

# Annual Report

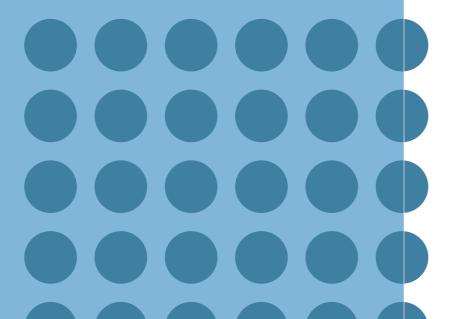
Paxman AB (publ)

Jan - Dec 2024

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# REPORT



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Our Past Year

Summary of the Year

# SUMMARY OF THE YEAR

Paxman continued to see growth throughout 2024, breaking the records set in the previous year and achieving a 20.5% growth rate in comparison.

In 2024, Paxman set out a clear goal at the beginning of the year: a company that would deliver sustainable revenue growth and a positive and consistent EBITDA quarter on quarter. The company has without a doubt delivered with strong momentum for 2025.

Paxman achieved the company's strongest sales to date setting new records in terms of revenues and profits. Net revenues of 253 MSEK were achieved for the year, compared to 210 MSEK in 2023, a 54.5% growth. An EBITDA of 50 MSEK for the year was achieved compared to 31 MSEK in 2023. The company sold and installed 618 (601) systems globally.

The USA continued to be Paxman's major growth market with 173 (126) systems installed, with utilisation and average daily treatment revenue (ADTR) being a key growth driver over systems installed. ADTR continued to grow throughout 2024 and reached its highest to date in Q3, due to Paxman's contract with the Veterans Affairs, at 253 TSEK for the quarter. The company's insurance-based billing model (IBBM) gathered even more momentum throughout 2024, greatly surpassing figures established in 2023. The IBBM accounted for around 20% of the US income in 2024. Coverage data collected by the company is showing an estimated 75% of patients scalp cooling through the insurance-based billing model are having positive coverage determinations. The patients with no coverage or poor coverage are being supported by Paxman's Patient Assistance Program (PAP), ensuring greater access for all patients delivering the company's mission to ensure all patients have the opportunity to scalp cool, no matter their

In the final quarter of 2024, major milestones and breakthroughs were achieved in delivering this vision for the US market. The American Medical Association (AMA) announced permanent CPT I codes for scalp cooling. The ruling recognises three distinct aspects of work

done by clinical staff to administer scalp cooling treatment and allows for all three components to receive coverage and establish payment by public and private payers.

The issuance of a permanent CPT® I code demonstrates that the AMA recognises mechanical scalp cooling; as a service performed frequently across the United States by physicians and other qualified healthcare personnel, as consistent with current medical practice and clinically efficacious.

The issuance of a CPT® I code also sends a strong message to payers, both commercial and Medicare and Medicaid, that there is now a path to consistent and predictable reimbursement and payment for scalp cooling for providers in the community and academic setting.

Moreover, a New York bill (A38-A/ S2063-A), requiring insurance coverage of scalp cooling systems to prevent hair loss during cancer treatment, was signed into law by the New York State Governor on 13th December 2024. This bill acknowledges the importance of scalp cooling to help reduce and manage chemotherapy-induced alopecia. In addition, this new legislation further highlights and narrows the disparities in access to the treatment.

Whilst the insurance-based billing model was a key driver for the growth in 2024, it will provide an even greater impact through 2025 as the company transitions and expedites facilities to the model in preparation for when CPT I coding comes into effect in January 2026, along with the New York legislative bill.

The UK and overseas markets delivered strong growth throughout 2024 and remained a key focus for 2024, including Germany, where the Paxman Group has increased its investment from 20% to 49% in Paxman GmbH. Further work is needed in these markets to continue to deliver through 2025. International expansion was also an important focus, with key

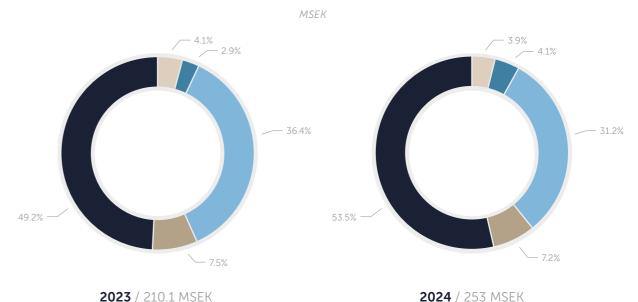
markets such as South Korea preparing to launch and the recruitment of a business development manager for markets in the Middle East. Given the successes in our various distributor markets throughout 2024, the company also recognises that further development is necessary to see continual growth here.

The development of the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy-induced peripheral neuropathy (CIPN) achieved continued progress in 2024 with positive initial findings from the Singapore trial. In addition, the large, randomised phase 3 trial in the USA with the SWOG Cancer Research Network has now recruited 283 patients from the intended cohort of 777 with 23 health systems involved. Paxman looks forward to seeing further preliminary results emerge in the coming year from the trial in Singapore.

2024 was also a year of increased event activity, with Paxman leading or supporting a number of presentations or symposia at large, prestigious oncology conferences. Most notably, Paxman supported a presentation by Dr. Wong, revealing positive preliminary data from the PLCS trial in Singapore at MASCC. In addition, the company sponsored a symposium at ESMO/EONS17, where nurses and a former patient at Paxman gave their perspectives on scalp cooling alongside Dr. Van den Hurk's presentation of the new and insightful Dutch Scalp Cooling Registry Data.

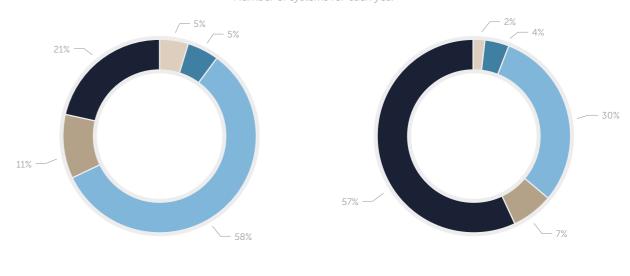
2025 will see Paxman build on the momentum of 2024 with a strong focus on preparing for the implementation of CPT I codes in the USA. The company will place a strong emphasis on regulatory approvals and commercialisation plans for its continued development of the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy-induced peripheral neuropathy (CIPN).

#### **Global Sales**



#### Sold and Installed Systems





**2023** / 601 systems **2024** / 618 systems



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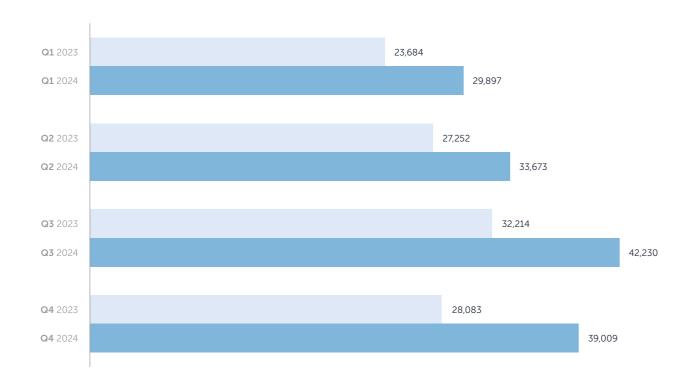
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Our Past Year

Summary of the Year

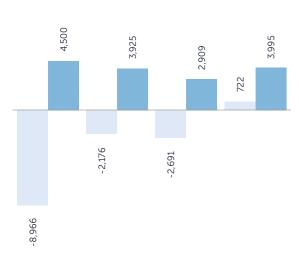
#### **Recurring Revenue**

TSEK, Q1-Q4 2023 and 2024



#### Cash Flow

TSEK. Q1-Q4 2023 and 2024



# **Q1 Q1 Q2 Q2 Q3 Q3 Q4 Q4** 2023 2024 2023 2024 2023 2024 2023 2024

#### EBITDA

TSEK, Q1-Q4 2023 and 2024



# Selected events in 2024

In February, the Paxman Group increased its investment from 20% to 49% in Paxman GmbH, working our partner Novidion to relaunch Paxman in the German Direct market. The German market is an excellent opportunity for the company and with the UK company's increased involvement traction is expected to improve through 2024.

Paxman was honoured to receive the Export Achievement Award during the prestigious Medilink North of England Healthcare Business awards in March, recognising our outstanding growth and success in international markets. Paxman's R&D team were also runners-up for the Partnership with Academia category for our collaborative efforts with academic institutions.

In May, the partnership between the University of Huddersfield and Paxman was awarded an outstanding grade from UK Research and Innovation. The award is the culmination of a two-year Knowledge Transfer Partnership (KTP) that designed and developed the Paxman device for the unmet clinical need of chemotherapy-induced peripheral neuropathy (CIPN).

In June, The Dutch Scalp Cooling Registry was published in The Oncologist – the world's largest real-world study into the determinants of scalp cooling efficacy. The cumulative study now has data from 7,424 scalp cooling patients across 68 hospitals in The Netherlands. You can find out more about this valuable study at: scalpcoolingstudies.com/dutchregistry2024

In July, Paxman announced it had secured a contract for the provision of scalp cooling systems to the U.S. Department of Veterans Affairs (VA) for the National Precision Oncology Program (NPOP). Paxman is partnering with Capri Construction 426 LLC, who were awarded an Indefinite Delivery, Indefinite Quantity (IDIQ) contract, with Paxman as the sole subcontractor. It is projected to be worth \$2.7 million over the contract period which has a base year and four option years spanning 1st July 2024 to 30th June 2029.

Paxman won the SMART award from Innovate UK in August for its work on a device for the prevention of chemotherapy-induced peripheral neuropathy (CIPN). The project will build on previous highly successful collaborations, between Paxman and the University of Huddersfield whilst also integrating expertise from University of Leeds, extending the collaboration network and strengthening Paxman's developing R&D team.

In October, the American Medical Association (AMA) issued 3 CPT® Category I codes for mechanical scalp cooling, effective from January 1st, 2026. This issuance of a permanent CPT® I codes is one of the most significant breakthroughs in Paxman's efforts towards widespread adoption of Paxman's Insurance-Based Billing Model.

CMS published the OPPS Final Rule on November 1st, this is the Hospital Outpatient Prospective Payment System. Based on the updated claims data available since the proposed rule earlier in the year, the payment rate calculated using their methodology falls within the cost band for New Technology APC 1519 (New Technology - Level 19 (\$1701-\$1800)). Therefore, they are assigning CPT code 0662T to APC 1519 for 2025 as opposed to APC 1515, which was \$1350.50.

On 5th December, Paxman announced that founder and board member Glenn Paxman, CIMON Venture Trust AB (represented by the chairman Per-Anders Johansson) and the board members Björn Littorin and Robert Kelly sold shares in the company.

All selling parties entered a lockup agreement for 180 days. In total, the transaction amounted to 2,000,000 shares. Among the new owners are SEB Investment Management, Carnegie Fonder, Aktia Asset Management, and Adrigo Asset Management. The high level of interest in the company is a clear signaller of performance, but more importantly a future opportunity to build a strong profitable business providing a clear impact socially.

A legislative bill (A38-A/S2063-A) in the State of New York was signed into law on 13th December 2024, requiring insurance coverage of scalp cooling systems to prevent hair loss. The bill is an acknowledgement of the importance of scalp cooling to help reduce and manage chemotherapyinduced alopecia and will highlight and narrow the disparities in access to a treatment.

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Our Past Year

Our Past Year

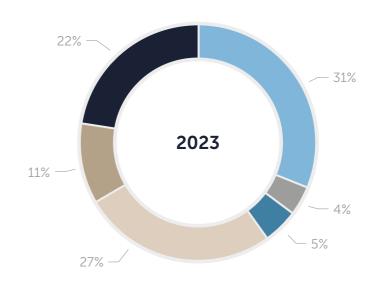
# Installed systems January-December 2024

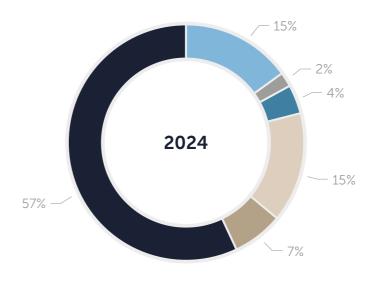
The systems are installed on-site following a signed delivery and rental agreement (in the USA, Canada and Mexico) or after being sold to the customer (rest of the world).

