to deliver new therapies and therapy-enhancing technologies which have compelling health and economic benefits for the global healthcare system. We will initially focus on the gastrointestinal endoscopy market, potentially expanding to bronchoscopy and laparoscopy over time.

SCALABILITY

Rich pipeline

Our pipeline of instruments is built around our core technologies, initially focused on applications throughout the gastrointestinal tract, with other devices targeting GI accessible soft tissue ablation and bronchoscopy.

Education-led commercial strategy

We build advocacy through a network of Key Opinion Leaders to endorse and deliver a training programme to endoscopists in the use of Speedboat and the CROMA Advanced Energy Platform. In addition, we are accelerating the Creo Education Programme through agreements with world-class distributors, who will deliver training for clinicians supported by Creo's clinical education team ensuring consistently high standards.

Large and growing addressable markets

The GI endoscopy market has an addressable market of \$3–4bn and estimated annual average growth in GI instruments of 4–6%. Other target applications are soft tissue ablation, bronchoscopy and laparoscopy markets.

Pragmatic manufacturing model

We have dedicated spaces for innovation (Bath), design and development (Bath/Chepstow), and cleanroom manufacturing and assembly (Chepstow). In the short-term we plan to retain manufacturing largely in-house to ensure quality control. We have initiated the outsourcing of aspects of the manufacturing process to increase capacity and reduce production costs in the medium-term.

Wide sales and distribution reach
We have framework distribution agreements with specialist partners in key markets around the world, initially covering clinical education and market seeding.

VALUE CREATION

We will share value with our stakeholders

Patients
Improved outcomes, including lower risk of remote burns and thermal damage to adjacent tissue, faster recovery and less time in hospital.

Physicians
Peace of mind from a safe, fast set-up of a procedure that can be used in surgery and endoscopy, with predictable tissue effect and saving of considerable time.

Healthcare providers
Improved outcomes and lower costs resulting from the use of endoscopy suites rather than operating theatres (and endoscopists rather than surgeons) and reduced need for hospital stays for patients.

Investors
Attractive growth prospects.

Employees
Dynamic, creative and entrepreneurial culture, with exciting opportunities for development.

Operational execution.

We recognise where Creo is in its evolution and our need to focus on 3 key strategic pillars.

PROJECTS TO PRODUCTS PROGRESS

Having gained FDA clearance and CE mark accreditation for our CROMA Advanced Energy Platform and Speedboat device and trained multiple clinicians, our clinical database has continued to grow. The majority of procedures were for lower GI conditions, but in a small number of cases Speedboat was also used in upper GI applications for the first time.

We launched our suite of GI devices at the United European Gastroenterology Week Congress in October.

We have completed the technical files for our suite of devices and, with revised arrangements with the Company's Notified Body, all four products will be CE marked in Europe simultaneously on receipt of the Company's new EC certificate.

In March 2020 we received FDA 501k clearance for our HS1 Haemostasis Device and we remain on track to gain clearance with the remainder of our suite of products in the USA.

PRIORITIES

We are focused on working with the FDA to obtain clearance for the suite of products to complete the pending CE Mark, to enable their launch into EU and US markets, and in Asia-Pacific.

PRODUCTION TO MANUFACTURING PROGRESS

We recruited a number of new employees during the period to further bolster the operations team. We have the ability to double output with minimal investment.

We are in the final stages of agreeing a third party manufacturing contract to facilitate larger scale production and have validated the first batches of products from a third party manufacturer and are confident of the high quality and consistency of production.

We are also appraising other third party manufacturers to ensure that we continue to de-risk our supply chain.

PRIORITIES

We have started and will continue to develop our initiative to partner with third party manufacturers to outsource selected elements to maximise efficiency and scalability.

TRAINEES TO USERS PROGRESS

We have now trained clinicians from the USA, India, South Africa, Japan, Australia and Europe, and are working to convert trainees into users by changing treatment pathways.

We have had trainees attend the Clinical Education Programme during a weekend and then deliver their first mentored upper and lower GI cases in clinic on the Monday following.

PRIORITIES

We will continue to broaden our coverage of new geographical markets by leveraging relationships with third party distributors, and will look to introduce additional products to our Clinical Education Programme once they are available for use. We will continue work with Key Opinion Leaders in the US to drive advocacy.

We intend to expand into adjacent markets, either organically, through partnership or acquisition.

Our 2019 focus.

Converting our four new game changing prototype devices to products that can be used to treat patients in 2020.

A compelling portfolio ready for commercialisation

Effective team working and drive over the last 12 months enabled us to take four new devices from the design freeze stage to fully validated products.

We believe that each new product offers sizeable clinical advantages in terms of focus and control of the energy delivered into target tissue, resulting in the potential to produce significantly better patient outcomes.

From a personal perspective, I am excited that we are now in a position to be able to treat a range of tumours within the body using our two new miniature flexible ablation devices.

We are proud to have developed what we believe to be the world's smallest flexible focused microwave antenna, capable of delivering energy into target tissue at one of the highest microwave frequencies ever used in electrosurgery to enable the necessary focus and overcome perfusion. We also believe we have the world's smallest diameter needle antenna, designed to be the same diameter as the small fine needle aspiration devices used to take small tissue biopsies to limit any disruption to the operation of the organ. To have devices such as these in our armoury to combat cancer makes the extreme dedication from the engineering teams all worthwhile.

The flexible devices have potential not only for treating tumours and nodules in the lungs, but also open up the opportunity to treat in ear, nose and throat (ENT) applications. For example, the sub 2mm diameter flexible antenna offers potential to treat nasopharyngeal cancer and nasal polyps, something that the business will consider further as we progress with our commercialisation plans.

With our new combined dual mode bipolar RF, with fixed field and variable field bipolar RF electrode arrangement, and microwave energy delivery miniature resector and non-stick microwave energy-based hemostasis device, we now have a full set of tools for treating the upper and lower GI tract as well as performing natural orifice transluminal endoscopic surgery (NOTES). The devices we have developed really open up the capability of our adaptive microwave and bipolar RF CROMA Advanced Energy Platform.

Our Speedboat device has gone from strength to strength this year, with trainees now converted to trainers around the world. Speedboat has been used to remove both cancerous and pre-cancerous lesions from the upper and lower GI tract to provide transformative outcomes. The device has also been used to perform per oral endoscopic myotomies (POEMs) in cases where the lower oesophageal junction is constricted, causing patients difficulty with eating. Speedboat has been used to tunnel between the submucosal and muscle layers within the oesophagus to cut and release the muscle, allowing the patient to eat food again!

Strong IP

In the last 12 months we have exceeded expectations in terms of filing new inventions to protect our Advanced Energy Platform and new devices. In total, 14 new inventions were filed in the period between 1st January 2019 and 31st December 2019.

The instrumentation for an additional energy modality based on nanosecond and picosecond pulses for irreversible electroporation (IRE) was captured and filed in 2019 – this offers another mode of therapeutic energy delivery to treat cancer and potentially be used to treat fine tissue structures without causing damage to the connective tissue or the extracellular matrix.

A number of key patent applications relating to our CROMA Advanced Energy Platform and miniature flexible instruments were also granted during the period. In the 2019 calendar year, 55 new worldwide patents were granted, taking Creo's patent estate to 188 granted patents and 599 pending applications in 15 jurisdictions across the globe, spanning Europe, UK, US, China, Japan, Singapore, South Korea, India, Australia, Hong Kong, Canada, Brazil, Russia, South Africa and Israel*.

* As at 31st December 2019.

Medium-term product roadmap

Beyond the immediate roadmap of flexible advanced energy devices, Creo has a large IP estate with a wide range of potential clinical applications, all powered by the CROMA Advanced Energy Platform.

The CROMA Advanced Energy Platform will benefit from a roadmap of improving capability based on the current and broadening IP portfolio and technological advances in microwave and RF power devices, signal processing, electromagnetic modelling tools and rapid prototyping equipment. Our research projects will bring additional modalities to the CROMA Advanced Energy Platform and a continuing versioning roadmap of software will deliver intuitively operated devices to the clinical community.

A significant portion of the Creo IP estate protects our non-thermal plasma technology for use in several applications, including wound care, urinary tract infections, hospital associated infections and endoscope sterilisation. This technology has been validated through work with microbiologists at UCL Hospital and the University of West of England where we have demonstrated that our non-thermal plasma produces a significant log reduction of microorganisms, as specified by the FDA. We also now have a project running with UWE to investigate the effect of our non-thermal plasma on biofilms.

A second family of devices on our medium-term roadmap is a family of laparoscopic devices, where a number of our flexible endoscopic devices, such as Speedboat and resector products, can be refactored to deliver microwave and RF energy at the end of a rigid 300mm-long catheter. The Creo IP families already in place to protect the Speedboat blade and a range of scissor structures and jaw arrangements that deliver both microwave energy for coagulating tissue and bipolar RF energy for cutting tissue cover both rigid and flexible laparoscopic devices.

Creo had further success in 2019 as the commercial partner in the HORIZON 2020 SUMCASTEC project. With responsibility for the cell neutralisation aspect of the work, in 2019 we developed both new high-voltage picosecond and low-power millimetre wave generators. These novel generator modules are delivering 'non-thermal' effects that are being analysed with regard to their impact on medulloblastoma, glioblastoma and other cells in fluid cultures. We are also about to embark on a study to apply irreversible electroporation (IRE) pulses to bulk tissue in the colon, pancreas and lungs to see if it is possible to destroy unhealthy or cancerous cells without causing any damage to connective tissue. Two new

patent applications on nanosecond and picosecond electroporation generators were filed in 2019. This research programme has potential to enhance the CROMA Advanced Energy Platform with the inclusion of non-thermal capability to complement RF, microwave and non-thermal plasma modalities.

Innovation in our IP

IP management

We take IP management very seriously. For a company of our size we have an extensive suite of patents, including an array of foreground and background patents to protect our core innovations. Our IP portfolio is centred on our CROMA Advanced Energy Platform and instruments that can be used to deliver microwave and RF energy into tissue to perform bronchoscopic, endoscopic (including endoscopic ultrasound), laparoscopic and open procedures.

From 1 January 2019 to 31 December 2019 Creo was granted or allowed 55 new patents. We also filed 14 new inventions during this period to protect future medical device ideas and to enhance the protection we have on our technology.

IP estate

The Creo IP estate has developed not only through new innovative inventions protected by the constant filing of new GB applications and existing patent applications reaching the International and National Phases, but through key applications being granted in the UK and all over the world.

188 granted patents.

599 patents pending

Overview of Creo Medical Families

Name	Patient	Application
Speedboat		
Speedboat	26	25
Haemostat	1	27
Resector & Grasper		
Graspers	23	60
Radiating Snare	11	27
Resector	12	19
Cold Snare	3	9
Kamaptive Technology		
Platform Generator & Interface Elements	57	212
Ablation		
End Ablator	1	14
Duodenal Ablation	0	20
Ligament Tightening	0	13
Scope-Conveyed Flexible Ablator	10	119
Fluid & Plasma		
Plasma Sterilisation	26	21
Abc/Apc	10	10
Lipotunneller	8	2
Cyst Treatment	0	12

As of 31 December 2019, we had 188 granted patents and 599 pending applications around the world.

Jurisdictions: US, CN, JP, CA, IN, SG, AU, HK, KR, IL, ZA, BR, RU, EP (AT, BE, CH, CZ, DK, DE, ES, FR, GB, GR, IE, IT, NL, NO, PT, SW)

CROMA

Our unique Advanced Energy Platform is built upon Creo's patented technology to allow the delivery of focused high-frequency microwave and bipolar radio frequency energy through a single accessory port.

Immediate Product Roadmap

CROMA Advanced Energy Platform

Our unique CROMA Advanced Energy Platform is built upon Creo's patented technology to allow the delivery of focused high-frequency microwave and bipolar radio frequency energy through a single accessory port, enabling the use of a range of novel miniature endoscopic devices with precise and highly controllable cutting, coagulation and ablation capabilities. The precise closed loop control on both the RF and microwave channel enables the quantum of energy delivered into patient tissue to be dynamically controlled to ensure optimal tissue effects are achieved.

Pending patents

599

Granted patents

188

Creo Medical Devices

CROMA's GI Suite powered by Kamaptive

Resector ('RG-1') is believed to be the only bipolar flexible RF and MW scissor device in the world with dual action RF energy delivery. Building on the Speedboat blade technology, RG-1 enables the clinician to grasp, cut and coagulate highly perfused tissue (such as in the colon, stomach, liver or spleen). The ability to alternate between cutting and coagulating using RF and MW energy across the 'jaws' of the RG-1 gives the clinician significantly more control and is a strong differentiator. The device provides a gliding cut using a fixed bipolar RF field as well as a conventional bipolar RF cutting between two jaws at opposite polarities, and offers great utility to bloodlessly resect/dissect and coagulate in a wide range of organs within the human body by sequentially applying the microwave field followed by the RF field to coagulate and then cut.

Speedboat ('RS-2') is our multimodality bipolar RF and focused microwave energy blade antenna, with integrated needle injection capability, superior rotation and a physical shape that provides underlying tissue protection. Speedboat has now been used in multiple applications all over the world for dissection of pre-cancerous and cancerous lesions in the lower GI tract and upper GI as well as other procedures such as Peroral Endoscopic Myotomies (POEMs). Speedboat enables the endoscopist to (i) lift tissue with viscous fluid injection via a retractable needle, (ii) cut tissue precisely using bipolar RF energy delivered along the edge of the instrument for localised energy transfer, allowing for a lower energy requirement reducing the risks associated with monopolar tissue resection (where the current passes through the delicate tissue structure, and returning via a large dispersive pad), and (iii) deliver high frequency controlled and focused microwave coagulation, all within a single instrument. The Speedboat device was CE marked for lower GI tract use gained FDA clearance for upper and lower GI tract use in 2017 and was commercially launched in October 2019.

Needle Probe tissue ablation device ('NP-1') is believed to be the smallest diameter MW ablation needle antenna in the world. With a diameter of less than 1mm, the NP-1 device can be used in a variety of ablation procedures such as open, laparoscopic and flexible endoscopic procedures. Designed to be the same form and dimensions as a standard biopsy needle, NP-1 is designed for the ablation of a wide range of tissue types (such as liver, kidney, lung, muscle and pancreas). Due to the small diameter of the device, it can be used to ablate tumours in highly perfused organs without the risk of bleeding prior to energy delivery due to the sub-mm insertion tract. The device also has potential to treat certain brain tumours.

Haemostasis probe ('HS-1') is thought to be the only non-stick, MW haemostasis device in the world for the treatment of upper and lower GI bleeds, such as stomach ulcers or bleeding polyps. While the market is dominated by RF energy devices, the HS-1 offers clinicians a MW energy option. Importantly, unlike traditional RF electrodes that require direct electrode contact for the current to flow, MW energy does not require a current path or direct tissue contact, allowing the device to have a non-stick coating applied. This non-stick coating allows the device to be removed without sticking to the coagulated tissue, thus overcoming a key disadvantage of traditional RF 'sticky' devices that can cause the bleed to restart, adding risk to the patient. Furthermore, with traditional RF devices energy is sometimes applied for longer than is necessary, which can result in tissue charring, which is extremely undesirable.

Flexible Ablation Device ('AB-1') is a new soft tissue ablation device, designed with the aim of being able to ablate nodules and tumours in the lungs, in particular the airways, using the highest frequency MW energy used for tumour ablation. This device also has potential to be used to treat a number of other conditions, where a small diameter flexible device enables access into otherwise inaccessible regions of the body. The device could be particularly useful to treat a range of ENT indications, including nasopharyngeal cancer and nasal polyps. Due to its small size and flexibility, the AB-1 has the potential to reach deep into the lung where, once in position, the device can be inserted through a catheter and into the tumour.



Professor Christopher Hancock

Chief Technology Officer
6 May 2020

Introducing Kamaptive Technology

Figure 1: Global market for Endoscopic Devices

1 GI Endoscopy

- Limited innovation in recent years
- Growing volume of interventional techniques
- Upper and lower GI either within the gastrointestinal tract or accessing close-by organs
- \$3–4bn addressable instrument market^{2,3}
- 4–6% annual growth²

2 Bronchoscopy

- Growth driven by screening
- No interventional options available
- Demand for new therapies

Long-term opportunities

- Other endoscopic markets
- Laparoscopy \$8bn addressable instrument market⁴
- Non-thermal plasma
- Endoscopic sterilisation
- Wound care

1. Data presented is total segment value – including imaging and devices; "Endoscopy Devices: Applications And Global Markets" (HLC093A), BCC Research, 2011.
2. Boston Scientific investor presentation, 2015.
3. Conmed investor presentation, August 2016.
4. Medtronic investor presentation, June 2016.

The long-term roadmap – open approach to innovation

Our ambition is for our CROMA Advanced Energy Platform and instruments to be used in all hospitals all over the world to treat as many clinical conditions as possible via endoscopic, bronchoscopic, laparoscopic and open surgical procedures, including wound treatment and tumour ablation.

We have a very open approach to innovation, both within Creo and beyond, ensuring that we work closely with diverse clinicians throughout the world and factor their feedback into our new products. Within the business, we hold regular innovation workshops. We also have a long history of collaborating externally with various academic institutions such as Bangor University, University College London (UCL) and University of West of England (UWE). A recently awarded Royal Academy of Engineering Visiting Professorship at UCL has enabled even closer links between Creo, UCL School of Engineering and UCL Hospital.

Long term, as the CROMA Advanced Energy Platform capability develops, we intend to explore opportunities to collaborate, partner with or license to device manufacturers and innovators, large and small, in multiple markets worldwide, where the device engineering capability exists. We are now working with a number of design houses that could potentially develop new devices compatible with Creo's CROMA Platform.

Any innovative partnering and engineering agreements we enter to stimulate wider IP creation will include crucial control steps to maintain the core values of intuitive, self-provisioning and safe to use advanced energy devices powered by the CROMA Advanced Energy Platform, to change the life of patients throughout the world, where we can offer improved patient outcomes.

What is Kamaptive technology?

Creo's CROMA Advanced Energy Platform is powered by Kamaptive full spectrum adaptive technology. Kamaptive technology is the seamless, intuitive integration of multi-modal energy sources, optimised without compromise to adapt to the tissue effect required for different procedures. Kamaptive intuitively adapts to the different devices in use, self-provisioning and adapting the settings of the CROMA Platform for the purpose of the device being used. Kamaptive utilises all modes available to make the clinical experience as simple and intuitive for the user as possible, combined with real-time adaptive feedback to optimise the clinical effect allowing the clinician to focus entirely on the patient and the procedure. Utilising the full spectrum of energy modalities available to it, Kamaptive creates a simple, intuitive and safe environment for the user and the patient.

Kamaptive & our products

Kamaptive technology's architecture allows multiple Creo Development teams to design, test and build innovative devices independently whilst functioning with the CROMA Platform without complex software changes or menu options for users. This plug and play architecture allows Creo's designers and engineers to focus on patient safety and the required clinical effect.

Investing / partnering opportunities

The architecture developed and capability within the CROMA Platform has multiple surgical applications. Powered by Kamaptive, joint development with key partners has the potential to become an integrated reality. Creo is developing collaborative development relationships with a number of potential key partners in areas such as Robotics and Laparoscopy where new technology could be developed carrying the 'powered by Kamaptive' seal.

Developer conference

During the development of CROMA, Speedboat and other devices, Creo has been approached many times by device developers from all over the world to explore developing their own devices for which they need an advanced energy source. CROMA is an integrated platform with multiple surgical modalities. These modalities are continuously being expanded to include higher frequency millimetre-wave sources, electroporation capability as well as thermal and non-thermal plasma control. Powered by Kamaptive technology, Creo will be stimulating worldwide developer conferences to allow third party device manufacturers to develop their own devices to be powered by Kamaptive.

COMMERCIAL REVIEW

2019 has seen some significant steps forward for the business across all areas of the commercial operation.

Building on the achievements in 2018, the primary goal during the reporting period focused on preparing to leverage the planned completion of the wider suite of GI devices to allow us to build on the great clinical results we continue to generate from the Speedboat device. Highlights for the period include:

- Validating the Creo's Clinical Education Programme's first training centre up and running in the USA with doctors through the program and getting great results in their patients
- Extending our distribution reach with additional framework agreements signed up in Germany, Italy, France and India
- Launching the entire suite of GI devices and CROMA powered by our Kamaptive full spectrum adaptive technology at UEGW in November
- Rolling out the Clinical Education Programme (CEP) for the first time in the US, Germany, Italy, France and India, with patients treated by several doctors in each territory
- Processing initial purchase orders for products for Speedboat as expected
- Holding multiple live Speedboat cases in Spain, UK, USA, Greece and India broadcast live to large audiences of physicians including cases broadcast live via Facebook
- Quadrupling our clinical nurse advisory resources as part of a program of increasing resources to support our direct and distributor led mentoring programs to strengthen our education and patient outcome focussed programme
- Ramp up of clinical cases in the US and UK
- Establishment of further COEs in the US and UK
- Attracting significant industry leadership to lead the commercialisation drive, bringing over 100 years' of surgical device sales and marketing experience into the team in the last 12 months
- Post period, securing senior leadership talent to lead the direct market development team in the USA

Education led market development strategy

The evolution of Creo's CEP during the reporting period has been extremely successful, resulting in a consistent, repeatable programme with predictable results. Our strategy of investing heavily in a novel, immersive peer-to-peer CEP continues to develop. Most pleasing of all is that on multiple occasions we have had trainees attending the programme during a weekend to then deliver their first mentored upper and lower GI cases in clinic on the Monday morning and with others utilising Creo's technology on their patients within a week of completing the course. This has taken place in the US, Australia, India and the EU. This is validating our program and investment in this area, which we are continually strengthening with the extension of our clinical mentoring and customer support resources irrespective of a distribution or direct sales approach.

