



2022

Annual report

PAXMAN^o
PIONEERS IN SCALP COOLING

ANNUAL REPORT

2022

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The picture shows Paxman's management and board.

SUMMARY OF THE YEAR

Record strong global sales, implementation of a new buy-and-bill model in the USA, and decision to conduct a large clinical study in CIPN prevention with SWOG in the USA

In 2022, Paxman achieved the company's strongest sales to date, as most markets started to normalise with fewer pandemic-related restrictions. Successful investments in increased international awareness and growth, including the world's first Scalp Cooling Summit in May with 50 speakers and over 1,400 participants, contributed to the company being able to successfully sell and install 528 (401) systems globally. The USA continued to be Paxman's leading market with 170 (146) installed systems and four consecutive quarters of increased growth for the company's recurring revenue.

In the USA, the first customers began to use Paxman's new buy-and-bill model, which enables reimbursement, and thus the opportunity to reach a much larger and more diverse patient group than before. This encouraging trend is expected to become an important driver of growth for the company in the USA in 2023.

The development of the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy-induced peripheral neuropathy (CIPN) achieved continued progress in 2022. In addition to clinical trials in Singapore, a large, randomised phase 3 trial in the USA was initiated in 2023 with the SWOG Cancer Research Network.

An exciting step towards continued expansion in Asia was taken when Paxman signed a letter of interest with the aim of entering into a distribution and marketing agreement for Greater China, including Macau, Taiwan and Mongolia, with Concord Medical. Initially, up to 300 patients will be treated during a 24-month evaluation period.

SELECTED EVENTS IN 2022

- In February, Paxman launched the "Scalp Cooling Study Library", a digital library website with a comprehensive database which unites key published clinical research studies and data on scalp cooling and cryocompression therapy.
- In April, Paxman signed a letter of interest, with a plan to enter into a distribution and marketing agreement with Guangzhou Concord Medical Sci-Tech Innovation Center Co., Ltd., a business subsidiary of Concord Medical Services Holdings Limited, to jointly develop the market for the Paxman Scalp Cooling System within the Greater China territory, including Macau, Taiwan and Mongolia. The initial collaboration is for a period of five years and will include an evaluation period of 24 months to treat up to 300 patients at Concord Medical's Guangzhou Concord Cancer Center, a National Health Commission certified tertiary specialty hospital, situated in Sino-Singapore Guangzhou Knowledge City.
- At the beginning of May, Paxman hosted the world's first Scalp Cooling Summit, a global and first of its kind conference with leading researchers and clinicians. The Summit was a great success, with 50 speakers and over 1,400 delegates attending.
- In May, it was also announced that the company signed its first contract under the new business model in the US with a comprehensive healthcare system in New Jersey, and that the company had launched its enhanced Paxman HUB services. Previously, in the U.S., scalp cooling has only been available to patients on a self-pay basis – to those who have the financial means to pay out-of-pocket, or those who qualify for foundation or grant assistance. Consequently, patient access to the treatment has been limited.
- In the beginning of November, it was announced that the US Centers for Medicare & Medicaid Services (CMS) published the final rule, which revised the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2023. The OPPS Final Rule will affect 3,411 hospitals and approximately 5,500 ASCs. This final rule confirmed that the payment rate of 1,850.50 USD for CY 2022 will be the same for CY 2023, and that CPT code 0662T will continue to be assigned to APC New Technology 1520.
- Later in November, it was announced that Paxman had been selected by the SWOG Cancer Research Network, an independent global cancer research community that designs and conducts publicly funded clinical trials, for the Paxman Limb Cryocompression System (PLCS) to be used in a prospectively designed study looking at prevention of Chemotherapy-Induced Peripheral Neuropathy (CIPN). The study aims to enroll 777 patients and PLCS devices will be shipped in February to a minimum of 25 locations, with an aim to open the study to enrolment in Q1 2023.

SUMMARY OF THE YEAR

- The group's turnover amounted to 145,921 (96,202) TSEK in 2022.
- The net profit/loss amounted to -10,324 (-12,776) TSEK.
- Earnings per share amounted to -0.54 (-0.67) SEK.
- Cash flow from operating activities amounted to 1,688 (-4,792) TSEK.
- Net cash balance amounted to 173,960 (166,341) TSEK at the end of the period.
- Net liquid assets totaled 21,108 (55,112) at the end of the period.
- Equity to assets ratio was 65.6 (75.6) % at the end of the period.

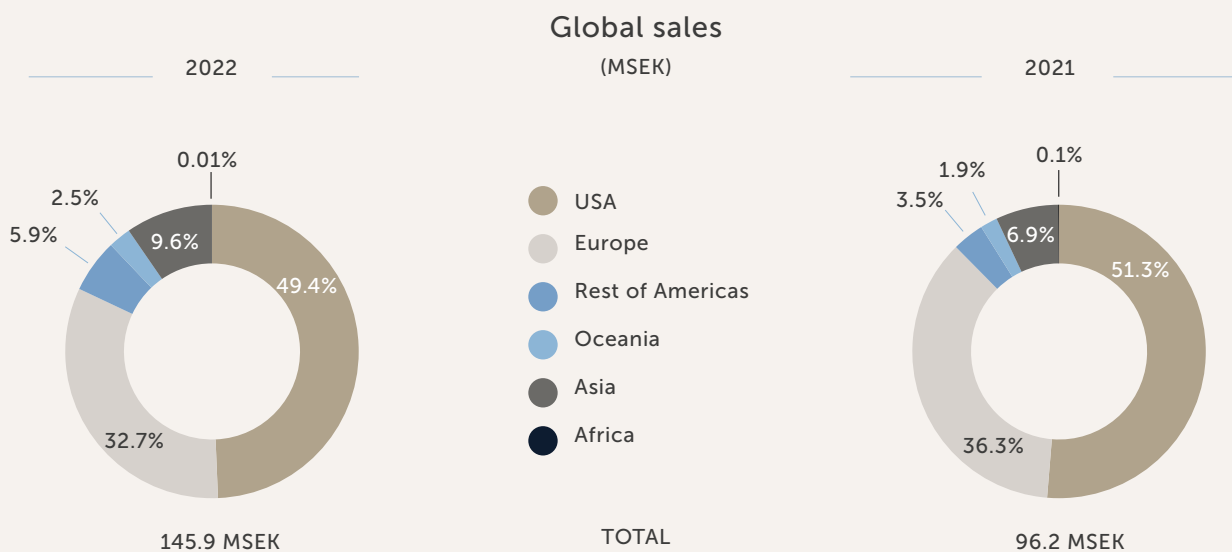
SOLD AND INSTALLED SYSTEMS IN 2022

- Sold and installed systems in the USA: 170 (146) systems
- Sold and installed systems globally: 528 (401) systems



PAXMAN'S STRONGEST YEAR TO DATE

A gradual normalisation after the pandemic, progress in reimbursement for scalp cooling in the USA and the company's extensive investment in continued international growth contributed to 2022 being Paxman's strongest year to date. The successful launch of the new business model in the USA means that 2023 is also expected to be a very exciting year.



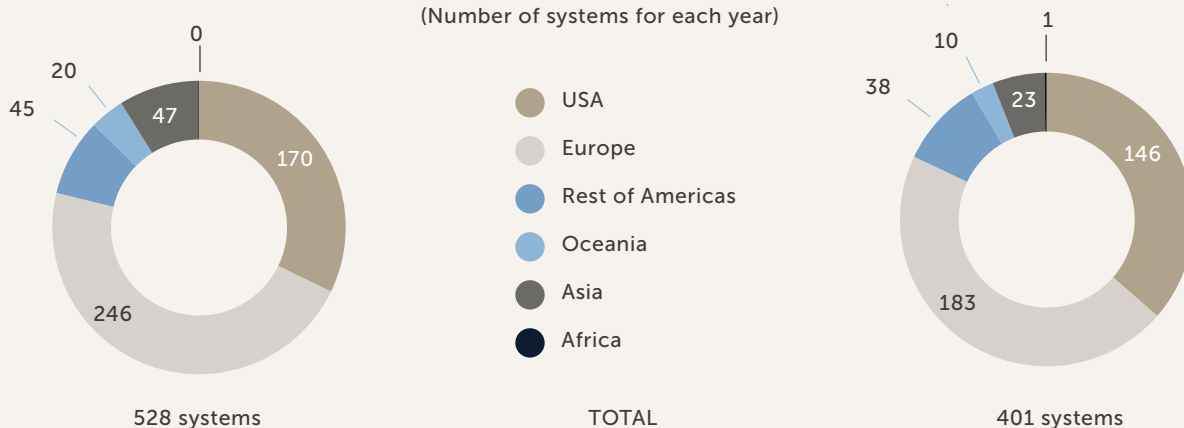
Countries using scalp cooling from Paxman

(Total number of countries with sold or installed systems)



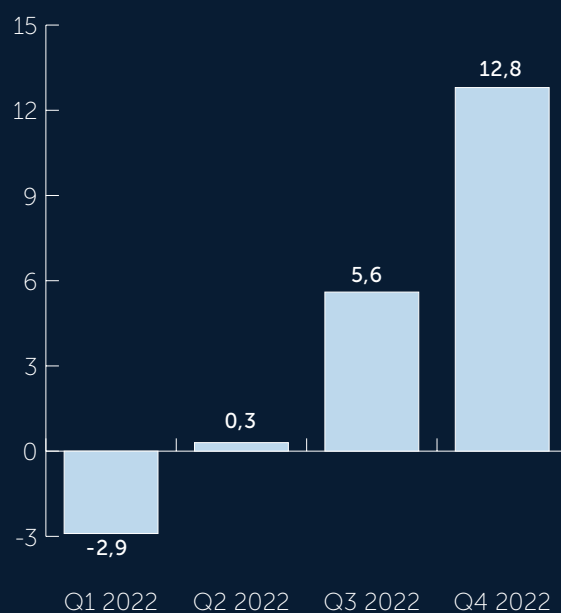
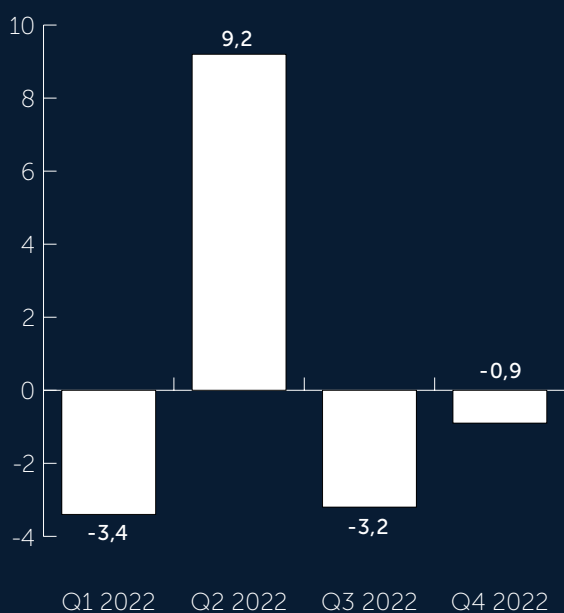

Sold and installed systems


(Number of systems for each year)



Operating cash flow/EBITDA

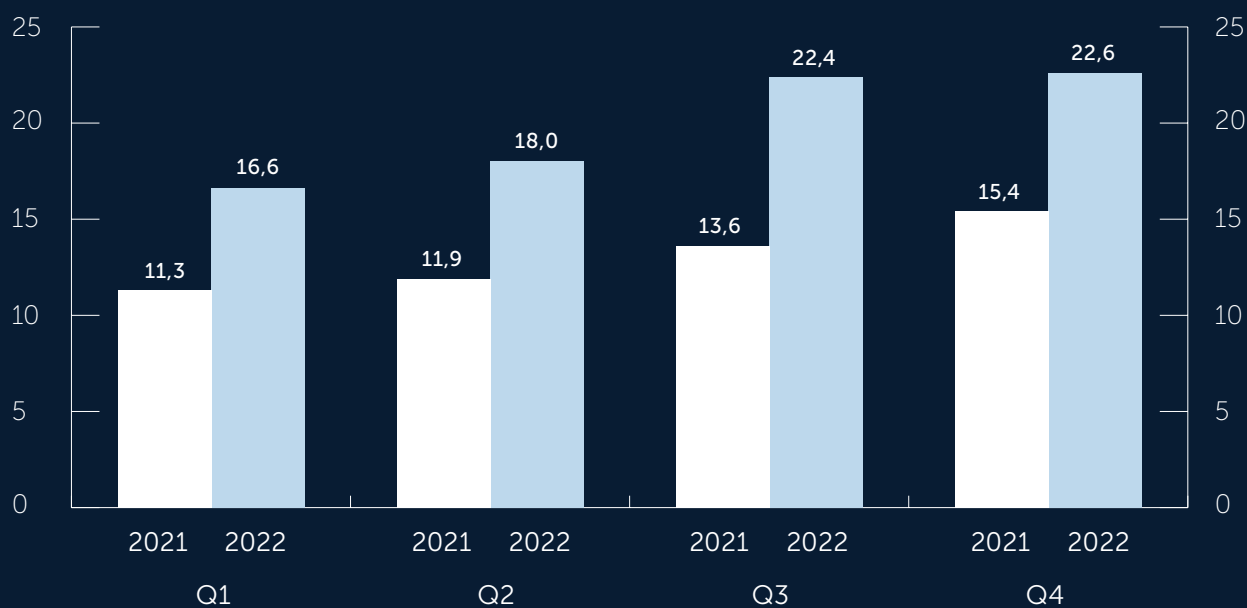
(MSEK, Q1-Q4 2022)


 Operating cash flow

 EBITDA

Recurring income

(MSEK, Q1-Q4 2022 and 2021)



CHANGING THE FACE OF CANCER

PAXMAN'S VISION

A WORLD WHERE ALL CANCER PATIENTS CAN AVOID HAIR LOSS

Paxman has made scalp cooling available to hundreds of thousands of cancer patients in many parts of the world. However, the company has a much more ambitious long-term goal, both when it comes to global outreach and the effect of scalp cooling.

Paxman's long-term vision, and its efforts to achieve it, is condensed into the slogan "Changing The Face of Cancer". This means aiming for a future where all chemotherapy patients worldwide are offered scalp cooling, with Paxman's system as the natural choice.

At the regulatory level, Paxman's determined work in recent years has contributed to gradually improved opportunities to realise this long-term vision. In 2019, scalp cooling was included as a recommendation for the prevention of chemotherapy-induced hair loss in breast cancer patients in the leading clinical guidelines published by the NCCN®, and inclusions for additional cancer types were added in 2020. Similar inclusions to a varying extent were made in guidelines published by ESMO in Europe as well as Cancer Australia and AFSOS in France, Germany and Japan. In 2021, the AMA in the USA issued two CPT codes for scalp cooling, and the CMS decided that Medicare claims filed using one of these codes shall be subject to a National Average Payment of 1,850.50 USD. In 2022, customers in the USA started to implement Paxman's buy-and-bill business model that facilitates reimbursement using the CPT codes.

Geographically, Paxman extended its outreach in 2019 by establishing the company in Japan, the world's second largest market for cancer care with over 1 million new cancer cases per year. In 2020 the company established itself in South Korea, with the initiation of a large clinical study in Q4 2020, and market clearance granted in November 2022. The study in South Korea will support the company's continued expansion in Asia, including a greater presence in India and a future expected establishment in China where a letter of intent was signed with a Chinese marketing and distribution partner in April, 2022.

On the patient level, Paxman is continuously working to improve the efficiency of scalp cooling. The company founded the Paxman Scalp Cooling Research Centre, the world's first scalp cooling-focused research and development centre, together with the University of Huddersfield in 2019, and the first-of-its-kind global Scalp Cooling Summit was held in May 2022 with almost 50 leading researchers and clinicians and over 1,400 participants. More information on Paxman's R&D efforts, which also includes the development of a product to prevent chemotherapy-induced peripheral neuropathy (CIPN), can be found on pages 30-42.



THREE MAJOR ACHIEVEMENTS IN 2022

IMPLEMENTATION OF NEW BUY-AND-BILL BUSINESS MODEL IN THE USA

In 2022, customers started to use Paxman's buy-and-bill model and related services to facilitate reimbursement via the CPT® codes issued, with a national payment rate decided by the US Centers for Medicare & Medicaid Services (CMS) of 1,850.50 USD.

This business model allows scalp cooling to reach a much wider and more diverse patient group, which is in line with Paxman's long-term vision.

PAXMAN CONDUCTS THE WORLD'S FIRST SCALP COOLING SUMMIT

In May, 2022, Paxman held the first ever global Scalp Cooling Summit conference, with almost 50 leading researchers and clinicians and over 1,400 participants.

This conference, including the comprehensive information transfer it facilitates, is a part of Paxman's continued international efforts to increase the awareness of scalp cooling and make the treatment available for larger patient groups throughout the world.

PAXMAN SIGNS LETTER OF INTENT WITH PARTNER IN CHINA

Initially, the system will be used and evaluated during an evaluation period of 24 months.

A launch in China would make scalp cooling accessible for many more cancer patients, and would thus be in line with Paxman's long-term vision.

"A launch in China would make scalp cooling accessible for many more cancer patients, and would thus be in line with Paxman's long-term vision."



A COMMENT FROM OUR CEO RICHARD PAXMAN

Dear Shareholders,

2022 marks our most successful year to date despite the continued strong macro headwinds, supply chain difficulties and uncertainty in different parts of the world. Our thoughts are with those affected. Our success should be celebrated, but it is also clear we have additional challenges ahead. 2022 has been a year of strong growth but also high investment. As we move into 2023 our focus shifts to delivering a strong return on those investments, a positive EBITDA and a drive towards cash flow positivity.

Reflecting on our achievements as I write to you, we set out at the beginning of 2022 to use the proceeds from the directed share issue to strengthen the company's financial position and continue to execute on its commercialisation strategy. This included investment in the commercial organisation to accelerate market access in the US through the roll-out of the new buy-and-bill business model to enable reimbursement, incorporating a supportive patient assistance program to assist eligible patients. We also planned to enhance our communication and education strategy relating to the new coding and payment strategies in the US. In addition, we planned to further strengthen and accelerate the company's R&D work. This includes the financing of clinical trials and regulatory approvals for the Paxman Limb Cryocompression System (PLCS) for the prevention of chemotherapy-induced peripheral neuropathy (CIPN), in addition to the Paxman Scalp Cooling Research Centre. Finally, the funds were used for general corporate purposes and repayment of existing credit facilities.

I am very satisfied that we have delivered in all these areas, and whilst not all US customers have transitioned to our new business model, we are gaining momentum. Importantly, those customers contracted to the new

model are seeing more successful reimbursement than expected. We have developed a strong and supportive infrastructure to deliver the next steps through 2023.