	2023	2024
UK	188	134
South America	24	23
Oceania	30	55
Europe	160	163
Asia	68	70
North America	131	173

618
systems installed

#### Revenue by Geographical Area







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Paxman Vision



# **OUR VISION**

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 when it comes to side effect management and supportive care interventions.

Alongside increasing accessibility to our technology, our core focus has expanded to include innovative solutions for the management of chemotherapy-induced peripheral neuropathy (CIPN) in addition to chemotherapy-induced alopecia (CIA).

Paxman's long-term vision is to ensure that any eligible cancer patient has access to our technology no matter their geographical location, ethnicity, financial situation, gender, or treatment regimen. The condensed slogan "Changing the Face of Cancer" encapsulates our determination that chemotherapyinduced side effects do not have to be inevitable, with Paxman's solutions as the natural side effect management choice.

The practical application of this aim divides into several clear areas of action within the business.

Paxman's determined work in recent years has contributed to gradually improved opportunities to realise this long-term vision through increased adoption and better standards of care. 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 National

Comprehensive Cancer Network® (NCCN®), and inclusions for additional cancer types were added in 2020. Similar inclusions to a varying extent were made in guidelines published by European Society for Medical Oncology (ESMO) in Europe as well as Cancer Australia and Association Francophone Des Soins Oncologiques De Support (AFSOS) in France, Germany and Japan.

In the USA our focus has been, and continues to be, reimbursement which enables more patients to access scalp cooling and is therefore critical to our vision. Working on our three key pillars on reimbursement - Coding, Coverage and Payment - Paxman has contributed to the manifestation of significant milestones in recent years for scalp cooling access. In 2021, the American Medical Association (AMA) issued two temporary Current Procedural Terminology (CPT) III codes for scalp cooling. In 2022, customers in the USA started to implement Paxman's insurance-based billing model, facilitating reimbursement using these CPT codes. Through continued efforts to increase access, 2024 saw the issuance of permanent CPT I codes by the AMA, effective from January 1st, 2026, demonstrating their recognition of mechanical scalp cooling. Shortly afterwards, New York became the

first state to sign a legally binding bill that requires insurers to provide coverage for scalp cooling. These recent events mark major breakthroughs in enabling scalp cooling access for all in the United States and are a major focus for the company. Learn more about the reimbursement landscape in the USA and what these breakthroughs mean on pages 30.

Growth in Asia has become another key focus of the Paxman vision. As we look to expand, the region presents a myriad of opportunity for the business, with significant progress already made in Japan and South Korea. Japan is the world's second largest market for cancer care with over 1 million new cancer cases per year and Paxman has maintained a presence in the country since 2019. 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. Distribution by our partner in the market commenced in March 2025. Strategies are in place to ensure a greater presence in our direct Indian market, which includes the onboarding of an independent licence holder and two additional distributors, allowing for enhanced penetration of the market. There is a future expected establishment in China, where a letter of intent was signed with a Chinese marketing and distribution partner in April 2022, followed by finalisation of a distribution agreement. The company is now following the NMPA regulatory pathway, where testing is ongoing and a clinical trial expected to follow. In 2024, Paxman began to further expand its reach in the Middle East with the hire of a new International Business Development Manager dedicated to growing business in the region.

2023 saw the expansion of Paxman's direct markets with its Canadian entity incorporating which is now looking to expand beyond its existing nine sites in 2025. The launch of Spain as a direct market in 2023 proved to be a great success evidenced by activity in 2024, including a Paxman-sponsored symposium at ESMO/EONS and presentations at SEOM and the IX Extremaduran Multidisciplinary Forum on Breast Cancer and Gynaecological Tumours in Cáceres. Subsequently, a user trial at Hospital San Pedro Alcántara was initiated, which led to a purchase of the device. The hospital is now capturing scalp cooling data with a view to presenting at SEEO congress in 2025.In France, Paxman played a role in presenting important scalp cooling data and preliminary CIPN data at the MASCC/AFSOS 2024 Annual Conference. In addition, a French scalp cooling trial which commenced in 2023 aiming to compare efficacy of manual gel caps against mechanised scalp cooling, has now enrolled 105 patients as of January 2025. Our Scandinavian market saw the installation of 3 units at Radium Hospitalet, a state-of-the-art cancer clinic in Oslo, alongside some great promotional activity via the CancerMentor podcast and the Oncology in Sweden Magazine. During 2024 the company finalised an agreement with Paxman GmbH in Germany to increase our investment in the entity to 49%. Working with partner Novidion, Paxman set

out to relaunch in the German market – an excellent opportunity for traction, proven beneficial thus far with steps being taken to provide reimbursement to patients in the market.

Our on-going market expansion efforts – both direct and non-direct – played a significant role in achieving record-breaking sales in Q3 2024, which was then surpassed in Q4. Read more on Paxman's internal markets on pages 36.

Patients remain Paxman's priority, as we continuously work to improve access, awareness and efficacy of scalp cooling, in addition to venturing into a wider chemotherapy side effect management space.

The company founded the Paxman Research & Innovation Centre, the world's first scalp coolingfocused research and development centre, a fiveyear collaboration with the University of Huddersfield which started in 2019. The centre was instrumental to the development of new technologies and innovation, with current projects transferring to our other institutional partners. Paxman are proud to continue its ambitious R&D programme alongside The University of Leeds, Sheffield Hallam University, King's College London and the National University of Singapore. 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 44.

Paxman redeveloped its patient facing resources in 2023 to deliver clearer, more comprehensive educational materials on scalp cooling and began delivering increased campaign activity targeted at clinicians throughout 2024.

The company attended a record-number of events in 2024, supported by greatly increased marketing activity. Paxman exhibited at healthcare and oncology conferences across the globe, collaborating with oncology professionals and patients to deliver meaningful presentations aimed at expanding scalp cooling adoption and introducing our solution to prevent CIPN. More information on a selection of these clinician campaigns and events can be found on pages 25.

We're moving excitedly through 2025 with the Paxman vision firmly in focus.

"Our on-going market expansion efforts played a significant role in achieving record-breaking sales."

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Comments from our CEO



66

2024 was a recordbreaking year for Paxman, delivering our highest level of top line sales - 20% growth on the prior year. Dear Shareholders, I am so incredibly proud of what the people at Paxman achieve year after year. It gives each and every one of us a real sense of pride, to not only deliver a social impact, supporting patients and their families around the world, but also satisfy our other stakeholders, from our growing cancer centre base to our increasing number of investors.

But it is clear we have so much more to do. There are over 20 million new cases of cancer diagnosed yearly, with 3 to 4 million patients needing chemotherapy and facing inevitable hair loss. Today, we treat less than 1% of those who need access to our technology. This presents a tremendous opportunity to help more people through treatment while building a successful and sustainable business.

2024 was a record-breaking year for Paxman, delivering our highest level of top line sales - 20% growth on the prior year. Combined with a strong EBITDA of 50 MSEK and cash flow positivity, the company entered its strongest position in history. Since our IPO in 2017, the company has delivered growth of over 800%, with revenue rising from 31 MSEK at the end of 2017 to 253 MSEK in seven

years. Prior to 2024, we raised over 160 MSEK through directed issues of shares and, as recently announced, a further 123.5 MSEK. This has allowed us to invest in our organisation, people, products, clinical trials, market access and, more recently, research and development. The most recent directed issue will focus on three key areas, the commercialisation of our new device to prevent the debilitating side effect of chemotherapy-induced peripheral neuropathy – an unmet need we are set to address in 2026, and investment into a state of the art facility to support our growth in addition to further advancing our understanding of novel therapies, how they cause hair loss, and how we can better protect against

2024 was a year filled with significant milestones across the business. Among them, we saw the exciting preliminary results that were presented by Dr Rachel Wong at the MASCC conference in June around CIPN and our study in Singapore. The study concluded that the treatment is safe and well tolerated in patients receiving taxane-based chemotherapy. It can be safely administered with scalp cooling therapy and shows promising data in preventing taxane-based CIPN.

The last quarter of the year became another key highlight, demonstrating a recognition of our investments into the US reimbursement landscape. The American Medical Association (AMA) issued 3 CPT® Category I codes for mechanical scalp cooling, effective January 1st, 2026. Centers for Medicare & Medicaid Services (CMS) published the OPPS Final Rule - this is the Hospital Outpatient Prospective Payment System - allocating a new rate within the cost band for New Technology APC 1519 (New Technology - Level 19 (\$1701-\$1800)), a significant increase from the previous level.

Additionally, on December 13th 2024, New York State Governor Kathy Hochul signed Bill A38-A/S2063-A into New York State law, requiring insurance coverage of scalp cooling systems to prevent hair loss during cancer treatment. This landmark legislation acknowledges the critical role of scalp cooling to help reduce and manage chemotherapy-induced alopecia. In addition, this new legislation will further highlight and narrow the disparities in access to a treatment, combatting one of the most difficult and demoralising side effects of cancer treatment. What a year 2024 was!

Paxman is defined by its people. The achievements and milestones above would not have been possible without them. It is therefore incredibly important to me that we continue to make Paxman a great place to work, which naturally becomes more difficult as we grow. Over the last eight years, we have grown in numbers from 35 to 105 by the end of 2024. Continued investment in our team, upskilling, building on our values, and creating a positive culture is critical for our success. I was pleased to see our strong engagement scores at the end of 2024, but we cannot rest, and we will continue to strive for more. Wellbeing and health remain high on our agenda when everyone works so hard. I was excited to also announce plans for a better work environment in 2026/27 with the investment into our new state-ofthe-art, purpose-built facility, improving our working conditions and supporting our growth.

Looking ahead to 2025 and 2026, we are setting a new bar for Paxman, driven by three key initiatives. Firstly, in March we announced a takeover offer to the shareholders in Dignitana. Paxman and Dignitana have developed a strong relationship over the past few years and it is clear that we share a very common vision. By combining our strengths, we are well positioned to achieve that vision in a faster and more meaningful way There is a clear synergistic value to be gained from the merger of these two great companies, and we look forward to this new position of greater strength as we enter a period of exciting change in the reimbursement landscape within the United States. Change is inevitable, of course, but for the better, ensuring that we are properly resourced for the next chapter in our growth story.

Second, a key focus for the year will be reimbursement; coding, coverage and pricing. Following the positive CPT I coding news, we are working to ensure Paxman and its stakeholders are well prepared for the implementation of these codes in January 2026. Clear communication will be critical with our existing, transitioned customers. We will also prioritise customers who are not on the insurance-based billing model, either expediting or supporting their transition for 2026. Working with commercial and public pavers on improved coverage policies will be crucial, with the publication of CPT I codes now moving from investigational and temporary codes to permanent codes. The AMA's rigorous

process strengthens scalp cooling's position as a key treatment and medical necessity which in turn, supports greater coverage. We shall be working with CMS to support their pricing decisions relating to both the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System rulings for the new CPT® I codes. While there is much work ahead, we are excited about the potential impact on our patients and utilisation.

And finally, we have clear pathway to commercialisation of our new devices, both for chemotherapy-induced alopecia and chemotherapy-induced peripheral neuropathy. Testing is well underway, with submissions to the FDA and European authorities expected in Q3 2025. We anticipate clearance and approvals in Q1 2026 with commercialisation to follow that year. We are so excited for this, providing future possibilities of growth, but most importantly, providing patients around the world access to this life changing technology.

I am incredibly excited about the coming years ahead. I am deeply grateful for the team I work with and the shared vision that unites us. I would also like to thank our investors, both longstanding and new, for their ongoing support. Together we will make a difference.

Huddersfield, April 2025, Richard Paxman OBE, CEO

Paxman AB (publ)

# ABOUT THE COMPANY

# Paxman AB (publ): an international group with its parent company in Sweden

Founded in the UK in 1996, Paxman is the global market leader in scalp cooling to prevent chemotherapy-induced hair loss with thousands of systems installed globally. 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 multiple successful clinical studies with leading clinics and cancer centres all over the world, including the world's first randomised multicentre study with a scalp cooling system in the US in 2017 (read the study <a href="https://example.com/here">here</a>. 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.

The company is now on the precipice of delivering another chemotherapy side effect management solution to the market and continues to explore how cryotherapy can benefit patients in other ways.