As we now embark on the launch of a full suite of GI devices, leveraging the existing estate of CROMA installations, it is very satisfying to continually gain feedback from our doctors regarding the performance of our technology and Speedboat with the coagulation performance described with phrases such as "wow!" and "amazing!". With the recent FDA 510(k) clearance of our first non-stick haemostasis technology adding to the suite, we are now working hard to line up initial use of each of the wider suite of new products to treat patients in our current markets as soon as the COVID-19 restrictions are lifted.

In short, in 2019 we have validated our CEP with our own trainers enabling new doctors to use the technology with their patients. After a number of their own cases, these doctors have gone on to operate the same programme successfully, enabling the next wave of doctors to treat their patients within the year. This validates how we can scale the program around Speedboat, our challenge in the years to come is to enhance the CEP to include the new devices with similar results. We continue to receive routine feedback from our customers who tell us this is the best executed, most immersive programme they have experienced.

Expanding our distribution network

As in previous years, demand from potential distribution partners remains strong and we have selected and appointed additional distribution partners in Europe and Asia. We have taken a deliberate approach to introductory framework contracts to remain agile and adaptive to build the business. The product marketing and CEP is heavily supported by Creo with on the ground logistical support from our distribution partners. We have selected different types of distribution partners in different markets and as we fully roll-out the suite of products we will be in a position to maximise which approach and business fit our model. Some of our partners are large corporate entities, some are smaller, focused, family run distributors, each with strengths and weaknesses. They are all united in a passion and desire to build Creo, CROMA and our devices powered by Kamaptive technology into their businesses. As our experience grows, this will inform the continuing expansion of our distribution into additional markets in the EMEA, APAC and South American markets.

Equally satisfying, as above, we have quickly rolled out the CEP in these new territories, enabling doctors to use the technology to care for their patients within a much shorter time frame than during our early commercialisation. Prior to the COVID-19 lock down we had a full CEP booked in for the first 4 months of the year at multiple Clinical Centres of Excellence and multiple trainers. With the recent progress made with the GI suite of devices, we also look forward to working with our Horizon network of worldwide key opinion leaders to integrate these new devices into the CEP and launching these into treating patients in many areas over the next few months.

Building the commercial foundations of the future

The soft launch Speedboat and CROMA Advanced Energy Platform in the last 18 months has given us the kernel of infrastructure we need ahead of launching the wider suite of devices. Now, with a global network of initial distribution partners and the beginnings of a direct market presence in the US we have been working hard to extend the resources within the team in tandem with securing the financial resources which may assist with M&A to strategically acquire growth in direct sales and clinical support presence. We continue to build the clinical support resources to support both direct and indirect markets where we will always target a direct local clinical presence in our markets as our range of game changing devices extends in the coming years.

The clinical support team has quadrupled in size during the period, with highly experienced nurse endoscopists joining the business and spending time every week on the road with our clinicians in the endoscopy unit while patients benefit from our technology. In addition, we have built on the team with senior leadership to oversee our commercial operations in the UK, EMEA, APAC and the USA. This leadership team is driving the expansion of our sales, marketing, service and logistics operations. Our goal is always to stay ahead of the curve, striving to be recognised as an industry leading, patient focused, sales, service and clinical support organisation to complement our CEP and challenging our distributors to step up with us.

Expanding the brand

With the initial launch of the suite of GI products in October, we worked hard to step up the branding of the business, the platform, our devices and our full spectrum multi-modality advanced energy platform. We launched a fresh brand for the CROMA Advanced Energy Platform and began

rolling out the Kamaptive brand with an integrated brand hierarchy enabling us to maintain brand identity from the corporate branding, through CROMA, our devices and to Kamaptive. The Kamaptive brand will become an increasingly important dimension as this powers third party devices developed and powered by Kamaptive technology.

During 2019, we increased our commercial presence, attending four major international conferences in three continents, in particular at UEGW in the final quarter where we launched the GI suite into our first distributor conference. In addition, we have supported several distributors and Key Opinion Leaders at live endoscopy events with live Speedboat cases broadcast to auditoriums of visiting physicians as well as live via social media. These events again were spread across the key markets of the EU, US and APAC.

As the portfolio develops our conference attendance in the next few years will develop across broader GI conferences as well as conferences representing other clinical associations including interventional radiology, pancreobiliary and pulmonary.

We have recently hired Marketing and Communications leadership to lead the challenge of customer, distributor marketing and communications, securing the brand identity with an expanding web, social media and more importantly a range of digital, on-line, remote and on-site material support for the CEP and our ambition to launch an expansive and immersive remote mentoring, peer-to-peer support, review and publishing framework.

COVID-19 and the medium-term outlook

The COVID-19 crisis has clearly impacted the commercial operations to a greater extent than the rest of the business. While the development, research and regulatory sides of the business can continue to produce almost unhindered, the front line CEP has been stalled completely, with most of our users redeployed to COVID-19 related care as routine diagnostics have been completely stalled. However, the lock-down has given us the opportunity to accelerate our remote mentoring and peer-to-peer review program. In the spirit of focusing on what we can do not what we can't do, with the cancellation of our biggest conference of the year at DDW in Chicago, we will be operating a remote version of DDW with remote workshops and case reviews with groups of on-line physicians who would otherwise have attended the hands-on learning zone we had planned to host at DDW.

Planning for the introduction of the new products into first human use has stalled, but we expect this to pick straight up where we left off once the lock-downs are lifted and hospitals get back to more normal operation. Our expectation is a lifting of restrictions starting at the end of Q2-2020, but we do not expect CEP to be kick-started again until towards the end of Q3-2020 along with more routine endoscopy procedures. Overall, we expect a short-term surge in screening endoscopy to catch up on 6 months of stalled service. Sadly, our working assumption is a shift to later stage of diagnosis for a period of time due to the gap in screening which our devices may well be able to help with.

Our vision is to improve patient outcomes through the development and commercialisation of a suite of electrosurgical devices, each powered by our **CROMA ADVANCED ENERGY PLATFORM.**

OUR PEOPLE

Exceptional leaders and partners.

Our talented team at Creo is complemented by our network of key opinion leaders and distribution partners.

The Creo Medical team

We are a broad church. Led by our founder and CTO Chris Hancock, our development team includes specialists from multiple sectors. We think laterally and fish from a broad pool when it comes to recruiting the best talent.

Our backgrounds may be diverse, but our enquiring minds, hunger for solutions and relentless drive mean we work as a cohesive team. We love nothing more than bouncing ideas around and get very excited when concepts from our different fields come together. Our monthly innovation workshops are open to all colleagues.

In addition to two Professors, Team Creo is an amazingly well-qualified team with:

- >10% Phd**
- >20% post graduate**
- >60% degree qualified**

Wider Creo family

We don't limit ourselves to our recruited talent. Our ever growing network enables Creo to utilise a wide range of consulting talent with extensive experience drawn from product design, microwave engineering, software development and medical devices.

Our culture is fundamental to the way we work, and we have distilled this into five core values:

Collaborative

- Collaboration makes being disruptive positive, beneficial and effective.
- Collaboration with our colleagues and business partners enables us to turn our creative ideas and inventions into real innovations.

Creative

- Our diverse team means that we create original and therefore more effective approaches to medical device challenges.
- This approach is born from being inquisitive, always learning, and being passionate about turning ideas into reality.

Life changing

- Our aim is for medical devices to be simpler and safer to enable better patient outcomes that are less invasive.
- Our innovations and the clinicians who use them change lives for the better.
- We have an uncompromising adherence to ethical excellence.

Can-do

- We believe that our 'can-do' approach, the energy to take action and our hunger for solutions mean that we can succeed in our goals.
- We face challenges with the kind of courage that comes from a personal belief in not only what we are doing, but why we are doing it and what it means for the wider world.

Disruptive

- We challenge assumptions and the status quo.
- Our goals are nothing less than a paradigm shift in the medical device market and to deliver life changing products.

PRINCIPAL RISKS AND UNCERTAINTIES

Approach to managing risk.

The Audit Committee formally reviews the effectiveness of the Group's risk management processes and internal control systems on behalf of the Board. The Board has overall responsibility for risk management and internal controls. Our risk management process is designed to identify, evaluate and mitigate significant risks to the business.

Although we believe that our risk management procedures are adequate, the methods used to manage risk may not identify current or future risks or the extent of future exposures.

Commercial, operational, regulatory and legal risks

Risk	Description	Mitigation
Market acceptance of current and new products	There can be no assurance that our technology will prove to be an attractive addition or alternative to existing surgical devices. Conversely, the business needs to be able to scale up in the event of rapid adoption of our products. The development of a market for our products (and the timing of this) is affected by many factors, including: (i) the emergence of newer, more competitive technologies and products; (ii) the cost of our products; (iii) regulatory requirements; (iv) customer perceptions of the efficacy and reliability of our products; and (v) customer reluctance to buy a new product.	We engage with Key Opinion Leaders and clinicians on the development of our products, gathering feedback in order to develop products that meet their needs. • Our Clinical Education Programme is designed to educate clinicians on the safe and effective use of our products. • We continue to develop our product portfolio beyond the initial suite of products to give depth and breadth to the business. • We have designed the business to be scalable, for example with the management structure, facilities and our approach to training clinicians. • Our strategy to work through multiple channels to market will share some risk with third party distributors.
Product development	Much of our future revenues will depend on our ability to continue to develop new products. These products may take longer to develop than planned, require more resources or may pose technical challenges that we cannot solve.	• New product development is complementary to work already being undertaken by the business. We are therefore able to leverage existing skills and knowledge. • The Creo team have a depth of knowledge and experience in the devices that they are developing. • We plan to allow select third parties to develop devices that are compatible with Creo's CROMA Advanced Energy Platform. In doing so, product development risks are passed to third parties whilst increasing the end user's ability to exploit the benefits of Creo's platform technology.
Regulatory risk	Our products are regulated by national and regional medical device regulations; there can be no assurance that we will receive regulatory approvals on a timely basis, or at all. There may also be regulatory changes that could require additional studies and a need to resubmit products to the regulatory authorities. We also need to comply with ongoing regulatory requirements, such as to maintain a quality system, for which we are subject to periodic inspections (scheduled and unscheduled), restrictions in relation to promotional materials and post-market safety surveillance programmes. Reimbursement of medical devices in Europe is determined on a country-by-country basis, at a national level or, in some cases, by regional authorities within countries. Securing reimbursement may require us to collect and disseminate further data to demonstrate the clinical value and cost-effectiveness of our products, and there can be no assurance that the reimbursement process will be successful. On Brexit, the UK may require alternative standards to the prevailing CE standards requiring additional regulatory approval of our products before they can be offered for sale in the UK.	• We have CE marking and FDA clearance for our Speedboat device and CROMA Platform. Post period end we received FDA clearance for our HS1 device. As at 31 December 2019, our suite of devices are in varying stages of the regulatory clearance process. • Our QMA team is focused on the regulatory needs for product development and develops quality documentation to support all regulatory applications. • We are ISO: 13485 accredited and are subject to regular audits from bodies such as ISO and BSi. • All documentation is stored and available should any resubmission be necessary, and our quality systems are designed to be sufficiently robust to withstand any necessary scrutiny. • We are working with local distribution partners to mitigate exposure to reimbursement risk. Local distributors will identify the pricing locally to establish whether a particular market is worth pursuing. • We have taken steps to ensure that our CE registrations remain valid within the EU post Brexit, by novating our notified body to BSi in the Netherlands.

Risk	Description	Mitigation
		We continue to monitor the UK's exit from the EU and will take necessary actions to register products in any alternative UK-based system as and when required.
Risks relating to IP, proprietary rights and confidential information	We rely primarily on a combination of patents and proprietary knowledge, as well as confidentiality procedures and contractual restrictions to establish and protect our proprietary IP rights. There can be no assurance of obtaining new patents, or that existing patents will provide us with sufficient protection in the case of an infringement of our technology or that others will not independently develop comparable or superior technology. We may inadvertently infringe a third party's patent, which could lead to litigation, the requirement to obtain a licence, or the need to cease development or commercialisation of the infringing technology or product.	- We have a long-standing track record of IP generation and successful applications, and have a long-standing relationship with our patent agent who has a deep understanding of our technology and the medical device sector and who advises us on the application and execution of patents. - We undertake freedom to operate searches at the early development stages of a new device and seek to ensure all devices are covered by strong IP coverage. - There is an ongoing review of terms and conditions with third parties to ensure that IPR is retained and protected wherever possible.
IT security	The risk of industrial hacking for sensitive information and/or with the intention of deliberate malice. In the event of a data breach the Group is liable to be fined for a breach of GDPR legislation.	- Strong IT security measures have been implemented and are reviewed to ensure that we are adequately protected. - The Company holds limited personal and sensitive data and policies are in place that are designed to ensure compliance with GDPR.
Product liability or other legal risks	Criminal or civil proceedings might be filed against Creo Medical by study subjects, patients, the regulatory authorities, other companies and any other third party using or marketing our products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialisation of our products if approved. Successful defence of any such claims could require significant financial and management resources.	- A number of our products have obtained approvals/clearance from third party regulatory bodies in the EU and United States. - Our design process seeks to mitigate issues by including pre-clinical and clinical trials in the development of our products. - We invite input from Key Opinion Leaders on product development and their needs. - Our QMS system is designed to comply with ISO 13485. - We review our insurance coverage annually. - Our Clinical Education Programme is designed to educate clinicians on the safe and effective use of our products.
Dependence on key executives and personnel	The future success of the Group will depend in part upon the expertise and continued service of certain key executives and technical personnel. In particular, Professor Chris Hancock has been, and remains, essential to the development of the Group. Our ability to successfully develop commercial products will also depend on our ability to attract and retain suitable personnel.	- We have implemented a share option scheme to retain key employees and enter into contracts that contain limited non-competition provisions with key personnel. - We have taken great steps over the last 12 months to continue to recruit more people across the whole business. - Our HR team are focused on obtaining, developing and managing talent within the business. - By capturing IPR through patent applications, we are able to ensure ownership of knowledge and create foundations for our product pipeline.
Dependence on distributors in certain geographical areas	Sales of our products depend, in part, on the financial resources, expertise and clients of our distributors, agents and other channel partners. In 2016 we entered into a distribution agreement with HOYA Group, PENTAX Medical to distribute our products, once commercialised, in key Asia-Pacific markets. We do not currently have a distribution partner in the USA. We cannot ensure that we will be able to retain our distributors, renew existing distribution agreements on commercially favourable terms, enter into new distribution agreements for target geographical markets or that distribution partners will dedicate the resources necessary for the commercial success of our products.	- HOYA Group, PENTAX Medical is a significant shareholder, therefore our success is their success, and we are involved in ongoing discussions to ensure that the distribution agreement we have together meets the needs of all parties. - We have recruited employees with direct and relevant experience in sales in the medical device sector. They are responsible for establishing distribution partners in key territories as well as developing a direct sales team. - In the last 12 months we have entered into additional framework agreements with distribution partners, including India and key markets in Europe.
Dependence on key suppliers and internal resource to manufacture products	The manufacture of our products involves a number of parts, some of which may only be available from a limited number of third parties and/or rely on key internal processes within the business. Failure by a third party to deliver components or a third party ceasing to manufacture components could result in delays in the manufacture of products or the need to redesign certain elements.	- Wherever possible we seek to have a number of suppliers for components. As we move to manufacturing, we are seeking to ensure that all critical components have at least two sources. - We have engaged with outsourcing partners to assist with part or all of certain manufacturing processes. - We have designed our manufacturing to be scalable and have a number of operatives trained in all aspects of manufacturing.

Risk	Description	Mitigation
		Our procurement teams are working to identify alternative and complementary suppliers to ensure that our supply chain is robust.

Political risks

Risk	Description	Mitigation
The UK's exit from the European Union	We face risks in relation to the political and economic instability associated with the UK leaving the European Union, as well as potential changes to the legal framework applicable to our business.	- Our strategy is not to focus solely on EU markets. Alongside the EU, we will focus on the UK and the US along with other markets. - We monitor developments on an ongoing basis to allow the business to react when necessary. - Employees that are not UK citizens currently have the right to work, and our HR team will seek to manage processes to ensure that this will continue to be the case post Brexit. - We have established a presence in Ireland to give us an entry point to the EU market if required.
Events taking place in other jurisdictions may adversely impact on Creo's ability to market products	We face certain geopolitical risks in relation to countries seeking to on-shore or pursuing a 'buying local' policy which could fetter international sales of products manufactured outside of such countries.	- We have established a US subsidiary to assist with product exploitation in the US. - Local distributors are engaged to seed local markets and generate initial demand of products therefore giving us a local presence with established persons.
COVID-19	There is significant uncertainty worldwide in relation to the social and economic impact from the spread of Coronavirus (COVID-19) and the various national responses. National travel restrictions and social distancing measures will prevent Creo personnel from visiting countries where restrictions are in place and will limit potential users of our products from attending training and/or trainers from providing training on the safe use of our products. Medical resources at national and local levels will be focused on mitigating the impact of COVID-19 rather than undertaking non-urgent or elective procedures that would otherwise be able to utilise our products. There are restrictions on the ability of sales representatives to attend customer sites. Should personnel become infected or show symptoms, they will be required to self isolate and/or take extended time off work. National social distancing responses require alternative working methods (i.e. homeworking) which may not be suitable for all employees.	- The business is continually monitoring the development of COVID-19 and the possible impact it could have on our business. We are seeking to comply with and, where possible, go beyond government guidance as issued from time to time. - Guidance has been provided to all employees on the steps that they need to undertake to mitigate the risk of Coronavirus spreading between employees. We are seeking to comply with and, where possible, go beyond government guidance to do all that we can to protect employees and partners. - Employees are required to work from home where possible and, until social distancing measures are lifted are only permitted to travel on business when it is absolutely necessary. - All employees have access to conference call and videoconference facilities and have been provided with IT equipment to allow them to work from home. - For the foreseeable future we will continue to minimise the number of in person meetings that are taking place. - Our H&S employees are monitoring the development of events on a daily basis to ensure that all appropriate steps are being taken. - We are in regular communication with supply chain partners to ensure that we can adequately plan for disruption to the supply of raw materials and components. - We are actively working with professional advisors to ascertain what government support can be provided to Creo to limit the financial impact arising from COVID-19 and social distancing measures.
Events beyond the control of the management of the Company may have adverse effects on the business	The possible threat of natural disasters affecting the ability to trade and manufacture.	- The Company property is well secured and we have taken reasonable steps to protect the contents. - A disaster recovery plan has been developed.

Financial risks

Risk	Description	Mitigation
Availability and terms of additional financing required	Our financing requirements depend on numerous factors, including the rate of market acceptance of our technologies and our ability to attract customers. We may be unable to obtain adequate financing on acceptable terms, if at all, which could cause us to delay, reduce or abandon research and development programmes or hinder commercialisation of some or all of our products.	• The 2019 fund raise added significant strength to the balance to allow Creo to achieve its near-term objectives. • We work closely with a number of agencies and bodies to maximise the amount of grant funding that is available to assist with our technological development while minimising our spend. • A significant amount of our development spend is subject to research and development tax relief. • We also have in place controls and procedures to manage expenditure in line with budgets.
Foreign exchange rate fluctuations	We record transactions and prepare our financial statements in Sterling, but a substantial proportion of our income is expected to be received in US Dollars and Euros. We also incur some expenditure in US Dollars and other currencies. To the extent that the Group's foreign currency assets and liabilities are not matched, fluctuations in exchange rates may result in realised or unrealised exchange gains and losses on translation of the underlying currency into Sterling.	• We enter into various derivative financial instruments to manage our exposure to foreign exchange risks, including forward exchange contracts and cross currency swaps as are required from time to time. • The majority of our contracts are based in Sterling therefore mitigating our exposure to direct FOREX risk.

FINANCIAL REVIEW

I am pleased to announce our third report and accounts following our admission to AIM in December 2016. The £51.9m raised in December of 2019 was further confirmation of the continued investor confidence in Creo as it commercialises its products. These funds will further provide Creo with the long-term platform to enable us to further develop multiple products through to commercialisation and provide the Company with the platform for future development including potential M&A activities.

Revenue and other income

2019 saw some major milestones for the Company. During the period we received the first commercial orders for Speedboat from the USA, continued shipments of our CROMA Advanced Energy Platform and Speedboat devices pursuant to the framework agreements entered into with our distribution partners, as well as commercially launching the Speedboat device to the market. Revenues billed in the period totalled £0.2m of which £13k has been recognised as revenue with the balance accounted for below the line in administrative expenses.

Other operating income of £0.1m in the 12-month period to 31 December 2019 (18-months to December 2018: £0.3m) relates to research grants.

Operating loss

The operating loss for the period increased to £18.9m (18 months to December 2018: £17.7m), reflecting the increased operating expenses in relation to clinical and development activities together with further investment in headcount and business infrastructure to support the business and enable it to continue to develop and commercialise its technology. This continued investment in the business will support anticipated growth and development in the coming periods.

The underlying operating loss (also referred to as adjusted EBITDA) for the period was £14.0m (18 months to December 2018: £12.6m).