Even though the number of cancer centers that adopted our new buy-and-bill model in the US in 2022 was lower than hoped for, the calibre of the institutions that have done so speaks volumes and includes RWJBH, MD Anderson and Duke University. This is a strong signaller to other healthcare systems. 2023 sees the adoption by additional health systems including Ohio State University among others, along with one pilot site within US Oncology Network. Overall, the data is looking promising in terms of positive coverage by payers, including the government payers Medicare, Medicaid, and commercial payers such as Aetna, BCBS, Cigna, United, etc. In addition, payment rates look strong as previously discussed. Importantly, we are also seeing increased patient access and therefore increased utilisation when the model is adopted. We are seeing increases in patients at a North Carolina institution of 327%, a health system in Texas of 300%, a health system in Ohio of 340% and a New Jersey health system of 82%.

In 2022 I am proud that we have continued to build a

great team as well as making Paxman a great place to work and we shall continue to make this a priority. The people in our organisation make Paxman what it is today, living by our values each day, which includes determination, passion, commitment, one global team and integrity, all of which are built into our Paxman People Pathway, a tool to support and invest in our team.

Our international presence has continued to grow, and this has been shown by the strong growth in our overseas sales. Continued support in our global brand has helped enhance our efforts including initiatives such as the Scalp Cooling Summit, a huge success; the launch of our www.scalpcoolingstudies.com clinical data resource website and internationalisation of our other digital platforms, along with presence at key global cancer conferences. I am proud of the relationships we have developed globally with some of the biggest names and thought leaders in oncology and healthcare.

Strong investments in reimbursement (7.1 MSEK) and the US capital installations (12.5 MSEK) have equated to over 19.6 MSEK through 2022. Further investment shall be made in our reimbursement activities to ensure greater adoption, coverage and utilisation, whilst slowing our US equipment roll out to focus on our existing 500 strong cancer centers.

We continue to make solid headway with our drive, not only to improve the efficacy of our scalp cooling devices, but also to allow the company to evolve, allowing greater recurring revenue streams. Our research centre in partnership with the University of Huddersfield has gone from strength to strength. With the support of grant funding through Innovate UK we are striving for an improved fit, lower cost and more sustainable cooling cap. In 2022, further breakthroughs were made in this area including advances in materials and forming to deliver this ambition. Further regional funding has accelerated our development work into follicular-targeted antioxidant formulations to enhance the efficacy of scalp cooling, an area I am incredibly excited about. The resultant nano formulations require incorporation into a topical product that can be applied to a patient's scalp prior to chemotherapy. Potential products include hair serum, mousse/foam or a lotion to ensure even coverage of the scalp.

In 2022, we have made significant investments and progress with the development of the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy induced peripheral neuropathy (CIPN). CIPN, an unmet and increasing clinical need, is a severe side-effect of chemotherapy for cancer treatment. It causes progressive and often irreversible pain/sensitivity in hands and feet and affects cancer survival rates as it can cause delays and discontinuation of chemotherapy, affecting almost 1.4 million cancer patients annually worldwide. CIPN contributes to long-term morbidity for patients and significantly increases economic burden, with healthcare costs estimated to be 17,000 USD more in cancer patients with CIPN than those without CIPN and patient work-loss (productivity loss of 50 days with usual care).

Total investments to date have been in excess of 15 MSEK, most of which has been incurred in 2022/2023. This will now reduce drastically. A large part of this cost relates to the production of 100 PLCS systems (200 devices) for both our Singapore clinical trial and US SWOG trial. Both of these trials are being funded through external innovation and cancer bodies due to the significance of this treatment and device, socially because of its health benefits but also economic potential. This continues to be an exciting opportunity for Paxman. Whilst the clinical trials are in progress however our focus remains on our core business – scalp cooling.

I would like to take this opportunity to thank all our stakeholders, our patients, their families, our team and the incredible work they all do to make Paxman a success and of course our shareholders for their continued support and belief in what we do. This continues to be an exciting journey and I look forward to delivering on our 2023 goals including a positive EBITDA and a move towards cash flow positivity.

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"Even though the number of cancer centers that adopted our new buy-and-bill model in the US in 2022 was lower than hoped for, the calibre of the institutions that have done so speaks volumes and includes RWJBH, MD Anderson and Duke University. This is a strong signaller to other healthcare systems."

Richard Paxman, CEO



Richard Paxman, CEO
PAXMAN AB (publ)

Huddersfield, May 2023



ABOUT THE COMPANY

PAXMAN AB (PUBL): AN INTERNATIONAL GROUP WITH ITS PARENT COMPANY IN SWEDEN

Paxman was founded in the UK in 1996, and the company is the global market leader in scalp cooling to prevent chemotherapy-induced hair loss with over 5,000 systems installed. The company has a strong connection to Sweden as the CIMON group, an investment company with approx. 200 MSEK in annual turnover, became a large shareholder in 1999.

Paxman is investing substantially in research and development and a target-focused global expansion. The company has conducted several successful clinical studies with leading clinics and cancer centers all over the world, including the world's first randomised multicenter study with a scalp cooling system. The results from these studies formed the basis of market approvals in Europe, the United States, Japan and Australia as well as additional markets in South America and Asia.

Paxman was listed on Nasdaq First North Growth Market in 2017. A secondary listing in the United States, or another significant market, can become relevant even though no decision in this direction has been made.

MARKET LEADING AND PERSONAL SCALP COOLING

Paxman develops and offers the Paxman Scalp Cooling System, a market leading scalp cooling system used to minimise hair loss in connection with chemotherapy treatment.

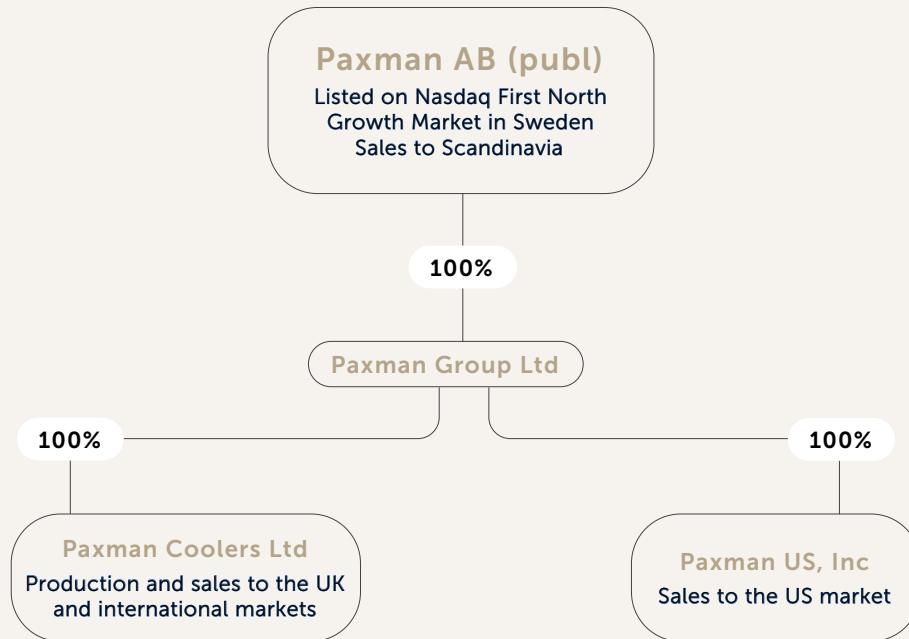
Today, the system is used at a large number of cancer centers and hospitals in Europe, North-, Central- and South America, Asia and Oceania, and more installs are added continuously. The company is also developing a medical cryocompression device to prevent chemotherapy-induced nerve damage in hands and feet (CIPN), with initiated clinical studies in Singapore in 2021 and a large clinical study in the USA to be initiated in 2023.

The company was founded as a family business by Glenn Paxman following his wife Sue Paxman's hair loss in connection with chemotherapy treatment. Glenn realised that there were shortcomings in the existing methods for scalp cooling and developed a liquid-based system together with his brother.

Today, Glenn and Sue's son Richard Paxman is the CEO of Paxman, and their daughter Claire Paxman holds the position Brand Ambassador & Director of Global Training. Their understanding of how important it is for cancer patients to keep their hair, and thereby a degree of control over their daily lives, is reflected in all of Paxman's business operations. The company's vision is to make the technology available for all cancer patients worldwide.

Paxman has a close collaboration with HairToStay, an organization that contributes financially to patients who cannot afford to pay for scalp cooling themselves. In honour of Sue Paxman, the parties have started a separate fund in her name specifically aimed at mothers with very low income.

GROUP STRUCTURE



PAXMAN'S SENIOR LEADERSHIP TEAM (SLT)

Paxman's Senior Leadership Team (SLT) is comprised of the following members:



Susy Brown
Head of Brand & Marketing



Patrick Burke
Head of Research,
Design & Development



Richard Paxman
CEO



Liza Hirst
Executive Assistant to CEO



Anna Parker
Head of International Sales



Claire Paxman
Brand Ambassador &
Director of Global Training



Stuart Rowling
Head of UK Sales & Training



Alexandra Sheldrake
Head of Quality
& Operations



Emma Thornhill
Finance Director



PAXMAN'S HISTORY

1996 – 2022

- 1996**

Paxman is founded, the first scalp cooling system is launched after many years of research and development

The company's first system is installed at Huddersfield Royal Infirmary
- 1999**

Systems are installed in Norway as the first country outside of Great Britain

CIMON Venture Trust AB based in Karlshamn, Sweden, invests in Paxman
- 2000**

The company meets the regulatory guidelines in Great Britain in compliance with ISO 9001:2008

International launch with installations in Ireland, Netherlands, Australia, Sweden, Switzerland and Egypt
- 2003**

The first clinical study is conducted with Paxman's system
- 2006**

Paxman reaches 500 installed systems
- 2012**

Paxman reaches 1,000 installed systems
- 2013**

Richard Paxman is appointed as Paxman's CEO
- 2014**

Paxman initiates the world's first randomized multicenter study in the USA
- 2015**

The company initiates clinical studies with five leading cancer centers in Japan

Paxman reaches 2,000 installed systems
- 2016**

Paxman's randomized multicenter study in the USA is completed and shows good results
- 2017**

The company obtains FDA clearance in the USA

Paxman AB (publ) is listed at Nasdaq First North

A large number of systems are installed in the USA, including prominent cancer centers such as Texas Oncology and Memorial Sloan Kettering

Paxman obtains market approval in Taiwan and Argentina

2018

License agreement for Mexico is signed with global pharmaceutical company Teva Pharmaceutical

Milestone of 250 installed systems in the USA is achieved within 12 months of receiving FDA clearance

Paxman receives extended FDA clearance in the USA covering solid tumours

2019

Development of a cooling and compression system to prevent chemotherapy-induced peripheral neuropathy (CIPN) is initiated with the National University Hospital in Singapore

Paxman Scalp Cooling Research Centre is founded in collaboration with the University of Huddersfield

NCCN® in the USA includes scalp cooling as a recommended treatment to prevent hair loss in its guidelines for breast cancer patients

Paxman obtains market approval for its scalp cooling system in Japan

Milestone of 500 installed systems in the USA achieved

2020

Patent applications submitted for Paxman's CIPN product in development.

The AMA in the USA decides to create CPT codes for mechanical scalp cooling.

ESMO in Europe includes scalp cooling as a category IIB recommendation to prevent chemotherapy-induced alopecia in its clinical practical guidelines.

2021

The AMA in the USA issues CPT codes for mechanical scalp cooling.

The CMS in the USA decides that Medicare claims for scalp cooling reimbursement shall be subject to a National Average Payment of 1,850.50 USD, effective January 1, 2022.

Clinical studies with Paxman Crycompression System are initiated.

2022

First customers start to use the new buy-and-bill business model in the USA

Paxman's hosts the global Scalp Cooling Summit conference

Letter of interest signed with potential distributor in China

Market clearance granted in South Korea

HOW SCALP COOLING PREVENTS HAIR LOSS

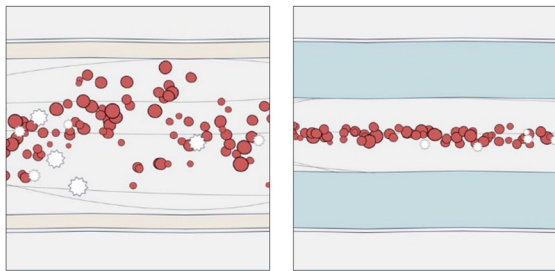
A FUNDAMENTALLY SIMPLE YET STILL VERY EFFICIENT METHOD

Scalp cooling is a simple yet highly effective method to prevent hair loss in connection with chemotherapy treatment of solid tumours. Globally, the number of potential users amounts to at least 4 million annually.

Scalp cooling in connection with chemotherapy works as follows:

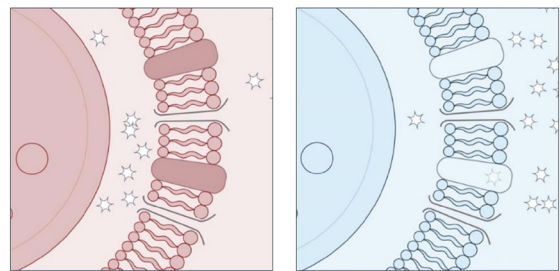
1. Vasoconstriction

- Cooling induces vasoconstriction
- Reduces cutaneous drug perfusion to 20-40%
- Therefore, less drug enters into the hair follicle cells



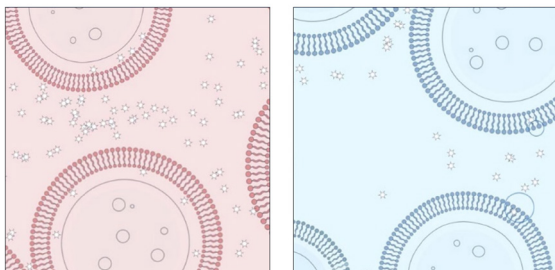
2. Reducing chemotherapy transport into hair follicle cell. Cooling...

- Reduces active transport/diffusion of drug into cells
- Lowers hair follicle cellular activity
- Reduces kinetic energy & membrane fluidity



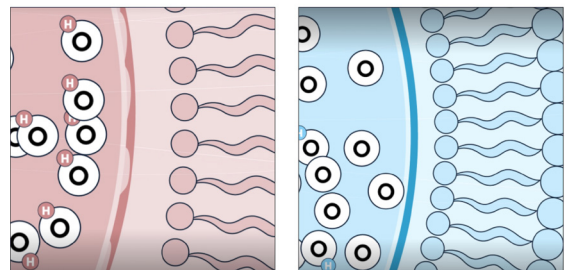
3. Reducing rate of hair follicle cell division

- Cell division is an energy dependent process
- A slower rate of division makes cells less susceptible to chemotherapy



4. Reduces metabolic activity

- And thereby reduces chemotherapy cytotoxicity in hair follicle cells, as range of processes decelerate



Reference: Cooling-mediated protection from chemotherapy drug-induced cytotoxicity in human keratinocytes by inhibition of cellular drug uptake Christopher Dunnill, Khalidah Ibraheem, Michael Peake, Myria Ioannou, Megan Palmer, Adrian Smith, Andrew Collett, Nikolaos T. Georgopoulos

THE PAXMAN SCALP COOLING SYSTEM (PSCS)

PAXMAN'S MOST EFFECTIVE, FLEXIBLE AND PERSONAL SCALP COOLING TO DATE

Paxman's scalp cooling system and the technology behind the product have been developed over decades. This allows PSCS, the latest version of the system, to deliver strong clinical results for different types of chemotherapy treatments and patient groups. At the same time, the system is easy to use for medical staff and offers an unmatched user experience for patients.

PSCS is available in versions for one or two simultaneous users. The version for two users provides the opportunity to treat up to twice as many patients per day without taking up too much extra valuable space.

To ensure optimal results as well as excellent comfort and hygiene, PSCS has the option to be used with single patient use cooling caps available in different sizes and versions. This opportunity is offered in several markets, and it is especially utilised in the United States and Japan. The single patient use cooling caps allow each patient to find a size with an optimal fit and prepare for the treatment in advance. Additionally, Paxman is able to continuously refine its range of cooling caps to fit different head shapes, and the company launched cooling caps produced specifically for the company's Asian markets in 2019. Paxman is also developing a new version of the cooling cap, striving for an improved fit, lower cost and increased sustainability, as well as one or several products with antioxidants to be topically applied to the scalp with the aim of increasing the scalp cooling efficiency. More information on the company's R&D projects can be found on pages 30-38.

In addition to offering Paxman's most efficient scalp cooling to date, PSCS has both single patient use and reusable options for its vast global customer base, offering flexibility for commercialisation. This flexibility allows the company to customise its business model to establish its offering in many different markets with varying healthcare and cost reimbursement systems, and thus to reach out to an increasing number of patients.



EU MDR CERTIFIED PRODUCTION FACILITIES IN THE UK

Paxman's manufacturing facilities are located in the UK at the company's headquarters in Huddersfield, enabling Paxman to maintain high quality and stability in the production process as well as to minimise prototyping lead times.

The advantages of conducting its manufacturing inhouse were evident in 2023. Paxman was able to receive EU Medical Device Regulation (MDR) approval for its scalp cooling system, while also rapidly upgrading the Paxman Limb Cryocompression System (PLCS) in development to prevent chemotherapy-induced peripheral nerve damage (CIPN).

MDR CERTIFICATION ENSURES GLOBAL MARKET ACCESS

MDR certification is not just a required certification for being able to continue to market and sell medical device products in Europe. It is being implemented in over 100 countries, becoming an important global standard with higher requirements on the manufacturing as well as being able to provide relevant documentation. Paxman

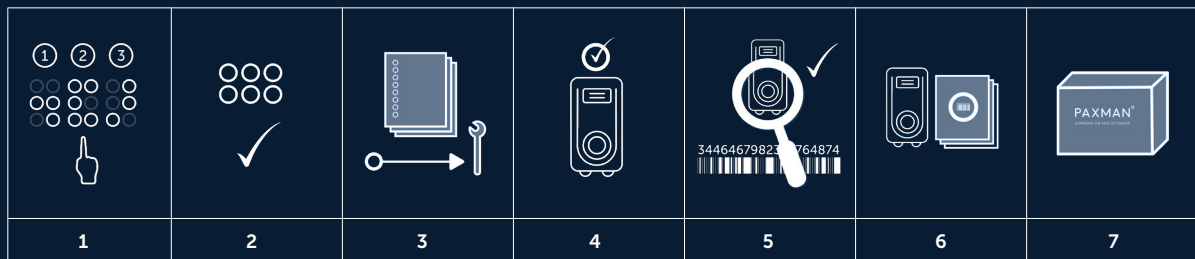
received MDR certification at the beginning of 2023, following significant time and financial investments to improve processes to capture and analyse the data required.