The company vision is to make our chemotherapy side effect management technology available to all eligible cancer patients worldwide.

# Market leading and personal scalp cooling

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

Today, the system is used at a large number of cancer centres and hospitals in Europe, North-, Central- and South America, Asia and Oceania, and more installs are added continuously. The company is also developing and trialling a medical cryocompression device to prevent chemotherapy-induced peripheral neuropathy (CIPN) which causes permanent nerve damage in hands and feet, with initiated clinical studies in Singapore in 2021 and a large clinical study in the USA, initiated in 2023. Preliminary results from 2024 have been very positive, setting an excellent foundation for initiating its release to market.

The company was founded as a family business by Glenn Paxman following his wife Sue Paxman's hair loss in connection with chemotherapy treatment. Seeing the trauma that Sue experienced as a result of her hair loss, Glenn realised that there were shortcomings in the existing methods for scalp cooling that needed to be improved, so he developed a liquid-based cooling system with the support of 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 personal 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 who would like to use it.

Greater understanding of the protective mechanisms of cooling has allowed Paxman to explore other avenues for the management of chemotherapy side effects. After over two decades of pioneering scalp cooling, Paxman now has limb cryocompression prototypes that are being trialled to prevent peripheral neuropathy, paving the way for a wider portfolio of chemotherapy side effect management solutions.

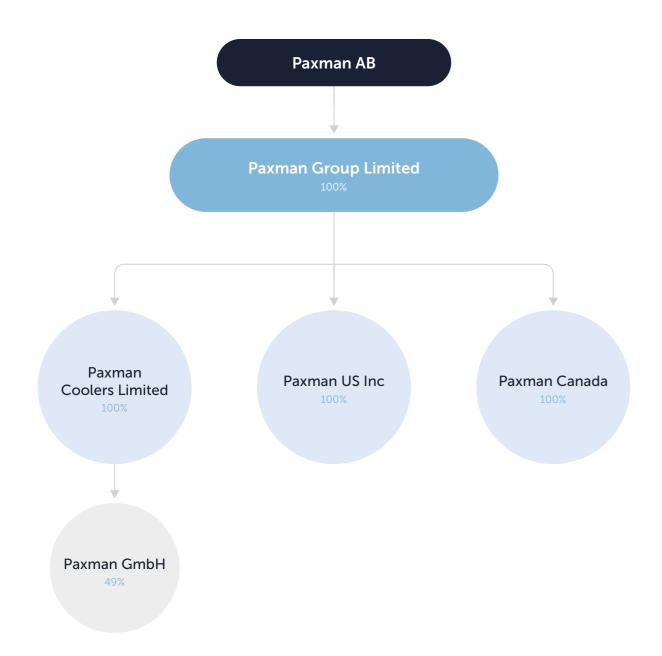


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About the Company

About Us

# **Group Structure**





# Senior Leadership

Stuart Rowling Head of UK Sales & Training

Claire Paxman Brand Ambassador & Director of Global Training

Anna Parker Head of International Sales

Karin Buck VP of US Operations

Alexandra Sheldrake Head of Quality & Operations

Liza Hirst EA to CEO / Head of HR

Patrick Burke Head of Research & Development

Louise Aspey-Smith Head of Brand & Marketing

Richard Paxman, OBE CEO

Emma Thornhill Finance Director

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**2024** 

AMA issues CPT category I codes for

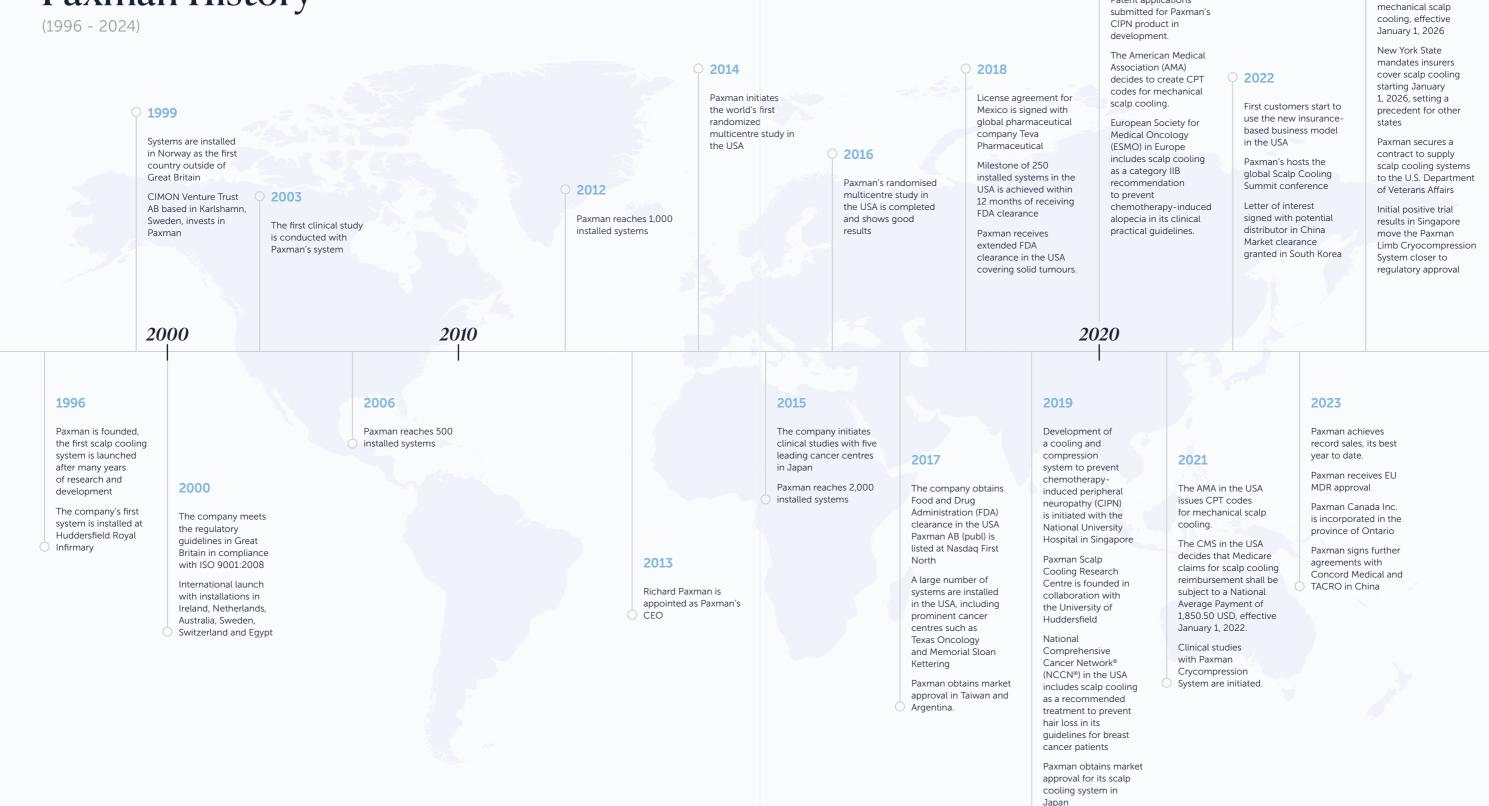
**2020** 

Milestone of 500 installed systems in the USA achieved

Patent applications

# Paxman History

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About Us

Scalp Cooling and the System



# How scalp cooling is preventing hair loss

Scalp cooling is a highly effective, yet simple 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 There are four known mechanisms of scalp cooling in connection with chemotherapy.

01

Inducing vasoconstriction, reducing drug perfusion into hair follicle cells 02

Reducing chemotherapy cransport into the nair follicle cell due to reduced cellular activity, kinetic energy and

03

Reducing the rate of hair follicle cell division making it less susceptible to chemotherapy

04

Reduced metabolic activity thereby decelerating processes





# The Paxman Scalp Cooling System

Paxman's scalp cooling system (PSCS) and the technology behind the product have been developed over decades. This allows the 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.

The 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 additional 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. Paxman is developing a new and improved version of the cap cover with a refined mechanism for achieving the correct cap fit which should increase patient and clinician confidence and lead to more positive results. More information on the company's R&D projects, including the new cap and cap cover, can be found on pages 44.

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.

65
countries worldwide scalp cooling

618
systems installed and sold in 2024



addition to delivering supportive patient resources.

Bridging the gaps between product, healthcare practitioner and patient, the marketing team is responsible for branding and product positioning, delivery of clear messaging considerate of Paxman's audiences, creation of collateral, and facilitating lead generation. An essential piece of their scope also involves communicating valuable clinical messaging and data on scalp cooling to grow confidence among healthcare providers.

services and philanthropic endeavours.

Through regular review and performance analysis, the team continually refines strategies for enhancing engagement, building brand trust and driving longterm success in the market

#### Louise Aspey-Smith

#### Head of Brand & Marketing

As a member of the Paxman Senior Leadership Team, Louise also sits at the helm of the Marketing Team. Responsible for the development and management of the global marketing and communication strategy, Louise drives the development and execution of strategic marketing tactics and engaging omni-channel campaigns. Her efforts shape and elevate the Paxman brand, ensuring a positive experience for both clinicians and patients, strengthening brand trust and recognition worldwide

Louise is an accomplished and versatile marketing professional with a proven record of developing and executing impactful marketing strategies, product launch activity and meaningful content, to meet commercial targets within the med-tech and healthcare industry. With a strong skill set in strategy development, branding, positioning, messaging, product launch, content generation, digital, events and communication, she leverages her previous experience operating at global level, within EMEA and regionally for the UK, for large multinationals, SME's and start-up organisations throughout her career

#### Kathryn Daniel

#### Senior Marketing Manager

Kathryn is an accomplished Senior Marketing Manager, leading the marketing function for the key markets of the US, Canada, and the UK. She possesses a deep understanding of the unique strategic goals in these regions, with a particular focus on the US and its complex reimbursement landscape. In her role, Kathryn works closely with commercial teams, offering tactical support and ensuring the successful implementation of strategic marketing and communications initiatives to boost product adoption and create a positive brand experience for healthcare professionals (HCPs) and patients alike.

Kathryn is skilled at building and nurturing strong relationships with external stakeholders, including patient advocates, Key Opinion Leaders (KOLs), and charity and advocacy groups. Additionally, she

manages the global public relations (PR) strategy and oversees a wide range of external events across the globe.

Her career at Paxman spans many years, having joined the company in 2002 in Operations. Kathryn's diverse experience across multiple departments ultimately led her to the Marketing Team, where she supported the clinical trials for FDA clearance and the subsequent US product

#### Daniel Milner

#### **Content Marketing Lead**

Daniel is responsible for the development and execution of content marketing strategies tailored to engage Paxman's audiences and stakeholders. His role encompasses the creation and management of various content mediums, both digital and print, including brochures, flyers, articles and website

From concept to delivery, Daniel coordinates content campaigns and ensures a seamless flow of strategy implementation. He has also authored articles for The Clinical Services Journal and Oncology in Sweden Magazine, demonstrating his ability to communicate effectively within specialised and technical fields.

Daniel joined Paxman in December 2023, bringing over five years of agency marketing experience. He has a strong background in content creation, copywriting, branding, social media, placemaking and advertising, having worked with a diverse range of clients across the U.K. Before transitioning to marketing, Daniel gained valuable experience in the PPE industry and pharmacovigilance for consumer goods, where he developed a solid understanding of working with regulated products.

#### Megan Brown

#### Digital Marketing Manager

Meg graduated from Sheffield Hallam University with a First-Class Honours degree in Digital Media, laying the foundation for a successful career in

marketing. With six years of experience in the industry, she has honed her skills in digital strategy, content creation, and campaign management.

Joining Paxman in 2023 as the Digital Marketing Manager, she is dedicated to leveraging innovative approaches to enhance Paxman's digital presence and connect with audiences in meaningful ways. In her role, she is responsible for managing Paxman's digital assets websites, email campaigns, and social media - and the delivery of digital communications and processes. She is also skilled in DSLR photography, providing professional visuals to support digital campaigns.

Meg assists with adjustments and updates to the website, ensuring all content is up-to-date and optimised for SEO. She plays a key role in creating and delivering impactful communications to engage audiences and support Paxman's mission.

#### Emma Russell

#### **Events Manager**

Emma joined Paxman in December 2024 and is responsible for managing Paxman's busy and varied events schedule across the globe. Collaborating with crossfunctional teams, she is central to ensuring events run successfully from planning to execution and beyond.