Whilst EBITDA is not a statutory measure, the Board believes it is helpful to investors to include as an additional metric to help provide a meaningful understanding of the financial information as this measure provides an approximation of the ongoing cash requirements of the business as it continues to pursue its future development and begins to commercialise its approved products. The Adjusted EBITDA position excludes share-based payment expenses which are non-cash and incorporates the recovery of research and development expenditure from which the Group is able to benefit through R&D Tax credit schemes.

	12 months to 31 December 2019 £	18 months to 31 December 2018 £
Operating loss	(18,875,378)	(17,663,786)
Loss before Income tax	(18,615,381)	(17,576,187)
Total comprehensive loss for the period	(15,911,150)	(14,808,608)
Underlying operating loss adjustments:		
Share-based payments	1,554,845	1,804,820
Depreciation and amortisation	641,725	497,421
R&D expenditure recovered via tax credit scheme ¹	2,710,239	2,786,181
Underlying operating loss, also referred to as adjusted EBITDA (non-statutory measure)	(13,968,569)	(12,575,364)

1. R&D expenditure includes a £6,008 claimed under the large company ('RDEC') scheme in relation to monies received from Research Grants.

Expenses arising from share issue

Following a share placing of 28,835,173 ordinary shares which raised £51.9m before expenses in December 2019, the expensed costs incurred in the period were £nil (18 months to December 2018: £nil), with capitalised costs in the period of £2.8m (18 months to December 2018: £2.6m).

Tax

The tax credits recognised in the current and previous fiscal year relate solely to R&D tax credit claims. A deferred tax asset has yet to be recognised due to the uncertainty over the timing of future recoverability.

Expenses

Administrative expenses comprising R&D, operational support, sales and marketing, and finance and administration costs totalled £19.0m (18 months to December 2018: £17.9m). Adjusting for share-based payments, depreciation, amortisation and tax income as shown in the table below, underlying administrative expenses are £14.0m (18 months to December 2018: £12.6m).

This annualised increase of £7.1m reflects the continued investment made by the Group in clinical and development activities and the move from small discrete production batches into full-scale manufacturing. Personnel costs continue to be the largest expense and represent approximately 60% of the Group's underlying administrative expenses.

Loss per share

Loss per share was 13 pence (18 months to December 2018: 16 pence).

Dividend

No dividend has been proposed for the period to 31 December 2019 (18 months to 31 December 2018: £nil).

Cash flow and balance sheet

Net cash used in operating activities was £11.9m (18 months to December 2018: £14.3m), driven by the continued investment in research and development of new devices during the period and the further strengthening of our IP portfolio. Net cash generated from the share issue in December 2019 was £49.3m (18 months to December 2018: £46.1m), strengthening the balance sheet and enabling us to further develop multiple products through to commercialisation, whilst also providing the platform for future development including potential M&A activities.

Total assets at the end of the period increased to £88.3m (31 December 2018: £49.7m), a 77% increase, reflecting the increase in cash arising from the issue of new ordinary shares, offset by the operating cash outflow for the period. Cash and cash equivalents at 31 December 2019 was £81.0m (31 December 2018: £44.6m). Net assets were £82.7m (31 December 2018: £47.7m), a 73% increase.

Accounting policies

The Group's financial statements have been prepared in accordance with International Financial Reporting Standards. The Group's accounting policies have been applied consistently throughout the period and are described on pages 66 to 73.

Principal risks and uncertainties

The principal risks and uncertainties facing the Group are set out on pages 30 to 35.

Directors

Details of the Directors who served during the period ending 31 December 2019 are set out on pages 42 to 43. All six of the Directors serving on the Board at the year end were male. Post period and with effect from 1 February 2020 Ivonne Cantu was appointed in the role of independent Non-Executive Director.

Conflicts of interest

To address the provisions of Section 175 of the Companies Act 2006 relating to conflicts of interest, the Company's Articles of Association allow the Board to authorise situations in which a Director has, or may have, a conflict of interest. Directors are required to give notice of any potential situation or transactional conflict that are to be considered at the next Board meeting and, if considered appropriate, conflicts are authorised. Directors are not permitted to participate in such considerations or to vote regarding their own conflicts.

**Richard Rees**

Chief Financial Officer
6 May 2020

SECTION 172(1) STATEMENT

The Board of Directors' Statement on s172(1)

In accordance with the duties set out in s172(1) of the Companies Act 2006, Creo's Board of Directors act in a way that they consider, in good faith, would be most likely to promote the success of the Company for the benefit of its members as a whole, underpinning the Board's ultimate objective of designing the business for long-term growth and success. Key decisions and matters that are of strategic importance to the Company are appropriately considered in light of the requirements of s172(1), the Board having regard (amongst other matters) to:

- (a) the likely consequences of any decision in the long-term;
- (b) the interests of the Company's employees;
- (c) fostering business relationships with suppliers, customers and others;
- (d) the impact of the Company's operations on the community and the environment;
- (e) maintaining a reputation for high standards of business conduct; and
- (f) the need to act fairly between members of the Company,

(The '172(1) Matters').

The Board's overarching strategy is to (a) develop technology and products for which there is a long-term clinical need supported by sizable addressable markets (see page 10); (b) ensure that the business has the appropriate infrastructure in place to support the development and commercialisation of such products; (c) when releasing products to the market to do so in a measured and controlled manner to minimise the risk of misuse and to ensure that the products are customer sponsored for the long term (i.e. through clinical education and peer support by KOLs); and (d) deploy capital appropriately in support of (a), (b) and (c).

The size and nature of our business enables regular, direct and indirect, feedback from relevant stakeholders. Through an open and transparent dialogue with key stakeholders, we have been able to develop a clear understanding of their needs, assess their perspectives and monitor their impact on our strategic ambition and culture, thus ensuring that we are designing Creo's business for long-term growth and success. The Board considers the potential impact of decisions on relevant stakeholders during its decision-making process whilst also having regard to a number of broader factors, including the impact of the Company's operations on the community and environment, responsible business practices and the likely consequences of decisions in the long term.

Set out below is a summary of how we communicate with the relevant stakeholders and how we take into account s172(1) Matters.

Employees

The complex and innovative nature of the products that Creo is developing requires many committed and talented employees. Page 29 sets out more details about our team.

The relatively small size of the business allows the executive team to engage directly with all employees on a daily basis. The Company holds regular 'all employee' meetings to discuss progress of product development against current business plans. Our engagement with employees provides immediate and direct feedback on individual and collective needs and the impact on them of actions taken by the business. This includes feedback on areas that need greater support and resource for which the Company may need to plan.

We strive to empower all employees to take control of their career development, not least to support the longer-term growth of Creo. During the last twelve months we have put in place a number of measures to support the health and well-being of all employees, from on-site well-being services to discretionary time off after long periods of intensive work.

All employees have the ability to raise grievances and to escalate concerns through our whistleblowing procedures.

We continue to develop our performance management and to promote a culture of continuous improvement throughout the business.

In making decisions, the Board always takes into account the relevant impact on our employees (whether positive or negative). For example, the 2019 Fundraising allowed the Board to give employees some certainty around the business's cashflow and their continued employment, thus enhancing the long-term opportunities that we can offer all employees.

Customers, business partners and suppliers

Customers

Our customers will drive the long-term growth of Creo's business. Creo engages with key opinion leaders (KOLs) around the world, starting well before any prototype devices are made to ensure we develop products for which customers have an identified need and will ultimately use.

Throughout the product development process, KOLs and other clinicians provide feedback on our devices, through the design process, usability studies and pre-clinical testing and analysis. This input allows the Board to make strategic decisions to ensure we deploy capital on concepts and products that could make the most impact for our customers and our business.

Creo's Clinical Education Programme provides immediate feedback from the initial use of our devices including any specific needs that they may have.

Business partners and suppliers

We interact in an ethical and equitable manner with all business partners and suppliers. We strive to have an open, constructive and effective relationship through regular meetings and dialogue, recognising that such communication is beneficial for the whole supply chain. Over the last twelve months we have recruited additional employees into our procurement team who have prior experience of managing long-term partnering supply chain relationships.

Further detail around compliance is set out below in respect of conduct of business.

Community and the environment

We are a small business committed to making a positive contribution to the communities in which we operate. This extends beyond the immediate locality of our offices into the wider clinical community, for example through our Clinical Education Programme.

Our head office is located in Chepstow in Wales. From here, we employ a large number of local individuals, providing employment opportunities which may otherwise be lost to a larger conurbation in the region or, indeed, further away. With the support of the local government networks, Creo and the Board remain committed to making a positive economic impact on the region and take this into account when making decisions.

Where possible, we try to source locally to support our community, from buying milk for our kitchen from the local farm shop to engaging with industrial contractors and suppliers within the area.

Many of our community agendas are led by our employees, from collecting for the local foodbank to offering employee donations to specific campaigns.

We have a number of environmental initiatives within the business and are conscious of our carbon footprint. In the last twelve months, the business has increased the recycling of waste materials and encourages all employees to do the same.

Whilst some of our technologies are by necessity single use, we strive to ensure that as many materials as possible can be recycled and/or sourced sustainably.

Shareholders

We are committed to active and regular communication with all shareholders, not least to ensure that they understand our strategy and business model and that we can understand any concerns they may have. The Board believes that such active engagement should secure the Company a stable long-term shareholder base.

The Annual General Meeting ('AGM') offers an opportunity for shareholders to meet and have direct discussions with the Board. In addition, we hold investor roadshows following the release of half and full year results and have held an investor 'open afternoon' in Chepstow and an investor briefing following our full year results.

The Directors and employees also attend a number of investor and sector specific conferences that allow interested parties to speak with us in person.

As an early stage business, the Board is conscious of the need to balance the desire to establish immediate revenue and a break-even position against building long-term profitability, capital growth and income generation for our shareholders. Discussions with our shareholders suggest that the latter is the preferred position.

In undertaking the 2019 Fundraising the Board were conscious of the need to mitigate any dilution on smaller shareholders whilst attracting existing and new institutional capital to bolster the Company's shareholder register and to provide substantial funding. The structure of the 2019 Fundraising, through a placing and an open offer, allowed all shareholders to participate in the 2019 Fundraising whilst giving some certainty to the transaction to warrant proceeding with it. The Board is now working to deploy the capital raised against its overall strategy.

Regulators and conduct of business

Ethical values and behaviours are at the heart of what we do and the Board seeks to enshrine such ethical values and behaviours within all of Creo's business activities. Our values are set out in our policies, our working practices, and our systems.

Our products are designed to improve lives through improved patient outcomes and reduced costs and time of procedures for healthcare providers. We are required to have a robust quality management system which is third party audited to ISO: 13485 standards. This is essential for our products to be adopted in our targeted markets. This system is regularly audited by independent third parties with whom we engage on a frank and open basis.

The Company is not required to report annually on Modern Slavery Act compliance. However, we have adopted an Anti-Slavery and Human Trafficking policy and continue to seek to ensure that all suppliers and business partners adopt and adhere to similar policies.

The Company has adopted an Anti-Bribery and Corruption policy which is communicated to all employees. We emphasise to our employees the need to undertake business in an appropriate and transparent way. We include provisions in our agreements with third parties to ensure that bribery and corruption does not form part of either any business undertaken by or on behalf of the Company or any of our supply chains.

As we expand into new territories, we seek to ensure that we comply with local requirements that are analogous to the UK legislation (i.e. the USA's Foreign Corrupt Practices Act).

During the last twelve months, the business has added internal resource to ensure that compliance remains front and centre of the business. We have a dedicated employee dealing with Health and Safety compliance. Our supply chain team is working with our suppliers to ensure that compliance flows throughout our supply chain (see above). In addition, we are taking initial steps to investigate the benefit of gaining ISO 14001:2015 accreditation.

The Strategic Report was approved by the Board of Directors on 6 May 2020 and was signed on its behalf by:



Richard Rees
Chief Financial Officer
6 May 2020

CORPORATE GOVERNANCE

The Directors recognise the importance of sound corporate governance and are committed to maintaining high standards of corporate governance.

THE BOARD

Craig Gulliford

Chief Executive Officer

Craig is a founding angel investor in Creo Medical and joined the company as CEO in 2012. Craig qualified with an MSc in Electronic Engineering from the University College of North Wales and has over 20 years' experience in building international businesses from early stage through to significant scale. Craig's early career developed in the Middle East working with large corporates delivering complex commercial projects.

In January 1999, Craig joined a start-up software and hardware business where, as COO, he was part of a small team that grew the company both organically and through acquisition, from a loss-making start-up to a profitable business delivering significant shareholder returns and an exit in 2007.

Professor Christopher Hancock

Chief Technology Officer

Chris is the founder of Creo Medical with over 20 years' experience in medical device development including four years at Gyrus Group plc in his role as Senior Engineer.

Chris holds a personal Chair in the Medical Microwave Systems Research Group at Bangor University. Chris is a Fellow of the Institute of Physics, a Chartered Physicist, Fellow of the Institute of Engineering and Technology, a Chartered Engineer and a Senior Member of the IEEE. Chris is also a Royal Academy of Engineering Visiting Professor at UCL and was awarded Katherine Burr Blodgett Gold Medal and Prize in 2018 for work on Creo's CROMA Advanced Energy Platform technology. Chris is a named inventor and lead author on over 800 granted patents, patent applications and international journal publications.

Richard Rees

Chief Finance Officer

Richard joined Creo Medical as CFO in July 2016. Prior to joining Creo, Richard was CFO of SPTS Technologies, a UK-based, global manufacturer of semiconductor capital equipment. In 2011, Richard was part of a management team at SPTS Technologies that, together with Bridgepoint Capital, acquired SPTS Technologies for \$200 million from Sumitomo Precision Products. In 2014, SPTS Technologies was acquired by Orbotech Ltd for more than \$350 million. Prior to joining SPTS Technologies, Richard spent 7 years at KPMG in audit.

Charles Spicer

Chairman

Charles is an experienced director of public and private companies, primarily in the MedTech sector. Charles is chairman of IXICO plc and MJ Hudson Group plc. In addition, Charles is Chair of the UK Department of Health's Innovation for Innovation (i4i) Funding Panel.

Charles was a Director of Aircraft Medical (acquired by Medtronic Inc. in December 2015) and Stanmore Implants (acquired by Stryker Inc. April 2016). Charles was also previously Chief Executive of MDY Healthcare plc, a strategic healthcare investor and, prior to that, head of healthcare corporate finance at both Numis Securities and Nomura International.

David Woods

Non-Executive Director

David is an industry veteran within the med-tech sector. His experience in the medical device market encompasses general and orthopaedic surgery, gastroenterology, pulmonology and ENT. David is currently the President and CEO of PENTAX Americas and M&A Director of HOYA Group PENTAX Medical. David was awarded the ASGE Presidents award in 2010 recognising exceptional contributions to the society and its mission.

John Bradshaw

Independent Non-Executive Director

John is a chartered accountant with more than 20 years' experience as a Chief Financial Officer with venture capital backed and listed companies. John is the Chief Financial Officer of Syncona Investment Management Limited, the Investment Manager of Syncona Limited a FTSE250 listed life sciences investment company. John is a Non-Executive Director and audit committee chair of AIM listed IXICO plc.

John is the chair of the Company's Audit Committee and is a member of the Company's Remuneration Committee.

Ivonne Cantu

Independent Non-Executive Director

Ivonne joined Creo's board on 1 February 2020. Ivonne has extensive experience in corporate finance acting as corporate finance adviser to UK and international companies for more than 20 years at Cenkos Securities plc and previously at Merrill Lynch.

Ivonne is currently Director of Investor Relations and Corporate Development at Benchmark Holdings plc, an AIM listed aquaculture technology company. Ivonne is also a trustee of La Vida, a UK charity established to help disadvantaged people residing permanently in Latin America, in particular, by preserving and protecting health, relieving sickness, relieving poverty and advancing education.

Ivonne holds a BSc in Engineering from Universidad Panamericana in Mexico and an MBA from the Wharton School of Business. Ivonne will become Chair of the Company's Remuneration Committee and a member of the Company's Audit Committee.

The Directors recognise the importance of sound corporate governance and are committed to maintaining high standards of corporate governance.

Introduction

Creo Medical Group plc is traded on the AIM market of the London Stock Exchange (LSE:CREO). The Directors recognise the importance of sound corporate governance and are committed to maintaining high standards of corporate governance. As a company whose shares are admitted to AIM, the Board has adopted and complies with the Quoted Companies Alliance's Corporate Governance Code ('the Code').

The Board is of the unanimous opinion that the Company complies with the Code but any divergence from the Code (details of which are set out below) are, in the circumstances, reasonable, appropriate and in the best interests of shareholders of the Company as a whole.

At the heart of Creo is one very simple principle: to improve lives. This principle resonates throughout the business:

- with patients, by bringing advanced energy to flexible medical devices for surgical endoscopy to improve patient outcomes;
- with customers, by seeking to develop products that reduce procedure times and costs;
- with business partners, by interacting in an ethical and equitable manner;
- with employees, by offering rewarding careers with support and encouragement to allow everyone to fulfil their potential; and
- with shareholders, by deploying capital against a well thought through and measured business plan to achieve long-term, sustainable growth.

It is the role of the Board to ensure that Creo is managed for the long-term benefit of all its shareholders. Our corporate governance processes are designed to ensure control, reduce risk and enhance long-term value generation, underpinning Creo's long-term objectives.

The Quoted Companies Alliance Corporate Governance Code

In accordance with AIM Rules, the Company publishes an annual summary setting out how the Company complies with the Code. The 2019 summary is available on the Company's website.

The Code is constructed around 10 principles, taking key elements of good governance and applying them in a manner which is workable for the needs of a growing company in pursuit of medium to long-term value creation for shareholders. Each principle is set out below, together with a commentary of Creo's compliance. To the extent that an explanation of Creo's compliance set out against one principle is equally as relevant against another principle, the explanation is deemed to apply to all relevant principles.

Deliver growth

1. Establish a strategy and business model which promote long-term value for shareholders

Creo is a medical device company focused on the development and commercialisation of minimally invasive medical devices, by bringing advanced energy to endoscopy. Creo's mission is to improve patient outcomes by applying microwave and radiofrequency ('RF') energy to surgical endoscopy. Creo has developed CROMA, an electrosurgical advanced energy platform, that delivers both bipolar RF for precise localised cutting and microwave energy for controlled coagulation through a single accessory port. This technology provides clinicians with flexible, accurate and controlled surgical solutions, initially in the field of gastrointestinal ('GI') therapeutic endoscopy and later bronchoscopy.

Our strategy is to bring our CROMA Advanced Energy Platform ('CROMA') to market through a suite of medical devices, which we have designed, initially for the emerging field of GI therapeutic endoscopy, an area with high unmet needs. CROMA has been designed around the 'razorblade model', with a single accessory port that is compatible with a suite of single-use devices that aim to deliver superior outcomes for physicians and patients. CROMA will be developed further for bronchoscopy, endoscopic ultrasound and laparoscopy procedures. We believe our technology can impact the landscape of surgery and endoscopy by providing a safer, less-invasive and more cost-efficient option for treatment.

To achieve our goal, we:

- invest in developing and protecting our strong intellectual property portfolio, comprising, in total, 188 granted patents and 599 pending applications;
- recruit staff with a strong pedigree from the MedTech and other relevant sectors; with depth of expertise spanning R&D, quality, regulatory approval and commercialisation;

- invest in the development of our people by supporting ongoing academic qualifications and promote an entrepreneurial and collegiate working environment;
- nurture long-term strategic relationships with: eminent clinicians and key opinion leaders practicing in our fields of interest around the world;
- distribution partners to give us scalable geographical reach into key markets; and
- shareholders to ensure that we have access to the support and capital that we need to achieve our goal.

As with other businesses in our sector, we face a number of key challenges in the execution of our strategy. These challenges include:

- uncertainty that the technology under development will be an attractive addition or an alternative to existing surgical devices. This is mitigated by engaging with key opinion leaders to ensure that we gather relevant feedback to develop products to meet clinical needs and by ensuring that we provide education to clinicians on the safe use of our products through our Clinical Education Programme; and
- uncertainty that we can obtain regulatory clearances for products in a timely manner (if at all). To mitigate this, we employ a dedicated team focused on the regulatory requirements of products and who provide the necessary regulatory documentation to support our regulatory applications.

Further detail on the principal risks and uncertainties that may affect the business are set out on pages 30 to 35.

2. Seek to understand and meet shareholder needs and expectations

We are committed to and encourage active communication with all shareholders not only to ensure that our strategy and business model is understood by our shareholders but so that we can understand any concerns that shareholders may have. The Board believes that active engagement provides the Company with a stable shareholder base for the long term.

Our active dialogue with shareholders means that the Board receives regular updates on the views of shareholders.

The Annual General Meeting ('AGM') offers an opportunity for all shareholders to meet and have direct and meaningful discussions with the Board. In addition to our AGM, we seek to hold investor roadshows following the release of half and full year results. We have also held an investor open afternoon in Chepstow and an investor results briefing post our full year results. Both events give our retail shareholders the opportunity to have direct access to the management of the Company and to understand the steps we are taking towards our commercial goals.

In addition to Creo specific events, our Directors and employees attend a number of investor and sector specific conferences to allow interested parties the opportunity to speak with us directly.

Our Chairman and senior independent Non-Executive Director regularly engage with institutional shareholders to gain feedback and discuss any areas of concern to ensure that they can be addressed at an executive level.

3. Take into account wider stakeholder and social responsibilities and their implications for long-term success

Whilst we are growing as a business, we are still able to receive regular direct feedback from all relevant stakeholders. This allows the Board, and thus the Company, to ensure that it is designing the business for long-term growth and success. Together with our shareholders and the ultimate users and beneficiaries of the products that we are developing, our employees, business partners and suppliers are our key stakeholder groups. How we seek to engage with them and ascertain their feedback is set out below.