CONTINUED INVESTMENTS IN EXPANDED PRODUCTION CAPACITY

In the coming years, Paxman expects a continued rise in global demand from existing as well as new markets. Ongoing efforts to expand the company's physical and digital presence in important regional markets, as well as a probable future launch in China, are expected to support this development.

To be able to handle this demand, there are ongoing efforts at Paxman to significantly expand the company's production capacity in the UK. This initiative also facilitates the development of new and innovative products such as the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy-induced peripheral nerve damage (CIPN). The company has already manufactured a significant number of prototypes of this cryocompression device for use in the ongoing clinical evaluation program in Singapore and the USA.

This is how a scalp cooling system is made



1. Parts are ordered and delivered from subcontractors and undergo quality tests before appropriately stored. The parts are divided into category 1, 2 and 3, with extended quality checks for category 1 parts.
2. The production plan is determined based on the order book in consultation with sales teams and the company's management.
3. The list of parts (BOM) is prepared, and all components are picked from stock and supplied to the production team that prepares them for assembly and production.
4. Production involves three stages, with quality assessments by the quality team at each step against strict criteria.
5. When a device is fully complete, a further quality inspection is undertaken which involves functionality testing and electrical safety testing. The device is then appropriately labelled with a unique serial number plate.
6. The fully tested equipment is allocated to a customer order, and the internal paperwork is then generated.
7. The customer order is finally packed and palletised with the required accompanying documentation and associated accessories, and the coordinator ensures that customer-specific and any export-related documentation is prepared and that the order is picked up and delivered to the customer by the shipping company.



HIGHER NATIONAL PAYMENT RATE: IMPORTANT PROGRESS FOR REIMBURSEMENT

An important ruling was made by the Centers for Medicare & Medicaid Services (CMS) in November 2021. By reassigning one of the CPT codes issued for scalp cooling by the AMA, this code was allowed a much higher national payment rate of 1,850.50 USD compared to the earlier rate of just 34.72 USD. While this payment rate specifically covers Medicare patients, many commercial payers also use CMS rulings as guidelines for their own policies. The higher payment was implemented from the start of 2022, and has also been confirmed for 2023.

BACKGROUND TO THE CMS RULING

In July 2021, the scalp cooling CPT code 0662T was issued by the AMA for the initial measurement and calibration of the cap. There was also a CPT code issued, 0663T, to be used for each scalp cooling treatment. The new 0662T CPT code is temporary and will remain in effect for a number of years. Clinical and claims data is collected during this period to determine if the establishment of permanent CPT code is justified. During this period, the new CPT code, and any associated payment rates, are reviewed annually by the CMS. This annual review could result in the payment rate going up or down.

Under Medicare, hospitals are paid based on the assignment of CPT billing codes to Ambulatory Payment Classifications (APCs). Medicare sets the payment rates for each of these APCs. In July 2021, CMS made the initial proposal to assign CPT code 0662T to APC 5732 (Level 2 Minor Procedures) with a proposed national payment rate

of just 33.84 USD, and for 2022 the proposed payment rate was just 34.72 USD. Paxman and others commented on this proposed rate as it wasn't sufficient for physicians and health systems to implement scalp cooling.

REASSIGNMENT FOR A HIGHER PAYMENT RATE

Based on comments to the proposed ruling and information presented at a panel meeting in August 2021, CMS reassigned CPT Code 0662T to New Technology APC 1520 in a new Hospital Outpatient Prospective Payment System (HOPPS) ruling. This APC has a much higher proposed payment rate of 1,850.50 USD. In its new ruling, CMS took into account the substantial hospital resource costs associated with the calibration and fitting of the scalp cooling cap. The company will continue to work on improving this rate.

CPT codes for scalp cooling

Code	Range
0662T	Initial measurement and calibration of cap
0663T	Placement of device, monitoring and removal of device (each treatment)

Resources:

CMS Final Ruling Nov 2, 2021 – CMS-1753FC (page 232-233, scalp cooling)

CMS Press Release Nov 2, 2021 "CMS OPSS/ASC Final Rule Increases Price Transparency, Patient Safety and Access to Quality Care"

CMS Fact Sheet Nov 2, 2021 – CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1753FC)

Q&A ON THE NATIONAL PAYMENT RATE FOR SCALP COOLING

WHICH PATIENT GROUPS ARE AFFECTED BY THE PAYMENT RATE OF 1,850.50 USD FOR CPT CODE 0662T?

The national payment rate is related to hospital outpatient payment for Medicare services. It does not impact commercial plans, although commercial plans often look to Medicare and CMS's actions as informative or guiding in their own payment policies and determinations.

CAN A PATIENT BE CERTAIN THAT THE SCALP COOLING TREATMENT WILL BE COVERED?

The assignment of a CPT code or approval of a service for assignment to a New Technology APC does not assure coverage. To receive payment, a new technology service must be considered reasonable and necessary. Each use of a new technology service is subject to medical review for determination of whether its use was reasonable and necessary. Paxman offers patient services including determining insurance coverage for patients and filing for pre-approval as part of its new buy-and-bill business model in the USA.

COULD THE PAYMENT RATE BE SUBJECT TO ADDITIONAL CHANGES?

The rate for APC 1520 may be updated annually, and that may be monitored by following the proposed and final HOPPS rules issued by CMS annually. The same payment rate was confirmed for 2023. Since this is a New Technology APC, according to CMS, the service assigned to it of 0662T will be paid under this APC until sufficient claims data has been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. CMS says this will typically occur within two to three years from the time a new code becomes effective.



PAXMAN INTRODUCES BUY-AND-BILL MODEL TO ENABLE REIMBURSEMENT

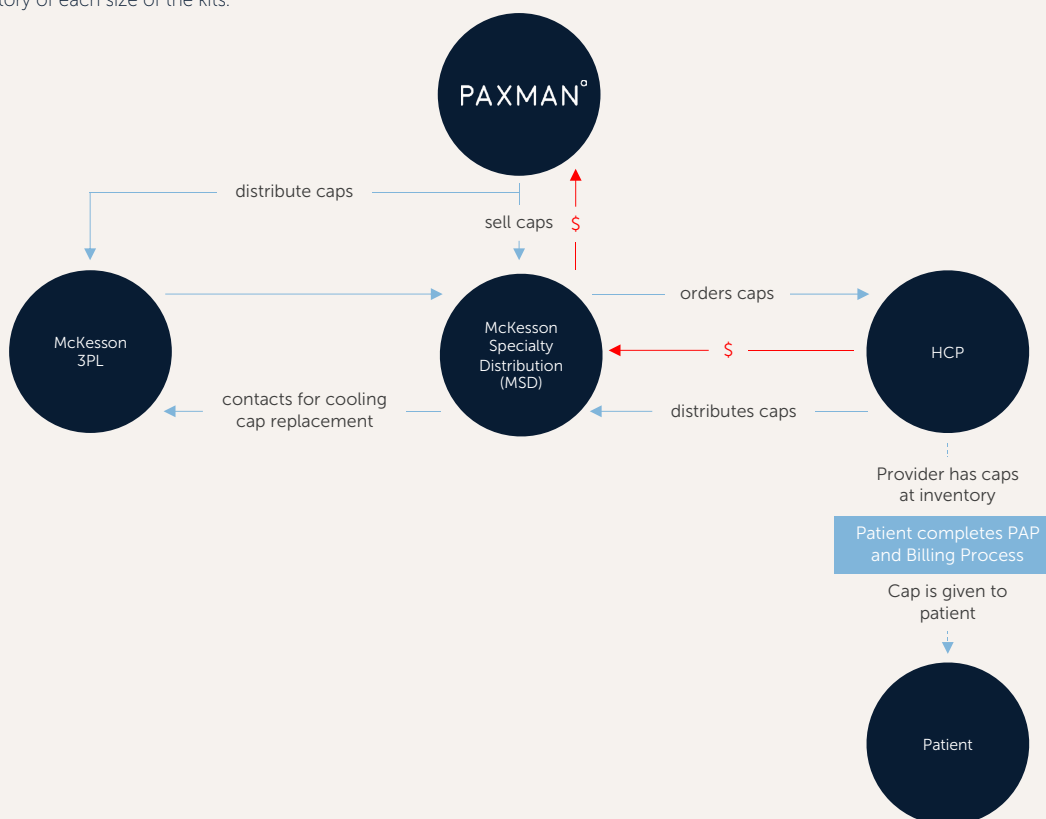
Paxman is excited to transition its customers to a new buy-and-bill business model in the US market, which allows providers to bill insurance on behalf of their patients. Previously, patients have had to pay for scalp cooling on their own, which has limited the company’s growth in the USA. Leading institutions such as RWJBH, MD Anderson and Duke University are already using this model.

Paxman’s goal is to transition 40 percent of its US customers to the buy-and-bill model by the end of 2023. Interest in the new model from the provider network is very positive, and it has been shown to lead to increased patient usage (read more on page 24).

The buy-and-bill process is as follows:

- Providers and health systems contract with Paxman to install systems for its facilities.
- Paxman sells cooling cap kits in all sizes through a number of McKesson distribution channels (MSCD, MPB etc.). McKesson Specialty Care Distribution (MSCD), the company’s new distributor, is also warehousing the cap kits. Providers and systems contract with McKesson individually or as part of a Purchasing Organization.
- McKesson sells the cooling cap kits to providers and health systems, who will maintain an inventory of each size of the kits.

- McKesson distributes orders to providers and health systems.
- When a provider prescribes the cap to the patient, the patient is enrolled in the Paxman Hub Scalp Cooling Program.
- Either the Paxman Hub or the provider will do a benefits investigation to determine if the patient’s insurance will cover scalp cooling.
- The patient is measured and the cap is calibrated, and then the patient is given the cap and brings it along with them for each treatment. At this point the provider will bill the payer using 0662T.
- In connection with all treatments, the provider bills 0663T, which is for the cooling treatment itself.



NEW PATIENT ASSISTANCE PROGRAM AND EXPANDED PAXMAN HUB SERVICES

COMPREHENSIVE SERVICES TO FIND THE BEST SOLUTION FOR EVERY PATIENT

In 2022, Paxman continued to implement a process to help open access to Paxman Scalp Cooling to any US patient regardless of their insurance coverage or financial situation.

Previously, Paxman Scalp Cooling was only available to patients in the USA who could pay for the treatment themselves. Some patients submitted their itemized receipt to their insurance companies and received reimbursement, but many were not reimbursed. Furthermore, many patients cannot afford to pay outright for scalp cooling, regardless of whether or not they would be reimbursed. Therefore, many patients were not able to use Paxman Scalp Cooling.

SEVERAL NEW PROGRAMS LAUNCHED IN 2022

Paxman launched several programs in 2022 designed to help patients and their providers with access to Paxman Scalp Cooling. In connection with the introduction of the new buy-and-bill business model in the USA, the company is also expanding its service offerings to patients and providers through Paxman Hub services, and these services are offered through CoverMyMeds – a McKesson Company.

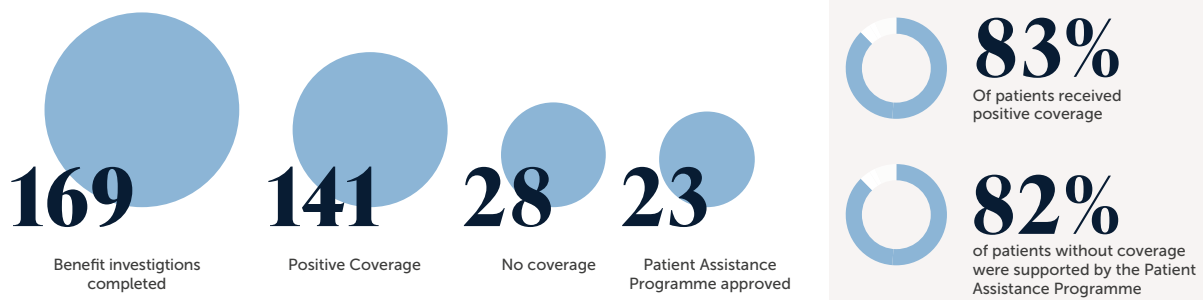
These enhanced services include:

- Benefits investigation to determine patient insurance coverage and its level
- Prior authorization assistance to support use of Paxman Scalp Cooling
- Appeal support to support Paxman use when coverage denied by insurance company
- Paxman Patient Assistance Program (PAP) for free goods to qualifying patients

PATIENT-SPECIFIC SUPPORT BY PAXMAN AND MCKESSON

Providers will start with completing the Paxman Hub Enrollment Form with patients and submit the form to the Paxman Hub. This form captures patient information that will help determine which services the patient qualifies for. McKesson will then determine if patients have insurance coverage, and what the level of coverage is. Additionally, if patients are uninsured or underinsured, based on household income they may qualify for patient assistance – free goods – from Paxman.

RESULTS FOR PROVIDERS USING FULL PAXMAN HUB SERVICES



These results only include providers using the full hub services – during the period June 22, 2022 up until March 23, 2023.

About McKesson Specialty Care Distribution

Based in Irving, Texas, McKesson unites independent providers with manufacturers and payers to deliver end-to-end efficiencies and clinical excellence.

The Company delivers a third of all pharmaceuticals used in North America and employs over 78,000 people.

McKesson's CoverMyMeds solution network includes approximately 75 percent of electronic health care record systems, over 50,000 pharmacies, 750,000 providers and most health plans and Pharmacy benefit managers (PBMs) – companies that manage prescription drug benefits on behalf of health insurers.

THE NEW BUSINESS MODEL IN THE USA INCREASES PATIENT USAGE

Paxman's new business model in the USA that enables reimbursement began to gain momentum in 2022, and figures from some well-known institutions that have started using it show increasing patient usage. Paxman's goal is for 40% of its customers in the USA to use the new model by the end of 2023.

EXAMPLES OF WELL-KNOWN INSTITUTIONS USING THE NEW MODEL OR IMPLEMENTING IT IN 2023

- New Jersey
- Texas
- North Carolina
- Ohio
- New York
- Florida
- One pilot facility within US Oncology Network

EXAMPLES OF PUBLIC AND PRIVATE PAYERS

Public health care systems

- Medicare
- Medicaid

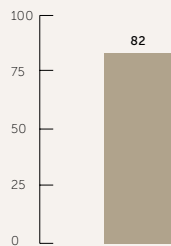
Private insurance companies

- Aetna
- BCBS
- Cigna
- Humana
- United

INCREASING PATIENT USAGE AT INSTITUTIONS USING THE NEW MODEL

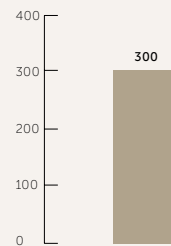
New Jersey

82% increase



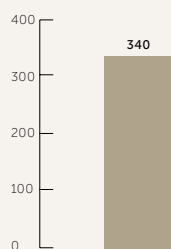
Texas

300% increase



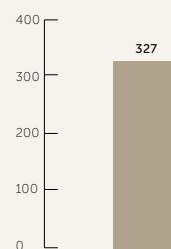
Ohio

340% increase



North Carolina

327% increase





INTERVIEW WITH LARGE US ACADEMIC HEALTH SYSTEM USING THE NEW MODEL

One of the first customers using the new buy-and-bill model in the USA, a large academic health system, recommends it to other health systems as it greatly improves patient access and reduces the patient's burden of out-of-pocket expense compared with the prior model.

What was the extent of your scalp cooling program before implementing the new buy-and-bill business model?

We have two different sites doing scalp cooling. At the site where I work (breast cancer) we had around 50 patients per year doing scalp cooling as I understand it. The second site (gynaecologic oncology) had much less volume.

Did you implement the new model at both sites at the same time, or are you making the switch gradually?

Both sites at approximately the same time.

Has the implementation of the new model been easy so far, or have you had to make any major changes in the way you work in your scalp cooling?

The entire billing model changed significantly, which caused additional steps in our workflow. We have worked to keep our clinical team from having to discuss financial details of scalp cooling coverage with patients. It has definitely not been easy. Paxman have given us as much support as they could.

Can you describe the main benefits of this new way of offering scalp cooling for a) you as a health care provider and b) for your patients?

a) Perhaps that we have the scalp cooling caps onsite and have more control to ensuring patients get them timely. b) the huge benefit for patients is that a substantial portion are

able to utilize payor support for the caps or the generous Paxman Patient Assistance Program, thereby significantly improving access and lowering out of pocket burden.

Can you describe your experience so far when it comes to the related support services from Paxman to assist in the reimbursement process?

We are primarily relying on our internal pre-certification process rather than the BI assessment of coverage. When we need to respond to requests from payors, I believe the materials from Paxman have been helpful. As noted, the Patient Assistance Program is a great support.

All in all, would you say that you are now able to offer scalp cooling to more patients than before due to the implementation of this new model?

It's early to conclude this, but it certainly seems to be trending in that way. I personally predict an approximate doubling of the number of patients who pursue scalp cooling this first year that we're using the buy-and-bill model.

Would you recommend other health care providers to switch to this new model of offering scalp cooling?

Yes, to greatly improve patient access and reduce the burden of out-of-pocket expense with the prior model.

The new model is recommended as a way to greatly improve patient access and reduce the cost burden of the patient.

CONTINUED GLOBAL EXPANSION FOR SHORT- AND LONG-TERM REVENUE

PAXMAN'S FLEXIBLE SCALP COOLING SYSTEM ENABLES REGIONAL BUSINESS MODELS

With PSCS, the company's latest scalp cooling system, single patient use and regionally adjusted cooling caps can be used to provide the best possible patient results and a more personal experience. Paxman is also able to use regional business models with payment received for each treatment and/or sold single patient use cooling cap. The company is now developing a more cost-efficient version of the single patient use cooling cap for increased flexibility and potentially expanded utilisation of these business models in important growth markets.

The USA, Paxman's largest market, became the first market where the company finances the full cost of the system in return for a payment per treatment and each single patient use cooling cap sold. Similar business models are also used in Japan, Mexico with the license partner Teva and Canada. In 2022, Paxman took the next step in the USA as customers started to use its buy-and-bill model which enables reimbursement for both publicly and commercially insured patients. With increasing possibilities to achieve reimbursement, a very powerful increase in sales is expected in the USA over time.