Emma's journey into events management started as a teenager working as a silver service waitress at a local hotel. She soon realised she loved playing a part in delivering high quality events, which inspired her to study Hospitality Management at university. Upon graduation, she worked in 4- and 5-star hotels in various sales and events roles across Yorkshire and the Northwest of

Eleven years ago, Emma made the move from hospitality into the medical device sector, specialising in exhibition and event management for an orthopaedic device company. Having recently joined the company, Emma is excited to bring her versatile experience of event planning and delivery to the Paxman team.

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Articles

Spotlight on the Marketing Tear



Megan Brown, Daniel Milner, Emma Russell, Louise Aspey-Smith, Kathryn Daniel, Eleanor Middleweek, Lucy Collingwood, Joshua Straw

#### Joshua Straw

#### Lead Graphic Designer

Joining Paxman in September 2022, Josh brought in-house design capacity to the company for the first time. A multidisciplinary designer, his work touches most corners of Paxman with a key focus on collaboration with the marketing team's output including campaigns, exhibitions, literature, reports and a variety of digital assets. Josh is also responsible for managing a consistent visual identity of the Paxman brand through our communications.

Studying Interactive Design at the University of Lincoln, School of Art and Design, Josh's extensive experience varies across the discipline. First starting in a design agency as a Junior Designer, he then progressed on to becoming its Digital Lead. Josh then led freelance projects with various external companies and more recently worked in other in-house graphic design roles prior to joining the team at Paxman.

#### Eleanor Middleweek

#### **Digital Marketing Executive**

Eleanor graduated from Sheffield Hallam University with a First-Class Honours degree in Marketing Communications and Advertising with a successful placement year in industry, working for technology company in their Corporate Communications and Sustainability department as a Digital Marketing Assistant.

Graduating in 2023, Eleanor joined Paxman as the Digital Marketing Executive later that year. Her role oversees the day-to-day management of Paxman's social media channels including content generation, video and photography, case studies and user interaction, with the goal of increasing brand awareness and offering support for patients via the Paxman social media channels. Since joining Paxman, Eleanor has also expanded her role to support event organisation and printed literature management.

#### Lucy Collingwood

#### International Marketing Manager

The newest addition to the Paxman marketing team, Lucy is responsible for developing and executing marketing strategies across international markets, with a particular focus on the core distributor networks. Lucy works closely with international stakeholders and distributors to understand localised healthcare needs, trends, regulations and identify new opportunities to amplify the Paxman brand globally. Lucy is the overseas brand guardian and is skilled at adapting marketing strategies to international markets with various needs, driving high impact business growth and global expansion of the Paxman portfolio.

Lucy is an experienced cross-channel marketeer with 6 years' experience in the implementation of brand marketing strategies, new product development, campaign management, social media, influencer marketing, PR and offline activations. Over the past 4 years Lucy has worked within medical aesthetics, launching injectable products into the UK and international markets, with a focus on increasing brand awareness amongst HCPs and end users.



In 2024, there was an increased focus from the marketing department on its healthcare practitioner audience, disseminating valuable resources, tools and information on recently published studies into scalp cooling. Notably, there were two significant studies published this year on which the team focused: The Dutch Scalp Cooling Registry to investigate determinants for scalp cooling efficacy and a study by the Samsung Medical Centre into the effects of scalp cooling on regrowth through the prevention of permanent chemotherapy-induced alongois.

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#### The Dutch Scalp Cooling Registry

The Dutch Scalp Cooling Registry stands as the largest real-world, multicentre study focused on identifying the determinants of scalp cooling efficacy. Spanning over thirteen years (2006-19), this extensive registry includes data from 7,424 patients who underwent scalp cooling across 68 hospitals in The Netherlands. By examining patient outcomes across 24 different chemotherapy regimens, the study aims to provide valuable insights into the determinants that affect the efficacy of scalp cooling to mitigate chemotherapy-induced alopecia (CIA).

The study found the following key results:

Scalp cooling was successful in 56% of patients, determined by whether patients self-reported usage of a head covering and WHO alopecia scores.

Chemotherapy type was the only identifiable determinant of scalp cooling success. Scalp cooling with taxanes saw an efficacy rate of 78% compared to anthracyclines at 40% and anthracycline/taxane in combination at 45%.

Gender, lifestyle factors, eligible cancer type or chemotherapy naivety played no significant role in the outcomes of success, tolerability or premature cessation of scalp cooling.

#### Paxman's Campaign

To date, it is the best snapshot of scalp cooling in the real world and a significant number of patients from this study used the Paxman Scalp Cooling System. As such, the publication of this study in June was extremely vital for encouraging further adoption of mechanised scalp cooling, leading to its subsequent dissemination and campaign by the Paxman marketing team in September and October. Working closely with co-authors of the study, Paxman received support from Toni Brook, Corina van den Hurk and Nik Georgopoulos to deliver this comprehensive campaign. social media or in directly participating in Paxmansponsored sessions.

At the core of the campaign sat three main elements:

A Dutch Registry landing page with a detailed overview of the study, signposting to more external resources. It introduced visitors to the page to its methods, criteria for evaluation, analysis and results as well as conclusions and implications for practice. The page also signposted to a shorter summary and a Paxman whitepaper on the study.

An internal toolkit for sales teams and distributors, including the published manuscript, presentation deck, brochure, summary overview, a whitepaper, social media assets and more. The toolkit will enable Paxman to approach business leads with a full resource pack for demonstrating the efficacy of the Paxman Scalp Cooling System.

Events activity including data presentations and co-author involvement at events such as MASCC and EONS17. Corina van den Hurk, Toni Brook and Nik Georgopoulos have all shared their thoughts and conclusions on the data via Paxman channels, either via social media or in directly participating in Paxman-sponsored sessions.

The campaign's educational materials were supported by events, emails, social media and website activity and internal channels to raise awareness.

41

external resource downloads

459

landing page sessions

8,045

accounts reached on social media

\*data for the period 16th September 2024 to

# A valuable tool for adoption

The Dutch Registry data will be a staple in our efforts for market expansion, acting as valuable evidence that scalp cooling is effective in difficult markets for many years to come.

Since the first campaign came to a close, Paxman has received PR coverage from a range of outlets such as Oncology News Today and has submitted self-written articles to both the Clinical Services Journal and the Oncology in Sweden Magazine.

The collateral for the campaign can be used into 2025 and beyond for demonstrating the efficacy of scalp cooling and is a working example of reusable content for a better return on investment. The team will also be working on other methods of delivery throughout 2025 whilst supporting the co-authors on the development and awareness of an International Scalp Cooling Registry.



#### Persistent Chemotherapy-Induced Alopecia

A study by Samsung Medical Centre in Seoul, South Korea, was also published in 2024, delivering key insights to support other clinical trials that determine scalp cooling is successful at preventing persistent chemotherapy-induced alopecia (PCIA).

PCIA is hair loss that continues for more than six months after chemotherapy treatment ends, and in some cases, can be permanent. Originally thought to affect up to 10-30% of patients receiving taxanes, this new study showed 50% of patients not receiving scalp cooling developed PCIA. An incredibly high figure, which for Paxman, further highlighted the importance of raising awareness of the condition.

In the study, 139 patients were randomly assigned groups, at a 2:1 ratio; scalp

cooling or usual clinical practice (control group). Their hair thickness and density were measured 6 months after chemotherapy using trichoscopic imaging. Patients in the scalp cooling group used Paxman's PSCS2.

01.

Significantly reduced the incidence of PCIA

02.

Promoted faster recovery of hair density and thickness

03.

Reduced psychological distress and improved quality of life

The study yielded three clinically meaningful outcomes

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#### Paxman's Breast Cancer Awareness Month Campaign

Generating awareness of PCIA and scalp cooling's efficacy in helping prevent the condition was tied into our campaign for Breast Cancer Awareness Month in October 2024. As with most cancers, patients navigating a breast cancer diagnosis could potentially find themselves on a chemotherapy regimen known to cause PCIA, such as taxanebased drugs.

Communicating the risks of PCIA and the protection that scalp cooling offers was a focus of our campaign, particularly toward clinicians. Paxman wanted to encourage clinicians to appropriately inform their patients of the risk at cancer diagnosis or within discussions around chemotherapy. Shining light on people now living with PCIA and how it affects their daily life in numerous ways hoped to demonstrate to clinicians that hair loss is not simply a cosmetic issue.



"You go to bed and the last glimpse you've had is your cancer diagnosis. It affects every aspect of your life... you no longer have a spontaneous life."

#### Shirley Ledlie,

Patient Advocate, Ahead of our Time

The campaign also touched upon some digestible but gentle messaging towards patients to equip them with enough

information to advocate for themselves and bring the topic to the discussion, should their clinician fail to do so.

The PCIA campaign had the following core elements:

A clinician landing page dedicated to information on PCIA and the study. It provides an overview of the study with a link to the full paper and a Paxman whitepaper. Alongside an introduction to PCIA, it shares personal stories from individuals living with PCIA and positive hair retention stories from our case studies.

A patient landing page on coldcap.com dedicated to sharing information about PCIA. The approach was much softer in this instance, to avoid overwhelming and worrying patients but with just enough information to raise awareness of the risks.

An internal toolkit, as with the Dutch Registry, for sales teams and distributors, including the published manuscript, presentation deck, summary overview, a whitepaper, and social media assets. Not only will these provide our teams with more material to support scalp cooling adoption, but it can also support our training materials when delivering to existing facilities that offer scalp cooling.

The campaign was disseminated by a comprehensive social media campaign (supported by a number of influencers, both via original content and collaboration with Paxman), targeted LinkedIn advertising, emails and PR coverage in outlets such as Fem Tech World, Health Tech Digital and Connect Yorkshire The campaign resulted in a request from Spire Leeds Hospital for additional patient resources around PCIA and CEO of Paxman, Richard Paxman OBE, also published an article on the campaign via LinkedIn.



"At Paxman, we believe that every person navigating a cancer diagnosis deserves to be informed about all potential side effects of chemotherapy and to make their own decisions regarding scalp cooling. Numerous studies, along with countless patient stories, remind us that retaining hair—or regrowing it—can have a profound impact on a patient's confidence and emotional well-being. Throughout the company, we have seen positive patient stories where people have been able to retain some of their hair, sometimes citing hair regrowth as their primary motivation to scalp cool.

We are deeply grateful to be part of this important work, and we hope this campaign helps further educate and empower patients and healthcare professionals alike on the real risk of PCIA and the life-changing potential of scalp cooling."

Richard Paxman, OBE,

19,632 accounts reached on social

media

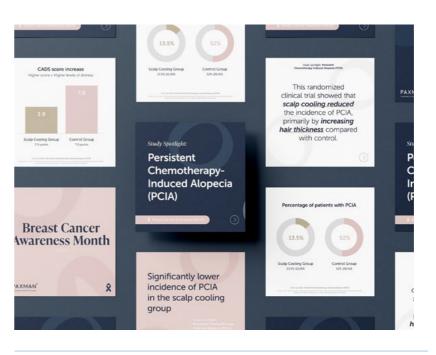
**751** 

engagements on social media

2,712

sessions on PCIA campaign pages

\*data for the period 1st October 2024 to 31st October 2024





# Uniting Professionals, Researchers and Patients: Paxman's EONS17 Symposium

The marketing team, with the support of Paxman's commercial teams, facilitated a satellite symposium as part of ESMO 2024 & EONS17 in Barcelona titled, 'Achieving successful scalp cooling – the importance of nursing in chemotherapy side effect management'.

The session shared wisdom from experts already deploying scalp cooling successfully and important data to inform clinical practice, in addition to the patient perspective. We were joined by guest speakers Prof. Annie Young, Dr. Corina Van den Hurk, nurses Aisling Burke & Laura Marqués Jiménez, and Paxman's Begoña Parrado.

Prof. Annie Young chaired the symposium as Dr. Corina van den Hurk began the session with her presentation of scalp cooling data on retention and regrowth, including the aforementioned Dutch Registry. Aisling Burke and Laura Marqués Jiménez co-hosted the next presentation by discussing the importance of the role of nursing in successful scalp cooling, followed by Begoña Parrado, from Paxman, who shared her own scalp cooling experience.