Employees

The Company holds regular 'all employee' meetings to discuss progress of product development against current business plans. These meetings allow us to focus on areas that need greater support and also consider what resource the Company may need going forwards. This collegiate approach is taken into the workplace on a day to day basis.

To reflect our growing employee base, we have created multiple fully resourced product development teams (one for each product family). This allows faster feedback and greater teamwork within the business.

We continue to employ graduates and encourage continuous development and education for all employees.

Business partners and suppliers

Notwithstanding the early stage of development of the business, we believe that the achievement of long-term success requires us to forge good and equitable relationships with our business partners and suppliers. We seek to pay suppliers within agreed credit times and, as we move to the next phase of our development, will introduce further audit checks on our supply chain to encourage all suppliers and business partners to meet and adhere to the high ethical standards that we seek to achieve.

During the last 12 months we bolstered our procurement team with several key hires to ensure that supplier relationships, and the management thereof, are core to our supply chain processes.

Modern slavery

The Company is not required to annually report on Modern Slavery Act compliance. However, in line with our underlying principle to improve lives, the Company has adopted an Anti-Slavery and Human Trafficking policy and we continue to seek to ensure that all suppliers and business partners adopt and adhere to similar policies (to the extent that they are not already in place).

Anti-bribery and corruption

The Company has adopted an Anti-Bribery and Corruption policy which is communicated to all employees along with other policies. Many of our employees have previously worked for large established businesses and are therefore well versed in the need to undertake business in an appropriate and transparent way. We do not simply rely on this, however. We seek to include provisions in our agreements with third parties to ensure that bribery and corruption does not form part of any business undertaken by or on behalf of the Company and is not within our supply chains.

As we expand into new territories, we seek to ensure that we comply with local requirements that are analogous to the UK legislation (i.e. the USA's Foreign Corrupt Practices Act).

Compliance

During the last 12 months the business has added to its internal resource to ensure that compliance remains front and centre of the business. We have a dedicated employee dealing with Health and Safety compliance and our supply chain team are working with our suppliers to ensure that compliance flows through our supply chain (see above). In addition, we are taking initial steps to investigate the benefit of gaining ISO 14001:2015 accreditation for the business.

4. Embed effective risk management, considering both opportunities and threats, throughout the organisation

Internal controls

The Board is responsible for maintaining a sound system of internal financial and operational control and the ongoing review of their effectiveness. The Board's measures are designed to manage, not eliminate, risk and, as such, provide reasonable but not absolute assurance against material misstatement or loss. Some key features of the internal control system are:

- Management accounts information, budgets, forecasts and business risk information which are regularly reviewed by the Board;
- Due to the nature of the products being developed by the Company, we have a rigorous quality management system that is compliant with ISO: 13485 and which is regularly audited by independent third parties;
- Operational, accounting and employment policies are in place and regularly reviewed and updated when appropriate;
- Clearly defined organisational structure within the Company; and
- Established financial reporting and control systems within the Company.

The Company reviews its internal controls regularly to ensure that they give the Company the flexibility that is necessary to allow it to grow and deliver long-term value to shareholders while having the correct checks and balances in place.

During the last 12 months we have invested in a new Enterprise Resource Planning (ERP) system, IFS Applications. The ERP system enforces compliance and rigour around internal processes and controls.

Risk register

The Company maintains a risk register which is reviewed regularly. This register allows the Board to appraise external and internal threats to the business and to plan and mitigate accordingly. Principal risks and uncertainties that may affect the business are set out on pages 30 to 35.

Legal

The Company's General Counsel assists the management team and advises on all legal aspects of the business. The General Counsel manages external legal support where necessary and takes an active role in the management of the business to ensure that compliance is at the core of all that we do.

Intellectual property

The Company has a close working relationship with its patent agent, Mewburn Ellis, with whom we have worked since 2003. Our Patent Agent advises on the application for patents and the execution of our portfolio. Further, they offer strategic advice and support to assist in the identification of areas where the business may want to consider further development or registration to support existing applications and/or protection.

Code of conduct

The Company has adopted a Code of Conduct which sets out the standards that it expects all employees and representatives of the Company to meet to ensure that we maintain the high standards that we set ourselves. It is the Board's view that by encouraging high working standards we will mitigate against risks arising in our day to day activities.

Insurance

In the last 12 months Creo has undertaken a strategic review of its insurance requirements and determined that it would engage AON to act as its broker for insurances. The markets in which we seek to operate have unique risks which, if they materialise, could significantly impact on the business and its stakeholders. Accordingly, under the advice and guidance of AON, we have sought to put in place a scheme of insurance which reflects both the current and medium-term needs of the business. We monitor our insurance needs through periodic reviews with our advisors and our underwriters.

Maintain a dynamic management framework

5. Maintain the Board as a well-functioning, balanced team led by the chair

The Board

Creo has a strong and effective leadership team. Creo's Board comprises an Independent Non-Executive Chairman, three Executive Directors, and two further Non-Executive Directors, one of which acts as Creo's senior independent Non-Executive Director. Post period, an additional independent Non-Executive Director has been appointed to the Board. The Board is made up of the following individuals:

Executive Board Members

Craig Gulliford, Chief Executive Officer

Richard Rees, Chief Finance Officer

Prof. Christopher Hancock, Chief Technology Officer

Non-Executive Board Members

Charles Spicer, Independent Non-Executive Chairman

John Bradshaw, Senior Independent Non-Executive Director

David Woods, Non-Executive Director

Ivonne Cantu, Independent Non-Executive Director (from 1 February 2020)

Brief biographies for each Board member together with their respective Board Committee memberships are set out on pages 42 to 43.

The Company's articles of association require one third of its Directors to stand for re-election at each AGM. Charles Spicer and Craig Gulliford stood for re-election at the last AGM, with both being duly re-elected.

Charles Spicer acts as Creo's Independent Non-Executive Chairman. Charles has a limited shareholding in the Company and a limited interest in the Company's share option scheme. Given Charles' limited participation, the Board does not consider his share and option holdings to be significant and therefore consider him to be an independent Non-Executive Director.

John Bradshaw acts as Creo's senior independent Non-Executive Director. John has a limited interest in the Company's share option scheme. Given John's participation in the share option scheme is limited, the Board does not consider his share option holding to be significant and therefore consider him to be an independent Non-Executive Director.

David Woods is the President and CEO of Pentax Americas, a division of Hoya Group. David brings extensive market knowledge that is invaluable to the Board and its decision-making process. Hoya Group is one of the Company's significant shareholders. Other divisions within the Hoya Group of companies have agreements with Creo in respect of the distribution of Creo's products. To prevent conflicts of interest, David Woods does not participate in or attend discussions with regards to matters which may give rise to a conflict of interests. David has a limited personal shareholding in the Company. The Board does not consider David's shareholding to be significant.

The Board feels that it has an appropriate balance between independence, knowledge of the Company's technology, sector experience and professional standing to allow it to discharge its duties and responsibilities well. All Directors are encouraged to debate and use independent judgement based on their respective knowledge and experience on all matters affecting the business.

The time commitment expected of the Directors is commensurate with the size and complexity of a quoted company and as necessary to properly perform their duties.

During the 12 months ending 3 December 2019, the following meetings were held:

Name of director	Scheduled Board Meetings	Ad hoc meetings*	Audit Committee	Remuneration Committee
Charles Spicer	5/5	9/9	2/2	1/1
John Bradshaw	5/5	8/9	2/2	1/1
David Woods	5/5	6/7		
Craig Gulliford	5/5	7/7		
Richard Rees	5/5	9/9		
Christopher Hancock	5/5	7/7		

* (i.e. update calls, sub-committee meetings, or meetings where only a quorum is required)

Conflicts of interest

To address the provisions of Section 175 of the Companies Act 2006 relating to conflicts of interest, the Company's Articles of Association allow the Board to authorise situations in which a Director has, or may have, a conflict of interest. Directors are required to give notice of any potential situation or transactional conflict that are to be considered at the next Board meeting and, if considered appropriate, conflicts are authorised or Directors do not attend or participate in such discussions. Directors are not permitted to participate in such considerations or to vote regarding their own conflicts.

6. Ensure that between them the Directors have the necessary up-to-date experience, skills and capabilities

The Board considers that it contains an appropriate range of skills, experience and knowledge and is mindful of the need to continuously review the needs of the business to ensure that this remains true. The Board members are of sufficient calibre to bring independent judgment of issues of strategy, performance, resources, and standards of conduct, which are vital to the future growth and success of the Group. The Board believes that it operates in an open and constructive manner, working effectively as a team.

Each Director is aware of the importance of keeping their skills and capabilities up to date. The Board are kept up to date on changes to the AIM rules via annual briefings by the Company's nominated adviser, as well as other regulatory and market matters on an ad hoc basis.

The Board is supported by a number of professionals both internal and external, including the Company's General Counsel, the CFO (who is a chartered accountant), the Senior Independent Non-Executive Director (who is a chartered accountant) and external advisors (details of which are set out on pages 42 to 43).

The Company engages with a number of healthcare professionals around the world. To support the Board, Creo has established its Horizon Group which consists of key opinion leaders and physicians who serve the important advisory function of assisting Creo to identify and assess unmet market opportunities in gastrointestinal endoscopy that could contribute to the improvement of patient outcomes but also to provide Creo with important perspectives on market dynamics.

7. Evaluate Board performance based on clear and relevant objectives, seeking continuous improvement

The Board seeks to improve the ways in which it interacts and the manner in which information is presented to it. The processes that have been put in place allow for a consistent approach to reporting, thus aiding analysis by the Board of all matters at hand.

While the Company does not currently have any formal appraisal processes or evaluation criteria for Board members, the Chairman and Senior Independent Non-Executive Director regularly meet and discuss performance with members of the executive team, which in the Board's opinion is currently sufficient for the Company's purposes. This will be kept under review and the Board will consider whether formal evaluations are appropriate in the future.

8. Promote a corporate culture that is based on ethical values and behaviours

Our core principle is clear: to improve lives. As such, ethical values and behaviours are at the heart of what we do. The Board seeks to enshrine such ethical values and behaviours throughout the conduct of all of Creo's activities. Our values are set out in our policies, our working practices and our systems.

For our products to be adopted by our targeted markets, and thus enabling Creo to improve lives through, amongst other things, improved patient outcomes and reduced costs and time of procedures for healthcare providers, we are required to have a robust quality management system which is third party audited to ISO: 13485 standards. Underpinning this quality management system are processes to ensure that necessary safeguards are in place to ensure the integrity of this system and accordingly the quality of the products under development.

The Board leads by example. The Board seeks to treat all persons fairly and equitably, through clearly defined parameters of operation. This includes full compliance with safe working practices but also maintaining and protecting a positive and supportive working environment.

9. Maintain governance structures and processes that are fit for purpose and support good decision-making by the Board

The Chairman provides leadership to the Board and is responsible for agreeing the agenda for Board meetings, ensuring (with the Company Secretary) that the Directors receive the information that they need to participate in Board meetings, and that the Board has sufficient time to discuss issues on the agenda, especially those relating to strategy and governance.

The Chief Executive Officer is responsible for the day to day leadership of Creo, the management team and its employees. The Chief Executive Officer is responsible, in conjunction with senior management, for the execution of the Company's strategy approved by the Board and the implementation of Board decisions.

The Board is collectively responsible for the long-term success of the Company. Its principal role is to provide leadership within a framework of prudent and effective controls, which enables risk to be assessed and managed. The Board considers the management team's strategic proposals and, following a rigorous review, determines strategy and ensures that the necessary resources are in place for the management team to execute against that strategy.

Board meetings

The Board seeks to meet regularly, but in any event to hold Board meetings on a quarterly basis, together with meeting for an annual strategy event. In addition to the scheduled meetings, informal discussions with both Executive Directors and senior operational managers of the Company in relation to strategic business development and other topics important to the Company's progress are held by members of the Board regularly. Further, Board calls are held when needed to allow the executives to update the Board on specific matters and/or to approve specific actions for which Board approval is required.

The Board and its Committees are provided with information ahead of meetings to give time for review and analysis. For each Board meeting an agenda is prepared and approved by the Chairman and followed. The Board maintains an ongoing list of matters arising from the Board meetings which are then followed up at subsequent meetings to ensure that matters and decisions are being implemented.

Reserved matters

The Board has adopted a schedule of specific matters reserved for the Board to consider and, if thought appropriate, decide upon. These reserved matters relate to:

- strategy and oversight, including the approval of annual budgets;
- changes to the capital structure of the Company and the corporate structure of the Group;
- approval of financial statements and reports and any capital spend above agreed limits;
- approval of contracts outside of the ordinary course of the business;
- changes to Board and Committee membership;
- remuneration of Executive Directors and issues relating to share options;
- any delegation of authorities;
- governance; and
- approval of policies.

Board Committees

The Board delegates certain duties to Board Committees, all of which operate within clearly defined terms of reference and, where applicable, in accordance with the Code.

Audit Committee

The Audit Committee is chaired by John Bradshaw and its other members are Charles Spicer and Ivonne Cantu, each of whom are independent Non-Executive Directors. The Audit Committee seeks to ensure that the financial performance of the Company is properly reported on and reviewed. Its role includes monitoring the integrity of the financial statements of the Company (including annual and interim accounts and results announcements), reviewing internal control and risk management systems, reviewing any changes to accounting policies, reviewing and monitoring the extent of the non-audit services undertaken by external auditors and advising on their appointment.

The Board considers that the members of the Audit Committee have sufficient competence to understand, analyse and when necessary challenge the management accounts and public financial statements of the Company. The Company's Auditor has unrestricted access to the Chairman of the Audit Committee. The Chief Financial Officer and a representative of the Auditor of the Company are normally invited to attend meetings of the Audit Committee.

Remuneration Committee

The Remuneration Committee is chaired by Charles Spicer and its other member is John Bradshaw. Post period Ivonne Cantu has replaced Charles Spicer as the chair of the Remuneration Committee. The Remuneration Committee ensures that the Company's remuneration policy and practice promotes, encourages and drives the long-term growth of shareholder value in an effective manner and in accordance with the Board's strategy and policies. More particularly, the Remuneration Committee determines, within the agreed terms of reference, the Company's policy on the remuneration packages of the Company's Chief Executive, Chairman, the Executive Directors, the Company Secretary, senior managers and such other members of the executive management as it is designated to consider. The Remuneration Committee also has responsibility for determining (within the terms of the Company's policy and in consultation with the Chairman and/or the Chief Executive Officer) the total individual remuneration package for each Executive Director, the Company Secretary and other designated senior executives (including bonuses, incentive payments and share options or other share awards). The remuneration of Non-Executive Directors will be a matter for the Chairman and Executive Directors of the Board. No Director or manager is allowed to partake in any discussions as to their own remuneration.

Further details of the Remuneration Committee's activities and recommendations are set out on pages 53 to 55.

Build trust

10. Communicate how the Company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders

We seek to maintain dialogue with shareholders and other relevant stakeholders through a number of channels. Our Annual Report and accounts, full year and half year announcements are the primary sources of information for shareholders. These are supplemented by regular and appropriate RNS and RNS Reach announcements.

The above, together with other relevant information on the Company, can be obtained from our website.

The Company's collegiate and open working environment means that all employees are able to relay concerns to the executive team on a daily basis. The Company has a whistleblowing policy to allow and encourage all employees to bring matters which cause them concern to the attention of certain persons within the Company and, ultimately, to the attention of the Chairman.

The Company has engaged Walbrook PR to advise on its communications strategy and to assist in the drafting and distribution of regular news and regulatory announcements. If shareholders or interested parties would like to contact Walbrook regarding any communications they can be contacted at creo@walbrookpr.com.

Going concern

The Board is required to assess whether the Group has adequate resources to continue operations for the foreseeable future. After making enquiries, the Directors have a reasonable expectation that the Company and the Group will continue in operational existence for the foreseeable future (being a period of at least 12 months from the date of this report). For this reason, they continue to adopt the going concern basis for preparing the financial statements.

By order of the Board

**Richard Rees**

Director
Creo House
Unit 2, Beaufort Park
Beaufort Park Way
Chepstow
Wales
NP16 5UH
6 May 2020

DIRECTORS' REPORT

The Directors present their report together with the audited consolidated financial statements for the 12 months to 31 December 2019. These will be laid before the shareholders of the Company at the next Annual General Meeting (AGM).

Creo Medical Group plc (admitted to the AIM market of the London Stock Exchange (LSE:CREO)) is incorporated in England and Wales, registration number 10371794. The Company's registered office is at Creo House, Unit 2, Beaufort Park, Beaufort Park Way, Chepstow, Wales, United Kingdom NP16 5UH.

Principal activity

The principal activity of the Group during the period continued to be that of research and development and the manufacture and sale of medical devices and instruments. The principal activity of the Company is that of a holding company.

Results and dividends

The results of the Group for the 12 months to 31 December 2019 are set out in the Consolidated Statement of Profit or Loss and Other Comprehensive Income on page 62.

The Directors do not recommend the payment of a dividend.

Review of the period

A summary of the Group's progress and development is set out in the Chairman's Statement, the Chief Executive's Statement, The Chief Technology Officer's Statement and the Financial Review, which form part of the Strategic Report on pages 7, 8, 16 and 36 respectively. This analysis includes comments on the position of the Group at the end of the period, an indication of likely future developments in the business of the Group and details of the Group's activities in the field of research and development and the steps taken to commercialise its technology.

Directors

The Directors who held office during the year and up to the date of approval of the financial statements were as follows:

- Professor Christopher Paul Hancock
- Craig Jonathan Gulliford
- Richard John Rees
- David Gerard Woods
- Charles Alexander Evan Spicer
- John Bradshaw
- Ivonne Maria Gloria Cantu (appointed 1 February 2020)

Directors' interests and indemnity arrangements

The Directors' interests in the shares of the Company are disclosed in the Remuneration Report on pages 53 to 55.

In accordance with Section 234 of the Companies Act 2006 and as permitted by the Articles of Association of the Company, the Company maintained insurance throughout the year for its Directors and officers against the consequences of actions brought against them in relation to the execution of their duties for the Company.

No Director had, during or at the end of year, a material interest in any contract which was significant in relation to the Group's business except in respect of service agreements and share options and as disclosed in the Directors' Remuneration Report on pages 53 to 55. It is noted that David Woods is President and CEO of PENTAX Americas and M&A Director of HOYA Group PENTAX Medical, a significant shareholder of Creo Medical Group plc and with whom the Company has entered an agreement for the distribution of its products in key markets in the Asia-Pacific region and Germany, France and Italy.

The Company has not granted any indemnities to any of its Directors against liability in respect of proceedings brought by third parties.

Share capital

Details of the Company's issued share capital are shown in Note 21 to the consolidated financial statements.

The share capital comprises one class of ordinary shares and these are admitted on the AIM market of the London Stock Exchange. As at 31 December 2019 there were 150,378,758 fully paid ordinary shares in issue. All shares are freely transferable and rank *pari passu* for voting and dividend rights.

Substantial holdings

As at 31 December 2019, shareholders holding more than 3% of the share capital of Creo Medical Group plc were as follows:

Name of shareholder ¹	Number of shares	% of voting rights
Canaccord Genuity	28,024,770	18.6
Baillie Gifford	13,309,909	8.9
Finance Wales Investments	12,776,727	8.5
M&G Investments	8,333,000	5.5
Tellworth Investments	5,025,635	3.3
AXA	4,816,646	3.2
Hoya Corporation	4,799,880	3.2
FIL Investment International	4,655,344	3.1

1. Information taken from 31 December Equiniti Analysis – note 2 differences from the Jan 20 published numbers.

Save as referred to above, the Directors are not aware of any persons as at 31 December 2019 who were interested in 3% or more of the voting rights of the Company or could directly or indirectly, jointly or severally, exercise control over the Company.

Financial risk management objectives and policies

The Company's financial risk management objectives and policies are shown in Note 1 to the consolidated financial statements. The main risks arising from the Company's financial instruments are interest rate risk, exchange rate risk, credit risk, and liquidity risk, which are continuously monitored by the Board.

Political contributions

The Company made no political donations or incurred any political expenditure during the year.

Disclosure of information to auditor

The Directors who held office at the date of approval of this Directors' report confirm that, so far as they are each aware, there is no relevant audit information of which the Company's auditor is unaware; and each Director has taken all the steps that he ought to have taken as a Director to make himself aware of any relevant audit information and to establish that the Company's auditor is aware of that information.

Other information

An indication of likely future developments in the business and particulars of significant events which have occurred since the end of the financial year have been included in the Strategic Report on page 26.

Auditor

KPMG LLP were reappointed as auditor during the period. In accordance with Section 489 of the Companies Act 2006, a resolution for the reappointment of KPMG LLP as auditor of the Company is to be proposed at the forthcoming AGM.