Strong business outlook in Asia

In addition to the USA, Asia is expected to become a strong growth region for Paxman in the coming years with Japan and China as key markets. In Japan, the world's second largest cancer market, Paxman receives

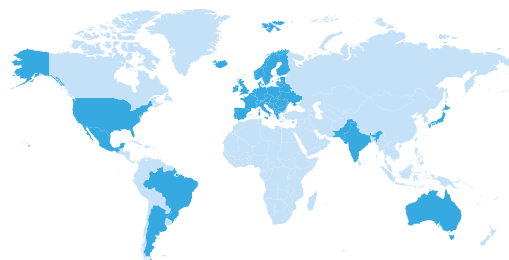
payment for each system sold and each single patient use cooling cap sold, and the company and its distributor CMI is now working to increase the growth after the pandemic. The company is also established with market clearance in South Korea, including a large ongoing clinical study. In China, Paxman signed a letter of intent with the intended distribution partner Concord Medical in April 2022.

Balancing short- and long-term cash flows

By using several regional business models, Paxman is able to create a good balance between short- and long-term revenue streams. A model with payment per treatment and/or per each cooling cap sold is also gradually implemented in other markets where possible, for example when upgrading older systems to the new PSCS model when they reach the end of their life cycle of around 6-8 years.

PAXMAN'S REGIONAL BUSINESS MODELS

- USA: Paxman finances the equipment and installation costs and receives payment from patient or customer (new model) for each treatment and cooling cap sold (new model).
- Canada: Business model similar to the one in the USA.
- Mexico: Business model similar to the one in the USA together with the license partner Teva.
- Central- and South America (except Mexico): System sales while also phasing in a model with payment per treatment and/or single patient use cooling cap when installed systems are upgraded.
- Europe: System sales while also phasing in a model with payment per treatment and/or single patient use cooling cap when installed systems are upgraded.
- Japan: System sales to the distributor CMI and payment for each single patient use cooling cap sold.
- Asia (except Japan): System sales while also phasing in a model with payment per treatment and/or single patient use cooling cap when installed systems are upgraded.
- Oceania: System sales while also phasing in a model with payment per treatment and/or single patient use cooling cap when installed systems are upgraded.

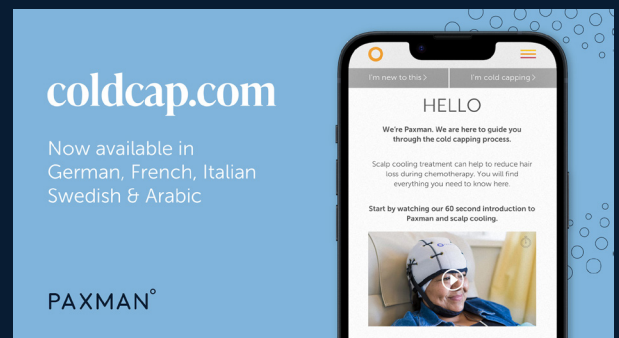


PAXMAN'S INCREASED INTERNATIONAL COORDINATION

DIRECT SALES, DIGITALISATION AND INCREASED REGIONAL PRESENCE

Paxman has expanded its direct sales efforts in recent years, and the company is also investing in expanding the local presence, adjusted marketing and digital solutions, together with local distributors. Regional Managers have so far been appointed for India, France, Scandinavia and Germany and Spain.

By strengthening the marketing function in the UK, Paxman is expanding its international coordination and digital support to all markets. Activities encompass updated digital and printed communication, including translation of coldcap.com to several languages, as well as the launch of new digital efforts such as the research-focused website the Scalp Cooling Study Library and the global conference Scalp Cooling Summit which was held in May 2022.



SOME OF PAXMAN'S MARKETS COVERED BY REGIONAL MANAGERS

Sweden

- Population: 10.2 million
- Diagnosed cancer cases (2020): 62,494, 33,689 male and 28,805 female
- Most common cancers: prostate (17.5%), breast (12.1%), colorectum (10.8%)
- Health care system: Mostly public, tax-funded system with universal access

India

- Population: 1,409,307 million
- Diagnosed cancer cases (2020): 1,324,413, 646,030 male and 678,383 female
- Most common cancers: breast (13.5%), lip, oral cavity (10.3%), cervix uteri (9.4%)
- Health care system: Universal access in public, government facilities, however underfunded and mostly based on out-of-pocket payments. 37% have governmental or employment-based access to private healthcare, 63% are not covered at all

Germany

- Population: 83.8 million
- Diagnosed cancer cases (2020): 628,519, 344,451 male and 284,068 female
- Most common cancers: breast (11.1%), prostate (10.8%), lung (10.3%)
- Health care system: Universal access, dual public-private system

France

- Population: 65.5 million
- Diagnosed cancer cases (2020): 467,965, 260,169 male and 207,796 female
- Most common cancers: prostate (14.1%), breast (12.4%), lung (10.3%)
- Health care system: Universal access, mix of public and private providers and insurers

Spain (from 2023)

- Population: 46,8 million
- Diagnosed cancer cases (2020): 282,421, 163,730 male and 118,691 female
- Most common cancers: prostate (21.1%), colorectum (15%), lung (13.1%)
- Health care system: Mostly public, tax-funded system with universal access



INTERVIEW WITH THE DISTRIBUTOR CENTURY MEDICAL IN JAPAN

Miyu Kusayanagi, MD Marketing Team at Century Medical Inc. talks about the activities in 2022 and the outlook for 2023 as the market is normalised after the pandemic.

Can you start by giving us a summary of your activities in 2022 to increase awareness and support sales of the Paxman Scalp Cooling System in Japan?

We have deployed several activities to help with our main objective of raising awareness of the importance of scalp cooling.

Initially we held a webinar for those oncology practices located in rural areas to try to address the perception that patient demand for scalp cooling is not as wide in these areas. In the less densely populated areas of Hokuriku and Northern Kantou Area we are keen to increase awareness that their patients are equally keen to access the treatment option.

A new patient focused website was launched in August 2022 including scalp cooling resources and information and facility listings showing where patients can access Paxman scalp cooling. Compared to the initial release in August, the number of visitors has increased by 1,000%.

We have attended multiple congresses and congress seminars including Breast Cancer meeting, Breast reconstructive surgery meeting and other local related congresses. During the Breast Cancer meeting, Dr. Inokuchi presented a seminar which helped drive sales in 2022.

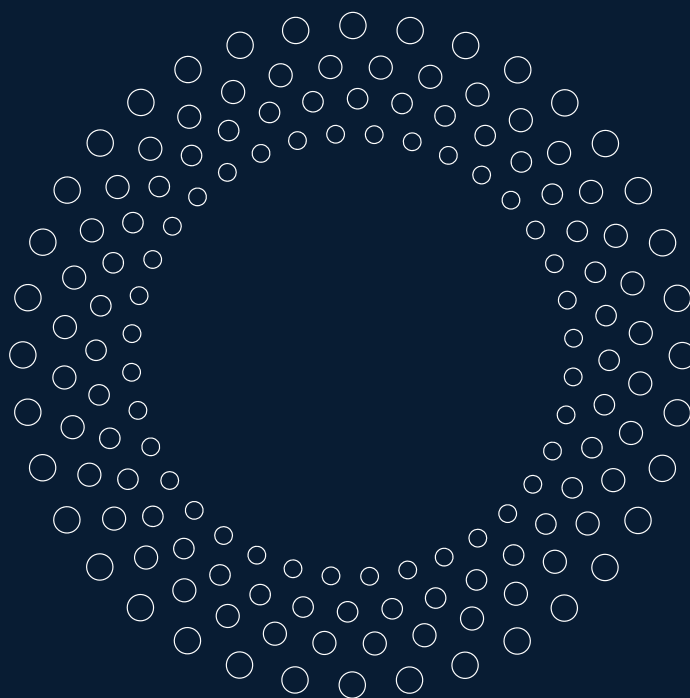
In addition, we hosted the first Paxman Clinical Pioneer Programme to be delivered in Japan and launched a video to assist with cap sizing and fitting which is available for all clinical teams to refer to for ongoing training and development. We also developed a guide, highlighting two case studies to assist clinical teams in the effective implementation of scalp cooling into their practice.

Are you seeing a continued increase in general awareness of the benefits of using the scalp cooling system among cancer centers and patients?

Yes. Paxman Scalp Cooling has been mentioned in multiple media and news broadcasts in the period which we believe helped the above significant increase in web traffic to our new site.

When it comes to your sales of the systems in 2022, are you mostly getting orders from new cancer centers, or are you also seeing that existing customers are adding more systems to current or additional sites?

In general, we are seeing the expansion of scalp cooling at existing sites as they are finding this is an easier way to progress. Facilities can more easily expand their scalp cooling capability whereas it takes much more time to implement a new scalp cooling programme.



Are you noticing any difference between the demand in different parts of the country?

This is true not only in Tokyo, but in the rural areas and countryside as well. There could be some difference due to the smaller population in the rural areas, however once scalp cooling is implemented, they start to see the hidden needs and that actually patients in these areas are equally keen to access the treatment.

Did restrictions related to the pandemic continue to have an effect on your activities related to the scalp cooling system in 2022, and if so, do you think the situation will normalise in 2023?

Yes, to some extent, but we did not see a great impact in our own sales activities.

We did see an impact at existing facilities where they had stopped taking on new patients, but we are pleased to see that it is springing back to the normal situation in 2023.

What will you be focusing on in 2023 when it comes to scalp cooling system related activities?

We will focus on multiple activities including:

Increasing scalp cooling at existing sites where scalp cooling is already implemented.

Creating a regional network of scalp cooling across the country, arranging seminars at existing facilities and inviting sites from the surrounding area to create a network of scalp cooling in each region. The first seminar is planned to start at a HOPE facility.

Our ongoing KPI is to establish Paxman in every prefecture and maintain Paxman as the first choice for scalp cooling.

Educate and raising awareness. We will host a seminar at Japanese Association of Supportive Care in Cancer (JASCC) this year, and we will kick off a scalp cooling committee with the HOPE facilities.

Do you see an overall trend in Japan towards quality of life and treatment of side effects becoming more important for cancer centers, as cancer treatments become more effective?

Yes. JASCC started this 8 years ago, and this has led to wide acceptance for the need of supportive cancer care. In order for a facility to be registered as a Cancer Center it is now mandatory to have these SOPs implemented and addressing side effects relating to appearance is a part of this.

RESEARCH AND DEVELOPMENT

Paxman is committed to an ambitious research and development program, allowing the company to continuously pursue improvements of the scalp cooling system's efficiency and user-friendliness, as well as lowering its environmental impact. The company is also developing a portable cryocompression product to prevent the related indication chemotherapy-induced peripheral neuropathy (CIPN). A prototype version of this product has been completed to be used in the clinical trials in Singapore which was initiated in November 2021, and a large randomised multicenter trial in the USA which will be initiated in 2023.

PAXMAN SCALP COOLING RESEARCH CENTRE – THE WORLD'S FIRST MULTIDISCIPLINARY RESEARCH CENTRE FOCUSED ON SCALP COOLING

A significant share of Paxman's research and development program is conducted in collaboration with a multidisciplinary research team at the University of Huddersfield. The research team has expert knowledge in relevant areas, including biological and chemical research on hair follicles and product development. In February 2019, the collaboration was formalised into the Paxman Scalp Cooling Centre, the world's first multidisciplinary research centre focused on scalp cooling.

During the first five years, the parties will invest a total of 12 MSEK in liquid funds, personnel, and other resources in the centre. Paxman's investment during the first year was covered by a partly EU-funded grant of 1.2 MSEK.



The picture shows Pat Burke, Head of Design & Development, Dr. Ertu Unver and Richard Paxman at the Paxman Scalp Cooling Research Centre/University of Huddersfield.

SELECTED RESEARCH AND DEVELOPMENT PROJECTS AT THE PAXMAN SCALP COOLING RESEARCH CENTRE

Biological research with cultivated human hair follicles

By examining cultivated human hair follicles in connection with chemotherapy treatment and scalp cooling under different conditions, researchers can deepen their knowledge of underlying biological and chemical mechanisms. This research is used in the further development of Paxman's current and future product range in scalp cooling and to prevent chemotherapy-induced peripheral nerve damage (CIPN).

Product to prevent chemotherapy-induced nerve damage in hands and feet (CIPN)

Researchers at the Paxman Scalp Cooling Research Centre are collaborating with the National University Hospital in Singapore (NUH) within the project to develop a new product in chemotherapy-induced peripheral neuropathy (CIPN) that causes nerve damage to the hands and feet. A prototype version has been completed, and it is being used in the clinical trial program which was initiated in Singapore in November 2021.

Individual 3D-printed cooling caps for a more efficient scalp cooling

Individual 3D-printed cooling caps have the potential to increase the efficiency of Paxman's scalp cooling in markets where the company currently uses single patient use cooling caps, including the USA, Canada, Japan and Mexico.



Development of a miniaturised cooling and compression system

As a part of the CIPN development project, Paxman is developing a cooling system with compression capability that has a significantly smaller size compared to the current scalp cooling system. A smaller size means taking up less valuable space in hospitals and cancer centres, which can sometimes be a limiting factor.

Topically applied product to enhance the effect of scalp cooling

The biology team is developing several formulations with antioxidants for topical use to reach the hair follicle and enhance the effect of scalp cooling in connection with chemotherapy treatment. The goal is to reach the market together with a commercial partner. The product can be applied directly onto the head of the patient, which means that it can be used together with Paxman's current scalp cooling systems, allowing a faster and broader market launch.



INTERVIEW ON PAXMAN'S BIOLOGICAL R&D PROJECTS

Dr. Nikolaos Georgopoulos, Reader (Associate Professor) in Cell Biology and Dr. Andrew Collett, Senior Lecturer Biological Sciences, at University of Huddersfield, research the biological effects of scalp cooling and cryotherapy, and are making strong progress in developing a topical product to enhance the effect of scalp cooling.

Can you provide a general update on your progress in 2022/so far in 2023 when it comes to the topical product to increase the effectiveness of scalp cooling?

We have developed formulations (nanoparticulates) of three antioxidants. Two of these antioxidants (actives) have been incorporated into nanostructured lipid carriers (NLCs), we have shown that they are robust formulations and stable on storage. These have been tested on skin models and we have demonstrated efficient skin permeation of the antioxidants and successful targeting of hair follicles (compared with actives alone). We are currently working on refining the formulation of a third antioxidant, which has been incorporated into lipid nanoparticles (LNs).

What is the status specifically when it comes to choosing a nanoformulation to reach the hair follicle?

Our nanoparticle-based formulations have been developed using excipients that are not only safe for human skin (with evidence of use in approved pharmaceutical products), but also have the properties required to target the follicles. In particular, we have ensured that nanoparticles exhibit the correct size, and have optimal surface chemistry (electrical charge) to successfully reach the hair follicle. Moreover, we have taken into consideration the chemical properties of each antioxidant and have designed bespoke formulations to efficiently deliver the different antioxidants.

Are you currently aiming for one formulation of the product, or several depending on the chemotherapy type used?

Based on our extensive previous biological work that demonstrated the efficacy of the antioxidants against the most commonly used chemotherapy drugs that cause hair loss, we have several potential options.

Although the first topical product(s) used in conjunction with scalp cooling will be single formulations, it is certainly a possibility that combinatorial formulations may be used to ensure better protection against certain chemotherapy regimens. In preparation for this scenario, we have preliminary experimental evidence that we can concurrently target two antioxidants to the follicles.

What will you be focusing on in 2023 in this project?

Our focus will be to work with a commercial partner that has a proven track record in dermatological / skin care products, in order to formulate a product (lotion, serum or cream) for application of the nanoformulation to the hair and scalp. Initially this will be carried out with one antioxidant to provide a product that can be used clinically and provide proof-of-concept data. This is the most exciting stage of the work where the real product can be available for use! We will also be optimizing the LN-based formulation of the third antioxidant and using the skin models to test for successful targeting to the follicle area, whilst also confirming that the nanoformulation retains stability upon storage.

What are the biggest challenges left before reaching the market with this product? Will you need to do any clinical studies to collect data for market certification, and if so, have you started the planning for this?

The aim is to follow the most straightforward and fastest route-to-market approach. The advantage of our nanoformulations is that they deliver natural antioxidants, thus our plan is to develop and market the formulations as cosmetic haircare products. This approach will not require clinical trial testing and the topical products will comply with cosmetics regulations with clear safety for human use, which negates the need for compliance



Dr. Nikolaos Georgopoulos



Dr. Andrew Collett

with regulatory authority requirements and/or market certification.

What is a reasonable time to market for the topical product based on the current status of the project?

Although making the product available as a cosmetic (instead of a pharmaceutical) will undoubtedly accelerate the path to patient use, the timelines to market will become clearer and better defined once we have entered a commercial agreement with the partner that will assist in the manufacturing and distribution of the cosmetic formulation.

Can you update on any additional biological R&D activities related to scalp cooling that you have conducted in 2022/so far in 2023?

Our cell biology team has vast expertise in the mechanisms of cell death in human cells and our work has recently led to an exciting discovery. Whilst continuing to investigate the mechanisms by which chemotherapy drugs trigger cytotoxicity in hair follicles (and hair loss), we observed that one of the most frequently used chemotherapy drugs in the clinic activates a new type of cell death. This has not only moved us one step closer in understanding how chemotherapy causes hair loss, but has also provided the exciting possibility of new treatments in combination with scalp cooling.

What biological R&D activities related to scalp cooling in addition to the topical product are you planning in 2023?

Following the exciting discovery described in previous answer, we now aim to further understand the role of this relatively newly discovered type of cell death in chemotherapy drug-mediated hair follicle toxicity. Moreover, we will test inhibitors of this type of cell death for their ability to enhance the ability of cooling to protect cells. This approach is different to using an antioxidant, therefore we face the exciting possibility of a completely novel combinatorial approach to minimise hair loss.

Anything else you would like to add related to biological R&D that could be of interest for Paxman's shareholders?

Although hair loss represents the most traumatic side effect of chemotherapy for patients, a chronic and severely debilitating effect of the treatment is chemotherapy-induced peripheral neuropathy (CIPN). Our research has therefore recently expanded towards the development of neuronal cell culture models to systematically study for the first time how chemotherapy drugs cause cellular 'stress' (which underpins nerve damage caused by CIPN) and how cooling may suppress such cellular stress. This work will complement the exciting clinical trials that Paxman are leading with clinicians at the National University of Singapore (NUS).

DEVELOPMENT OF A NEW PAXMAN PRODUCT TO PREVENT CHEMOTHERAPY-INDUCED NERVE DAMAGE

In 2022, the first phase of the clinical trial in Singapore was completed, and the second phase was initiated, while a large, randomised phase 3 study with SWOG in the USA is prepared with initiation in 2023.

Paxman is well aware of the fact that chemotherapy can cause other serious side effects in addition to hair loss, chemotherapy-induced peripheral neuropathy (CIPN). CIPN can cause several different symptoms from tingling and sensory impairment to severe pain and temperature sensitivity. Therefore, the company is developing the Paxman Limb Cryocompression System (PLCS), a portable cooling and compression system to prevent CIPN.