To encourage connection at the Congress, the marketing team developed a communications strategy, with additional marketing collateral for the

#### Not Just Hair Retention

This study, supported by many others, confirms that scalp cooling is not only a proven method for initial hair retention during chemotherapy, but is also helpful in promoting hair regrowth and preventing permanent hair loss.

This message has spread over recent years, and we have seen an increased number of anecdotes from patients stating hair regrowth has been their primary motivation. In addition, this new mentality around scalp cooling, thanks to our marketing campaigns over the years, has demonstrated more realistic expectations among patients. Hair loss to a degree may still occur with scalp cooling but its regrowth benefits cannot be underestimated.

Paxman's campaign materials will continue to prove useful into 2025 and beyond as we aim to change attitudes across the world to scalp cooling and its huge impact on improving quality of life for chemotherapy patients.

symposium. Collaborating closely with our guest speakers, the team effectively utilised presentations, email marketing, social media, web and printed material to raise awareness of the symposium in the lead up to the event.

The theatre for the symposium was full and the event was a huge success, having welcomed and connected with international delegates and with distribution partners from Belgium, the Netherlands, Luxembourg, Georgia and the Middle East. For greater return on investment, the marketing strategy included directing business leads, after the event, to a dedicated landing page for the recording of the symposium, should they have been unable to attend due to other commitments or capacity constraints.

The team also provided shareable materials for our distributor network to better support them in encouraging attendance to the symposium among their own leads and customer base.

This successful approach has paved the way for similar strategies at other large events in the future.

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Reimbursement in the US

Reimbursement in the US



# Reimbursement in the US

Paxman recognises that despite growing demand for scalp cooling in the US, there is an ongoing disparity in access to this essential treatment. Historically, self-pay was the only option, making it financially inaccessible for many. However, reimbursement is now becoming a reality, improving access.

Since securing FDA clearance for the Paxman Scalp Cooling System in 2017, US expansion has been a priority. While the system is now offered at 9 of the top 10 US cancer centres, limited insurance coverage has restricted equitable access.

Even as a self-pay treatment, scalp cooling signified high-quality cancer care, but the financial burden often made it unattainable for many patients.

After years of advocacy, 2024 marked a turning point for reimbursement. Key milestones included permanent CPT I coding and a New York legislative bill mandating payer coverage. With these achievements, Paxman now focuses on transitioning US facilities to the insurance-based billing model, further expanding access.

## A history of the reimbursement landscape

The journey towards reimbursement is a long and complex one that has taken many years of work to travel. There are a number of hurdles that stand in the way of insurers taking a treatment seriously, ranging from established utilisation to recognition by notable organisations. It is reassuring to see that after such a long road, reimbursement for scalp cooling is now being taken more seriously.

# A history of the reimbursment landscape

#### 2017 - 2020

Paxman's first major milestone was securing FDA clearance for breast cancer in 2017, later expanded to all solid tumours in 2019. This approval established Paxman's reputation in the US as a trusted, high-quality scalp cooling provider.

Another breakthrough came in 2019 when the National Comprehensive Cancer Network® (NCCN®) added scalp cooling as a Category 2A recommended treatment for chemotherapy-induced alopecia in invasive breast cancer patients. This endorsement, a respected benchmark in oncology, reinforced scalp cooling as essential side effect management. In 2020, NCCN® expanded its recommendation to ovarian cancer, further validating the treatment. These milestones, combined with rising patient demand, drove the increasing adoption of scalp cooling across the US. Insurers now look to these guidelines when making coverage decisions, further strengthening the case for reimbursement

#### 2021 - 2023

2021 was a pivotal year for Paxman. In July, the American Medical Association (AMA) issued two CPT III codes for scalp cooling: 0662T for initial cap fitting and 0663T for each treatment, enabling cancer centres to bill insurers. While temporary, these codes allowed time to assess the need for a permanent code, with annual reviews determining payment rates.

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, Medicare proposed a low reimbursement rate for CPT 0662T, but following advocacy efforts, the Centres for Medicare & Medicaid Services (CMS) reassigned it to a higher-paying category, APC 1520, with a rate of \$1,850.50, taking into account the substantial hospital resource costs associated with the calibration and fitting of the scalp cooling cap. While this didn't directly impact commercial insurers, they often follow Medicare's lead, laying the groundwork for broader reimbursement. The codes were finalised in November 2021 and took effect in January 2022.

O22 saw the real work of crafting the Paxman surance-based billing model and beginning e work of rolling this out to existing self-pay odel sites across the US, ensuring a structured pproach involving clinical teams, prescribers,

and administrators. Though adoption was initially slow, this allowed for refining the process. By June, the first site transitioned to the new model, receiving Medicare, Medicaid, and commercial insurance payments at rates that exceeded expectations. More facilities followed, accelerating access to reimbursement. February 2023 brought another breakthrough: Palmetto GBA, a Medicare Administrative Contractor (MAC), issued the first-ever Local Coverage Determination (LCD) for scalp cooling, deeming it "reasonable and necessary" for solid tumour patients. This opened a direct reimbursement pathway for Medicare patients in seven southern states, where Paxman systems are

A MAC is a private healthcare insurer that has been awarded a geographic jurisdiction to process claims for Medicare beneficiaries. The Palmetto GBA services two jurisdictions in the US Medicare system covering seven states in the southern US: Alabama, Georgia, North Carolina, South Carolina, Tennessee Virginia, and West Virginia.

CMS assigns MACs the task of developing LCDs to describe reasonable and necessary services within the Medicare program. CMS also assigns MACs the task of developing coverage articles that give direction on how to bill or code for a service or to provide education on a specific topic. In the Billing and Coding Guide: Scalp Cooling for the Preventior of Chemotherapy-Induced Alopecia, Palmetto GBA reaffirms guidance from CMS, "CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, 110.6 Scalp Hypothermia During Chemotherapy to Prevent Hair Loss is not a barrier to coverage or to pricing/ payment of the Category III Temporary CPT® codes for professional/facility services related to scalp cooling (CPT® Codes 0662T and 0663T)."

I his achievement helped to solidify localised coverage taking a further large step towards reimbursement, as well as creating a strategy to be utilised with other MACS around the US.

However, in November 2023, CMS reduced the APC ate for scalp cooling from \$1,850.50 to \$1,250.50, citing low 2022 claim volumes. With fewer than .00 claims filed, CMS classified it as a low-volume service. Despite this reduction, MACs can set their own, often higher, reimbursement rates, ensuring continued progress towards wider insurance coverage.

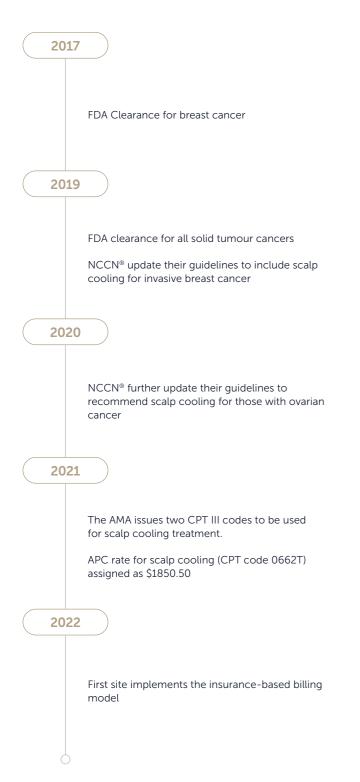
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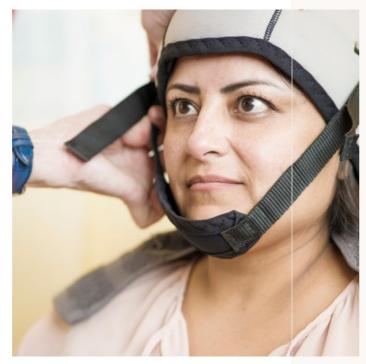
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## Reimbursement timeline







"A huge milestone for coverage, the bill is an acknowledgement of the importance of scalp cooling to help reduce and manage chemotherapy-induced alopecia."

#### 2024 and beyond

Based on the updated claims data available for HOPPS Final Rule for 2024, the CMS found the geometric mean cost to be approximately \$1,110, the median to be \$1,750, and the arithmetic mean to be \$1,420. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1519 (New Technology - Level 19 (\$1701-\$1800)). Therefore, for 2025, they are assigning CPT code 0662T to APC 1519 as opposed to APC 1515, which was \$1350.50.

In October 2024, Paxman announced that in the Summary of Panel Actions issued on October 18, 2024, the American Medical Association (AMA) had issued 3 CPT® Category I codes for mechanical scalp cooling. The current CPT III codes are temporary and do not have an associated Relative Value Unit (RVU).

Published on the AMA website, September 2024: CPT® Editorial Summary of Panel Actions | AMA (ama-assn.org), these new codes will be effective on January 1, 2026, and descriptors will be included in the CPT® 2026 code set.

AMA will recommend three separate and distinct codes for scalp cooling, ensuring that no code is bundled with the administration of chemotherapy, unlike previously with the CPT® III code 0663T. Importantly, this recognises three distinct aspects of work done by clinical staff to administer scalp cooling treatment and allows for all three components to receive coverage and establish payment by public and private payers.

The issuance of a permanent CPT® I code demonstrates that the AMA recognises mechanical scalp cooling; as a service performed frequently across the United States by physicians and other qualified healthcare personnel, consistent with current medical practice and clinically efficacious. The issuance of a CPT® I code also sends a strong message to payers, both commercial and Medicare and Medicaid, that there is now a pathway for consistent and predictable reimbursement and payment for scalp cooling for both providers in the community and academic settings.

Work in 2025 will commence alongside CMS to understand the payment rates set for the three new CPT I codes in 2026.

Furthering the adoption of reimbursement for scalp cooling, a legislative bill (A38-A/S2063-A) in the State of New York was signed into law on 13th December 2024, requiring insurance coverage of scalp cooling systems to prevent hair loss. A huge milestone for coverage, the bill is an acknowledgement of the importance of scalp cooling to help reduce and manage chemotherapy-induced alopecia and will highlight and narrow the disparities in access to a treatment.

2024 proved to be a year of significant achievement drawing us closer to our own vision for scalp cooling: Regardless of gender, ethnicity, cancer type, chemotherapy type or location and financial situation, every patient should have access to our technology.

As the CPT® I coding comes into effect from January 1, 2026, the company will be continuing work with longstanding Paxman users across US healthcare systems, preparing existing facilities for the influx of reimbursement requests, transitioning and expediting them to the Insurance-Based Billing Model (IBBM). This will enable them to remove the barrier of financial toxicity and widen patient access to this important means of side effect management for their patient community. Paxman are committed to spreading the word throughout 2025 and providing a clear transitional framework for existing facilities, ready for 2026.

geometric

Palmetto GBA MAC issue a LCD to provide coverage guidance for scalp cooling

APC rate for scalp cooling (CPT code 0662T) assigned at \$1250.50

2024

2023

The AMA issues permanent CPT I codes for scalp cooling treatment, effective from January 1, 2026

New York Bill is passed requiring insurers to provide reimbursement for scalp cooling in the

New Technology APC 1519 (New Technology - Level 19 (\$1701-\$1800)).

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# The Paxman Insurance-Based Billing Model

The Paxman insurance-based billing model allows the cancer centre to bill the patient's insurer, via CPT codes. While it is relatively simple, the multidisciplinary team needed to execute successful implementation of the model which requires time and fully engaged stakeholders from clinical staff (RNs and MDs), administration, compliance, regulatory affairs, billing, patient financial services, supply chain director, and legal.

Workflows are simplified for patients and clinicians with Cap Kits purchased by sites and given to patients at their appointment, rather than being managed and distributed by McKesson as is done in the self-pay model. Patients receive their Cap Kit as soon as they decide on scalp cooling, allowing more time to prepare for treatment, which is fundamental to success and a positive patient experience.

Facilities that have been offering scalp cooling as a self-pay treatment require

around 6 to 9 months to transition to the new model, reflecting the complexities that often occur when deploying projects involving so many stakeholders.