By order of the Board



Richard Rees

Director
Creo House
Unit 2, Beaufort Park
Beaufort Park Way
Chepstow
Wales
NP16 5UH
6 May 2020

DIRECTORS' RESPONSIBILITIES

The Directors are responsible for preparing the Annual Report and the Group and Parent Company financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and Parent Company financial statements for each financial year. Under the AIM Rules for Companies they are required to prepare the Group financial statements in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU) and applicable law and they have elected to prepare the Parent Company financial statements in accordance with UK accounting standards and applicable law (UK Generally Accepted Accounting Practice), including FRS 101 *Reduced Disclosure Framework*.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Parent Company and of their profit or loss for that period. In preparing each of the Group and Parent Company financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable, relevant, reliable and prudent;
- for the Group financial statements, state whether they have been prepared in accordance with IFRSs as adopted by the EU;
- for the Parent Company financial statements, state whether applicable UK accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- assess the Group and Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Parent Company's transactions and disclose with reasonable accuracy at any time the financial position of the Parent Company and enable them to ensure that its financial statements comply with the Companies Act 2006. They are responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error, and have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

Under applicable law and regulations, the Directors are also responsible for preparing a Strategic Report and a Directors' Report that comply with that law and those regulations.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

DIRECTORS' REMUNERATION REPORT (UNAUDITED)

Remuneration Committee

The responsibilities of the Remuneration Committee are to advise upon and make recommendations to the Board on the Group's remuneration policies and, within the framework established by the Board, to recommend the remuneration of the Executive Directors.

The CEO and CFO are invited to attend meetings to discuss remuneration packages and bonus schemes for senior executives within the Group, as well as the awarding of share options to such persons under any share scheme adopted by the Group.

Charles Spicer chaired the Committee and John Bradshaw served on the Committee during the period. Post period Ivonne Cantu assumes responsibility as chair of the Remuneration Committee.

The Remuneration Committee assesses the performance of the Executive Directors and other senior managers in the context of recommending their annual remuneration, bonus awards and share option grants to the Board for final determination. The remuneration of the Non-Executive Directors is recommended by the Executive Directors and takes account of the time spent on Board and Committee matters. The Board will make the final determination although no Director will participate in any discussion about his own remuneration.

An important objective of the Committee is to ensure that a competitive and appropriate base salary is paid to Directors and senior managers, together with incentive arrangements that are:

- aligned with shareholders' interests and with long-term business strategies;
- measured against challenging and well-defined financial targets (which are set in advance); and
- transparent and without 'soft' non-financial targets which could otherwise allow undue discretion to award bonuses that do not reflect actual financial performance of the Group.

Remuneration policy

The main elements of the remuneration package for Executive Directors and senior management are:

Base annual salary

The base salary may be reviewed annually by the Remuneration Committee. In determining the base annual salary the Remuneration Committee takes into account several factors, including the current position and development of the Group, individual contribution, and market salaries for comparable organisations.

Discretionary annual and transaction bonus arrangements

All Executive Directors are eligible for a discretionary annual bonus which is paid in accordance with a bonus scheme developed by the Remuneration Committee. This takes into account performance against defined personal objectives and the financial performance of the Group. In certain circumstances, the Remuneration Committee may award a separate, specific transaction related bonus.

Share incentive schemes

The Group operates certain share option plans (further details of which are set out in Note 8 Share based payments), under which certain Directors, employees and certain contractors have been granted options to subscribe for ordinary shares. All options are equity settled. The options are subject to service conditions and have varying vesting periods and exercise prices (depending on the time of grant). The Group has no legal or constructive obligation to repurchase or settle the options in cash.

Remuneration Policy for Non-Executive Directors

Non-Executive Directors are employed on letters of appointment which have an initial term of one year and then which may be terminated at any time by either party with three months' notice.

Remuneration for Non-Executive Directors is set by the Executive Directors of the Board. Non-Executive Directors do not participate in bonus schemes. Charles Spicer and John Bradshaw have been awarded share options.

Directors' remuneration

The remuneration of the Board of Directors of Creo Medical Group plc during the 12-month period was:

(All figures £)	Salary and taxable benefits	Pension	Share-based payments	12 months to 31 December 2019	18 months to 31 December 2018
Executive:					
Professor Christopher Hancock	562,244	5,000	261,831	829,075	963,181
Craig Gulliford	674,947	20,000	342,017	1,036,964	1,243,762
Richard Rees	532,782	20,500	264,083	817,365	927,199
Total executive	1,769,973	45,500	867,931	2,683,404	3,134,142
Non-executive:					
Charles Spicer	93,000	–	17,835	110,835	125,995
John Bradshaw	63,000	–	11,890	74,890	71,496
David Woods	–	–	–	–	–
Total non-executive	156,000	–	29,725	185,725	197,491
Total Directors' remuneration	1,925,973	45,500	897,656	2,869,129	3,331,633

Pension contributions include payments contributed on a salary sacrifice basis during the year and are shown in the salary and taxable benefits line. Salary and taxable benefits during the 12 month period include an annual bonus for 2019 plus the 12 month element of the 2018 transaction bonus. The transaction related bonus relating to the £48.1m share placing in 2018 is being accrued over a two year period commencing September 2018. The share-based payment charge relates to share options issued by the Group. The charge for the year of £897,656 for Directors compares to the charge incurred by the Group in total for all employees and suppliers of £1,554,845.

Directors' shareholdings

The interests of the Directors holding office at 31 December 2019 in the shares of the Company, including family interests, were:

(All figures £)	31 December 2019	31 December 2019
	Number	%
Executive:		
Professor Christopher Hancock	4,400,098	2.93%
Craig Gulliford	609,886	0.41%
Total executive	5,009,984	3.34%
Non-executive:		
Charles Spicer	93,810	0.06%
John Bradshaw	—	—
David Woods	25,000	0.02%
Total non-executive	118,810	0.08%
Total Directors' shareholdings	5,128,794	3.42%

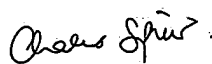
Directors' interests in share options

Directors' interests in share options, granted under either the Creo Medical Group plc Enterprise Management Incentive Share Option Scheme or the Creo Medical Group plc Unapproved Share Option Scheme, to acquire ordinary shares of £0.001 pence each in the Company at 31 December 2019 were:

(All figures £)	31 December 2018 Number	Granted during year	Exercised during year	31 December 2019 Number	Vested but unexercised	Exercise price
Executive:						
Professor Christopher Hancock	417,240	–	–	417,240	417,240	16.67p
Professor Christopher Hancock	72,000	–	–	72,000	72,000	16.67p
Professor Christopher Hancock	1,184,210	–	–	1,184,210	1,184,210	76.00p
Professor Christopher Hancock	107,914	–	–	107,914	–	113.00p
Professor Christopher Hancock	268,293	–	–	268,293	–	153.75p
Professor Christopher Hancock	–	114,035	–	114,035	–	171.00p
	2,049,657	114,035	–	2,163,692	1,673,450	–
Craig Gulliford	540,000	–	–	540,000	540,000	16.67p
Craig Gulliford	936,000	–	–	936,000	936,000	16.67p
Craig Gulliford	1,578,948	–	–	1,578,948	1,578,948	76.00p
Craig Gulliford	143,885	–	–	143,885	–	113.00p
Craig Gulliford	325,203	–	–	325,203	–	153.75p
Craig Gulliford	–	143,275	–	143,275	–	171.00p
	3,524,036	143,275	–	3,667,311	3,054,948	–
Richard Rees	288,000	–	–	288,000	288,000	16.67p
Richard Rees	1,184,210	–	–	1,184,210	1,184,210	76.00p
Richard Rees	118,705	–	–	118,705	–	113.00p
Richard Rees	268,293	–	–	268,293	–	153.75p
Richard Rees	–	114,035	–	114,035	–	171.00p
	1,859,208	114,035	–	1,973,243	1,472,210	–
Total executive	7,432,901	371,345	–	7,804,246	6,200,608	–
Non-executive:						
Charles Spicer	118,421	–	–	118,421	–	76.00p
John Bradshaw	27,000	–	–	27,000	27,000	21.39p
John Bradshaw	78,947	–	–	78,947	–	76.00p
David Woods	–	–	–	–	–	–
Total non-executive	224,368	–	–	224,368	27,000	–
Total Directors' shareholdings	7,657,269	371,345	–	8,028,614	6,227,608	–

All share options are subject to employment conditions, those issued on or post admission at 76p, 113p, 153.75p and 171p are also subject to performance conditions.

Other transactions that occurred with Directors during the year are detailed in note 23 to the financial statements under Related Party Transactions.



Charles Spicer
Chairman of the Remuneration Committee
Creo House
Unit 2, Beaufort Park
Beaufort Park Way
Chepstow
Wales
NP16 5UH
6 May 2020

FINANCIAL STATEMENTS

A year of achievements.

We made pleasing progress against our commercial strategy in 2019.

INDEPENDENT AUDITOR'S REPORT

1. Our opinion is unmodified

We have audited the financial statements of Creo Medical Group plc ('the Company') for the year ended 31 December 2019 which comprise the Consolidated statement of profit and loss and other comprehensive income, Consolidated statement of financial position, Consolidated statement of changes in equity, Consolidated statement of cash flows, Parent Company statement of financial position, Parent Company statement of changes in equity, and the related notes, including the accounting policies in note 1.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2019 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with International Financial Reporting Standards as adopted by the European Union;
- the Parent Company financial statements have been properly prepared in accordance with UK accounting standards, including FRS 101 Reduced Disclosure Framework; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) ('ISAs (UK)') and applicable law. Our responsibilities are described below. We have fulfilled our ethical responsibilities under, and are independent of the Group in accordance with, UK ethical requirements including the FRC Ethical Standard as applied to listed entities. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion.

Overview

Materiality: £140,000 (2018:£120,000)
group financial statements as a whole 0.73% (2018: 0.67%) of total expenses

Coverage 100% (2018:100%) of group loss before tax

Key audit matters vs 2018

Recurring risks	The impact of uncertainties due to the UK exiting the European Union on our audit	◀▶
	Treatment of development costs	▲
	Recoverability of parent company's investment in subsidiary and debt due from subsidiary	◀▶

2. Key audit matters: including our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgment, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In arriving at our audit opinion above, the key audit matters, were as follows (unchanged from 2018):

	The risk	Our response
The impact of uncertainties due to the UK exiting the European Union on our audit Refer to page 33 (principal risks and uncertainties)	Unprecedented levels of uncertainty: All audits assess and challenge the reasonableness of estimates, in particular as described in treatment of development costs below, and related disclosures and the appropriateness of the going concern basis of preparation of the financial statements. All of these depend on assessments of the future economic environment and the Group's future prospects and performance. Brexit is one of the most significant economic events for the UK and its effects are subject to unprecedented levels of uncertainty of consequences, with the full range of possible effects unknown.	We developed a standardised firm-wide approach to the consideration of the uncertainties arising from Brexit in planning and performing our audits. Our procedures included: Our Brexit knowledge: We considered the Directors' assessment of Brexit-related sources of risk for the Group's business and financial resources compared with our own understanding of the risks. We considered the Directors' plans to take action to mitigate the risks. Sensitivity analysis: When addressing the treatment of development costs and other areas that depend on forecasts, we compared the Directors' analysis to our assessment of the full range of reasonably possible scenarios resulting from Brexit uncertainty and, where forecast cash flows are required to be discounted, considered adjustments to discount rates for the level of remaining uncertainty. Assessing transparency: As well as assessing individual disclosures as part of our procedures on the treatment of development costs we considered all of the Brexit related disclosures together, including those in the Strategic Report, comparing the overall picture against our understanding of the risks.

The risk	Our response
Treatment of development costs (£500,000 capitalised and £3,025,000 expensed; 2018: £150,000 capitalised and £3,794,000 expensed) Refer to page 69 and 73 (accounting policies) and Note 12 page 79 (financial disclosures)	However, no audit should be expected to predict the unknowable factors or all possible future implications for a company and this is particularly the case in relation to Brexit. Our procedures included: • Accounting analysis: Critically assessed the Group's accounting policy for determining whether or not costs incurred on a project should be capitalised against the criteria of the relevant accounting standard and our understanding of the progress of the projects. • Test of detail: Obtained evidence and documentation to assess and challenge the status of the projects including assessing the technical feasibility and commercial viability by reviewing regulatory approval submissions, results of clinical trials and procedures undertaken, market analysis and customer correspondence. • Test of detail: Agreed a sample of costs allocated to development projects to supporting documentation, primarily timesheets and payroll records for relevant employees in relation to labour costs and purchase invoices for other costs. • Challenged amortisation: Challenged the timing of the commencement of amortisation of capitalised development assets by determining the point at which the asset is available for use, being when the related product is physically ready to be distributed to a customer. • Assessing transparency: Evaluated the adequacy of the disclosures of the judgements involved, compared with the requirements of the accounting standards and our understanding of the business. Accounting treatment: The Group aims to develop cutting-edge surgical endoscopy products and devices. Development costs are capitalised in accordance with the relevant accounting standards when specific criteria are met. The application of accounting standards to determine whether the criteria for capitalisation have been met is inherently subjective as this involves an assessment of the technical feasibility and commercial viability of the project concerned. As the number of development projects being undertaken by the Group has increased in the year, the risk associated with the application of the correct accounting treatment for development costs has also increased.
Recoverability of Parent Company's investment in subsidiary and debt due from subsidiary (Investment in subsidiary £1.3m, 2018: £0.6m; amount owed by subsidiary undertaking £40 million, 2018: £21.6 million) Refer to pages 89 to 91 (accounting policies and financial disclosures)	Low risk, high value The investment in subsidiary and amounts owed by the subsidiary undertaking is significant and represents 35% (2018: 34%) of the Company's total assets. The carrying value of an investment in a subsidiary undertaking is assessed for impairment and expected credit losses ('ECLs') are calculated on the amounts owed by the subsidiary. The application of accounting standards to determine any impairment or ECLs is inherently subjective as this involves judgements to be made in relation to the future performance of the subsidiary and possible default events over the expected life of the loan. Whilst the overall risk is assessed as low, we determined that due to their materiality in the context of the Parent Company financial statements, the impairment assessment and calculation of ECLs are considered to be the areas that had the greatest effect on our Parent Company audit. Our procedures included: • Accounting policies: Assessing the relevant accounting policies, especially those requiring the exercise of judgement such as the definition of default for an on demand loan. • Control reperformance: We tested the controls over the expected credit loss estimation process, including the annual approval and challenge of those estimates by the Directors. • Qualitative indicators: In relation to the amounts owed by the subsidiary, assessing the Company's conclusions on whether default has occurred with reference to indicators such as relevant clinical and regulatory data. • Benchmarking assumptions: Assess the carrying value of the investment in subsidiary by challenging assumptions used in the cash flows included in the budgets based on our knowledge of the Group and the markets in which the subsidiary operates. • Historical comparisons: Assessing the historical accuracy of the previous forecasts by comparing to actual costs incurred.

3. Our application of materiality and an overview of the scope of our audit

Materiality for the Group financial statements as a whole was set at £140,000 (2018: £120,000), determined with reference to a benchmark of Group total expenditure, of which it represents 0.73% (2018: Group total expenditure, of which it represents 0.67%). We consider total expenditure to be the most appropriate benchmark as the entity is still within the start-up phase of the business cycle.

Materiality for the Parent Company financial statements as a whole was set at £84,000 (2018: £108,000). This is lower than the materiality we would otherwise have determined by reference to total assets, and represents 0.07% of the Company's total assets (2018: 0.2%).

We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £7,000 (2018: £6,000), in addition to other identified misstatements that warranted reporting on qualitative grounds.

Of the Group's five (2018: four) reporting components, which include the Parent Company, we subjected two (2018: two) to full scope audits for group reporting purposes.

The components within the scope of our work accounted for the following percentages of the Group's results. The Group team approved the component materialities, which ranged from £84,000 to £126,000, having regard to the mix of size and risk profile of the Group across the components.

For the residual three components, which are currently dormant, we performed analysis at an aggregated Group level to re-examine our assessment that there were no significant risks of material misstatement within these.

The work on both components, including the audit of the Parent Company, was performed at the Company's head office in Chepstow by the Group team.

4. We have nothing to report on going concern

The Directors have prepared the financial statements on the going concern basis as they do not intend to liquidate the Company or the Group or to cease their operations, and as they have concluded that the Company's and the Group's financial position means that this is realistic. They have also concluded that there are no material uncertainties that could have cast significant doubt over their ability to continue as a going concern for at least a year from the date of approval of the financial statements ('the going concern period').

Our responsibility is to conclude on the appropriateness of the Directors' conclusions and, had there been a material uncertainty related to going concern, to make reference to that in this audit report. However, as we cannot predict all future events or conditions and as subsequent events may result in outcomes that are inconsistent with judgements that were reasonable at the time they were made, the absence of reference to a material uncertainty in this auditor's report is not a guarantee that the Group or the Company will continue in operation.

In our evaluation of the Directors' conclusions, we considered the inherent risks to the Group's and Company's business model and analysed how those risks might affect the Group's and Company's financial resources or ability to continue operations over the going concern period. The risks that we considered most likely to adversely affect the Group's and Company's available financial resources over this period were:

- availability of cash resources.
- achievement of regulatory approvals and commercialisation of the company's products.
- achievement of forecasts.

As these were risks that could potentially cast significant doubt on the Group's and the Company's ability to continue as a going concern, we considered sensitivities over the level of available financial resources indicated by the Group's financial forecasts taking account of reasonably possible (but not unrealistic) adverse effects that could arise from these risks individually and collectively and evaluated the achievability of the actions the Directors consider they would take to improve the position should the risks materialise. We also considered less predictable but realistic second order impacts, such as the impact of Brexit and the erosion of customer or supplier confidence, which could result in a rapid reduction of available financial resources.

Based on this work, we are required to report to you if we have concluded that the use of the going concern basis of accounting is inappropriate or there is an undisclosed material uncertainty that may cast significant doubt over the use of that basis for a period of at least a year from the date of approval of the financial statements.

We have nothing to report in these respects, and we did not identify going concern as a key audit matter.

5. We have nothing to report on the other information in the Annual Report

The Directors are responsible for the other information presented in the Annual Report together with the financial statements. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

Strategic Report and Directors' Report

Based solely on our work on the other information:

- we have not identified material misstatements in the Strategic Report and the Directors' Report;
- in our opinion the information given in those reports for the financial year is consistent with the financial statements; and
- in our opinion those reports have been prepared in accordance with the Companies Act 2006.

6. We have nothing to report on the other matters on which we are required to report by exception

Under the Companies Act 2006, we are required to report to you if, in our opinion:

- adequate accounting records have not been kept by the Parent Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the Parent Company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of Directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

We have nothing to report in these respects.

7. Respective responsibilities

Directors' responsibilities

As explained more fully in their statement set out on page 52, the Directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and, Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue our opinion in an auditor's report. Reasonable assurance is a high level of assurance, but does not guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

A fuller description of our responsibilities is provided on the FRC's website at www.frc.org.uk/auditorsresponsibilities.

8. The purpose of our audit work and to whom we owe our responsibilities

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.



Jeremy Thomas (Senior Statutory Auditor)

for and on behalf of KPMG LLP, Statutory Auditor
Chartered Accountants

3 Assembly Square

Britannia Quay,

Cardiff,

CF10 4AX

7 May 2020

CONSOLIDATED STATEMENT OF PROFIT AND LOSS AND OTHER COMPREHENSIVE INCOME

(All figures £)	Note	12 months to 31 December 2019	18 months to 31 December 2018
Revenue	2	13,473	–
Cost of sales		(8,522)	–
Gross Profit		4,951	–
Other operating income	2	126,719	279,959
Administrative expenses		(19,007,048)	(17,943,745)
Operating loss		(18,875,378)	(17,663,786)
Finance expenses	9	(51,291)	(16,744)
Finance income	9	311,288	104,343
Loss before tax	3	(18,615,381)	(17,576,187)
Taxation	10	2,704,231	2,767,579
Loss for the year/period		(15,911,150)	(14,808,608)
Other comprehensive income		–	–
Total comprehensive loss for the year/period		(15,911,150)	(14,808,608)
Loss per share			
Basic and diluted	11	(0.13)	(0.16)

The Notes on pages 66 to 91 form part of the financial statements.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(All figures £)	Note	12 months to 31 December 2019	18 months to 31 December 2018
Assets			
Non-current assets			
Intangible assets	12	865,241	307,814
Property, plant and equipment	13	1,295,818	906,256
Other financial assets	18	–	10,857
Other non-current receivables	15	8,400	8,400
		2,169,459	1,233,327
Current assets			
Inventories	14	727,158	302,472
Trade and other receivables	15	1,616,319	1,052,766
Tax receivable	16	2,702,198	2,569,631
Cash and cash equivalents		81,048,448	44,588,722
		86,094,123	48,513,591
Total assets		88,263,582	49,746,918
Shareholder equity			
Called up share capital	21	150,378	120,495
Share premium		115,111,506	65,835,555
Merger reserve		13,602,735	13,602,735
Share option reserve		4,647,915	3,093,070
Retained earnings		(50,849,190)	(34,938,040)
		82,663,344	47,713,815
Liabilities			
Non-current liabilities			
Interest bearing liabilities	19	543,892	392,892
		543,892	392,892
Current liabilities			
Trade and other payables	17	4,883,153	1,599,620
Interest bearing liabilities	19	173,193	40,591
		5,056,346	1,640,211
Total liabilities		5,600,238	2,033,103
Total equity and liabilities		88,263,582	49,746,918

These financial statements were approved by the Board of Directors on 6 April 2020 and were signed on its behalf by:



Richard Rees
Director

Company registered number: 10371794

The Notes on pages 66 to 91 form part of the financial statements.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

(All figures £)	Note	Called up share capital	Retained earnings	Share premium	Merger reserve	Share option reserve	Total equity
Balance at 30 June 2017		80,712	(20,129,432)	19,810,393	13,602,735	1,288,250	14,652,658
Total comprehensive income for the period							
Profit or loss		–	(14,808,608)	–	–	–	(14,808,608)
Total comprehensive income		–	(14,808,608)	–	–	–	(14,808,608)
Transactions with owners, recorded directly in equity							
Issue of share capital		39,783	–	46,025,162	–	–	46,064,945
Equity settled share-based payment transactions	8	–	–	–	–	1,804,820	1,804,820
Balance at 31 December 2018		120,495	(34,938,040)	65,835,555	13,602,735	3,093,070	47,713,815
Total comprehensive income for the period							
Profit or loss		–	(15,911,150)	–	–	–	(15,911,150)
Total comprehensive income		–	(15,911,150)	–	–	–	(15,911,150)
Transactions with owners, recorded directly in equity							
Issue of share capital		29,883	–	49,275,951	–	–	49,305,834
Equity settled share-based payment transactions	8	–	–	–	–	1,554,845	1,554,845
Balance at 31 December 2019		150,378	(50,849,190)	115,111,506	13,602,735	4,647,915	82,663,344

The Notes on pages 66 to 91 form part of the financial statements.