PROGRESS IN RESEARCH, CLINICAL TRIALS AND PRODUCT DEVELOPMENT

At the beginning of 2019, Paxman signed a research collaboration agreement with the National University Hospital in Singapore, (NUH) for the development of PLCS. The research team is led by Dr. Raghav Sundar, who has examined the possibility of using cooling and compression to prevent CIPN for some time, while the development of the actual device is conducted in collaboration with researchers from the Paxman Scalp Cooling Research Centre at the University of Huddersfield.

Paxman further developed its relationships with key clinical opinion leaders in 2020, including the renowned Prof. Charles Loprinzi from the Mayo Clinic, Rochester, USA, who was elected as a new member of Paxman's advisory board. Prof. Loprinzi is one of the world's top key opinion leaders in the CIPN field and the first author of the ASCO 2020 CIPN guidelines. He is now involved in the work of designing the project's clinical program.

In 2021, a research grant of 1.57 million SGD was received from National Research Foundation (NRF) in Singapore, and a clinical trial was initiated with National University

Hospital, Singapore, in collaboration with The N.1 Institute for Health, National University of Singapore to evaluate the system with healthy volunteers and cancer patients. The first phase of the trial was completed in 2022, and the second phase was initiated later the same year (read the interview on p. 38-39 for more information).

A larger randomized phase 3 efficacy study will be initiated together with the cancer organisation SWOG in 2023 (read the interview on p. 36-37 for more information).

The data from the trials will be used in regulatory documentation required to achieve market clearance for PLCS in Singapore and the USA.

PAXMAN HOLDS THE EXCLUSIVE RIGHT TO COMMERCIALISE THE TECHNOLOGY

Any patents and additional intellectual properties conceived from the partnership will be jointly owned by the two parties, and the first applications were filed in 2020. Paxman holds the exclusive rights to commercialise and sell PLCS. The goal is to launch a product used to reduce the amount of cytotoxin that reaches hands and feet, as well as minimising its harmful effects by slowing down the metabolic activity in the nerve cells.





INTERVIEW ON THE CIPN CLINICAL STUDY IN THE USA WITH SWOG

Melissa K. Accordino, MD, MS (SWOG) Assistant Professor of Medicine Columbia University Medical Center and Kathryn Pennington, MD (NRG) University of Washington talk about the work with the large randomised clinical Phase 3 study in the USA that will be initiated in 2023.

With the study just about to start, what can you say about the planning and preparation process in 2022/early 2023, the collaboration with Paxman and SWOG, and the interest from sites to participate?

The study has been initiated by the National Cancer Institute (NCI) and will start accruing patients soon. Sites have been extremely interested in this study – there is a lot of enthusiasm. The collaboration between Paxman and SWOG has been very smooth and we appreciate the Paxman team very much!

The Paxman Limb Cryocompression System (PLCS) is a relatively small and portable device. Has this made the planning of the study, including site selection, easier?

It has been feasible for our sites. Being portable on a cart is very helpful, however I am unaware how many potential sites may not have applied due to concerns about space. If the study is successful and becomes a standard of care, the current size could still be an issue for some cancer centers. However, given the portability of the device, having the option to transfer the patient from an infusion chair to a waiting room to complete the post-taxane cooling helps to improve feasibility concerns.

Have you received any general feedback on the ease of use of the device from the sites and/or patients that have tried it during the preparations that you can tell us about?

Not yet, however our colleagues at the National University of Singapore have seen positive indications.

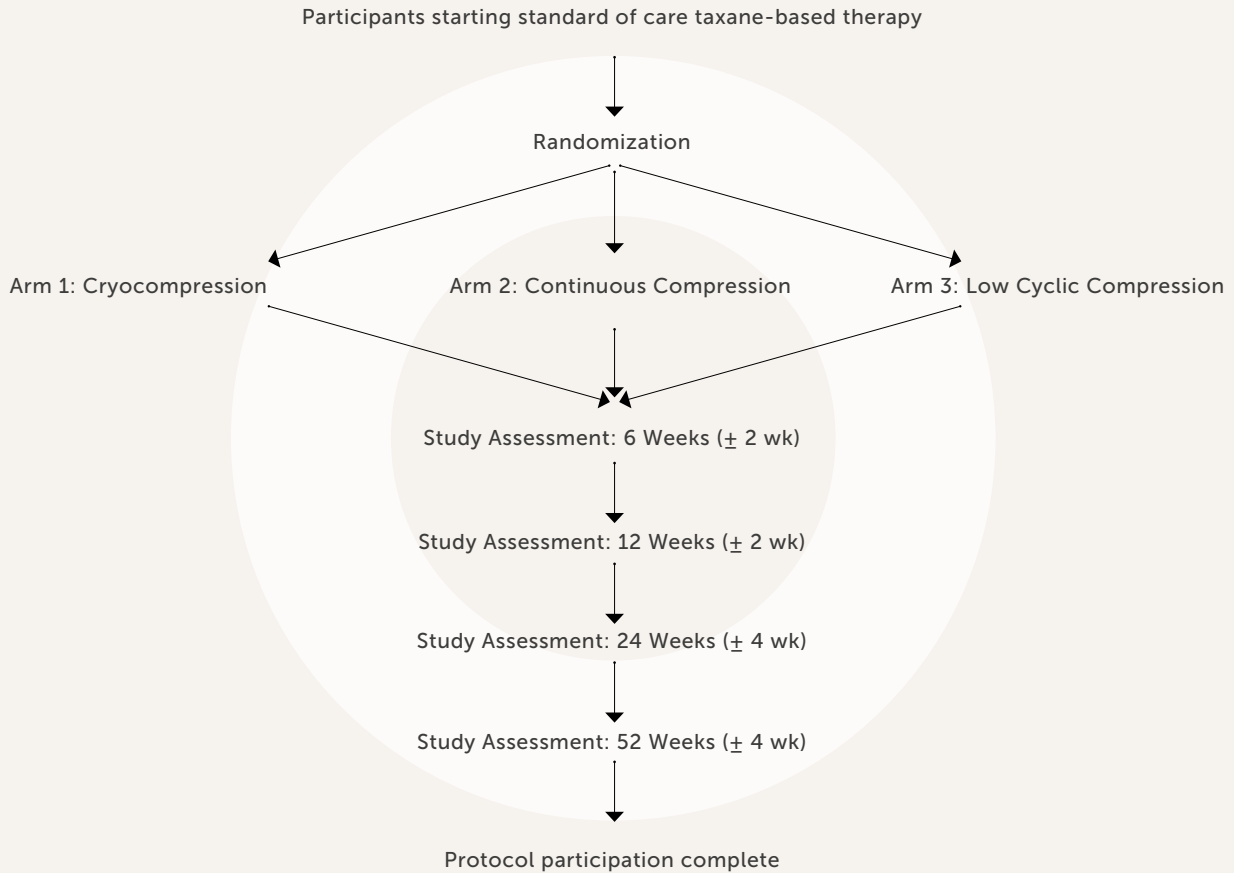
How many sites do you expect will participate in the study, and how long do you expect that the inclusion of all 777 participants will take?

25 SWOG Centers will participate, along with the additional sites which are approved to join the study, we anticipate recruitment will take 2 years.

This study will include participants undergoing taxane-based therapy, and they will be divided into three groups (cryocompression therapy, continuous compression therapy and low cyclical pressure alone). Can you describe the reasoning behind these design choices?

Evidence that both cryocompression and continuous compression may be effective. Low cyclical pressure serves as control. It is important to not have a non-treatment arm, such as standard of care, given that the primary endpoint is a patient reported outcome, and not having a treatment could bias participant's responses to questionnaires.

SCHEMA



Are there any other study design choices that could be interesting to tell us about, and why you made them?

For CIPN, the most meaningful endpoint is patient reported outcomes, as investigator assessed CIPN tends to not capture the full experience of the patient. Thus, it was very important for the primary endpoint to be CIPN assessed at week 12 using a patient reported outcome [EORTC-CIPN-20 sensory neuropathy subscale].

If this clinical study is successful, what would this entail when it comes to market certification and creating a new standard of care to prevent CIPN?

Currently, we are looking at HSA approval in Singapore and thereafter a 510K in the USA however our core focus is the clinical trials at present. The clinical study is not being undertaken for the purpose of regulatory approvals, rather to evaluate efficacy, safety, and tolerability of the PLCS in the prevention of taxane-induced CIPN. The knowledge gained from this large, randomized Phase III study could be practice changing and lead to significant quality of life improvements among cancer survivors and will also help clinicians determine the most effective and most tolerable strategy to prevent taxane-induced CIPN.

When working with the study, what can you say about the general interest in and demand for a method to prevent CIPN from cancer centres, organisations such as SWOG, and potential users/patients?

Finding an effective therapy to prevent CIPN is a huge unmet need – there is immense interest from cancer centers, patients, and from the cooperative groups. This is also a top priority for the NCI.

Is there anything else you would like to add about the study that could be of interest to Paxman's shareholders/stakeholders?

We are so excited to start enrolling patients and try to identify an effective strategy to prevent CIPN and hopefully improve patients' quality of life.



QUESTIONS ON THE CIPN DEVELOPMENT WITH THE PAXMAN'S R&D TEAM IN SINGAPORE

Dr Aishwarya Bandla , Principal Investigator & Head of Translational Core at The N.1 Institute for Health, NUS and R&D Manager Paxman, and Dr Raghav Sundar, Consultant Medical Oncologist specialising in gastrointestinal cancers and early phase clinical trials, are very pleased with the extensive progress achieved in 2022 and so far in 2023.

Can you give us an overview of the status of the clinical trial program for the PLCS system in Singapore and the USA?

The Phase III study in the United States (SWOG S2205 ICE COMPRESS) is gearing up, it is now officially activated by the National Cancer Institute (NCI) and will soon begin recruiting patients.

The clinical trials in Singapore are progressing very well, the first phase of the trial has been completed. 15 breast cancer patients receiving weekly paclitaxel chemotherapy underwent concomitant limb cryocompression for 12 weeks. Feedback from the trial has been used to improve the design and user experience of the PLCS.

The second phase of the study has commenced. There has been a steady demand for the PLCS among physicians and patients as investigators believe that the product helps patients. Currently we have 6 patients recruited at the National University Hospital, out of which 1 has successfully completed 12 cycles of cryocompression, and 1 patient has withdrawn from the study due to reasons other than safety or intolerance. We also have 10 patients recruited at Curie Oncology, out of which 2 patients have completed 12 cycles of cryocompression.

Do you have some early feedback from the study to share?

Preliminary feedback and data from the first phase of the trial suggest the efficacy of the PLCS in preventing CIPN. 2 out of the 15 patients (13%) were determined to have developed clinically meaningful CIPN at 12 weeks. Cryocompression delivered by the PLCS was well tolerated over multiple cycles of chemotherapy averaging

durations of 3 hours. Patient user satisfaction levels have been generally good, and nurses have expressed their appreciation of the improved design of the PLCS used in the second phase of the study.

The expansion phase study in Singapore has included, not only our own site at NCIS, NUH, but also Curie Oncology. Curie Oncology is a private oncology practice in Singapore bringing together several medical oncologists subspecialising in various solid tumors and a hematologist. Together, they provide personalized care and treatment for cancer patients. This clinical trial is conducted at Curie Oncology's Clinic at Mount Elizabeth Novena Specialist Centre.

We are also looking at opening a third hospital in our single arm non-randomized study with a focus on user experience, logistical workflows and to gain further feedback on device improvements.

We continue to work with the Paxman team to ensure all the US study sites start off on time. With the first orders received for devices from various sites we should see patients hopefully starting treatment with the device in Q2 2023.

Are you satisfied with the progress for the development project and clinical program in 2022 and so far in 2023, and what have been the highlights during this time?

From a device development aspect over the past year, the team has done tremendously well in determining proof of concept for the device which was deployed in the early pilot studies. The team developed the

beta prototype which was included in the expanded phase I study and is now ready for the phase III study in the US. Integration of valuable feedback from various stakeholders such as nurses, patients, device administrators, biomedical engineers and clinical trial coordinators has really made the prototype trial device ready for both the forthcoming large scale clinical trials and also for the regulatory approval steps.

In terms of regulatory approval, the determined pathway is to start with the HSA – preparing for labelling submission and then leading into the 510k FDA route and gearing up to CE marking. There have been no major questions from the FDA and HSA in our pre-registration discussions and so we feel that this process is very much on track, particularly thanks to Paxman's experience in this field. We are hopeful that we should have everything in place to readily gain regulatory approval.

From the clinical development side, we are looking to expand even further. The US trial, with randomisation, is the definitive one and multiple centres across the world are showing interest in joining. In Singapore we are looking at logistics and multiple expansion into other sites, we are in deep discussions with a centre in the UAE which we are hopeful will look to start this year. We also have interested parties and collaborators in Japan and Europe. No additional investment would be needed from Paxman at this stage.

Have you received any general feedback on the ease of use of the device from the sites and/or patients that have used it so far?

Very early anecdotal feedback from Curie Oncology, a private oncology practice in Singapore, that very quickly recruited 10 patients in just over 3 months – even faster than our own patient recruitment – saw the real potential benefit to their patients from using the PLCS device. Minor device-related issues have given important feedback to ensure these were ironed out prior to the production of the US devices.

Important ergonomic feedback has also been gained on the wraps, allowing us to improve comfort for patients. This valuable feedback, almost on a live basis, ensured swift feedback from Singapore to the development and product design team in the UK ahead of the large-scale trial environment ensuring ease of use for not only patients, but nursing staff who will administer the device.

One major milestone and an important achievement to highlight, has been the training of 50 NUH nurses on the PLCS device. These clinical teams are already familiar with the Paxman Scalp Cooling device and their positive feedback has shown that the PLCS device is equally straightforward and simple to use to deliver treatment.

What kind of general feedback have you received from clinical study partners such as SWOG regarding the system and its potential of your system as a method to prevent CIPN? Do they share your view of how important it is to find an effective method to prevent CIPN?

Yes, absolutely. We all share the hope that results from this trial will help us to identify a strategy to safely and

effectively prevent chemotherapy induced peripheral neuropathy, which will lead to a remarkable improvement in the lives of many patients with cancer.

In terms of feedback on the device itself, initially there were some concerns over the size of the device however the beta prototype is already smaller than we had initially suggested and further trial-based feedback will be integrated into the design for future iterations of the device.

Can you also elaborate on the interest/feedback from clinical sites to participate in the trials?

Yes, as previously mentioned, we have significant interest from multiple centres around the world showing interest to join the trial. In terms of device feedback, most patients and healthcare providers are very happy from a usability standpoint due to the fact that they are already using the Paxman Scalp Cooling System and so are familiar with the user interface, which means this is much less of a barrier to clinical integration.

How complete is the current version of the PLCS device compared to the potential commercial version?

The beta prototype used in the current clinical trial already incorporates a lot of feedback from the Singapore clinical trials. We are applying user-centric medical device design, whilst also incorporating design for manufacture and regulatory compliance meaning we are quite close to a final commercial version.

Can you describe your overall goals for the development project and the clinical trial program in 2023?

The broadly highlighted points previously made above cover many of our goals, however getting the US trials up and running, recruiting more patients along with receiving regulatory approval are our key goals.

We have recently successfully obtained a grant for Practice Changing Innovations in Singapore to help us to determine clinical deployment aspects for the device. The award identifies innovations that have gone past the initial research level stage, helping to address, and overcome barriers to enable devices to be deployed into clinic – such as integration of ordering into Electronic Medical Records (EMR), maintenance of devices, and the design of chemotherapy suites to accommodate these sorts of devices.

Can you update on the planned commercial strategy for the PLCS device and expected time to market given successful clinical studies?

The most important step at present is to focus on the clinical trials both in Singapore and the USA. The company will however first commercialise in Singapore based on the opportunities and support outlined above. A clear commercialisation plan will be shared in the future at the right time for the company. The opportunity and interest is exciting.

CLINICAL STUDIES AND COLLABORATIONS

Paxman's scalp cooling is continuously evaluated with different types of chemotherapy treatments and patient groups in order to gain further knowledge and improve the treatment effect. Paxman are pleased to have not only the most published peer reviewed data using its scalp cooling systems, but the most open and active studies, advancing our knowledge with a view to improve efficacy and access globally.

Scalp Cooling in Metastatic Breast Cancer (MBC)

Location: Dana-Farber Cancer Institute

This study is a prospective, controlled, pivotal clinical investigation to assess the efficacy of the Paxman Scalp Cooling System (PSCS) at preventing hair loss in people undergoing treatment for metastatic breast cancer with either Sacituzumab govitecan (IMMU-132 or Trodelvy™), trastuzumab deruxtecan (DS-8201a or Enhertu®), or Eribulin (Halaven®). Participants will receive study treatment with scalp cooling with standard of care chemotherapy treatment and will be followed for 2-4 weeks after completion of treatment with chemotherapy. It is expected that about 120 people will take part in this research study.

[Full text \(Clinicaltrials.com\)](#)

Scalp Cooling for Chemotherapy-Induced Alopecia in Patients of Color

Location: Montefiore Medical Center

The purpose of this study is to evaluate hairstyling techniques aimed at increasing efficacy of scalp cooling in the prevention of chemotherapy-induced alopecia, determine scalp cooling effect on persistent chemotherapy-induced alopecia, and elucidate molecular mechanisms and predictive biomarkers associated with scalp cooling success in patients with skin of color receiving chemotherapy for breast or non-small cell lung cancer.

This study is being conducted because prior studies have found scalp cooling to be highly effective in preventing hair loss resulting from chemotherapy. However, minority representation was largely limited in completed trials. A recent study found that scalp cooling devices are less efficacious in patients of color, likely because patients of color have hair is predominantly types 3 (curly) and 4 (kinky), that tend to become bulkier when wet and can interfere with scalp cooling cap fitting. The investigators plan to test two techniques aimed at improving scalp cooling efficacy in patients of color through hairstyling methods that minimize hair volume in order to increase cooling cap to scalp contact: 1) cornrows/braids/twists or 2) water/conditioner emulsion on hair. Preliminary data shows that breast cancer patients with type 3 or 4 hair receiving taxane chemotherapy and scalp cooling using these techniques to prepare the hair for scalp cooling

cap fitting all experienced hair preservation. Additionally, the investigators will also assess persistent chemotherapy-induced alopecia outcomes and incidence by following patients up to 6 months after completing treatment. Finally, specific gene expression changes in taxane-induced chemotherapy-induced alopecia in vitro have been described previously. The investigators will test the hypothesis that scalp cooling reverses such changes in chemotherapy-induced alopecia, assess for biomarkers predictive for scalp cooling success, and investigate persistent chemotherapy-induced alopecia molecular mechanisms using non-invasive transcriptome sequencing on plucked hair follicles. Estimated enrolment is 30 participants.