#### The model process is as follows:

- Providers and health systems contract with Paxman to install systems for its facilities (if not already installed).
- Paxman sells Cap Kits in all sizes through McKesson Plasma Biologics, McKesson Specialty Distribution or OnMark/Unity, McKesson's Group Purchasing Organization.
- McKesson sells the cooling Cap Kits to providers and health systems, who 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 carry out a benefits investigation to determine if the patient's insurance will cover scalp cooling.
- The patient is measured, the Cap is calibrated, and then the patient is given the Cap Kit which they will bring to each treatment. At this point the provider will bill the payer using code 0662T. In connection with all treatments, the provider bills 0663T, which is for the cooling treatment itself
- Under the insurance-based billing model only, the Paxman Patient Assistance Program (PAP) provides free goods to allow access to treatment for those who are under or uninsured.

# The Paxman Patient Assistance Program

66

It's not fair that those who are struggling to pay hospital bills, have childcare during treatments and have to take off time from work can't afford to keep, what I consider, a piece of their soul! Their hair! It has made all the difference for me when my world fell apart completely.

Raquel

To ensure the most equitable access possible, Paxman have developed a generous Patient Assistance Program (PAP) to support the insurance-based billing model. If patients qualify for the PAP, they will receive a Cap Kit free of charge from their provider, and the Paxman Hub will send a replacement Cap Kit to the provider. The provider will not charge the patient for the Cap Kit or any scalp cooling treatments.

This Program is a best-in-class offering and emphasises Paxman's commitment to ensuring equitable access for all patients who want to scalp cool.

Under the insurance-based billing model contract, the Paxman PAP assists patients who:

- Are uninsured or underinsured for scalp cooling
- Reside in the US and have a physical US address
- Have an on-label diagnosis
- Have a valid prescription for scalp cooling from a licensed prescriber
- Have a household income of 6x US Federal Poverty Level or below

# Commitment

to transition

The acknowledgement of the value of scalp cooling from guideline organisations such as NCCN® and the integration of scalp cooling into legislation represents the importance of the treatment and the impact it can have on a patient's experience of cancer treatment. Countless clinical studies reflect the trauma of chemotherapy hair loss and the option to limit and manage that process can be invaluable to patients.

Paxman's commitment to the insurance-based business model stems from the recognition that no patient should have to face hair loss if they don't want to, and the intention to convert all existing sites to the new model by the end of 2025, ready for CPT I coding to take effect on January 1, 2026, will ensure that chemotherapy-induced alopecia does not have to inevitable for any patient in the United States.

## Improved utilisation

Interest in the Paxman Insurance Based Billing Model (IBBM) from the provider network continues to remain strong albeit slower than our original expectations. Paxman are seeing strong coverage results, with government payers slightly less, but to a good standard, and commercial payers frequently exceeding expected coverage rates. Importantly the business model has led to increased patient usage, with utilisation being a key growth driver for Paxman. On average, sites have seen an increase in usage of 300% when switching to Paxman's IBBM with some reporting figures as high as 800%. Coverage for the cost of the cooling cap, the physician, nurse and chair time has been positive even under the current temporary investigational codes.

In an interview with a large academic health system, one of the first customers using the Paxman insurance-based billing model in the US, the new model was recommended to others as it has greatly improved patient access to scalp cooling – "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."

Brooke, a patient who was treated at a cancer centre using the Paxman insurance-based billing model spoke of her experience of being able to access reimbursed scalp cooling treatment – "I didn't realize how lucky I was until almost after the fact that I had 100% coverage. But it shouldn't come down to finances. It should be available to all that have the opportunity to experience it."

Investment continued in 2024 and will do so throughout 2025 on the three key pillars of insurance: coding, coverage and payment. The company's key focus will be on the following:

- Communicating the announcement of the CPT I codes to all stakeholders and educating them on what this means to prepare them for the switch.
- Working closely with Centers for Medicare and Medicaid Services (CMS), both local MACs and commercial payers on coverage policy.
- Working with CMS on payment of the three codes, which represent the three distinct aspects of work performed by clinical staff to administer scalp cooling treatment.

66

I was able to 'live' my life whilst undergoing treatment; I felt 'normal' and retaining my hair enabled me to remain confident and positive.

Karen

In conclusion, while the road has been long and at times challenging, Paxman are proud of the progress they have been able to achieve in a relatively short time in the US. While there is still a long way to go, a momentum has been established that will ensure that in conjunction with further hard work, 2025 and 2026 will be even more successful. We are determined that more patients than ever before will be able to access scalp cooling, an essential side effect management tool that is growing in importance in the oncology space.

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Paxman saw its most successful year to date in 2024, due in part to its endeavours in its internal markets.

# Direct Market

The prevalence of cancer is growing globally.

On average, one in two people will get cancer in their lifetime. There were approximately 19,976,499 new cancer diagnoses in 2022, around 90% of which were solid tumour cancers<sup>1</sup>. As awareness of the efficacy of scalp cooling and other chemotherapy side-effect management grows in both patient and clinician populations, so does the demand for the treatment. The International Agency for Research on Cancer estimates that by 2045, the estimated number of annual cancer cases will have increased to 32.6 million<sup>2</sup>.

Paxman saw its most successful year to date in 2024, due in part to its endeavours in its internal markets, the UK, France, Spain, Scandinavia, India and now Germany, where Paxman sells directly to the customer, rather than a distributor. Paxman operates a hybrid business model in Canada, offering pay for use services through Paxman personnel in large academic and high-volume cancer centres and the sale of capital equipment to smaller regional cancer centres.

<sup>2</sup>International Agency for Research on Cancer (IARC) (2025) Cancer Tomorrow. Available at: https://gco.iarc.who.int/tomorrow/en/dataviz/isotype. [Accessed: 30 January 2025]

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Active since 2006, there are 65 hospitals utilising Paxman systems in continental France and 3 hospitals in the country's offshore territories – a total of 156 systems. 2024 has been a year of substantial growth with 20 new systems sold and 8 new customers, building on the back of a series of significant achievements:

- Paxman is directly mentioned in the supportive oncology care guidelines for France.
- 2. The company is the preferred supplier for mechanised scalp cooling in the country and for the Helpévia Group, a private sector purchasing platform.
- Paxman is currently partnering with the first ever clinical scalp cooling study in France, funded by the Ministry of Health
- The business was awarded SME of the Year at the Franco-British Trade and Investment Awards in 2023.

In France, the commitment to improving cancer care continues with updates and expansions across a range of hospitals throughout the year, including trials, upgrades and new systems, as well as new centres adopting scalp cooling.

# MASCC/AFSOS/ISOO 2024 in Lille

This year the MASCC/AFSOS/ISOO Annual Meeting took place in Lille, France. During the 3-day event, alongside a whole host of presentations and symposiums in the field of supportive cancer care, there were a number of highlights for the Paxman team.

Toni Brook from the University of Huddersfield presented the abstract of the Dutch Scalp Cooling Registry, a study published in The Oncologist in 2024. As the largest real-world multi-centre analysis of determinants for scalp cooling efficacy it is a cumulative study that collates data from 7,424 patients across 68 Dutch hospitals between 2006 and 2019. It is regarded as a major milestone study due to the significant amount of people studied.

Rachel Wong, from the National Cancer Institute in Singapore presented the preliminary results of the ongoing CIPN trial using the Paxman Limb Cryocompression System (PLCS) in collaboration with the National University of Singapore. The early data suggests it is safe, easily tolerable at 11°C, even with concurrent scalp cooling and reduces the rates of CIPN in patients. For more information on the PLCS trial see page 48.

Both presentations of data were extremely popular, signalling great interest from the Healthtech sector. Paxman's Regional R&D Manager, Dr. Aishwarya Bandla, was also honoured with the prestigious MASCC Innovator Award for her ongoing research for the prevention of CIPN.

#### The ICELAND Trial

A multicentre study is underway in Caen and Lille to compare efficacy between the Paxman Scalp Cooling System and manual gel caps, which are much more common in France. The Centre François Baclesse, which sees up to 125 chemotherapy patients a day and is leading the study, acknowledged that

patients are not entirely satisfied with manual gel cap outcomes. Additionally, due to the fear of hair loss, it has been reported that some patients only accept chemotherapy if there is a chance of preserving their hair.

The centre hopes to demonstrate the efficacy of Paxman's mechanised system and convince facilities using manual gel caps that a viable, if not superior, alternative exists. Study coordinator, François Gernier, noted that while research exists on each method's individual efficacy, there are next to none that compare the two. With almost 200 patients recruited into the study, the company is optimistic about favourable results for the Paxman system – results which could help challenge entrenched practices and drive growth in both France and other regions heavily reliant on manual gel caps

#### Attending the British Ambassador to France's Garden Party

Paxman were offered the opportunity to attend a garden party hosted by Dame Menna Rawlings, the UK's ambassador to France, after winning the SME of the Year at the Franco-British Trade and Investment Awards in 2023. The party, hosted in September of 2024, celebrated the inclusivity of the Paralympics and its progress. Paxman representatives had the opportunity to meet some of the Paralympians, including Erin Kennedy. Coxswain for the GB Rowing Team, Erin scalp cooled with Paxman during her breast cancer diagnosis and received support from the company's Brand Ambassador, Claire Paxman.

# 16th Monegasque Biennial of Oncology

The Paxman France team attended the 16th Monegasque Biennial of Oncology at the Grimaldi Forum in January 2024 to discuss scalp cooling and its challenges. The biannual event, with over 1,500 participants, plays a vital role in uniting the French-speaking oncology community to share knowledge, discuss therapeutic advancements, and collaborate on improving cancer treatment and patient outcomes.

# Germany

Paxman announced in 2024 that the company had finalised an agreement with Paxman GmbH in Germany to increase investment in the entity to 49%. Working with partner Novidion, Paxman set out to relaunch in the German market — an excellent opportunity for traction, proven beneficial thus far with steps now being taken to provide reimbursement to patients in the market.

## Increased accessibility and expansion

Paxman GmbH introduced a dynamic leasing model in Q4, offering customers greater flexibility alongside traditional purchase and rental options. This initiative has already gained traction, with two out of the last five customers opting for leasing. These options help break down financial barriers for hospitals and centres, meaning even more patients can access scalp cooling treatment in Germany.

Increased demand from Northern Germany has led to a major new customer acquisition in Hamburg, trial phases in additional centres, and numerous presentation appointments scheduled for 2025.



## Scandinavia

One of Paxman's longer standing markets, Scandinavia has been active for 25 years with 39 PSCS systems currently installed across 25 hospitals.

#### Growing awareness in the region

A significant amount of work was undertaken in the region in 2024 to increase awareness of scalp cooling and change long-held attitudes toward the treatment. The team in the region attended high-profile oncology conferences such as Oncology Days in Malmö, Sweden and Onkologisk Forum in Bergen, Norway to attract new customers and encourage the adoption of scalp cooling into cancer treatment pathways.

Paxman's representative for the region, Camilla Magnusson, successfully instigated a range of promotional ventures: discussing her own cancer journey on the CancerMentor podcast; speaking about her life after cancer and Paxman's chemotherapy side effect management solutions in the OncoDaily podcast; and commissioning an article by Paxman, published in the Onkologi I Sverige magazine, outlining the importance of the Dutch Scalp Cooling Registry.

Our work in the region led to the installation of three PSCS systems at Radiumhospitalet, a state-of-the-art cancer clinic in Oslo, Norway with many other sites being encouraged to upgrade to the PSCS from older systems.

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## Spain

Spain, a part of the Paxman distributor network since 2014, transitioned to a direct market model in April 2023 and has resulted significant expansion and increased activity since. There are currently 37 Paxman systems in the market across 8 regions of Spain.

As with other markets, there was an increase in marketing and awareness initiatives which have yielded positive results, reflecting in the year's sales figures.



# The 'Un Pèl Més Fàcil' fundraising campaign

The Hospital General de Granollers in Barcelona placed their first order with Paxman for a dual scalp cooling system in November 2024 after a successful fundraising campaign supported by Paxman's representative in Spain, Begoña Parrado.

The *Un Pèl Més Fàcil* campaign (A Little Easier in Catalan) coordinated by the hospital aimed to fundraise for the implementation of a Paxman Scalp Cooling System.

Recognising that cancer treatment can have a huge impact on social needs along with emotional, psychological and physical ones, the team at the hospital wanted to be able to offer a more human approach to their oncology treatments.

A device was secured as a result of the fundraiser, and the hospital began offering treatment in 2025. The team at Hospital General de Granollers will benefit from Paxman training on how to use the device and best practices, alongside continued support.