CONSOLIDATED STATEMENT OF CASH FLOWS

(All figures £)	12 months to		18 months to
	Note	31 December 2019	31 December 2018
Cash flows from operating activities			
Total comprehensive loss for the period		(15,911,150)	(14,808,608)
Depreciation/amortisation charges		641,725	497,421
Increase in share option reserve		1,554,845	1,804,820
Fair value adjustment to derivatives		27,894	(10,857)
Finance expenses		23,397	16,744
Finance income		(311,288)	(93,486)
R&D expenditure credit		(5,362)	(18,602)
Taxation	10	(2,704,231)	(2,767,579)
Loss on disposal of property, plant and equipment	13	–	12,278
		(16,684,170)	(15,367,869)
Increase in inventories	14	(424,686)	(211,139)
Increase in trade and other receivables		(552,696)	(514,256)
Increase in trade and other payables		3,283,533	143,746
		(14,378,019)	(15,949,518)
Interest paid		(51,291)	(16,744)
Tax received		2,577,026	1,666,525
Net cash from operating activities		(11,852,284)	(14,299,737)
Cash flows from investing activities			
Purchase of intangible fixed assets	12	(633,795)	(304,462)
Purchase of tangible fixed assets	13	(484,006)	(1,083,391)
Interest received		311,288	104,343
Net cash from investing activities		(806,513)	(1,283,510)
Cash flows from financing activities			
Capital received in respect of lease liabilities		–	121,595
Capital repaid in respect of lease liabilities		(187,310)	(45,333)
Capital received in respect of long-term borrowings		–	342,000
Share issue	22	49,305,833	46,064,945
Net cash from financing activities		49,118,523	46,483,207
Increase in cash and cash equivalents		36,459,726	30,899,960
Cash and cash equivalents at beginning of period		44,588,722	13,688,762
Cash and cash equivalents at end of period		81,048,448	44,588,722

The Notes on pages 66 to 91 form part of the financial statements.

NOTES TO THE FINANCIAL STATEMENTS

1. Accounting policies

General information

Creo Medical Group plc is a public company, limited by shares, registered and domiciled in England and Wales in the UK. The Company's registered number is 10371794 and the registered office is Creo House, Unit 2, Beaufort Park, Beaufort Park Way, Chepstow, Wales NP16 5UH.

The Group financial statements consolidate those of the Parent Company and its subsidiaries (together referred to as the 'Group'). The Parent Company financial statements present information about Creo Medical Group plc as a separate entity and not about its Group.

The Group financial statements have been prepared and approved by the Directors in accordance with International Financial Reporting Standards as adopted by the European Union ('adopted IFRSs'). The Company has elected to prepare its Parent Company financial statements in accordance with FRS 101. The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods presented in these Group financial statements.

Basis of preparation

This is the third annual financial report of the Company since the incorporation of Creo Medical Group plc on 12 September 2016 and the subsequent acquisition of Creo Medical Limited via a share for share exchange on 9 November 2016. The financial statements are presented in Sterling and rounded to the nearest pound.

This financial report for the 12-month period ended 31 December 2019 (including comparatives for the 18 months ended 31 December 2018) was approved by the Board of Directors on 6 May 2020. The accounting period in the prior year was extended by 6 months to 31 December 2018 to align the accounting reference date to annual calendar and our annual budgeting process.

Changes in accounting policy and disclosures

New standards, amendments and interpretations

The following new standards, amendments and interpretations have been adopted by the Group for the first time for the financial year beginning on 1 January 2019:

- Annual improvements 2015 – 2017 cycle.
- Amendment to IFRS 2, 'Share-based payments' which clarifies the classification and measurement of certain share-based payment transactions.
- IFRS 16 'Leases'.
- Amendments to IFRS 9 'Financial Instruments' which clarifies the accounting for prepayment features with negative compensation.
- Amendment to IAS 28 'Investments in associates and joint ventures' which clarifies the accounting for long-term interests in an associate or joint venture, which in substance form part of the net investment in the associate or joint venture, but to which equity accounting is not applied.
- Interpretation 23 'Uncertainty over Income Tax Treatments' which explains how to recognise and measure deferred and current income tax assets and liabilities where there is uncertainty over a tax treatment.
- Amendments to IAS 19 'Employee Benefits' which clarifies the accounting for defined benefit plan amendments, curtailments and settlements.

With the exception of IFRS 16 noted below, the adoption of these standards, amendments and interpretations has not had a material impact on the financial statements of the Group or Parent Company.

New standards, amendments and interpretations issued but not effective and not adopted early

The following new standards, amendments to standards and interpretations have been issued but are not yet effective and therefore have not been applied in preparing these consolidated financial statements.

- Amendments References to Conceptual Framework in IFRS Standards. Effective for periods beginning on or after 1 January 2020.
- Amendments to IFRS 3 'Definition of a business'. Effective for periods beginning on or after 1 January 2020.
- Amendments to IAS 1 and IAS 8 'Definition of Material'. Effective for periods beginning on or after 1 January 2020.
- Amendments to IFRS 7, IFRS 9 and IAS 39 'Financial reporting in the period leading up to IBOR reform'. Effective for periods beginning on or after 1 January 2020.

The Directors anticipate that none of the new standards, amendments to standards and interpretations is expected to have a significant effect on the financial statements of the Group or Parent Company.

IFRS 16 Leases

The Group has applied IFRS 16 using the modified retrospective approach and therefore the comparative information has not been restated and continues to be reported under IAS 17 and IFRIC 4. The details of accounting policies under IAS 17 and IFRIC 4 are disclosed separately.

At inception of a contract, the Group assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, the Group uses the definition of a lease in IFRS 16.

This policy is applied to contracts entered into, on or after 1 January 2019. The Group has taken the practical expedient not to reassess whether contracts at the date of initial application constituted a lease.

At commencement or on modification of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of its relative stand-alone prices. However, for the leases of property the Group has elected not to separate non-lease components and account for the lease and non-lease components as a single lease component.

The Group recognises a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received. On transition, the right of use assets were recognised at an amount equal to the lease liability, adjusted by the amount of prepaid lease payments relating to that lease recognised in the statement of financial position immediately before the date of initial application.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term, unless the lease transfers ownership of the underlying asset to the Group by the end of the lease term or the cost of the right-of-use asset reflects that the Group will exercise a purchase option. In that case the right-of-use asset will be depreciated over the useful life of the underlying asset, which is determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

The Group determines its incremental borrowing rate by obtaining interest rates from various external financing sources and makes certain adjustments to reflect the terms of the lease and type of the asset leased.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is measured at amortised cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, if the Group changes its assessment of whether it will exercise a purchase, extension or termination option or if there is a revised in-substance fixed lease payment.

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets that do not meet the definition of investment property in 'property, plant and equipment' and lease liabilities in 'interest bearing liabilities' in the statement of financial position.

Short-term leases and leases of low-value assets

The Group has elected not to recognise right-of-use assets and lease liabilities for leases of low-value assets and short-term leases, including IT equipment. The Group recognises the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

Impact on transition

On transition to IFRS 16, the Group recognised additional right-of-use assets and additional lease liabilities. The impact on transition is summarised below.

Right-of-use assets	£470,913
Lease Liabilities	£430,663

When measuring lease liabilities for leases that were classified as operating leases, the Group discounted lease payments using its incremental borrowing rate at 1 January 2019. The weighted-average rate applied is 3%.

All figures
£

Operating lease commitments at 31 December 2018 as disclosed under IAS 17 in the Group's consolidated financial statements	510,915
Recognition exemption of for leases of low-value assets	—
Recognition exemption for leases with less than 12 months of lease term at transition	(16,438)
Lease liabilities discounted using the incremental borrowing rate at 1 January 2019	430,663
Prepaid lease payments at 31 December 2018	40,250
Right-of-use asset recognised at 1 January 2019	470,913

Leases previously recognised under IAS 17

Operating lease payments

Payments made under operating leases in the period are recognised in the income statement on a straight-line basis over the term of the lease. Lease incentives received are recognised in the income statement as an integral part of the total lease expense.

Finance lease payments

Minimum lease payments are apportioned between the finance charge and the reduction of the outstanding liability. The finance charge is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability.

Measurement convention

The financial statements are prepared on the historical cost basis except that derivative financial instruments are stated at their fair value.

Business combinations and basis of consolidation

On 9 November 2016 Creo Medical Group plc offered a share for share exchange to the shareholders of Creo Medical Limited. As a result of this transaction, Creo Medical Group plc became the parent of Creo Medical Limited.

On the basis that there was no change in control following the share for share exchange, this is considered a common control transaction.

Therefore, within the parent Company accounts the acquisition of Creo Medical Limited, the new parent measured cost at the carrying amount of its share of the equity items shown in the separate financial statements of the original parent at the date of the reorganisation. Within the consolidated financial statements, the acquisition of Creo Medical Limited is considered to be a company reorganisation among entities under common control and as such IFRS 3 is not considered to apply, therefore book value accounting was applied to the acquisition. The Directors chose to restate the comparatives for the Company prior to the acquisition date to show the combination as though it has occurred prior to the start of the earliest period presented. This was deemed to provide the user with a truer view of the Company's performance through the period.

Accounting policies adopted are consistent across the Group. All Intra-Group balances and transactions, including unrealised income and expenses arising from intra-Group transactions, are eliminated on consolidation.

Going concern

The Group reported a loss for the period of £15.9m (18-months to 31 December 2018: loss £14.8m). Net assets as at 31 December 2019 were £82.6m (31 December 2018: £47.7m) and include cash and cash equivalents of £81.0m (31 December 2018: £44.6m).

The Board has considered the applicability of the going concern basis in the preparation of the financial statements. This included the review of internal budgets and financial results and a review of cash flow forecasts for the 12-month period following the date of signing the financial statements.

The Group completed a £51.9m share placing on AIM on 23 December 2019 and has prepared detailed forecasts and projections taking into account the available funding and its planned activities for the five-year period to 31 December 2024. Based on the current business plan the Group is forecasting to be cash generative (and profitable) within this period and its cash resources will extend beyond the year ending 31 December 2024.

The Group has strategic collaboration agreements in place with distributors in a number of geographies and has been delivering product for training and market penetration purposes throughout the period. In addition, the group received its first commercial orders for Speedboat and its first revenue from US hospitals in the period and is now expecting a period of ramp up as market penetration activities are drive physical sales being realised. However, the roll out of the Clinical Education Programme has been impacted by the ongoing travel restrictions and social distancing policies put in place by governments across the world to limit the spread of COVID-19. Training and mentoring events across the Company's clinical education programme in the US, EU and the UK have been cancelled or postponed. It is also expected that the undertaking of new procedures and elective cases will be reduced worldwide which will impact the volume of expected Speedboat cases in the short term. Whilst the Company has been able to offer online training and remote mentoring via video link, the number of Endoscopists trained on the Speedboat device, will be lower than expected for this year and as a result initial revenues from the early uptake of Speedboat are likely to be lower in the short term.

The cash flow forecasts prepared include the current estimated impact of the COVID-19 coronavirus. Whilst initial revenues from the early uptake of Speedboat are likely to be lower in the short term, EBITDA and cash is likely to be better than expected due to savings as a result of the slow-down.

Additionally, given the unprecedented situation, the directors have modelled further severe but plausible downside scenarios involving the cessation of sales for a period from April to December 2020. Even in this scenario, the 5 year forecast indicates that the Group will have sufficient funds to meet its liabilities as they fall due throughout the forecast period. The Directors consider the above scenario to be unlikely. However, if even more severe scenarios were to be realised, the Group would take mitigating actions and the Directors are confident, following the Company's £51.9 million fundraising in December 2019, cash reserves at the end of March were £77.5 million and are more than sufficient to secure the business activities and staff through the current situation and beyond.

The Board believes that the outlook for the medium and long term remains very much unchanged, and will not be impacted by a short term slowdown in the early market development. As the world begins to emerge from the COVID-19 restrictions the business is expected to have multiple devices regulatory cleared for multiple markets across the EU and US. This will allow the Company to introduce these devices into clinical practice once COVID-19 related restrictions are eased and to ultimately commercialise the full product range with four devices optimised around the core tissue effects of dissection, resection, haemostasis and ablation, as well as the already cleared Speedboat device.

Based on these factors, including the current level of cash resources, the Directors are satisfied that the Group will have adequate resources to continue in operational existence for the foreseeable future and for a period of not less than 12 months from the date of signing the financial statements. Thus, they continue to adopt the going concern basis of accounting in preparing the annual report.

Intangible assets

Intangible assets include the capitalisation of development costs and software for the period ending 31 December 2019.

Software which is not an integral part of hardware assets are stated at historic cost, including expenditure that is directly attributable to the acquired item, less accumulated amortisation and impairment losses.

Expenditure on research activities is recognised as an expense in the year in which it is incurred. Costs are classified as research expenditure rather than development unless all of the below criteria are met, in which case these costs are capitalised on the balance sheet.

Development criteria:

- completion of the intangible asset is technically feasible so that it will be available for use or sale;
- the Company intends to complete the intangible asset and use or sell it;
- the Company has the ability to use or sell the intangible asset and the intangible asset will generate probable future economic benefits over and above cost;
- there are adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the expenditure attributable to the intangible asset during its development can be measured reliably.

Amortisation commences when the project is available for sale or use within the business.

Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use.

Amortisation is charged so as to write off the costs of intangible assets over their estimated useful lives, on the following basis:

Software	– 3 years straight line
Development costs	– 5 years straight line

Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation and any impairment losses. Cost includes the original purchase price of the asset and the costs attributable to bringing the asset to its working condition for its intended use.

Leases in which the Group assumes substantially all the risks and rewards of ownership of the leased asset are classified as PPE. Where land and buildings are held under leases the accounting treatment of the land is considered separately from that of the buildings. Leased assets acquired are stated at an amount equal to the lower of their fair value and the present value of the minimum lease payments at inception of the lease, less accumulated depreciation and less accumulated impairment losses. Lease payments are accounted for as described below.

Depreciation is charged so as to write off the costs of assets over their estimated useful lives, on the following basis:

Leasehold property improvements	– 3 years straight line
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Office equipment	– 2, 3 or 4 years straight line
Fixtures and fittings	– 3 or 4 years straight line
Motor vehicles	– 4 years straight line
Plant and machinery	– 3 years straight line or 4 years reducing balance
Right of Use assets	– based on length of lease agreement

The gain or loss arising on the disposal of an asset is determined as the difference between sales proceeds and the carrying amount of the asset and is recognised in income on the transfer of the risks and rewards of ownership.

The Company has no class of tangible fixed asset that has been revalued. On transition to IFRS the net book values recorded at 1 March 2013 have been applied and these are based on historic cost at the date of acquisition.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is based on First In, First Out (FIFO) principle using standard costing techniques and includes expenditure incurred in acquiring the inventories, production or conversion costs and other costs in bringing them to their existing location and condition.

Financial instruments

The Company predominantly enters into basic financial instrument transactions that result in the recognition of financial assets and liabilities like trade and other accounts receivable and payable, loans from other third parties, loans to related parties and investments in non-puttable financial instruments. Any transactions relating to share options issued by the entity are disclosed in the share-based payment accounting policy and note. The Company is also able to enter into a variety of derivative financial instruments to manage its exposure to foreign exchange risk, including foreign exchange forward contracts and cross currency swaps.

Impairment

The Group recognises loss allowances for expected credit losses (ECLs) on financial assets measured at amortised cost, debt investments measured at FVOCI and contract assets (as defined in IFRS 15).

The Group measures loss allowances at an amount equal to lifetime ECL, except for other debt securities and bank balances for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition, which are measured as 12-month ECL.

Loss allowances for trade receivables and contract assets are always measured at an amount equal to lifetime ECL.

When determining whether the credit risk of a financial asset has increased significantly since initial recognition and when estimating ECL, the Group considers reasonable and supportable information that is relevant and available without undue cost or effort. This includes both quantitative and qualitative information and analysis, based on the company's historical experience and informed credit assessment and including forward-looking information.

The Group considers a financial asset to be in default when the borrower is unlikely to pay its credit obligations to the Group in full, when demanded.

Lifetime ECLs are the ECLs that result from all possible default events over the expected life of a financial instrument.

12-month ECLs are the portion of ECLs that result from default events that are possible within the 12 months after the reporting date (or a shorter period if the expected life of the instrument is less than 12 months).

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all cash shortfalls (i.e. the difference between the cash flows due to the entity in accordance with the contract and the cash flows that the Group expects to receive). ECLs are discounted at the effective interest rate of the financial asset.

Credit-impaired financial assets

At each reporting date, the Company assesses whether financial assets carried at amortised cost and debt securities at FVOCI are credit-impaired. A financial asset is 'credit-impaired' when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

Write-offs

The gross carrying amount of a financial asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery.

Provisions under IFRS 9 may still be made to account for the probability of such default events however such a provision being made is not indicative that an actual default event will occur.

Trade and other receivables

Trade and other receivables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method, less any impairment losses.

Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits. Bank overdrafts that are repayable on demand and form an integral part of the Company's cash management are included as a component of cash and cash equivalents for the purpose only of the cash flow statement.

Trade and other payables

Trade and other payables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method.

Interest-bearing borrowings

Interest-bearing borrowings are recognised initially at fair value less attributable transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortised cost using the effective interest method, less any impairment losses.

Derivative financial instruments

Derivative financial instruments are recognised at fair value. The gain or loss on remeasurement to fair value is recognised immediately in profit or loss. The Group has not applied hedge accounting in the current or comparative periods.

Foreign currencies

The functional currency of the Group is pounds Sterling. Transactions entered into by Group entities in a currency other than the reporting currency are recorded at the rates ruling when the transaction occurred. Foreign currency monetary assets and liabilities are translated into Sterling at the rates ruling at the statement of financial position date. Exchange differences arising on the retranslation of the unsettled monetary assets and liabilities are similarly recognised in the income statement.

Current and deferred tax

Current taxes are based on the results shown in the financial statements and are calculated according to local tax rules, using tax rates enacted or substantially enacted by the statement of financial position date.

Deferred tax is provided on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. The following temporary differences are not provided for: the initial recognition of goodwill, the initial recognition of assets or liabilities that affect neither accounting nor taxable profit other than in a business combination, and differences relating to investments in subsidiaries to the extent that they will probably not reverse in the foreseeable future. The amount of deferred tax provided is based on the expected manner of realisation or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the balance sheet date. A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilised.

The Company incurs research and development expenditure which qualifies for Research and Development (R&D) tax relief and as such, prepares and submits an R&D claim to HMRC in relation to each accounting period. The claims are made on the basis that the Company and its activities meet the necessary conditions.

As the Company is currently loss making, there is no corporation tax liability arising, therefore it has chosen to convert the tax relief into payable tax credits instead of carrying forward a loss. This results in the credit being paid in cash directly to the Company following the submission of a valid claim.

The Company is claiming R&D tax relief predominately under the small or medium sized enterprises ('SME') scheme, therefore the credit is accounted for as tax in accordance with IAS 12 'Income Taxes'. However, where the R&D expenditure is related to monies received from research grants, the Company is claiming an R&D expenditure credit ('RDEC') under the Large Company Scheme and as such the related credit is accounted for 'above the line' in accordance with IAS 20 'Accounting for Government Grants', specifically as a reduction from the related expenditure in the statement of comprehensive income.

Employee benefits

Bonus

As with wages, salaries, paid annual leave, bonuses and non-monetary benefits are accrued in the period in which the associated services are rendered by employees of the Group.

Defined contribution plans

A defined contribution plan is a post-employment benefit plan under which the Company pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution pension plans are recognised as an expense in the income statement in the periods during which services are rendered by employees.

Share-based payments

Equity-settled share options are granted to certain Directors, employees and certain contractors which have been granted options to subscribe for ordinary shares. Each tranche in an award is considered a separate award with its own vesting period and grant date fair value. Fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model or where they are based on market based performance conditions the Monte Carlo model. Compensation expense is recognised over the tranche's vesting period based on the number of awards expected to vest, through an increase to equity. The number of awards expected to vest is reviewed over the vesting period, with any forfeitures recognised immediately.

Share-based payment arrangements in which the Group receives goods or services as consideration for its own equity instruments are accounted for as equity-settled share-based payment transactions, regardless of how the equity instruments are obtained by the Group.

The grant date fair value of share-based payment awards granted to employees is recognised as an employee expense, with a corresponding increase in equity, over the period that the employees become unconditionally entitled to the awards. The amount recognised as an expense is adjusted to reflect the actual number of awards for which the related service, market and non-market vesting conditions are expected to be met, such that the amount ultimately recognised as an expense is based on the number of awards that do meet the related service, market and non-market performance conditions at the vesting date. For share-based payment awards with non-vesting conditions, the grant date fair value of the share-based payment is measured to reflect such conditions and there is no true-up for differences between expected and actual outcomes. The social security element of these equity instruments is treated as cash settled with the liability recognised in other taxation and social security within trade and other payables in the consolidated balance sheet.