[Full text \(Clinicaltrials.com\)](#)

Safety of Lower Scalp Cooling Temperature to Prevent Hair Loss From Chemotherapy in Breast Cancer Patients

Location: Memorial Sloan Kettering Cancer Center

This study is conducted to determine if using the Paxman Scalp Cooling System at temperatures lower than the current standard is a safe and tolerable approach to prevent hair loss in breast cancer patients receiving chemotherapy.

This is a single-center, prospective study to evaluate the safety and tolerability of lower temperature (-7.5°C and -10°C) of the Paxman Scalp Cooling System (PSCS) to prevent alopecia resulting from adjuvant anthracycline plus cyclophosphamide and paclitaxel (AC-T) regimens in patients with newly diagnosed stage I-III breast cancer.

The primary objective of this study is to assess the safety and tolerability of the PSCS at lower temperatures (-7.5°C, -10°C) in preventing chemotherapy-induced alopecia (CIA) in women with newly diagnosed early stage breast cancer receiving adjuvant doxorubicin plus cyclophosphamide (AC) followed by paclitaxel (T) at the completion of AC and T, which will be determined by the ability of patients to complete scalp cooling without any dose-limiting toxicities (DLT) during the 16-20 week period. Estimated enrolment 34 patients.

[Full text \(Clinicaltrials.com\)](#)

CLINICAL STUDIES AND COLLABORATIONS, CONT.

Cooling Cap Trial to Prevent Permanent Chemotherapy-induced Alopecia in Breast Cancer Patients

Location: Samsung Medical Center, Seoul

Adjuvant chemotherapy decreases the risk of recurrence. However, it has distressing side effects, including alopecia. Chemotherapy-induced alopecia (CIA) is a common and distressing side effect of many chemotherapy drugs. In previous studies, more than half of the breast cancer patients experienced higher distress due to CIA during cancer treatment, and this distress was strongly associated with negative body image, overall health status, and psychosocial well-being. Recently scalp cooling has been known to be one of the effective options for hair loss prevention. However, there was little information regarding the effect on prevention of permanent CIA (PCIA). This study aims to examine the impact of scalp cooling on prevention of PCIA as well as CIA.

Female adults who are newly diagnosed with stage 1-3 breast cancer and aged less than 70 years will be screened for plan of undergoing Adriamycin or/ and Taxane regimen as neoadjuvant or adjuvant chemotherapy. Eligible patients will be randomly assigned to intervention or control groups (2:1 ratio). Patients in the intervention group will have applied scalp cooling during 4 or 6 cycles of their chemotherapy whereas participants in the control group will be observed.

The objective of the study is to examine whether Paxman scalp cooling system is effective in reducing PCIA in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy. In addition, impact of Paxman scalp cooling on prevention of CIA, alopecia-related distress, quality of life and patient-reported alopecia related side effects will be also explored. Estimated enrolment is 170 patients.

Full text (Clinicaltrials.com)

Alopecia Prevention Scalp Cooling in Chinese Breast Cancer Patients

Location: Chinese University of Hong Kong

The Orbis Paxman Hair Loss Prevention System was introduced to Hong Kong in 2017. Although this device has been widely used in the United States, Europe and Australia, acceptability, efficacy and safety data in Chinese patients have not yet been available. The objective of this prospective study is to collect clinical data in Chinese patients using the Orbis Paxman Hair Loss Prevention System to prevent chemotherapy-induced alopecia.

This project seeks to demonstrate that the Orbis Paxman Hair Loss Prevention System is safe and effective in reducing chemotherapy-induced alopecia in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy. Estimated enrolment 100 patients.

Full text (Clinicaltrials.com)

Study Of Cold Cap Therapy For Prevention of Hairloss in Pediatric Patients Receiving Chemotherapy For Non-Malignant Indications and Solid Tumours

Location: St. Jude Children's Research Hospital

This study is conducted to see if the Paxman scalp cooling device can prevent hair loss in pediatric patients receiving chemotherapy for non-cancerous conditions or solid tumours.

The primary objective of this study is to assess the safety and feasibility for the usage of the scalp cooling device, while exploratory objectives are to assess the incidence and intensity of chemotherapy induced hair loss when using scalp cooling. Estimated enrolment of 40 participants.

Full text (Clinicaltrials.com)



INTERNATIONAL AND DIGITAL PRESENCE AT SCIENTIFIC CONFERENCES AND INDUSTRY EVENTS

Research conferences and industry events are two of Paxman's most important forums for raising awareness and knowledge of scalp cooling, and to create credibility and enthusiasm for its activities among leading researchers and clinicians. In 2022 it was possible to conduct in-person events in most regions throughout the world, which contributed to Paxman having a very busy event schedule during the year.

During the first half of the year, Paxman participated at events including Best of Breast, Miami Breast Cancer Conference, ONS annual conference, ASCO's annual conference and the international annual MASCC conference.

During the second half of the year, the company attended events including the annual ESMO conference, ACCC's national conference, the annual UKONS conference, European Breast Cancer Conference (EBCC), and San Antonio Breast Cancer Symposium (SABCS).

Paxman contributed with its own comprehensive range of activities and events in 2022, including its Clinical Pioneer Program, the Changing the Face of Cancer Podcast, and not least the first instalment of Scalp Cooling Summit; a global and first-of-its-kind conference with participants including almost 50 leading researchers and clinicians and over 1,400 participants.



Scalp Cooling Summit keynote discussions included, among others:

- Scalp Cooling with Anthracyclines – Breaking Away from 'Taxanes Only' with Dr Julie Nangia, Dr Jin Seok Ahn, Dr Takayuki Kinoshita, Dr Christian Kurbacher, and Nurse Lead Mary Fay,
- Oncodermatologist Perspective – Why Side-Effect Management Should be Preventative, Not Curative with Dr Nicole LeBoeuf, Corina van den Hurk, Dr Ian Tattersall, and Dr Beth McLellan,
- Development of the Chemotherapy-Induced Peripheral Neuropathy Cryocompression Device with Dr Charles Loprinzi, Dr Stephanie Graff, Dr Raghav Sundar, Aishwarya Bandla, Dr Melissa Accordino, and
- Patient Advocate Anne Marie Mercurio and The Importance of Protocols in Achieving Efficacious Scalp Cooling with Dr Lindsay Peterson, Dr Steven Isakoff, Mikel Ross, Corina van den Hurk, and Elisa Mills.

Complete information on the event can be found here:

<https://scalpcoolingsummit.com/>

Changing the Face of Cancer Podcast is available via common podcast platforms.



MARKETS AND SALES

SCALP COOLING TO PREVENT HAIR LOSS IN CONNECTION WITH CHEMOTHERAPY – A GLOBAL GROWTH MARKET

Paxman develops and offers complete scalp cooling solutions to prevent chemotherapy-induced hair loss. As cancer affects people in all countries, the market for scalp cooling is truly global and currently Paxman has customers in Europe, North-, Central- and South America, Asia, Oceania and Africa.

According to the Global Cancer Observatory, approx. 18 million new cancer cases were discovered in 2018, and 9 million people died of the disease. That makes cancer the most common cause of death after heart and lung diseases. The market for cancer drugs is the world’s largest pharmaceutical drug market with a turnover of about 97 billion USD in 2017 according to Global Data.

Chemotherapy is a common treatment for solid tumor cancers when the cancer has spread throughout the body. The company’s assessment based on data from UK National Cancer Registration and Analysis Service is that approx. 6 million patients are treated with chemotherapy every year, corresponding to 28 percent of all cancer patients depending on cancer type.

A majority of the patients who undergo chemotherapy are affected by hair loss, and it is one of the side effects that most patients worry about. That makes the issue doubly important for healthcare providers. Paxman estimates that approximately 4 million cancer patients could be eligible for scalp cooling treatment to reduce hair loss each year.

As the knowledge on the benefits of scalp cooling increases, and thus the demand from both healthcare providers and patients, the scalp cooling market is growing at a strong rate. The inclusion in the NCCN® guidelines in the USA, ESMO guidelines in Europe and Cancer Australia’s guidelines will also further contribute to the use and acceptance of scalp cooling. It is also of great importance that healthcare providers include reimbursement for scalp cooling. In 2021 the AMA in the USA issued two CPT codes for scalp cooling, and the CMS decided that Medicare claims using one of these codes will be subject to a National Average Payment of 1,850.50 USD. A new buy-and-bill business model to facilitate reimbursement started to be implemented by customers in 2022. Paxman had installed around 5,000

scalp cooling systems at the end of 2022, which means that only a fraction of all patients who could benefit from scalp cooling currently has access to the technology.

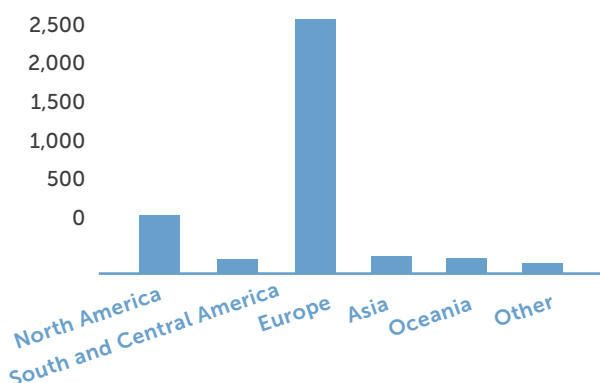
The USA is the world’s largest health care market, with approximately 1.8 million new cancer cases each year according to the American Cancer Society. About 270,000 of these are invasive breast cancer cases, of which many are treated with chemotherapy. Consequently, the USA is one of Paxman’s most important individual markets.

In Japan, where Paxman received market approval in March 2019, about 1 million new cancer cases are discovered each year. Japan is expected to become one of Paxman’s most important markets in the coming years, and the company is also aiming to increase its presence in markets such as India, while also establishing the company in China where a letter of intent was signed with a distributor in April 2022.

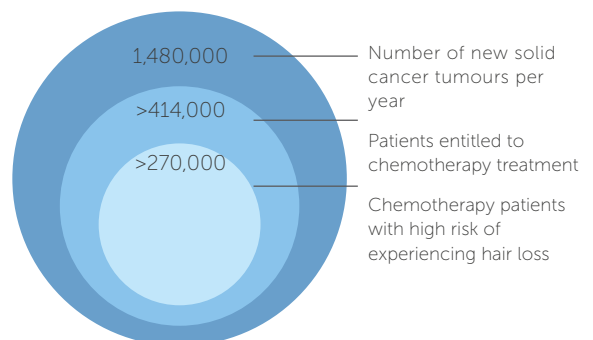
Competitors

Scalp cooling using gel caps has been used for many years, but requires careful and correct handling to work optimally and lack approval from important government bodies such as the FDA in the USA. Consequently, Paxman does not expect any meaningful competition from companies using this method. In the liquid-based scalp cooling sector, Dignitana is the most prominent competitor with some success globally and in the USA, and has sold hundreds of systems in total. However, Paxman has sold several times more systems and is the only company to have received market approval in Japan, giving Paxman a head-start of 1-2 years in the world’s second largest market. In the USA, Cooler Heads is a relatively new competitor with a device cleared to be marketed and sold since late 2021. In Japan, Reve21 is a competitor with a broader hair loss prevention and hair growth stimulation focus.

Total number of delivered systems per region



The North American market



Source: American Cancer society.



CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY

Many people know that chemotherapy treatment can cause hair loss, but nerve damage in hands and feet (chemotherapy-induced peripheral neuropathy, CIPN) is also a severe and common side effect. Paxman is therefore collaborating with the National University Hospital in Singapore (NUH) to develop Paxman Limb Cryocompression System (PLCS), a portable compression and cooling device to prevent CIPN. A clinical trial with healthy volunteers and cancer patients was initiated in Singapore in November 2021, and a large randomised multicenter study in the United States with SWOG Cancer Research Network will be initiated in 2023.

According to Dr. Raghav Sundar at NUH, around 30 to 40 percent of all patients who are treated with neurotoxic chemotherapy are affected by CIPN. The condition is thought to be underdiagnosed, partly because many patients are not aware of this side effect.

There is currently no cure for CIPN, while the market for pharmaceuticals relieving neuropathy-related symptoms has an estimated value of approximately 9 billion SEK (1 billion USD).

Clinical evaluation

Before PLCS can be launched, marketed and sold to customers, the product needs to complete clinical evaluation and receive market approval by relevant governmental bodies. Paxman has excellent knowledge on what is needed to receive market approval, as the company's scalp cooling system has completed a corresponding process. The development project in Singapore received a research grant of 1.57 million SGD from National Research Foundation (NRF) in Singapore in May 2021, and a clinical trial with National University Hospital, Singapore, in collaboration

with The N.1 Institute for Health, National University of Singapore to investigate the safety and tolerability of delivering limb cryocompression and efficacy in improving the preservation of peripheral nerves during chemotherapy. The efficacy of prevention will be monitored using various clinical and patient-reported outcomes. Optimal temperature and pressure of limb cryocompression has been established in healthy subjects, and now a group of cancer patients are undergoing limb cryocompression over multiple cycles of chemotherapy to establish safety and tolerability of repeated therapy. This study started in November 2021 with the completion date estimated to be September 2023. A larger randomized phase 3 efficacy study in the USA with SWOG Cancer Research Network will be initiated in 2023. The data from the trials will be used in regulatory documentation to support the cryocompression system as a new medical device, initially in Singapore, and then the United States. The company has also recruited Prof. Charles Loprinzi from the Mayo Clinic, Rochester, USA as a new member of Paxman's advisory board. Prof. Loprinzi is one of the world's top key opinion leaders in the CIPN field and the first author of the ASCO 2020 CIPN guidelines.

Competitors

To date, there are no market-approved cryocompression products to prevent CIPN. However, the UK-based company Hilotherm is selling a cooling device in this region that is being used for a number of treatment areas including CIPN prevention. There are also other medical device companies conducting research and development in this field. The Swedish company Braincool, listed on Nasdaq First North, is considered the most important competitor. Paxman believes that the company's solid experience from developing market leading scalp cooling equipment, collaborations with world-leading scientists at NUH, excellent relationships and collaborations with leading key opinion leaders in the clinical field, a strong global customer base and an exclusive focus on oncology-related applications constitute substantial advantages over this competitor.

"In addition to the United States, Asia including Japan, India and China is expected to become the most important region for Paxman's future growth.

GENERAL TARGETS AND OUTLOOK

The company's long-term goal is that all patients undergoing chemotherapy shall have access to scalp cooling, no matter their financial situation, gender, ethnicity, tumour or chemotherapy type, and that the Paxman Scalp Cooling System is the obvious first choice for cancer patients all over the world.

Paxman is the superior global market leader with nearly 5,000 sold and/or installed systems in Europe, North-, Central- and South America, Asia and Oceania. In addition to the United States, Asia is becoming an increasingly important region for the company, with Japan as the single leading market.

Market approval (Shonin) in Japan for use in connection with treatment of solid tumours like breast cancer was received in March 2019, and extensive marketing activities were then initiated together with the distributor CMI. With a recurring revenue model launched, Japan is set to be a strong growth market in the future. In addition to Japan, Paxman is already established in additional Asian markets such as India, Malaysia, Singapore and Pakistan, and the company is

finalising a distribution agreement with Concord Medical for a market launch on the very large Chinese market.

To further increase the global growth rate, Paxman's commercialisation strategy continues to focus on strengthening the company's sales organisation with direct presence as well as new and established distribution partners in key regional markets including China, India, Europe and the Middle East, supported by enhanced marketing support based in the UK. Paxman will also advance the company's reimbursement strategy in the USA, where customers started to implement the new buy-and-bill model in 2022 to facilitate reimbursement using established CPT III codes, and continue to invest in its R&D pipeline in both scalp cooling and cryotherapy to prevent

chemotherapy-induced peripheral neuropathy (CIPN).


Paxman will also continue the transition from selling equipment to clinics to generating income for each treatment in more countries in addition to the United States, where this is already fully implemented. A similar business model is used in Mexico in collaboration with the licensing partner Teva, as well as in Canada, and a modified model is used in Japan where the company sells scalp cooling systems to the distributor and receives payment for each single patient use cooling cap sold. This model is also gradually implemented in additional markets when the company is able to start offering or upgrade existing equipment to its PSCS model.

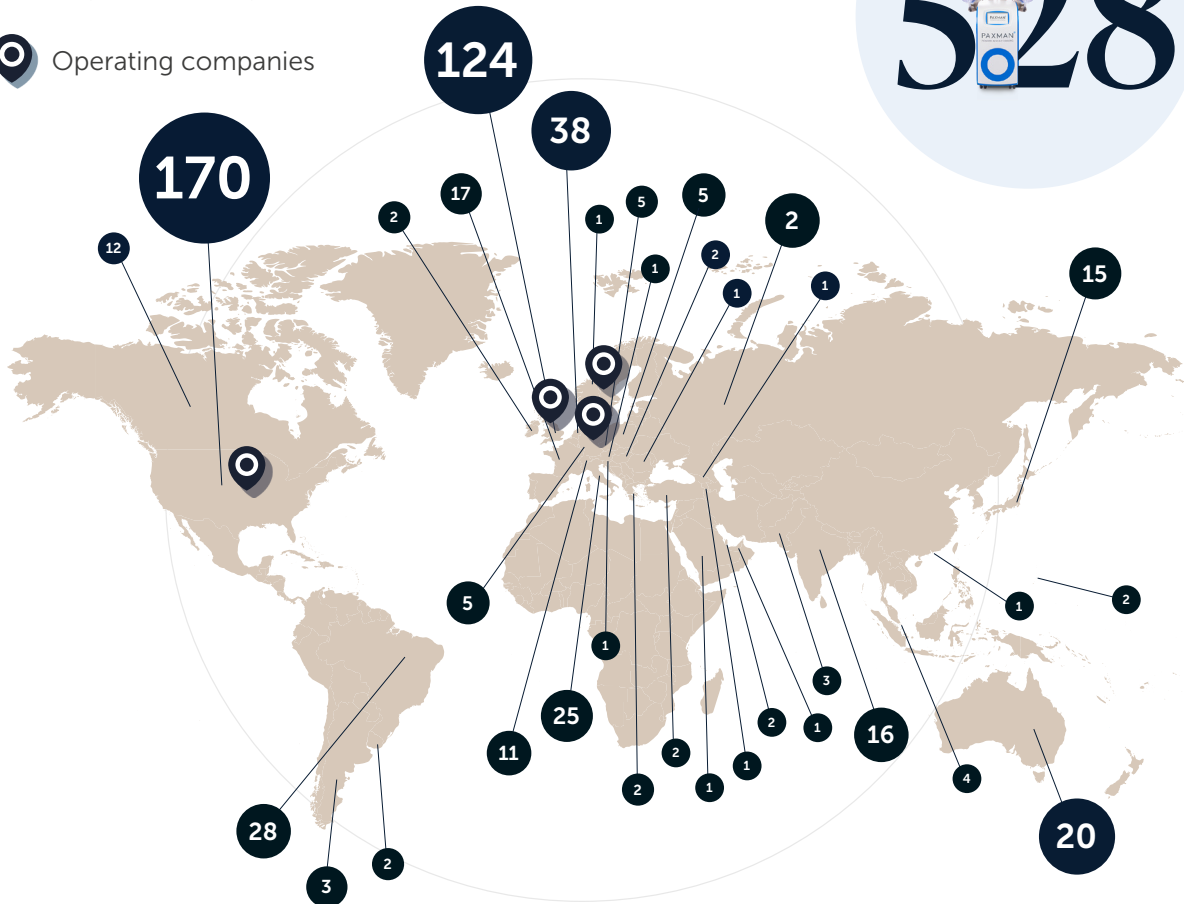


SYSTEMS INSTALLED IN JANUARY–DECEMBER 2022

The systems are installed on-site following a signed delivery- and rental agreement (in the United States, Canada and in Mexico) or after being sold to the customer (rest of the world).