#### LVR Magazine

La Vida En Rose (LVR) is a free Spanish magazine for women with cancer and their loved ones, offering medically endorsed information and covering topics like beauty, travel, fashion, and culture.

Begoña Parrado, our Spanish representative, was featured in the magazine in 2024. Reflecting on her deeply personal experience with breast cancer, she spoke about using scalp cooling technology to retain her hair, her privacy and to protect her children.

The magazine is distributed in hospitals, associations, and oncology beauty centres across Spain, allowing for a large audience to empathise with Begoña's brave experience and understand the positive impact of scalp cooling through her eyes.

#### **Exhibition Highlights**

In 2024, the company sponsored a symposium at the ESMO Congress 2024 & EONS17 in Barcelona. Paxman were joined by Prof. Annie Young, Dr. Corina van den Hurk, Aisling Burke, Laura Marqués Jiménez, and patient advocate Begoña Parrado. 34,000 participants from 149 countries attended the prestigious 5-day event, with the theatre filled to capacity for the symposium on 'Achieving Successful Scalp Cooling'. The schedule included the presentation

of scalp cooling data supported by new Dutch Registry findings, nursing perspectives and the experiences of a scalp cooling patient. With an auditorium full of engaged oncology professionals, the session demonstrated a high level of interest in the topic and led to meaningful discussions on enhancing patient care through scalp cooling.

Paxman was also present at both SEOM and the IX Extremaduran Multidisciplinary Forum on Breast Cancer and Gynaecological Tumours in Cáceres, where Begoña Parrado delivered a presentation. This successful activity resulted in a user trial at Hospital San Pedro Alcántara, which led to a purchase of the device. The hospital is now capturing scalp cooling data with a view to presenting at SEEO congress in 2025.

## Canada

Paxman has operated a hybrid business model in Canada since incorporating in 2023. The model offers pay for use services in larger centres, with tiered pricing per treatment taken directly from the patient, either in advance or on the day of treatment. A Paxman technician is present for each treatment to deliver scalp cooling. Devices are also sold to small centres.

Canada has emerged as a beacon of innovation for scalp cooling this year, marking notable achievements across multiple provinces. Two new hospitals in the nation's capital, Ottawa, began offering scalp cooling in 2024, which lays the groundwork for further adoption of Paxman technology in the region. In Toronto, four hospitals expanded their services to include additional areas of oncology, including gynaecological and gastrointestinal cancers.

2025 will see Paxman advocating for scalp cooling to be recognised as a prescribed treatment for chemotherapy-induced alopecia at the Provincial and Federal levels. Achieving this would pave the way for provincial insurance coverage, aligning the treatment with other supportive care interventions like breast reconstruction. Plans are also underway to extend scalp cooling to all solid tumour cancers in both new and existing locations.



2024 also included the onboarding of an independent licence holder, two additional distributors and installations in hospitals in Jaipur and Vadodara.



## India

India is a market with huge potential that has been active for Paxman since 2013 under the care of distributor Access Devices. In 2021, Paxman placed Garima Vyas as the Regional Manager for India, an additional resource and influence on the ground providing training and implementation guidance to hospitals using the Paxman system. At the end of 2024, there were a total of 70 hospitals in India using the PSCS system.

The Paxman Scalp Cooling System is offered at major hospitals chains such as MAX, Fortis, Manipal, ASTER, HCG, Rajiv Gandhi Cancer Institute, Hinduja, Mumbai Oncocare Centre, Narayan Health and most recently, TATA ACTREC Mumbai, a renowned medical institute, which purchased two PSCS systems in 2024 and is a significant breakthrough for Paxman's efforts in India. 2024 also included the onboarding of an independent licence holder, two additional distributors and installations in hospitals in Jaipur and Vadodara (following achieving compliance with Central Drugs Standards Control Organisation (CDSCO) regulations).

#### Exhibition Highlights

Paxman attended the Nanavati Hospital MAX conference in Mumbai during September 2024, sponsoring a symposium on "Success in Scalp Cooling - The Vital Role of Counselling and Nurses in Patient Management". Joined by Dr. Shruti Arora, Dr. Jeyhan Dhabhar and Tejaswini Patil, the session presented clinical research around scalp cooling efficacy and allowed attendees to gain an understanding of the Paxman system. It also highlighted the importance of managing expectations for patients, as scalp cooling success can be subjective and dependant on chemotherapy regimen. Finally, the symposium mirrored the messaging delivered at other events this year in relation to nursing - that they play a vital role in ensuring scalp cooling success

Paxman also attended the Best of ASCO conference in Mumbai the following month to exhibit the PSCS. The event attracts leading experts, researchers, and healthcare professionals, providing us with valuable opportunities to further increase our visibility in the market whilst forging partnerships and collaborations that can drive future growth.

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# United Kingdom

As Paxman's home market, the UK stands as a huge success story and an example of what can be achieved elsewhere in the world.

The UK market has been active since 1997, with a current count of 326 hospitals using over 1,000 Paxman systems. This is equivalent to 99% of all private and public hospitals utilising Paxman systems. Our sales activity in the UK is mainly concerned with maintaining relationships, training, and encouraging hospitals to upgrade from the old ORBIS systems to the PSCS.

Continued strong market performance, within what could be considered a saturated market, continued to be driven

by increased utilisation, improving efficiencies and capacity at existing sites. Performance was additionally driven by upgrades from obsolete or older generation systems to the PSCS. This continual upgrading of systems has proven its worth, providing scalp cooling as a standard of care within the National Health Service (NHS) and has resulted in a strong sales pipeline that will deliver in the medium to long term.

#### UK Oncology Nursing Society Annual Conference

A staple in maintaining our prosperous and valued relationships with UK nurses, Paxman once again attended the UKONS conference in 2024. Due to our extensive UK market penetration, the focus of the event was training and relationship building.

A new initiative which began in 2024 of allowing visitors to try the cold cap for themselves, was well received by attendees. This hands-on approach proved invaluable, as it allowed nurses to not only revisit the correct fitting techniques but empathise with patients and appreciate the tolerability of the treatment – findings that are supported by past clinical studies.

# Continued Clinical Pioneer Programme

2024 saw the continued expansion of the Paxman Clinical Pioneer Programme (CPP), both in the UK and in the United States. Led by Claire Paxman, Brand Ambassador and Director of Global Training, the programme is an in-depth educational session, instilling confidence and motivation in clinical teams, ensuring they can deliver scalp cooling excellence with the best possible outcomes for their patients. The CPP creates in-house scalp cooling experts, resulting in clinical team buy-in and therefore higher utilisation with improved treatment and outcomes.

#### Self-application of Scalp Cooling at Guy's and St. Thomas NHS Trust

In efforts to reduce the strain on nursing staff within the NHS, Guy's and St. Thomas Trust in London has issued information via their website on the self-application of the Paxman cold cap. Working closely with the Paxman team and signposting to the company's patient resources, this section of their website provides an overview on scalp cooling, how to prepare and instructions on how to perform the steps required by the patient. This is just one of the initiatives Paxman has seen throughout the UK in optimising scalp cooling delivery and patient care whilst easing strains on resources.

#### Volunteering at Gloucestershire Oncology Centre

To support staff at Gloucestershire Oncology Centre, the Trust recruited 5 volunteers in 2022 to assist with fitting the caps and preparing the patient for scalp cooling. Abstracts on the topic were presented at UKONS in 2023 and 2024.

Whilst one patient takes only 20 minutes to prepare at the centre, this equates to approximately 87 hours a year – a valuable portion of time that allows nurses to carry out other duties, such as administering treatment. This initiative also offers individuals to give back to the community, help others, and perform a valuable role in cancer treatment. Following this example, there is the potential for this volunteer blueprint to be integrated as part of Guy's and St. Thomas NHS Trust in the future and for Paxman to support from a training perspective.

#### The UK market as a blueprint

The immense strength of the UK market is something that Paxman is not only proud of, but we believe that is provides a blueprint of what can be possible in many markets globally. The world looks to the NHS for guidance and direction in healthcare and Paxman Scalp Cooling Systems are an embedded part of oncology care in the UK. We look forward to a time when scalp cooling is a similar standard of care for all cancer patients around the world.

## *Ireland*

Paxman's UK team also works to promote the adoption of scalp cooling in Ireland, where traction and desire for the treatment is starting to grow. There are currently 15 cancer facilities in Ireland with a Paxman system, however, barriers to accessing this treatment remain that are not present within the UK and require more considered navigation.

Fortunately, the National Cancer Control Programme in Ireland (NCCP), which operates under the Health Service Executive (HSE), allocates funding annually to cancer services across the country. There is currently a funding initiative to support the adoption of scalp cooling in cancer centres, with two sites securing funding and proceeding to the procurement stage

Paxman look forward to working with Irish hospitals in 2025 to increase patient access as government channels begin to endorse scalp cooling.



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# Research & Development

Research and development has become an increasingly important focus for Paxman. A recognition of the potential provided by innovation, not only for our existing product, but also the huge opportunities that pushing the boundaries of cryotherapy brings, have led Paxman to prioritise an ambitious programme of research and development. The capabilities and improvements being unlocked by this ongoing work ensure that Paxman moves forward from a position of strength. We recognise that investment in innovation now paves the way for significant future growth.

2024 proved to be another successful year, with on-going projects that leverage advancements in new technology and factor in sustainability draw even closer to the start of their regulatory pathways

Collaboration with institutions has been pivotal to both existing product innovation and exploring new applications for cryotherapy. Paxman is currently engaged in research and development projects with The University of Leeds, King's College in London, Sheffield Hallam University, The University of Huddersfield and the National University Hospital of Singapore. Paxman has a long and close history of innovation with the University of Huddersfield, including co-founding the Paxman Research and Innovation Centre.

# Preventing chemotherapy-induced peripheral neuropathy

Huge progress has been made in recent years with the Paxman Limb Cryocompression System (PLCS), a portable cryocompression product developed to prevent chemotherapy-induced peripheral neuropathy (CIPN). This less high-profile side-effect is a potentially debilitating outcome of taxane chemotherapy treatment impacting the hands and feet, ranging from a tingling sensation to excruciating pain.

Several pharmacological agents have been developed to prevent and treat CIPN, yet none have proven effective in large-scale clinical trials. Trials have shown the potential that cryotherapy may have as an effective preventative treatment, creating the need for a clinically tested medical device that can deliver consistent, reliable cooling to replace the currently available unregulated manual cooling in the form of frozen gloves, or mechanised cooling that isn't supported by a large-scale trial.

PLCS prototype systems were placed in Singapore for use in a pilot clinical trial to establish the efficacy of cryocompression that commenced phase one, testing in healthy individuals, in November 2021. The trial has progressed to phase II, with data on 47 cancer patients presented in 2024 showing positive initial findings. 2023 saw the initiation of a phase III trial in the US, a three-arm, multi-centre, randomised efficacy study using the PLCS, aiming to recruit 777 patients across 25 sites. To date PLCS devices have been placed at 22 clinical study sites across 19 health systems and had accrued 330 patients into the study as of 7th April 2025. Paxman initially placed 6 PLCS devices at each site, delivering onsite commissioning and training, technology adoption support and related resources. Four sites have taken on additional devices to cater for their high recruitment volume and interest from patients to enrol on the study. Read more on CIPN, the PLCS and preliminary trial findings on page 48.

#### Adoption of thermoelectric cooling

Building on previous highly successful collaborations with University of Huddersfield, and integrating the expertise from the University of Leeds, Paxman are utilising state-of-the-art technological advances to develop a wearable medical cooling device that employs thermoelectric cooling for the prevention of chemotherapy-induced peripheral neuropathy (CIPN). The project aims to maximise useability and self-administration, whilst minimising the impact on hospital resources through a human-centred, patient-friendly approach.

Paxman won the SMART Award from Innovate UK to pursue the project in the hopes that this device will address this accelerating and unmet clinical need, enhancing patient quality of life, accelerating returns to work and alleviating CIPN-associated burdens, both in healthcare and the economy.

#### Miniaturisation of cooling technology

Progression of the PLCS has allowed Paxman to investigate smaller and more compact cooling technology. The option to reduce the size of apparatus and therefore the amount of valuable space occupied in hospitals and cancer centres could have significant impact – removing additional barriers to cryotherapy adoption and implementation by making cooling more accessible and serving more patients without taking up additional room. Miniaturisation of the technology also paves the way for simultaneous limb cryocompression alongside scalp cooling to offer a more comprehensive chemotherapy side effect management solution.