Share-based payment transactions in which the Group receives goods or services by incurring a liability to transfer cash or other assets that is based on the price of the Group's equity instruments are accounted for as cash-settled share-based payments. The fair value of the amount payable to employees is recognised as an expense, with a corresponding increase in liabilities, over the period in which the employees become unconditionally entitled to payment. The liability is remeasured at each balance sheet date and at settlement date. Any changes in the fair value of the liability are recognised as personnel expense in profit or loss. Where the Company grants options over its own shares to the employees of its subsidiaries it recognises, in its individual financial statements, an increase in the cost of investment in its subsidiaries equivalent to the equity-settled share-based payment charge recognised in its consolidated financial statements with the corresponding credit being recognised directly in equity. Amounts recharged to the subsidiary are recognised as a reduction in the cost of investment in subsidiary. Where costs recharged match those incurred there is no net impact on the investment in subsidiary.

Financing income and expenses

Financing expenses comprise interest payable, finance charges on shares classified as liabilities and leases recognised in profit or loss using the effective interest method, unwinding of the discount on provisions, and net foreign exchange losses that are recognised in the income statement (see foreign currency accounting policy). Financing income comprises interest receivable on funds invested, dividend income, and net foreign exchange gains.

Provisions

A provision is recognised in the balance sheet when the Group has a present legal or constructive obligation as a result of a past event, that can be reliably measured and it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. Provisions are reviewed at each balance sheet date and adjusted to reflect the current best estimate. If it is no longer probable that an outflow of economic benefit will be required to settle the obligation, the provision is reversed. Provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects risks specific to the liability.

Critical accounting judgements and key sources of estimation uncertainty

The application of the Group's accounting policies requires judgments in certain areas and to make estimates and assumptions concerning the future. These estimates and judgments are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The resulting accounting estimates will, by definition, seldom equal the related actual results. The following are those areas that are deemed to involve judgments and/or estimation about matters that have the most significant effect on the amounts recognised in the financial statements.

a. Critical accounting judgements in applying the Group's accounting policies

Capitalisation of development costs

Capitalisation of development costs requires analysis of the technical feasibility and commercial viability of the project concerned. Capitalisation of the costs will only be made where there is clear demonstration that future economic benefit will flow to the Company.

FDA clearance for the Speedboat device and the CROMA Advanced Energy Platform was obtained in prior periods, following which the Company was able to train a number of physicians and undertake successful treatments in patients. Having then entered into strategic collaboration agreements with distributors, it was determined that both the technical and commercial feasibility of the asset had been established. The subsequent costs associated with progressing the devices to a Minimal Viable Product ('MVP'), of £150,000 were therefore capitalised as judged to have met the criteria. Amortisation of this development asset commenced during the year as it became available for use as commercially available for sale to customers.

In the current period, further development of CROMA and Speedboat has been undertaken relating to the modularisation of the CROMA Platform to allow a range of other devices to be used and thus future-proofing the platform. In addition to this, development of the Speedboat includes enhancements that remove complexity built into the first generation device, such as heat shrink and reduction of the profile allowing greater flexibility in use.

This activity represents significant enhancements to be incorporated as new and critical features into a subsequent version and is therefore determined to be development meeting the definition of an intangible asset. It has been determined that these enhancements meet technical and commercial feasibility and that the associated costs meet the general recognition criteria for intangible assets and as such, costs of £500,000 have been capitalised in the period. As these enhancements were not completed as at the balance sheet date the asset was not yet available for use and therefore remains as an asset under construction.

The Group determines an asset to be available for use from the point at which it is physically ready to be distributed to a customer. At this point it will have gone through additional testing and quality assurance required to be able to be sold by the Company. Once this has been achieved, the development costs are amortised over its useful life.

The Group's internal budgets demonstrate that the products will generate probable future economic benefits supporting its judgement to capitalise the relevant development costs.

Other development activities have continued in the period, primarily relating to a further four single-use devices to be used with the CROMA Advanced Energy Platform relating to dissection, resection, haemostasis and ablation. These devices are advancing through the regulatory approval process although this had not been achieved as at the balance sheet date. On the basis that obtaining regulatory approval is a key part of establishing technical and commercial feasibility of an asset and therefore demonstrating future economic benefits, the costs associated with this development activity are not deemed to have yet met the general recognition criteria for intangible assets and as such costs of £3,024,595 have been expensed in the period.

b. Recognition of deferred tax asset

Management judgement is required whether the Group should recognise any deferred tax assets for losses. A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilised. Given the nature and stage of development of the Group there are significant losses accumulated to date. To determine whether a deferred tax asset should be recognised in relation to the future tax deduction that these losses represent, the Directors have considered the estimated profits over a medium-term forecast. These forecasts continue to show tax losses for the medium term (3 – 4 years) as the Group continues to develop and commercialise its product base. Thus there is considered to be insufficient certainty over the timing and amount of loss recoverability for an asset to be recognised.

2. Revenue and other operating income

Revenue from contracts with customers

Revenue is recognised when substantially all of the risk and reward of ownership of the goods are transferred to the customer in accordance with the sales terms, and thus has the ability to direct the use and obtain the benefits from the goods. Revenue is recognised net of any sales tax.

Collaborative arrangements

The Group has entered into a number of collaboration agreements with distributors in order to develop and penetrate geographical markets for the Group's initial products (Speedboat device and the CROMA Advanced Energy Platform) and to establish a working relationship in readiness for the Groups' suite of products.

The agreements represent the transfer of goods to the distributor for cash and the receipt of services in the form of marketing, promotion and setting up training and qualifying centres.

In respect of these agreements, the distributor is not deemed to be a 'customer' of the entity as defined in IFRS 15. Instead they are a provider of services relating to the Group's commercialisation and market penetration activities and as such no revenue is recognised in respect of these agreements. As such, the overall arrangement represents a cost to the Group.

The overall cost of the services is determined at inception and spread over the period of the agreement. The assumptions upon which the estimates are made are periodically updated. Any impact on profit or loss is recognised in the period in which the updates are made.

Other operating income

Other operating income relates to research grants. Income is recognised necessary to match it with the related costs in the profit or loss on a systematic basis over the periods in which the entity recognises expenses for the related costs for which the grants are intended to compensate. Furthermore, income is recognised only when there is reasonable assurance that the Company will comply with any conditions attached to the grant and the grant will be received.

Segmental reporting

Operating segments are identified on the basis of internal reporting and decision making. The Board regularly reviews the Company's performance and balance sheet position for its operations and receives financial information for the Company. As a result, the Company has one reportable segment, which is being the research and development of electrosurgical medical devices relating to the field of surgical endoscopy. As there is only one reportable segment whole profit, expenses, assets, liabilities and cash flows are measured and reported on a basis consistent with the financial statements, no additional disclosures are necessary.

3. Loss before tax

The loss before income tax is stated after charging/(crediting):

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Depreciation – owned assets	369,382	471,745
Depreciation – assets on hire purchase contracts	41,545	18,132
Depreciation – right of use assets	154,429	–
Amortisation	76,368	7,544
Loss on disposal of property, plant and equipment	–	12,278
Operating leases – land and buildings	–	249,602
Operating leases – other	–	83,538
Research and development expenditure	8,146,338	7,846,144
Foreign exchange differences	(16,155)	18,411

4. Audit and non-audit fees

An analysis of auditors' remuneration is as follows:

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Audit fees	106,383	108,280
Audit-related assurance services	10,000	17,000
Tax compliance services	8,500	5,500
Corporate finance services	–	6,500
All other services	2,000	2,000
Non-audit fees	20,500	31,000

Corporate finance services in the prior year were associated with the Directors' remuneration review.

5. Staff numbers and costs

The cost of employees (including Directors) during the period was made up as follows:

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Wages and salaries	5,749,776	5,329,362
Social security costs	660,709	661,393
Pension	395,675	546,393
Share-based payments	1,554,845	1,804,820
Total remuneration	8,361,005	8,341,968

The average monthly number of employees during the period was as follows:

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Research and development	54	38
Administration	17	11
	71	49

Pension costs incurred in the year relate to all employees. The staging date for auto-enrolment was 1 July 2017.

6. Directors remuneration

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Directors' remuneration	1,925,973	2,123,584
Pension	45,500	48,882
Share-based payments expensed	897,656	1,159,167
Total directors' remuneration	2,869,129	3,331,633

Directors' emoluments disclosed above, including the fair value for share-based payment expenses, paid to the highest paid Director in the period was £1,036,964 (period to December 2018: £1,243,762), there were Company pension contributions of £45,500 made to defined contribution schemes during the current period (31 December 2018: £48,882), no shares were received or receivable for any Director in respect of long-term incentive schemes. The share options exercised in the period by the highest paid Director was £nil (31 December 2018: £nil).

Executive average salary and other pay related benefits in the year are below the median range for AIM listed companies of a similar market capitalisation. See Directors' remuneration report for emoluments and compensation, share options and contributions to the pension scheme split by Director which form part of these audited financial statements.

7. Research and development expenditure

During the current and comparative years, the principle activity of the entity was research and development. Expenditure on research activities is recognised in the statement of profit or loss as incurred.

8. Share-based payments

	Grant date	Number of optionsVesting conditions	Exercise price	Fair value	Contractual life of options
1	04 January 2012	2,003,760 Continual service of employment over 3 years	0.16 to 0.22	0.08 to 0.10	10 years
2	06 December 2013	243,720 Continual service of employment over 3 years	0.21	0.09	10 years
3	14 July 2015	1,121,400 Continual service of employment over 3 years	0.17	0.11	10 years
4	14 July 2015	670,680 Continual service of employment over 3 years	0.17	0.11	10 years
5	03 August 2015	1,242,000 Continual service of employment over 3 years	0.17	0.12	10 years
6	04 August 2015	216,000 Continual service of employment over 3 years	0.17	0.12	10 years
7	29 September 2016	1,944,000 Continual service of employment over 3 years	0.17	0.11	10 years
8	09 December 2016	5,907,896 Continual service of employment over 3 years	0.76	0.48	10 years
9	04 April 2018	875,902 Continual service of employment and market-based performance conditions	1.13	0.58	10 years
10	29 August 2018	1,746,718 Continual service of employment over 3 years and non-market-based performance conditions	1.54	0.84	10 years
11	18 October 2018	749,209 Non-market-based performance conditions	0.76	1.60	10 years
12	02 July 2018	1,000,000 Non-market-based performance conditions	1.26	0.67	10 years
13	17 October 2019	371,345 Non-market and market-based performance conditions	1.71	0.86	10 years
		18,092,630			

Share option activity for the period ended 31 December 2019 is presented below:

	31 December 2019 Number of options	31 December 2019 Weighted average exercise price	31 December 2018 Number of options	31 December 2018 Weighted average exercise price
Outstanding at start of period	14,015,546	£0.72	11,942,936	£0.46
Converted from old scheme	-	-	-	-
Granted during the period	371,345	£1.71	4,371,829	£1.26
Forfeited during the period	(1,591,045)	£1.22	(1,315,579)	£0.45
Exercised during the period	(1,048,200)	£0.16	(983,640)	£0.16
Outstanding at end of period	11,747,646	£0.75	14,015,546	£0.72
Exercisable at end of period	8,371,832	£0.53	4,367,400	£0.17
Weighted average remaining contractual life (in years) of options outstanding at the period end	-	7.1	-	7.9

The estimated fair value of the share options was calculated by applying a Black-Scholes model for shares with no market-based performance conditions and a Monte Carlo model for those with a market-based performance condition. The model inputs for the current period option grants were as follows:

	12 months to 31 December 2019	18 months to 31 December 2018
Exercise price	1.71	£0.76 to £1.54
Share price at date of grant	1.71	£1.16 to £2.09
Risk-free interest rate	0.75%	0.5% to 0.75%
Expected volatility	41%	41% to 51%
Dividend yield	0%	0%
Contractual life of option (years)	10	10

Share-based payment expense

	12 months to 31 December 2019	18 months to 31 December 2018
Expense arising from share-based payment transactions	1,554,845	1,804,820

The following amounts for share-based payments are reflected in the above Consolidated statement of profit and loss and other comprehensive income in relation to Directors:

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Professor Christopher Hancock	261,831	334,003
Craig Gulliford	342,017	441,736
Richard Rees	264,083	335,937
Charles Spicer	17,835	28,495
John Bradshaw	11,890	18,996
	897,656	1,159,167

9. Finance income and costs

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Finance income:		
Bank interest	311,288	93,486
Fair value adjustment for derivatives	–	10,857
Total finance income	311,288	104,343
Finance costs:		
Bank interest	3,831	3,673
Interest expense on leases liabilities	10,235	13,071
Fair value adjustment for derivatives	27,894	–
Unwind of the discount on lease liabilities	9,331	–
Total finance costs	51,291	16,744

10. Taxation

Recognised in the income statement

(All figures £)	Note	12 months to 31 December 2019	18 months to 31 December 2018
Current tax:			
Current year		(2,696,190)	(2,551,029)
Adjustments for prior years		(8,041)	(216,550)
Current tax credit		(2,704,231)	(2,767,579)
Deferred tax:			
Origination and reversal of temporary timing differences	16	–	–
Total tax credit		(2,704,231)	(2,767,579)

Reconciliation of effective tax rate

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Loss for the period	(15,911,150)	(14,808,608)
Total credit	(2,704,231)	(2,767,579)
Loss excluding taxation	(18,615,381)	(17,576,187)
Tax using the UK corporation tax rate of 19% (2018: 19.75%)	(3,536,922)	(3,339,476)
Research and development	(1,160,130)	(1,097,669)
Movement in deferred tax not provided	1,949,141	1,140,593
Difference arising due to tax rate changes	66,642	368,112
Non-deductible expenses	(14,921)	377,411
Prior year adjustment	(8,041)	(216,550)
Total tax credit	(2,704,231)	(2,767,579)

The tax credit of £2,704,231 (2018: £2,767,579) relates to R&D tax relief claims submitted by the Group under the small or medium sized enterprises ('SME') scheme and therefore is accounted for as a tax credit in accordance with IAS12 'Incomes Taxes'. In addition, the Group has also submitted R&D claims under the large company ('RDEC') scheme in relation to monies received from Research Grants. In accordance with IAS 20 'Accounting for Government Grants', an amount of £6,008 (2018: £18,602) has been accounted for 'above the line' as a reduction from the related expenditure in the statement of comprehensive income.

11. Earnings per share

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
(Loss)		
(Loss) attributable to equity holders of the Company (basic)	(15,911,150)	(14,808,608)
Shares (number)		
Weighted average number of ordinary shares in issue during the period	121,343,612	90,390,078
Earnings per share		
Basic and diluted	(0.13)	(0.16)
Ordinary shares start of year	120,495,385	80,711,745
Issued in year		
Issue 1 – Ordinary	770,840	115,000
Issued with months remaining	10	12
Issue 2 – Ordinary	277,360	276,320
Issued with months remaining	9	11
Issue 3 – Ordinary	28,835,173	20,000
Issued with months remaining	–	8
Issue 4 – Ordinary	–	38,800,000
Issued with months remaining	–	4
Issue 5 – Ordinary	–	63,880
Issued with months remaining	–	1
Issue 6 – Ordinary	–	336,000
Issued with months remaining	–	1
Issue 7 – Ordinary	–	172,440
Issued with months remaining	–	1
Closing ordinary shares	150,378,758	120,495,385
Average ordinary shares	121,343,612	90,390,078
Basic EPS	(0.13)	(0.16)

Earnings per share has been calculated in accordance with IAS 33 'Earnings Per Share' using the loss for the period after tax, divided by the weighted average number of shares in issue.

	12 months to 31 December 2019	18 months to 31 December 2018
(Loss)		
(Loss) attributable to equity holders of the Company (basic)	(15,911,150)	(14,808,608)
Expenses of the initial public offering (non-recurring)	–	–
Adjusted operating loss	(15,911,150)	(14,808,608)
Shares (number)		
Weighted average number of ordinary shares in issue during the period	121,343,612	90,390,078
Earnings per share adjusted		
Basic and diluted	(0.13)	(0.16)

12. Intangible assets

(All figures £)	Development costs capitalisation	Computer software	Assets under construction	Total
Cost:				
At 1 July 2017	–	14,509	–	14,509
Additions	–	1,300	303,162	304,462
At 31 December 2018	–	15,809	303,162	318,971
Amortisation:				
At 1 July 2017	–	3,613	–	3,613
Charge for period	–	7,544	–	7,544
At 31 December 2018	–	11,157	–	11,157
Net book value at 31 December 2018	–	4,652	303,162	307,814
Cost:				
At 1 January 2019	–	15,809	303,162	318,971
Additions	–	62,181	571,614	633,795
Transferred	150,000	153,162	(303,162)	–
At 31 December 2019	150,000	231,152	571,614	952,766
Amortisation:				
At 1 January 2019	–	11,157	–	11,157
Charge for period	30,000	46,368	–	76,368
At 31 December 2019	30,000	57,525	–	87,525
Net book value at 31 December 2019	120,000	173,626	571,614	865,241

Assets under construction in the year include the capitalisation of research and development costs of £500,000, additions to the Enterprise Resource Planning (ERP) system of £112,735 (31 December 2018 £153,162) and CAD software additions of £21,060.

13. Property, plant and equipment

(All figures £)	Leasehold property	Office equipment	Fixture and fittings	Motor vehicles	Plant and machinery	Assets under construction	Right of use asset leases	Total
Cost:								
At 1 July 2017	16,664	403,568	70,661	10,000	244,499	56,298	–	801,690
Additions	414,838	83,840	–	–	566,376	18,338	–	1,083,392
Eliminated on disposal	–	(37,594)	–	–	–	–	–	(37,594)
Transferred	55,214	–	–	–	1,084	(56,298)	–	–
At 31 December 2018	486,716	449,814	70,661	10,000	811,959	18,338	–	1,847,488
Depreciation:								
At 1 July 2017	10,469	210,915	65,005	10,000	180,282	–	–	476,671
Charge for period	125,403	139,182	4,783	–	220,509	–	–	489,877
Eliminated on disposal	–	(25,316)	–	–	–	–	–	(25,316)
Transferred	–	–	–	–	–	–	–	–
At 31 December 2018	135,872	324,781	69,788	10,000	400,791	–	–	941,232
Net book value at 31 December 2018	350,844	125,033	873	–	411,168	18,338	–	906,256
Cost:								
At 1 January 2019	486,716	449,814	70,661	10,000	811,959	18,338	470,913	2,318,401
Additions	82,165	99,913	–	–	60,891	241,037	–	484,006
Transferred	–	70,661	(70,661)	–	18,338	(18,338)	–	–
At 31 December 2019	568,881	620,388	–	10,000	891,188	241,037	470,913	2,802,407
Depreciation:								
At 1 January 2019	135,872	324,781	69,788	10,000	400,791	–	–	941,232
Charge for period	107,472	89,154	–	–	214,302	–	154,429	565,357
Transferred	–	69,788	(69,788)	–	–	–	–	–
At 31 December 2019	243,344	483,723	–	10,000	615,093	–	154,429	1,506,589
Net book value at 31 December 2019	325,537	136,665	–	–	276,095	241,037	316,484	1,295,818

The Group leases production equipment which secures lease obligations. At 31 December 2019, the net carrying amount of leased equipment was £27,023 (2018: £68,569).

During 2019, the Group acquired equipment with a carrying amount of £nil (2018: £121,595) under a lease agreement.

Assets under construction for the year of £241,037 relate to the creation and fitting out of our cell culture lab.

14. Inventories

(All figures £)	31 December 2019	31 December 2018
Raw materials and consumables	639,109	247,766
Finished goods	88,049	54,706
Total inventories	727,158	302,472

These carrying values are stated net of impairment provisions of £380,955 (2018: £22,193). Inventories of £146,624 (2018: £45,160) were written down during the period and the expense recognised in the income statement. The Directors are of the opinion that the replacement values of inventories are not materially different to the carrying values stated above.

15. Trade and other receivables

(All figures £)

31 December 2019 31 December 2018

Current:

Accrued other income	61,403	164,059
Other debtors	686,927	109,456
Prepayments	240,547	305,590
VAT	627,442	473,661
Total current	1,616,319	1,052,766

Non-current:

Other debtors	8,400	8,400
Total trade and other receivables	1,624,719	1,061,166

An expected credit loss provision was calculated for the other debtors balance and was deemed immaterial and therefore not recognised.

16. Deferred tax and other tax receivables

Deferred tax assets and liabilities are offset where the Company has a legally enforceable right to do so. The following is the analysis of the deferred tax balances (after offset) for financial reporting purposes:

The accelerated capital allowances deferred tax liability set out below is expected to reverse over the life of the related fixed assets. Deferred tax has been calculated at a rate of 19%.

(All figures £)

31 December 2019 31 December 2018

Balances:

Accelerated capital allowances	117,907	63,252
Tax losses offset (see below)	(117,907)	(63,252)
	-	-

There are unused trading losses at 31 December 2019 of £29,784,004 (31 December 2018: £18,185,117). A deferred tax asset of £5,006,054 (31 December 2018: £3,056,913) has not been recognised in respect of these tax losses due to uncertainty in respect of its recoverability.