 Operating companies




Utd. Arab Emirates	1	Hong Kong	1	Qatar	2
Argentina	3	Hungary	2	Romania	1
Armenia	1	India	16	Russia	2
Australia	20	Ireland	2	Saudi Arabia	1
Austria	1	Italy	25	Singapore	4
Brazil	28	Japan	15	Slovenia	1
Canada	12	Netherlands	38	Switzerland	11
Czech Republic	5	Northern Mariana Islands	2	Turkey	2
France	17	Norway	1	United Kingdom	124
Georgia	1	Pakistan	3	Uruguay	2
Germany	5	Poland	7	USA	170
Greece	2				

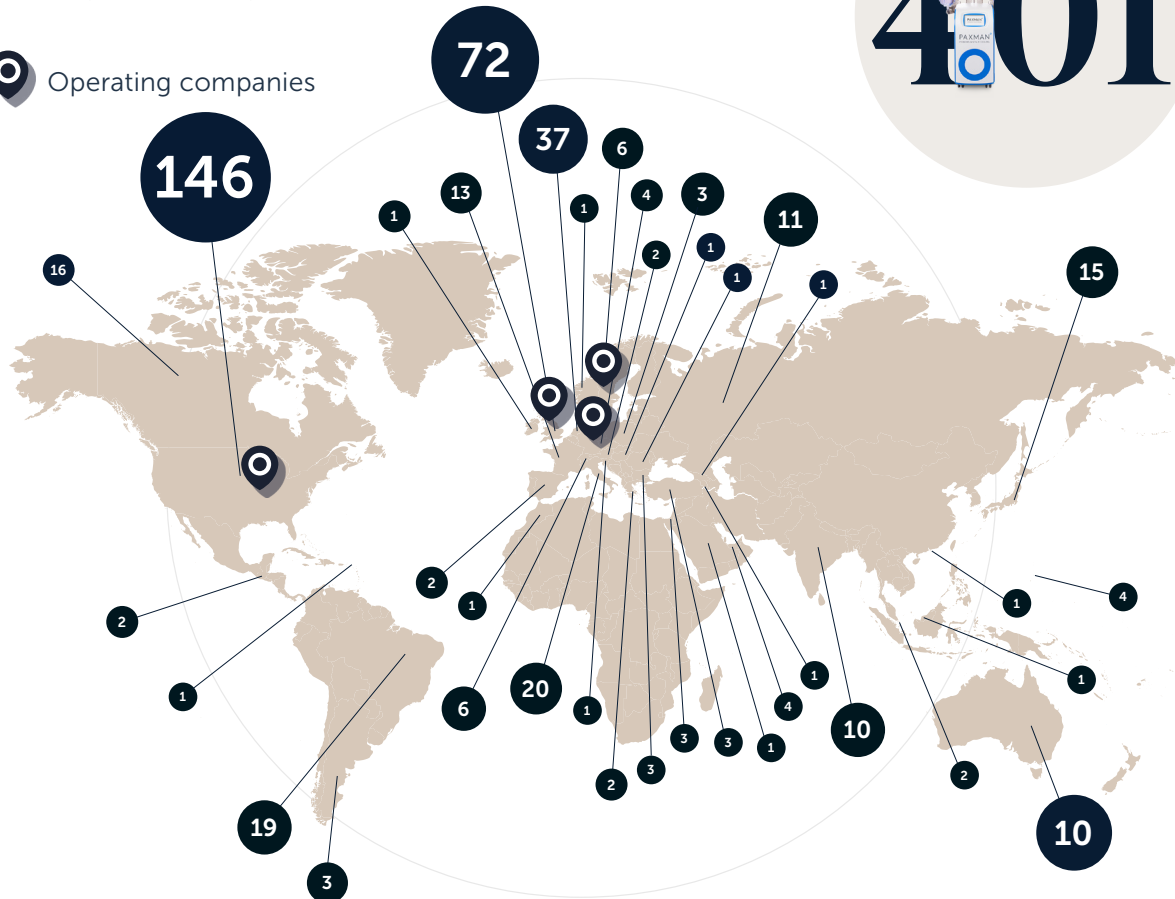
Total systems: 528

SYSTEMS INSTALLED IN JANUARY–DECEMBER 2021

The systems are installed on-site following a signed delivery- and rental agreement (in the United States and in Mexico) or after being sold to the customer (rest of the world).



 Operating companies



Australia	10	Ireland	1	Singapore	2
Austria	2	Israel	3	Slovenia	1
Brazil	19	Italy	20	Spain	2
Bulgaria	3	Malaysia	1	Sweden	6
Canada	16	Morocco	1	Switzerland	6
Czech Republic	4	Netherlands	37	Turkey	3
France	13	Poland	3	United Arab Emirates	4
Guatemala	2	Romania	1	United Kingdom	72
Hungary	1	Russia	11	USA	146
India	10	Saint Martin	1		

Total systems: 401

IMPLEMENTING ESG PRACTICES – A KEY PART OF PAXMAN’S SUCCESS STORY

The integration of sustainable practices, taking environmental, social and governmental (ESG) into consideration, is key to Paxman. Minimising the impact of business operations on the environment, making sure that Paxman Scalp Cooling can be used regardless of ethnicity and income, and striving to make all employees reach their full potential, are some of the things that make Paxman a trustworthy ally for partners, customers and patients.

By taking ESG factors into consideration when growing the business, Paxman has managed to constantly improve in many areas. These include, but are not limited to- production, product design, business models and employee policies.

Minimising environmental impact

The Innovate UK Smart Award will help to address the urgent need to generate a high-capacity, cost-effective and sustainable manufacturing approach to produce a recyclable scalp cooling cap with cover that can be used in certain markets to run alongside the current design. Championing eco-design and the circular economy, the project will see the development of a world-first recyclable scalp-cooling cap and an innovative manufacturing approach which advances current technological limitations. The project will

address significant manufacture and sustainability challenges and build on the existing expertise within the Paxman and University of Huddersfield’s team, alongside the intellectual property foundations of the current Paxman cap.

An optimised formulation of thermoplastic polyurethane (TPU), with the correct properties for the cap, will promote recyclability, minimising environmental impacts and providing long-term sustainability. In addition, a TPU foam material has been identified as an appropriate replacement for the neoprene material currently used for the cap cover.

Additionally, building and renovation works have been undertaken this year to bring on improvements on energy efficiency and to ensure accessibility to the manufacturing and office premises.



<h1>THE PAXMAN VALUES</h1>	<h3>Determination</h3> <p>To deliver our very best; to evolve and grow, through continuous change.</p>	<h3>One Global Team</h3> <p>We are respectful and supportive, and lead and learn from each other with a fun, family spirit. Together we make the difference.</p>
	<h3>Commitment</h3> <p>To patient-centric decision making at the heart of all strategy, ensuring longer term a strong and sustainable business.</p>	<h3>Passion</h3> <p>Approach every day with positivity and pride, a willingness to grow, learn and challenge ourselves and better those around us.</p>

Research for optimal effect regardless of ethnicity and hair type

As Paxman reaches patients in many parts of the world, it has become increasingly important to establish that scalp cooling is working in an optimal way for different patient groups. In addition to supporting research involving more chemotherapy treatments and cancer types, the company is also working to adapt its solutions to variations due to ethnicity, such as different head shapes and hair types. Paxman has among other things launched a cooling cap specifically developed for the Asian market, and the company is supporting various research projects and clinical studies. This includes an ongoing study where Paxman is collaborating with Montefiore Einstein Cancer Center in the USA to increase the knowledge on scalp cooling efficiency for patients with different ethnicities and hair types.

A healthy, inclusive and inspiring workplace

Paxman values its employees and supports them via several initiatives. The Paxman values lay at the heart of this commitment and lay the foundations for what the company cares about most. This common purpose along with transparency on the behaviours expected of the global team, lead to business success.

The succession planning process and the Paxman People Pathway (performance management process) both draw on the values to determine the identification of high potential within the organisation and support progression through aligned development plans.

Each stage of an employee's career with Paxman, from hire to exit, is provided in management guidelines set out in The Paxman Journey. Here, key phases such as onboarding, are clearly defined to ensure the best employee experience centring on development.

The company is committed to the wellbeing of all staff, with Employee Assistance programmes available, providing access to free confidential advice on a wide range of issues which may cause concern or anxiety, and the company also has an internal Mental Health Support Group. Wellbeing is encouraged, with support offered through various activities such as daily walking clubs and pool bicycles.

Paxman acknowledges the benefit of diversity and inclusion in an organisation and has made a commitment

to the variety of unique individuals in the company by providing an environment that allows them to work together as equally valued contributors. Quarterly education and discussion sessions are held to enhance understanding of lived experience for minority groups, and respectful behaviour.

Inspired employees perform better, and positive social impact correlates with higher job satisfaction. Paxman's second annual employee engagement survey, conducted in 2022, showed a satisfied and connected workforce. Overall employee engagement was 91% and 92% said they would recommend Paxman as a great place to work. This high survey response rate (92%) and the overall engagement score, led to Paxman being awarded a 5* Employer Award 2022.

As a UK employer, Paxman go further than the government minimum and voluntarily pay all staff the real living wage based on the true cost of living to meet every day needs. The company maintains longstanding and strong links with local schools, community organisations and charities and is also involved in a job scheme to help individuals that have experienced homelessness to get back into paid employment, giving them a sense of purpose and a second chance at life.

Promoting scalp cooling access for everyone

Paxman's strong links with US financial assistance organisations nationally and locally speaks to the commitment of the company in ensuring equitable access to scalp cooling treatment. The Sue Paxman Fund, in collaboration with US not for profit organisation HairToStay, honours the legacy of Sue to ensure that mothers who cannot afford scalp cooling can still access this important treatment.

In addition, the robust Patient Assistance Program (PAP) offered as part of Paxman's reimbursement business model ensures that those who are uninsured or underinsured are still able to access scalp cooling during chemotherapy treatment. This is an important initiative for Paxman and is set at six times the federal poverty level based on household income and household size, enabling broader and more equitable access to scalp cooling across the United States.

THE PEOPLE BEHIND PAXMAN

All holdings refer to current holdings at the time of publication for this annual report.

MANAGEMENT TEAM



Richard Paxman

CEO and member of the board since February 10th, 2017.

Richard Paxman has extensive experience from global market development, including design of clinical studies and regulatory approvals specifically related to scalp cooling. He has worked for the company since 2009. Before Richard Paxman started his assignment at Paxman Coolers Ltd he held a leading position at Brewfitt Ltd.

Born: 1983

Holding: 1,281,000 shares



Emelie Gustafsson

CFO since March 1, 2020.

Since 2015, Emelie Gustafsson is the CFO of the CIMON group, one of PAXMAN's largest shareholders, and she is also a board member of several companies in the CIMON Group. She has a solid academic background with a double bachelor's degree in economics and tax law at Kristianstad University.

Born: 1980

Holding: 2,000 shares

THE BOARD



Per-Anders Johansson

Chairman of the board since December 1st, 2016.

Per-Anders Johansson has extensive experience from technology and development companies and is an active investor through CIMON AB. CIMON AB has invested in and developed several successful companies. Per-Anders Johansson also has long industrial experience from the Karlshamns group, Nordico and Ellos where he has held leading positions.

Born: 1954

Holding: 1,263,992 shares via CIMON Venture Trust AB, 5,000 shares privately held, 310,000 shares via NOMIC AB.



Robert Kelly

Member of the board since January 10th, 2017.

Robert Kelly is a lawyer specialised in corporate law. He is also an authorized accountant and has extensive experience from management of both private and public companies before his career as a lawyer. Robert Kelly has also been CFO and later CEO of the technology company, Minorplanet Systems plc, that was listed on the London Stock Exchange. Before that he held leading positions at Caudwell Group and Kinuck plc.

Born: 1961

Holding: 11 250 shares



Björn Littorin

Member of the board since December 1st, 2016.

Björn Littorin has extensive experience as a management consultant, business leader and board member of both manufacturing and service-based companies as well as 20 years' experience as Investment Manager and board member of technology and development companies, mostly within medical technology. Some of the companies where he has been CEO or board member have been listed on the Stockholm Stock Exchange. He has also been a board member of Paxman Group Ltd and its subsidiary Paxman Coolers Ltd since 2001.

Born: 1947

Holding: 465,076 shares

THE BOARD

**Glenn Paxman****Member of the board since January 10th, 2017.**

Glenn Paxman is the founder of PAXMAN and responsible for the design and development of the scalp cooler. He has over 40 years of business experience including management strategy and product design of medtech products, and over 25 years of experience in developing manufacturing processes for the pharmaceutical and chemical industry sectors. Glenn is also the founder and chairman of Brewfitt Ltd. Currently, his role in the company is to support the board and management in strategic matters and assist in growth-stimulating projects on the American market.

Born: 1956**Holding: 5,857,395 shares****Richard Paxman****CEO and member of the board since February 10th, 2017.**

Richard Paxman has extensive experience from global market development, including design of clinical studies and regulatory approvals specifically related to scalp cooling. He has worked for the company since 2009. Before Richard Paxman started his assignment at Paxman Coolers Ltd he held a leading position at Brewfitt Ltd.

Born: 1983**Holding: 1,281,000 shares****Maria Bech****Member of the board since January 10th, 2017.**

Maria Bech has extensive experience from several companies in the biotech and pharmaceutical sector, and has held leading positions including Clinical Project Manager and Study Delivery Director at AstraZeneca, Director Clinical Operations and Principal Project Manager at Karo Bio AB and Chief Scientific Officer at Smartfish AB. Maria is a board member in Neuronano AB and Iconovo AB, and CEO in EpiEndo Pharmaceuticals.

Born: 1968**Holding: 4,200 shares held directly and 4,500 held through the company Bech Pharma Consulting AB**

DIRECTORS' REPORT 2022

The Board of Directors and the Chief Executive Officer of Paxman AB (publ), hereby submit the annual accounts and consolidated accounts for the financial year 1 January–31 December 2022.

Amounts in the annual report are reported in thousands of Swedish kronor (TSEK), unless otherwise stated.

CORPORATE INFORMATION

The company

Paxman AB (publ), with corporate registration number 559079-3898, was established in October 2016. Its current name and operations were registered on 14 December 2016. Paxman AB is a public limited liability company, and its legal form is thus regulated by the Swedish Companies' Act (2005:551). The parent company has its registered office in Karlshamn, at Pirgatan 13, SE-374 35 KARLSHAMN. Production and sales are handled by the UK subsidiary Paxman Coolers Ltd, International House, Penistone Road, Fenay Bridge, HD8 0LE HUDDERSFIELD, England. The group also has a subsidiary in the US, Paxman US, Inc. with its registered office in Houston, Texas. Paxman Coolers Ltd as well as Paxman US, Inc. are wholly owned subsidiaries of Paxman Group Ltd, in its turn a fully owned subsidiary of Paxman AB (publ).

Paxman AB has appointed FNCA Sweden AB (tel +46 8 – 528 003 99, info@fnca.se) its Certified Adviser.

Earnings and financial position

- The group's turnover amounted to 145,921 (96,202) TSEK.
- The group's net profit/loss was -10,324 (-12,776) TSEK, with profit/loss per share amounting to -0.54 (-0.67) SEK.
- Consolidated equity as of 31 December totalled 114,198 (125,755) TSEK. The equity/assets ratio for the group was 65.6 (75.6) %.
- The cash and bank balances for the group was 38,092 (72,266) TSEK.
- At year end, the group had 16,985 (17,154) TSEK in external interest bearing liabilities, of which 12,728 (11,328) TSEK were current.
- Cash flow from operating activities amounted to -3,687 (-4,143) TSEK, and this year's net investments affecting cash flow to -36,691 (-24,446) TSEK. Cash and cash equivalents increased by 34,174 (68,689) TSEK during the year.

The parent company

- The company's turnover amounted to 1,295 (244) TSEK.
- The parent company's cash and bank balances amounted to 36,400 (69,419) TSEK on 31 December.
- Cash flow from operating activities was -2,832 (-4,784) TSEK. Net investments affecting cash flow for the year amounted to 0 (-70) TSEK.
- The parent company had 1 (1) employee on the balance sheet date.

Multi-year summary for the group

	2022	2021	2020	2019
Operating income, TSEK	156,746	104,708	85,478	95,670
EBITDA ¹⁾	16,175	2,882	-1,045	2,438
Operating profit/loss, TSEK	-1,243	-10,587	-11,690	-5,960
Profit/loss after financial items, TSEK	-8,562	-12,670	-20,096	-2,674
Total assets, TSEK	173,960	166,341	77,011	84,973
Equity/assets ratio, % ²⁾	65.6%	75.6%	14.1%	33.4%
Total number of employees at year end	78	56	51	48

1) Earnings before interest income, interest expenses, tax and depreciation.

2) Adjusted equity as a percentage of total assets.

Multi-year summary for the parent company

	2022	2021	2020	2019
Operating income, TSEK	1,295	244	-	-
EBITDA ¹⁾	-5,383	-4,171	-3,622	-3,465
Operating profit/loss, TSEK	-4,065	-4,179	-3,622	-3,465
Profit/loss after financial items, TSEK	-2,850	-4,676	-5,284	-4,085
Total assets, TSEK	162,320	165,010	73,799	72,271
Equity/assets ratio, % ²⁾	99.3%	99.3%	53.8%	61.6%
Total number of employees at year end	1	1	-	1

1) Earnings before interest income, interest expenses, tax and depreciation.

2) Adjusted equity as a percentage of total assets.

Significant developments in 2022

In the beginning of the year, Paxman appointed Rocol International SAS as the company's exclusive distribution partner for the new territory of Colombia. As an established medical device distributor in the oncology space, Rocol International SAS is well positioned to introduce scalp cooling to the Colombian market from its headquarters in Barranquilla, the capital of Colombia's Atlántico Department.

In February, Paxman launched the Scalp Cooling Study Library, a digital library website with a comprehensive database which unites key published clinical research studies and data on scalp cooling and cryocompression therapy.

In the beginning of the second quarter, it was announced that a bill was introduced to the House in the USA to require coverage for scalp cooling under group health plans and group and individual health insurance coverage, specified Federal health care programs, and the Federal Employees Health Benefits Program. The bill would require all health insurers to provide coverage for scalp cooling treatments for the prevention of chemotherapy-induced alopecia for cancer patients. The next step for the bill is a vote by the full House Committee. It will then be considered by the Senate and in the House of Representatives. If passed, the bill will require final approval by the President before it is signed into law.

In April, Paxman signed a letter of interest with a plan to enter into a distribution and marketing agreement with Guangzhou Concord Medical Sci-Tech Innovation Center Co., Ltd., a business subsidiary of Concord Medical Services Holdings Limited, to jointly develop the market for the Paxman Scalp Cooling System within the Greater China territory, including Macau, Taiwan and Mongolia. The initial collaboration is for a period of five years and will include an evaluation period of 24 months to treat up to 300 patients at Concord Medical's Guangzhou Concord Cancer Center, a National Health Commission certified tertiary specialty hospital, situated in Sino-Singapore Guangzhou Knowledge City.

In the beginning of May, Paxman hosted the world's first Scalp Cooling Summit, a global and first of its kind conference with leading researchers and clinicians. The Summit was a great success, with 50 speakers and over 1,400 delegates attending.

In May, it was also announced that the company signed its first contract under the new business model in the USA with a comprehensive healthcare system in New Jersey, and that the company had launched its enhanced Paxman HUB services. Previously, in the U.S., scalp cooling has only been

available to patients on a self-pay basis – to those who have the financial means to pay out-of-pocket, or those who qualify for foundation or grant assistance. Consequently, patient access to the treatment has been limited.

At the end of the second quarter, it was announced that the American Medical Association (AMA) resolved to advocate for and seek through legislation and/or regulation, universal insurance coverage for scalp cooling therapy. At the annual meeting for its principal policy-making body House of Delegates (HOD), the AMA HOD approved two scalp cooling proposals put forward by New York to support a broad insurance coverage for scalp cooling.

In the beginning of the third quarter, Paxman received notification of medical device regulatory clearance in both Colombia and Uruguay. Paxman's exclusive distribution partner for the territory of Colombia, Rocol International SAS, received INVIMA Medical Device Regulatory Approval for Paxman Scalp Cooling from the Colombia National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos or INVIMA). In Uruguay, Nelson Arcos S.A. received confirmation from the country's Ministry of Health for the product registration of Paxman Scalp Cooling. Nelson Arcos is one of the leading medical technology companies in the country.

In the beginning of November, it was announced that the US Centers for Medicare & Medicaid Services (CMS) has published the final rule, which revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2023. The OPPS Final Rule will affect 3,411 hospitals and approximately 5,500 ASCs. This final rule confirms that the payment rate of 1,850.50 USD for CY 2022 will be the same for CY 2023, and that CPT code 0662T will continue to be assigned to APC New Technology 1520.

Later in November, it was announced that Paxman has been selected by the SWOG Cancer Research Network, an independent global cancer research community that designs and conducts publicly funded clinical trials, for the Paxman Limb Cryocompression System (PLCS) to be used in a prospectively designed study looking at prevention of Chemotherapy-Induced Peripheral Neuropathy (CIPN). The study aims to enroll 777 patients and PLCS devices will be shipped in February to a minimum of 25 locations, with an aim to open the study to enrolment in Q1 2023.

At the end of the fourth quarter, Paxman retained Arrowhead Business and Investment Decisions, LLC. ("Arrowhead") to provide investor relations services to the Company and develop its international market awareness. Arrowhead will advise Paxman on its international capital markets strategy and has been engaged to, among other matters, expand the involvement of the investment community.

In 2021, the ongoing Covid pandemic meant that the company had to change its strategy when it came to which markets the company would focus on, but also to find a more digital way of working for the entire operation regarding everything from installations to conferences. The majority of these digital ways of working have been retained even now that the pandemic is over, as it has offered opportunities that have given the business great advantages.

The conflict in Ukraine that began during the fiscal year is continuously monitored by the company's CEO and management team, and we follow all government sanctions. In addition, the company's operations have not been affected by the invasion of Ukraine.

For significant events after the end of the financial year, see note 2 (only included in the full Swedish version).

Employees

As of 31 December 2022, the Paxman group had a total of 78 employees, of whom 1 person in the parent company, 57 in Huddersfield, England and 10 in Houston, USA.

As of 31 December 2021, the Paxman group had a total of 56 employees, of whom 1 person in the parent company, 48 in Huddersfield, England and 7 in Houston, USA.

Incentive programmes

At the Annual General Meeting on May 23, 2019, it was resolved to issue warrants to employees of the subsidiary Paxman Coolers Ltd. A total of 68,478 warrants have been issued, with the right to subscribe for a maximum of 68,478 new shares in Paxman AB. The warrants entitle the holder to subscribe for shares from June 2020 until June 2029, at a subscription price of SEK 65.37 per share. Upon full subscription, the dilution effect amounts to 0.4% of the total number of shares in the company. The warrants have been issued free of charge and the benefit has therefore, according to current accounting principles, been valued at market value. In total, The group's personnel costs have been charged with 1.4 MSEK over three years (without any cash flow effect) with the last adjustment date 2022-06-30.

Environment

The Paxman group conducts no operations covered by, or requiring concessions in accordance with, the Environmental Code.

PROPOSED APPROPRIATION OF RETAINED EARNINGS

RETAINED EARNINGS AT THE DISPOSAL OF THE ANNUAL GENERAL MEETING:

Retained earnings	145 049 TSEK
Profit/loss for the year	-2 850 TSEK
	142 199 TSEK

THE BOARD OF DIRECTORS AND THE CEO PROPOSES THAT THE RETAINED EARNINGS ARE TO BE APPROPRIATED AS FOLLOWS:

Carried forward	142 199 TSEK
	142 199 TSEK

Paxman's net profit/loss for the accounting year 2022, as well as the company's financial position as at 31 December 2022, are disclosed in the following income statements, balance sheets and cash flow statements.

CONSOLIDATED INCOME STATEMENT

TSEK	Note	2022	2021
Operating income			
Net sales	4, 5	145,921	96,202
Work performed by the company for its own use and capitalized		10,825	8,506
Total operating income		156,746	104,708
Operating expenses			
Raw materials and consumables		-55,310	-40,190
Other external costs	6, 8	-35,789	-29,083
Personnel costs	7	-49,472	-32,553
Depreciation and write-downs	9	-17,418	-13,469
Total operating costs		-157,989	-115,295
Operating profit/loss		-1,243	-10,587
Result from financial investments			
Other interest income and similar profit/loss items	10	27	13
Interest expense and similar profit/loss items	11	-7,346	-2,096
Total result from financial investments		-7,319	-2,083
Profit/loss after financial items		-8,562	-12,670
Tax	12	-1,762	-106
Net profit/loss for the year		-10,324	-12,776
Net profit/loss per share*		-0.54	-0.67

* The calculation of net profit/loss per share is based on the average number of shares during the year.

CONSOLIDATED BALANCE SHEET

TSEK	Note	2022-12-31	2021-12-31
Assets			
Fixed assets			
Intangible assets	13		
Concessions, patents, licences, trademarks and similar rights		22,701	16,364
Total intangible assets		22,701	16,364
Tangible assets	14		
Plant and machinery		40,020	32,367
Equipment, tools, fixtures and fittings		7,802	3,518
Total tangible assets		47,822	35,885
Financial assets			
Deferred tax asset	12	7,378	6,380
Participations in associated companies	15	48	47
Total financial assets		7,426	6,427
Total fixed assets		77,949	58,676
Current assets			
Inventories etc.			
Finished products and goods for resale		27,161	18,111
Total inventories etc.		27,161	18,111
Current receivables			
Accounts receivable – trade	18	19,146	12,056
Receivables from associated companies	19	1,292	94
Other receivables		3,707	2,334
Prepaid expenses and accrued income	20	6,613	2,804
Total current receivables		30,758	17,288
Cash and bank balances		38,092	72,266
Total current assets		96,011	107,665
Total assets		173,960	166,341

CONSOLIDATED BALANCE SHEET

TSEK	Note	2022-12-31	2021-12-31
Equity and liabilities			
Equity	21		
Share capital (19 012 500 shares)		19,012	19,012
Non-restricted equity		105,510	119,519
Profit/loss for the year		-10,324	-12,776
Total equity		114,198	125,755
Provisions			
Provisions for taxes	12	1,451	939
Total provisions		1,451	939
Non-current liabilities			
Liabilities to credit institutions	22	4,257	5,826
Total non-current liabilities		4,257	5,826
Current liabilities			
Liabilities to credit institutions	22	12,728	11,328
Accounts payable – trade		24,170	16,506
Income tax liability		2,121	-
Other liabilities		2,088	512
Accrued expenses and deferred income	23	12,947	5,475
Total current liabilities		54,054	33,821
Total liabilities		58,311	39,647
Total equity and liabilities		173,960	166,341

For changes in equity for the group, see page 66.

CONSOLIDATED CASH FLOW STATEMENT

TSEK	Note	2022	2021
Cash flow from operating activities			
Profit/loss before financial items		-1,243	-10,587
Financial items	25	-7,319	-2,083
Income tax paid		-1,287	-106
Adjustments for:			
Depreciation and write-downs		17,418	13,469
Other non-cash items	25	-1,196	-712
Cash flow before working capital changes		6,373	-19
Cash flow from changes in working capital:			
Inventories etc.		-9,050	-4,365
Current receivables		-13,470	-5,299
Current liabilities		18,833	5,540
Cash flow from operating activities		-3,687	-4,124
Cash flow from operating activities		2,686	-4,143
Investing activities			
Investments in intangible fixed assets	13	-8,352	-5,590
Investments in tangible fixed assets	14	-27,340	-18,206
Investments in financial fixed assets	12, 15	-999	-650
Cash flow from investing activities		-36,691	-24,446
Financing activities			
New loans (+) / repayment of loans (-)	22	-169	-31,076
New share issue		-	128,354
Cash flow from financing activities		-169	97,278
Cash flow for the year		-34,174	68,689
Cash and cash equivalents, opening balance		72,266	3,577
Cash and cash equivalents, closing balance	25	38,092	72,266

PARENT COMPANY INCOME STATEMENT

TSEK	Note	2022	2021
Operating income			
Net sales	5	1,295	244
Total operating income		1,295	244
Operating costs			
Raw materials and consumables		-455	-68
Other external costs	6, 8	-3,875	-3,457
Personnel costs	7	-1,007	-890
Depreciation and write-downs	9	-23	-8
Total operating costs		-5,360	-4,423
Operating profit/loss		-4,065	-4,179
Result from financial investments			
Interest income and similar profit/loss items	10	1,215	823
Interest expense and similar profit/loss items	11	-	-1,320
Total result from financial investments		1,215	-497
Profit/loss after financial items		-2,850	-4,676
Tax	12	-	-
Net profit/loss for the year		-2,850	-4,676

PARENT COMPANY BALANCE SHEET

TSEK	Note	2022-12-31	2021-12-31
Assets			
Fixed assets			
Tangible fixed assets			
Machinery and other technical facilities	14	39	62
Total tangible fixed assets		39	62
Financial assets			
Participations in group companies	16	26,937	26,701
Receivables from group companies	17	97,864	67,677
Total financial assets		124,801	94,378
Total fixed assets		124,840	94,440
Current assets			
Current receivables			
Accounts receivable	18	65	143
Other receivables		722	1,008
Prepaid expenses and accrued income	20	293	-
Total current receivables		1,080	1,151
Cash and bank balances		36,400	69,419
Total current assets		37,480	70,570
Total assets		162,320	165,010

PARENT COMPANY BALANCE SHEET

TSEK	Note	2022-12-31	2021-12-31
Equity			
Restricted equity			
Share capital (19,012,500 shares)		19,012	19,012
Total restricted equity		19,012	19,012
Non-restricted equity			
Share premium reserve		145,049	149,489
Profit/loss for the year		-2,850	-4,676
Total non-restricted equity		142,199	144,813
Total equity		161,211	163,825
Liabilities			
Current liabilities			
Accounts payable – trade		87	245
Accounts payable – group companies		327	126
Other liabilities		31	33
Accrued expenses and deferred income	23	664	781
Total current liabilities		1,109	1,185
Total liabilities		1,109	1,185
Total equity and liabilities		162,320	165,010

For changes in equity for the parent company, see page 66-67.

PARENT COMPANY CASH FLOW STATEMENT

TSEK	Note	2022	2021
Cash flow from operating activities			
Profit/loss before financial items		-4,065	-4,179
Adjustments for:			
Financial items	25	1,215	-497
Avskrivningar och nedskrivningar		23	8
Cash flow from changes in working capital:			
Current receivables		71	-497
Current liabilities		-76	381
Cash flow from operating activities		-2,832	-4,784
Investing activities			
Investments in intangible fixed assets		-	-70
Cash flow from investing activities		-	-70
Financing activities			
New share issue		-	128,354
New loans (+)/repayment of loans(-)		-	-33,320
Loans to group companies		-30,187	-20,810
Cash flow from financing activities		-30,187	74,224
Cash flow from financing activities		-33,019	69,370
Cash and cash equivalents, opening balance		69,419	50
Cash and cash equivalents, closing balance		36,400	69,419

CHANGES IN EQUITY

The group TSEK	Share capital	Non-restricted equity	Profit/loss for the year	Total equity
Total equity as of 2020-12-31 (16,012,500 shares)	16,012	14,063	-19,186	10,889
Profit/loss carried forward		-19,186	19,186	-
New share issue excluding issuing costs	3,000	125,354		128,354
Translation gains/losses on consolidation		-712		-712
Profit/loss for the year			-12,776	-12,776
Total equity as of 2021-12-31 (19,012,500 shares)	19,012	119,519	-12,776	125,755
Profit/loss carried forward		-12,776	12,776	
Translation gains/losses on consolidation		-1,233		-1,233
Profit/loss for the year			-10,324	-10,324
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	105,510	-10,324	114,198

Parent company TSEK	Share capital	Share premium reserve	Profit/loss for the year	Total equity
Total equity as of 2020-12-31 (16,012,500 shares)	16,012	28,947	-5,284	39,675
Profit/loss carried forward		-5,284	5,284	-
New share issue excluding issuing costs	3,000	125,354		128,354
Share related remuneration regulated by equity instruments		472		472
Profit/loss for the year			-4,676	-4,676
Total equity as of 2021-12-31 (19,012,500 shares)	19,012	149,489	-4,676	163,825
Profit/loss carried forward		-4,676	4,676	
Share related remuneration regulated by equity instruments		236		236
Profit/loss for the year			-2,850	-2,850
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	145,049	-2,850	161,211

CHANGES IN EQUITY

The share

Paxman has issued a total number of 19,012,500 shares, all fully paid for. Each share has a quota value of 1 SEK, and a voting right of 1. There are no pre-emption clauses, refusal clauses or other restrictions on the transfer of shares in the company. Up to 12 March 2018, the company's four original shareholders were bound by a so-called lock-up agreement, entered into in connection with Paxman's listing on Nasdaq First North Growth Market. By this agreement, these shareholders committed themselves to refrain from selling shares (directly or indirectly) in a nine-month period from the first day of trading on Nasdaq First North. In all, 12,810,000 shares were bound by the lock-up agreement. Prior to the listing this corresponded to 100% of all issued shares; after the listing and the new share issue to 80%.

The share price

The listing price for Paxman's share on 12 June 2017 was SEK 9.50. The closing price at year-end was SEK 43.10 (2021: SEK 65.00, 2020: SEK 25.40, 2019: SEK 60.00, 2018: SEK 24.10, 2017: SEK 19.50).

SHAREHOLDERS

The company's 10 largest shareholders as of 2022-12-30 (Source: Euroclear 2022-12-30).

Name	Number of shares held	Shareholding in %
Paxman, Glenn	5,857,395	30.81
Försäkringsaktiebolaget Avanza Pension	2,307,636	12.14
Paxman, Richard	1,281,000	6.74
CIMON Venture Trust AB	1,263,992	6.65
BNY Mellon SA/NV	995,584	5.24
Alcur Grow	806,327	4.24
Länsförsäkringar Blekinge	585,000	3.08
Länsförsäkringar Kalmar län	545,185	2.87
Littorin, Björn	465,076	2.45
Andra AP-fonden	456,617	2.40

On 31 December 2022, Paxman had a total of 1,179 (2021: 1,155) shareholders. The 10 largest of these held 76.6 (76.7) % of all issued shares.

Data per share	2022	2021
Earnings per share, SEK ¹⁾	-0.51	-0.73
Earnings per share at full dilution, SEK ²⁾	-0.51	-0.73
Equity per share, SEK , ¹⁾	6.01	6.61
Cash flow from operating activities per share, SEK ¹⁾	-0.05	-0.27
Share price at the end of the period, SEK	43.10	65.00
Number of shares at the end of the period	19,012,500	19,012,500
Number of shares at the end of the period at full dilution ²⁾	19,080,978	19,080,978
Number of shares, weighted average during the year	19,012,500	17,470,833
Number of shares, weighted average during the year at full dilution ²⁾	19,080,978	17,539,311

1) Earnings and cash flow per share are based on the weighted average number of shares during the period. Equity per share is based on the total number of issued shares on balance sheet day.

2) As of December 31, 2022, the company implemented an incentive program for employees in the subsidiary Paxman Coolers Ltd. The decision to issue warrants was made at the Annual General Meeting on May 23, 2019, and the warrants were issued immediately thereafter. In total, 68,478 warrants have been issued, which entitles to subscription for a maximum of 68,478 new shares in the company. The warrants entitle the holder to subscribe for shares from June 2020 until June 2029, at a subscription price of SEK 65.37 per share. Upon full subscription, the dilution effect amounts to 0.4% of the total number of shares in the company. As of December 31, 2022, there was no dilution effect to report.



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PIONEERS IN SCALP COOLING



This annual report was made by Honeybadger together with Paxman

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A dark blue world map is centered in the background of the page. The map shows the outlines of continents and oceans in a slightly lighter shade of blue.

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