A reduction in the UK corporation tax rate from 19% to 17% (effective from 1 April 2020) was substantively enacted on 6 September 2016, and the unrecognised UK deferred tax asset as at 31 December 2019 has been calculated based on this rate. In the 11 March 2020 Budget, it was announced that the UK tax rate will remain at the current 19% and not reduce to 17% from 1 April 2020. This will have a consequential effect on the Group's future tax charge. If this rate change had been substantively enacted at the current balance sheet date the unrecognised deferred tax asset would have increased by £588,948.

Tax receivables at 31 December 2019 of £2,702,198 (31 December 2018: £2,569,631) relate solely to R&D Tax credits. The Company has submitted R&D tax credit claims for the periods presented in relation to its qualifying research and development expenditure and has taken the option of surrendering the resulting losses and claiming an R&D tax credit in the form of immediate cash payments from HMRC.

17. Trade and other payables

(All figures £)

31 December 2019 31 December 2018

Current:

Trade payables	923,318	739,015
Social security and other taxes	713,134	114,595
Other payables	24,636	16,074
Deferred income	-	79,647
Accrued expenses	3,205,028	650,289
Derivative liability	17,037	-
Total trade and other payables	4,883,153	1,599,620

18. Financial instruments

Carrying amount of financial instruments.

The amounts for all financial assets and liabilities carried at fair value are as follows:

(All figures £)

31 December 2019 31 December 2018

Foreign currency forward contracts:

Assets	–	10,857
Liabilities	17,037	–

Reconciliation to cashflow movements

(All figures £)	01 January 2019	Cashflows principal	Cashflows interest	Non-cash changes interest	31 December 2019
Gross loan	349,661	–	–	7,661	357,322
Lease liabilities	549,647	(187,310)	(11,905)	9,331	359,763

Reconciliation of lease interest

Equipment leases (previously finance leases)					2,574
Bank loan interest					7,661
Lease liability interest				9	10,235
Unwind of discount on lease liabilities				9	9,331
Total interest					19,566

Financial instruments measured at fair value

The fair value of forward exchange contracts is estimated by discounting the difference between the contractual forward price and the current forward price for the residual maturity of the contract using a risk-free interest rate.

Financial risk management

The main purpose of the Company's financial instruments is to finance the Company's operations. The financial instruments comprise leases, foreign currency forward contracts, cash and liquid resources and various items arising directly from its operations, such as trade receivables and trade payables. The main risks arising from the Company's finance instruments are exchange rate risk and liquidity risk. The Company's policies on the management of liquidity and foreign currency risks are set out below.

Fair values of financial instruments

All financial assets and liabilities are held at amortised cost apart from forward exchange contracts, which are held at fair value, with changes going through the Statement of profit or loss. The Company has not disclosed the fair values for financial instruments such as short-term trade receivables, payables and long-term financial liabilities, because their carrying amounts are a reasonable approximation of fair values.

The Company measured the fair value of instruments which are categorised as level 2 in the fair value hierarchy, being forward exchange contracts, by using the forward change rates at the measurement date with the resulting value discounted back to present values.

Liquidity

The Company's policy is to ensure that it has sufficient cash resources to cover its future trading requirements which is predominately sourced from its shareholders and investors. Short-term flexibility is available through current investor support via funding rounds held when required.

Credit risk

The maximum exposure to credit risk at the reporting date is the fair value of the derivative assets in the Consolidated statement of financial position.

Foreign exchange risk

The Company currently purchases certain materials throughout the world in connection with Research and Developments of its primary product. The consequence of this is that the Company is exposed to movement in foreign currency rates. Forward foreign exchange contracts are used to manage the net foreign exchange exposure where appropriate.

19. Interest-bearing liabilities

(All figures £)

31 December 2019 31 December 2018

Current:

Lease liabilities	25	173,193	40,591
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Non-current:

Lease liabilities	25	186,570	43,231
Bank borrowings		357,322	349,661
		717,085	433,483

Lease liabilities are payable as follows:

Less than 1 year		173,193	–
Between 1 and 5 years		186,570	43,231
More than 5 years		–	–
		359,763	43,231

Bank borrowings are payable as follows:

Less than 1 year		–	–
Between 1 and 5 years		357,322	349,661
More than 5 years		–	–
		357,322	349,661
		717,085	392,892

Bank borrowings relates to a loan from Barclays Bank Plc for the principal of £342,000 repayable in full in January 2021 being 3 years after the first drawdown. Interest is being accrued at a fixed rate of 2.24%.

20. Provisions

(All figures £)

31 December 2019 31 December 2018

Non-current:

Lease dilapidations provision		157,500	19,500
		157,500	19,500

The dilapidations provision relates to potential rectification costs expected should the Group vacate its head office at Chepstow and its R&D facility based at Bath.

The movement in dilapidations is summarised below:

(All figures £)

31 December 2019 31 December 2018

At beginning of period		19,500	23,735
Released through profit and loss		–	(23,735)
Provisions made in period		138,000	19,500
At end of period		157,500	19,500

Provisions for dilapidations are inherently uncertain in terms of quantum and timing, not least because they involve negotiations with landlords at future dates. The figures provided in the financial statements represent management's best estimate of the likely outflows to the Group.

21. Share capital and reserves

(All figures £)

31 December 2019 31 December 2018

Balance at start of period	120,495	80,712
Issue of share capital		
Number of shares	29,883,373	39,783,640
Price per share (£)	0.001	0.001
Share value (£)	29,883	39,784
Balance at 31 December 2019	150,378	120,495

On 23 December 2019 28,835,173 £0.001 ordinary shares were issued. During the period 1,048,200 share options were exercised. The total number of issues in the period was 29,883,373 £0.001 ordinary shares. The Group has a single class of share, ordinary shares £0.001.

Share capital

Share capital is the amount of nominal value of shares held by shareholders. At 31 December 2019 150,378,758 shares have been issued, each with the nominal value of £0.001 equalling a share capital for the Company of £150,378. All ordinary shares rank as pari passu with regards to voting, dividends and rights on winding up.

Share premium

The share premium reserve comprises the difference between the nominal value and the value received on share issue offset by the costs directly associated with obtaining the capital funding e.g. legal fees.

Merger reserve

The merger reserve reflects the difference between the existing share capital and premium of Creo Medical Limited prior to share for share exchange and the nominal value of shares issued. Refer to Note 1 Business combinations and basis of consolidation.

Share option reserve

The share option reserve reflects the cost to the Group of share options granted but not yet exercised. Refer to Note 8 Share-based payments.

Retained earnings

Retained earnings including profit or loss for the year comprises the earned profit of the Parent Company and its subsidiary.

22. Cash from share issue

(All figures £)

31 December 2019 31 December 2018

Share issue:		
Share options exercised	168,503	155,529
Advanced share subscription AIM admission 9 December 2016	-	-
Share subscription AIM admission 9 December 2016	-	-
Transaction costs AIM admission 9 December 2016	-	-
Share placing AIM 30 August 2018	-	48,500,000
Transaction costs AIM 30 August 2018	-	(2,590,584)
Share placing AIM 23 December 2019	51,903,311	-
Transaction costs AIM 23 December 2019	(2,765,981)	-
	49,305,833	46,064,945

Remuneration of Directors

As at 31 December 2019 the Directors of the Company control 3.42 per cent of the voting shares of the Company.

The remuneration of the Directors' of the Company are disclosed in the Directors' remuneration report and Note 6 above.

Share options held by Directors are detailed in the Directors' remuneration report.

ii. Lease Liabilities

(All figures £)

Maturity Analysis – contractual undiscounted cash flows	
Less than 1 year	142,760
1 to 5 years	194,857
More than 5 years	
Total undiscounted lease liabilities at 31 December	337,617
Lease liabilities included in the statement of financial position at 31 December	316,484
Current	134,034
Non-current	182,450

iii. Amounts recognised in profit or loss

2019 – Leases under IFRS 16

(All figures £)

Depreciation on right-of-use asset	154,429
Interest on lease liabilities	9,331
Expenses relating to short-term leases	28,980
Expenses relating to leases of low-value assets	–

2018 – Operating leases under IAS 17

(All figures £)

Lease expense	333,140
Total cash outflow for leases	154,428

iv. Extension options

Some property leases contain extension options exercisable by the Group up to 1 year before the end of the non-cancellable contract period. Where practicable, the Group seeks to include extension options in new leases to provide operational flexibility. The extension options held are exercisable only by the Group and not by the lessors. The Group assesses at lease commencement date whether it is reasonably certain to exercise the extension options. The Group reassesses whether it is reasonably certain to exercise the options if there is a significant event or significant changes in circumstances within its control. The Group does not consider any extension of the leases to be likely as at 31 December 2019.

26. Capital commitments

The amounts contracted for but not provided for as at 31 December 2019 in relation to Software and the Group's new Enterprise Resource Planning (ERP) system are £nil (31 December 2018 £153,162).

27. Subsequent events

With effect from 1 February 2020 Ivonne Cantu was appointed in the role of independent Non-Executive Director and chair of the Remuneration Committee.

The business is continually monitoring the development of COVID-19 and the current and future impacts it will have on our business. The actions to mitigate these risks have been noted in Principal risks and uncertainties section of the Annual Report. Cash reserves at the end of March 2020 were £75.5m which are more than sufficient to secure the business activities and staff through the current situation and beyond.

The Group has received 510(k) clearance from the US Food and Drug Administration ('FDA') for its HS1 Haemostasis device ('HS1'). This is the second device to gain FDA regulatory clearance within Creo's wider portfolio of flexible endoscopy devices for the gastrointestinal ('GI') and pulmonary markets.

There have been no other material events subsequent to the period end and up to the 6 May 2020, the date of approval of the financial statements by the Board.

23. Related party disclosures

Interests and related party transactions are disclosed below

David Woods is President and CEO of PENTAX Americas and M&A Director of HOYA Group, PENTAX Medical. During the period the Group entered into an addendum to the distribution agreement entered into with Hoya Group, PENTAX Medical in August 2016. Pursuant to the addendum, PENTAX agreed to remove India from the agreement during the period. All agreements with PENTAX have been made at an arms-length basis and David Woods receives no remuneration from his role as Non-executive Director.

During the period the Group also entered into a distribution agreement with PENTAX Europe GmbH ('PENTAX Europe') a subsidiary of HOYA Group, PENTAX Medical. The net cost of transactions in the period recorded in the accounts with PENTAX Medical was: £39,839 (18 months to 31 December 2018 £nil).

Christopher Hancock holds a Professorship with Bangor University and is the common-law spouse of Ling Chen. The fees paid in the period to Bangor University totalled £nil (18 months to 31 December 2018 £17,749), with the balance payable at 31 December 2019 being £nil. The fees paid in the period to Ling Chen totalled £30,379 (18 months to 31 December 2018 £53,200) for consultation on the research and development projects throughout the year, with the balance payable at 31 December 2019 being £4,500.

The Company has passed on the employers' national insurance contribution liability, arising from the share options granted, to the employees. As we still have a legal liability this has been recognised in the balance sheet under social security and other taxes. A corresponding asset has been recorded under sundry debtors for the right to pass this cost onto the employees.

Aggregate remuneration for the period for all key management totalled £1,971,473 (18 months to 31 December 2018 £2,172,466).

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018
Salary and taxable benefits:		
Professor Christopher Hancock	567,244	629,178
Craig Gulliford	694,947	802,026
Richard Rees	553,282	591,262
Charles Spicer	93,000	97,500
John Bradshaw	63,000	52,500
	1,971,473	2,172,466

24. Ultimate controlling party

By virtue of the shareholding structure, there is no sole ultimate controlling party.

25. Leases

The accounting policy for Leases under IFRS 16 has been explained in Note 1.

Leases as lessee (IFRS 16)

The Group leases building facilities in Bath and Chepstow. The leases typically run for a period of 5 years, with an option to renew the lease after that date. Lease payments are renegotiated every 5 years to reflect market rentals. Some leases provide for additional rent payments that are based on changes in local price indices. For certain leases, the Group is restricted from entering into any sub-lease arrangements. The building leases were entered into many years ago as combined leases of land and buildings. Previously, these leases were classified as operating leases under IAS 17.

The Group leases equipment under a number of leases, which were classified as finance leases under IAS 17.

The Group leases other equipment with contract terms of 1 to 5 years. These leases are short-term and/or leases of low-value items. The Group has elected not to recognise right-of-use assets and lease liabilities for these leases.

Information about leases for which the Group is a lessee is presented below.

i. Right-of-use assets

Right-of-use assets related to leased properties that do not meet the definition of investment property are presented as property, plant and equipment.

2019

(All figures £)	Land and buildings	Plant and machinery	Total
Balance at 1 January	460,424	10,489	470,913
Depreciation Charge	152,003	2,426	154,429
Balance at 31 December	308,421	8,063	316,484

PARENT COMPANY STATEMENT OF FINANCIAL POSITION

(All figures £)

18 months to
31 December 2018
Restated*

12 months to
31 December 2019
Note

Assets

Non-current assets

Investments in subsidiaries	30	1,301,089	643,900
		1,301,089	643,900

Current assets

Trade and other receivables	31	559,369	67,992
Cash and cash equivalents		75,875,830	43,675,948
		76,435,199	43,743,940

Non-current assets

Trade and other receivables	31	40,000,614	21,572,591
		116,435,813	65,316,531

Total assets		117,736,902	65,960,431
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Liabilities

Current liabilities

Trade and other payables	32	802,860	–
Total liabilities		802,860	–

Shareholder equity

Called up share capital	21	150,378	120,495
Share premium		115,111,506	65,835,555
Share option reserve		3,888,864	2,334,019
Retained earnings		(2,216,707)	(2,329,638)
		116,934,041	65,960,431
Total equity and liabilities		117,736,902	65,960,431

* The impact of 2018 restatement is described in Note 29 Prior period adjustments

These financial statements were approved by the Board of Directors on 6 May 2020 and were signed on its behalf by:



Richard Rees
Director

Company registered number: 10371794

PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

(All figures £)	Note	Called up share capital	Retained earnings Restated*	Share premium	Share option reserve	Total equity
Balance at 30 Jun 2017 as previously reported		80,712	(909,761)	19,810,393	529,199	19,510,543
Impact of restatement		–	(529,199)	–	–	–
Balance at 30 Jun 2017 as restated		80,712	(1,438,960)	19,810,393	529,199	18,981,344
Total comprehensive income						
Profit or loss (as previously reported)		–	271,697	–	–	271,697
Impact of restatement		–	(1,162,375)	–	–	(1,162,375)
Profit or loss as restated		–	(890,678)	–	–	(890,678)
Other comprehensive income		–	–	–	–	–
Total comprehensive income as restated		–	(890,678)	–	–	(890,678)
Transactions with owners, recorded directly in equity						
Issue of share capital		39,783	–	46,025,162	–	46,064,945
Equity settled share-based payment transactions	8		–	–	1,804,820	1,804,820
Balance at 31 December 2018		120,495	(2,329,638)	65,835,555	2,334,019	65,960,431
Total comprehensive income for the period						
Profit or loss		–	112,931	–	–	112,931
Other comprehensive income		–	–	–	–	–
Total comprehensive income		–	112,931	–	–	112,931
Transactions with owners, recorded directly in equity						
Issue of share capital		29,883	–	49,275,951	–	49,305,834
Equity settled share-based payment transactions	8		–	–	1,554,845	1,554,845
Balance at 31 December 2019		150,378	(2,216,707)	115,111,506	3,888,864	116,934,041

* The impact of 2018 restatement is described in Note 29 Prior period adjustments

NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS

28. Parent Company financial statements

As permitted by section 408(3) of the Companies Act 2006, a separate Statement of Comprehensive Income, dealing with the results of the Parent Company, has not been presented. The Parent Company profit for the period ended 31 December 2019 is £112,931 (31 December 2018 restated: loss £890,678).

29. Parent Company accounting policies

To the extent that an accounting policy is relevant to both the Group and Company financial statements, refer to the Group financial statements for disclosure of the accounting policy.

Basis of preparation

These financial statements were prepared in accordance with Financial Reporting Standard 101 'Reduced Disclosure Framework' ('FRS 101'). The amendments to FRS 101 (2014/15 Cycle) issued in July 2015 have been applied. In preparing these financial statements, the Company applies the recognition, measurement and disclosure requirements of International Financial Reporting Standards as adopted by the EU ('Adopted IFRSs'), but makes amendments where necessary in order to comply with Companies Act 2006 and has set out below where advantage of the FRS 101 disclosure exemptions has been taken.

In these financial statements the Parent Company has taken advantage of the following disclosure exemptions under FRS 101:

- A cash flow statement and related notes;
- Comparative period reconciliations for share capital;
- Disclosures in respect of transactions with wholly owned subsidiaries;
- The effects of new but not yet effective IFRSs;
- Disclosures in respect of the compensation of Key Management Personnel;
- Disclosures of transactions with a management entity that provides key management personnel services to the Company; and
- Certain disclosures required by IFRS 7 'Financial Instrument Disclosures'.

As the consolidated financial statements include the equivalent disclosures, the Company has also taken the exemptions under FRS 101 available in respect of the following disclosures:

- IFRS 2 'Share-Based Payments' in respect of Group equity-settled share-based payments;
- Certain disclosures required by IAS 36 'Impairment of assets' in respect of the impairment of goodwill and indefinite life intangible assets;
- Certain disclosures required by IFRS 3 'Business Combinations' in respect of business combinations undertaken by the Company.

The accounting policies set out above have, unless otherwise stated, been applied consistently to all periods presented in these financial statements.

Judgments made by the Directors, in the application of these accounting policies that have significant effect on the financial statements and estimates with a significant risk of material adjustment in the next year are discussed in Note 1 Critical accounting judgments and policy update.

Investments in subsidiaries are carried at cost less impairment.

Prior period adjustments

A prior year adjustment has been made in the Creo Medical Group plc Company financial statements in relation to Group equity-settled share-based payment arrangements, where the expense had previously been recognised in full by the subsidiary, Creo Medical Limited, with the charge recorded as an intercompany receivable by Creo Medical Group plc. It was established in 2019 that arrangements which commenced in 2016 should have been recorded as a share-based payment charge in Creo Medical Group plc, rather than in the Creo Medical Limited financial statements, as the employees to which the arrangements relate are contracted by Creo Medical Group plc. Further to this, arrangements which commenced in 2017 were made to both Creo Medical Group plc and Creo Medical Limited employees and therefore the charge relating to employees of the Company should have been recognised as an expense, with the charge relating to employees of Creo Medical Limited recorded as an increase in the cost of investment in the subsidiary.

The adjustment has resulted in the following impact on the 2018 Parent Company numbers presented as follows:

	01 July 2017 (as previously reported)	Adjustment	01 July 2017 (as restated)
Investment in subsidiaries	1,455	–	1,455
Intercompany receivable	5,984,639	(529,199)	5,455,440
Net assets	19,510,544	(529,199)	18,981,345
Retained earnings	(909,761)	(529,199)	(1,438,960)
Net (loss)	(909,761)	(529,199)	(1,438,960)

	31 December 2018 (as previously reported)	Adjustment	31 December 2018 (as restated)
Investment in subsidiaries	1,455	642,445	643,900
Intercompany receivable	23,906,610	(2,334,019)	21,572,591
Net assets	67,652,005	(1,691,574)	65,960,431
Retained earnings	(638,064)	(1,691,574)	(2,329,638)
Net (loss)	271,697	(1,162,375)	(890,678)

30. Investments

(All figures £)	Investment in subsidiary company (as restated)
Cost:	
As at 31 December 2017	1,455
Capital contribution	642,445
As at 31 December 2018	643,900
Capital contribution	657,189
As at 31 December 2019	1,301,089

The Company has the following investment in subsidiary companies:

(All figures £)	Aggregate of capital and reserves	Profit or loss for the period	Registered Office address	Class of shares held	Ownership 2017
Cost:					
Creo Medical Limited	(36,335,346)	(15,760,544)	Creo House, Unit 2 Beaufort Park, Beaufort Park Way, Chepstow Wales NP16 5UH	Ordinary	100%

The following Group companies held by Creo Medical Limited were non-trading at the period end:

(All figures £)	Aggregate of capital and reserves	Profit or loss for the period	Registered Office address	Class of shares held	Ownership 2017
Cost:					
Creo Medical, Inc.	–	–	251 Little Falls Drive Wilmington Delaware DE 19808 USA	Ordinary	100%
Creo Medical Innovations Limited	–	–	Creo House, Unit 2 Beaufort Park, Beaufort Park Way, Chepstow, Wales NP16 5UH	Ordinary	100%
Creo Medical (Ireland) Limited	–	–	70 Sir John Rogerson's Quay Dublin 2 D02 R296 Ireland	Ordinary	100%

The following Group companies held by Creo Medical Limited were non-trading at the period end:

- Creo Medical, Inc (US);
- Creo Medical Innovations Limited; and
- Creo Medical (Ireland) Limited.

31. Parent Company trade and other receivables

(All figures £)	12 months to 31 December 2019	18 months to 31 December 2018 Restated*
Current:		
Other debtors	528,573	67,992
VAT	30,796	–
Total current	559,369	67,992
Non-current:		
Amount owed by subsidiary undertaking	40,000,614	21,572,591
Total non-current	40,000,614	21,572,591

Amounts owed by subsidiary undertakings are unsecured and repayable on demand. An expected credit loss provision was calculated for the other debtors and amounts owed by subsidiary balances, both were deemed immaterial and therefore not recognised.

32. Parent Company trade and payables

(All figures £)	12 months to	18 months to
	31 December 2019	31 December 2018
Current:		
Social security and other taxes	528,573	–
Other creditors	274,287	–
Total current	802,860	–

*The impact of 2018 restatement is described in the 29 Prior period adjustments