Paxman continues to explore this area of vast potential with the eventual goal of developing a single device that incorporates both functions.

22 study sites

19 health sytems

330 patients accured

Phase III US trial

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# New cooling cap technology

As demand for scalp cooling has risen across the globe, so has the demand for Paxman scalp cooling caps and covers. Continuous development of the cooling cap has been central to Paxman's approaches since the business began. Continuous feedback from clinical and patient users of the caps has ensured that improving efficacy and usability has been prioritised. The current cap and cover, launched in 2017, factored in the need for a robust but lightweight cap, with an improved fit that would suit as many of the head shapes found across the world as possible. The cap also needed to be suitable for both single-use and regular use markets.

While the current cap and cover have seen a notable improvement in fit, which has improved scalp cooling outcomes for patients, as well as easier utilisation, there are a number of areas that Paxman are keen to improve on. Utilising the medical design expertise within the University of Huddersfield's award-winning product design team. Paxman launched a project to explore ways to improve the cooling cap and cover, to factor in sustainability and the best possible fit for all head shapes and sizes. With a heavy focus on innovation, advanced design and development, and technical material research Paxman have continued this project in collaboration with The University of Leeds to see it through to completion and subsequently release to the market.

This innovation ensures that scalp cooling treatment efficacy will be maximised through single-patient caps, promoting optimised cap fit and increasing treatment success.

Crucially, this project will also address the environmental impact associated with increased demand of this single-patient medical devices. The current cap is manufactured from silicone, the cover is produced from neoprene, neither of which are biodegradable. The focus on eco-design promotes a circular economy approach, extending the lifecycle of products and minimising the cap's end-of-life impact.

As we draw closer to the completion of this project, we look forward to the impact it will make, not only on patient experience but limiting the impact on the environment of increasing access to scalp cooling.

# Topical agent to improve scalp cooling efficacy

While scalp cooling efficacy has made significant improvements over the last decade, scalp cooling is not a perfect process, and even the patients with the highest levels of hair retention at the end of treatment will experience some level of shedding as a normal part of the treatment.

Paxman have been working with Dr Nikolaos Georgopoulos, formerly of the Paxman Research & Innovation Centre and now Sheffield Hallam University, to develop topical formulations which will aim to minimise or prevent chemotherapy-induced alopecia in conjunction with scalp cooling, improving patient experience and confidence in scalp cooling. The formulations use lipid nanoparticles with the ability to deliver antioxidants (AOs) to the hair follicle region in the skin, used as a precursor to scalp cooling.

During its final stage, the project focused on completing the development of the production of nano-particulates for the formulation of a panel of three reactive oxygen species (ROS) inhibitors (AO1, AO2 and AO3) using a range of formulations to encapsulate these ROS inhibitors/AOs for optimised skin delivery. These are AOs for which we have extensive laboratory (in vitro) data, proving their ability to prevent hair follicle cell cytotoxicity when used in conjunction with cooling against a variety of chemotherapy drugs.

# Main results of the experimental work

Two AOs (AO1 and AO2) were successfully incorporated into nanostructured lipid carriers (NLCs), which are robust and stable formulations (stable over a 6-month period at 4°C). The NLPs exhibit the correct size and surface properties, such as electrical charge, to successfully reach the hair follicle.

Our experiments confirmed efficient skin permeation and AO targeting, with the NLCs successfully delivering the required amount of AO to the follicular area within less than 6 hrs of application. AO1 remained highly stable upon delivery to follicles and was present more than 24 hrs post-application and even following formulation of AO1-loaded NLCs using different concentrations of AO, particle characteristics remained optimal. This formulation method was suitable for encapsulation of AO2 and its delivery to the skin hair follicle area, and these observations are confirmed to be fully in line with the findings for AO1.

Notably, in addition to the NLP-based approach, excipients commonly used in hair serum products were tested, and such preparations for AO1 were tested in vitro. Although the serum-type product exhibited lower efficacy in skin permeation compared to the nanoparticle platform, in the team's studies, serum formulations were more efficient in targeting the follicle area compared to AO solution only as shown in controls.

Finally, as we took into consideration the chemical properties of each individual AO, bespoke formulations were designed, particularly for AO3, to efficiently deliver all AOs. As AO3 has different properties to the other AOs, being more hydrophilic, a different approach was required for formulation. This was shown to be successful, and the AO was stable. However, for more efficient formulation and delivery to skin, the AO would be amenable to other type of liposomal products and polymeric nanoparticles.

# Implications of the results for future development

The successful formulation of a panel of AOs paves the way for a new era of scalp cooling-based patient care. The highly efficient delivery of the AOs, whether by nano-formulation or a serum-based product, combined with our knowledge that these AOs, in conjunction with

cooling, can suppress or prevent toxicity to hair follicles under conditions when cooling may not adequately protect, can 'transform' the efficacy of scalp cooling. The ability to deliver AOs of different properties and efficacy to cryoprotect against different drugs, provides application flexibility and raises the prospect of chemotherapy drug-specific approaches

The experimental evidence for rapid (less than 6 hours) delivery of the AOs to the hair follicle area has practical implications for clinical use of the topical products, and combined with the stability of the AO in the skin (more than 24 hrs) provides strong supportive evidence that clinical delivery to patients can not only be achieved in time for chemotherapy infusion but also, post infusion, the AOs remain in the hair follicles and will continue to protect.

Therefore, the formulations may not only dramatically enhance the efficacy of scalp cooling in protecting from hair loss, but also significantly accelerate recovery post chemotherapy treatment.

Paxman now looks to move forward with the advancements made by Dr Nikolaos Georgopoulos and his team, with formula optimisation of the Nano Lipid Carrier now underway with a chosen commercial partner to make this research a reality.

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# **CIPN**

# What is chemotherapy-induced peripheral neuropathy?

Chemotherapy-induced peripheral neuropathy (CIPN) is damage caused to the peripheral nervous system that carries messages between the brain, the spinal cord and the rest of the body, as a result of chemotherapy treatment. Sensory side effects are caused when nerves in the most distal parts of the limbs are damaged – the hands and feet.

Symptoms manifest themselves as deficits in sensory, motor and/or autonomic functions of varying intensity and they can significantly reduce a patient's functional quality of life. Patients may experience numbness, tingling, altered touch sensation, gait and balance disturbances, burning pain, thermal allodynia or hyperalgesia, impaired vibration sense, extreme temperature sensitivity, paraesthesia, and/ or dysesthesia. Although less common, motor symptoms can also occur including cramping, distal weakness, difficulty handling small objects, and impaired movements. In severe cases, motor symptoms can lead to complete immobilisation and severe disability. A patient experiencing CIPN symptoms may have difficulty performing daily functions such as walking, dressing themselves, writing, typing, and other activities related to the hands and feet.

The prevalence of these symptoms is usually highest in the first month after the completion of chemotherapy at 68.1%, but as many as 41.22% of patients still report chronic CIPN symptoms (three months after the completion of chemotherapy). Patients treated with platinum-based agents and taxanes exhibited the highest prevalence of chronic painful CIPN at 40.44% and 38.35%, respectively. CIPN is predicted to effect 1.4 million cancer patients annually worldwide. It also contributes to significantly increasing economic burden in terms of healthcare costs estimated to be US\$ 17,344 more in cancer patients with CIPN than those without.

There are currently no known treatments to prevent or reverse CIPN. Several pharmacological agents have been developed yet none have proven effective in large-scale clinical trials. To date the most effective treatment for peripheral neuropathy is to prevent further damage to the nerves by lowering the chemotherapy drug dose, or even stop the treatment altogether. Reduction or cessation of treatment is something that both clinicians and patient alike are keen to avoid. Cryotherapy and compression have shown significant potential in preventing CIPN, with preventative cryotherapy gaining prevalence. Studies have shown that cryotherapy could be a valuable tool in preventing CIPN, but there is an urgent need to develop a medical device that can deliver consistent cooling, since there are limited options for patients at present.

# The National University Hospital / National University of Singapore Trial

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 PLCS 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. to evaluate the safety and efficacy of the PLCS device in preventing CIPN in 80 patients receiving any taxane-based chemotherapy. By the end of 2023, 47 patients had been enrolled

Initial findings from phase I of the trial in Singapore were positive and promising. Concomitant scalp and limb cryotherapy during chemotherapy was found to be safe and feasible.

Dr. Rachel Wong, a clinician working on the study, presented further preliminary data from phase II of the trial at the MASCC Annual Meeting in June 2024. Dr. Wong reported data from 47 patients, the majority of which (79%) completed all planned treatments with cryocompression. Wong reported that limb cooling was well tolerated at 11°C, even with concurrent scalp cooling (applicable to one third of the patients studied). More than half (57%) of patients completed all planned treatments without any dose reduction or delay of taxane chemotherapy. Only 8% of patients required dose modification of their chemotherapy drugs due to CIPN.

Equally important in her findings from June 2024, 65% of patients did not experience CIPN, whilst just 32% developed Grade 1 CIPN; 50% of which were transient. Only 15% of patients experienced clinically meaningful CIPN at the end of chemotherapy treatment, with just one patient developing grade 2 CIPN.

These results show how important extensive data from phase three of the trial will be to further confirm these findings as well as providing extensive data from such a sizeable cohort to enable rigorous data analysis. A publication with further data on this trial is due for publication later this year.

#### **Key information**

**3** sites

**80** patients

**47** patients enrolled in the study to date

**79%** completed all planned treatments with crycompression

**Single-arm study** on safety and efficacy

#### The use of limb cryocompression:

- Is safe and well-tolerated in patients receiving taxane-based chemotherapy
- Can be safely and feasibly administered with scalp cooling therapy
- Shows promising data in preventing taxane-based CIPN with no significant change in sensory scores reported
- Facilitates the effective dose delivery of taxane-based chemotherapy
- Preserved CIPN-20 Quality of Life scores at 3 months post taxane chemotherapy
- Did not cause core hypothermia during a 3-hour observational period

Only 15% of patients experienced clinically meaningful CIPN at the end of the chemotherapy treatment, with just one patient developing grade 2 CIPN.

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# The US SWOG S2205 ICE **COMPRESS Trial**

SWOG S2205 ICE COMPRESS, a phase III, three-arm, multi-centre, randomised efficacy study supported by the National Cancer Institute in USA, together with cooperative research group (SWOG) and funded by the National Cancer Institute, was initiated in 2023. The trial plans to recruit 777 cancer patients across a minimum of 25 sites.

The study will compare the proportion of participants who develop clinically meaningful CIPN at 12 weeks, in participants treated with taxane-based chemotherapy, randomised into three arms: cryocompression therapy, continuous compression therapy and low cyclic compression therapy administered via the PLCS devices. Low cyclical pressure serves as a control.

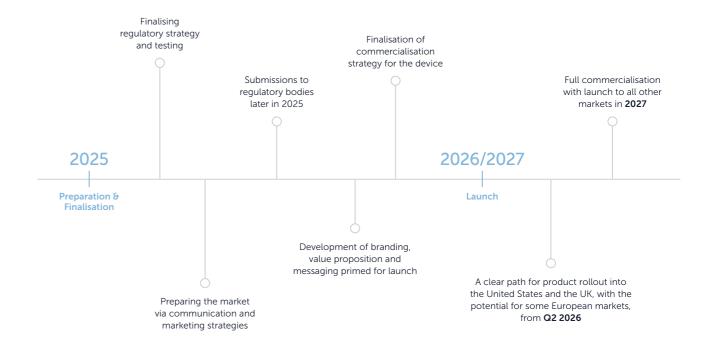
To date, the PLCS devices have been deployed in 23 sites accruing 330 patients as of April 2025. The study is being supported by Paxman: providing six PLCS devices to each site, delivering onsite commissioning and training, technology adoption support and related resources. Four sites have taken on additional devices to cater for their high recruitment volume and interest from patients to enrol on the study. The study will continue to accrue patients over its 2.5-year period and each patient will receive follow-ups for 52 weeks following treatment commencement.

**Product Useability and Regulatory** Pathways

A trial of such significant size, along with early feedback from the SWOG trial, has provided an opportunity to collect information beyond that which reflects on patient experience.

The phase II trial in Singapore has provided us a clear regulatory pathway for 2025. A trial of such a significant size, along with early feedback from the SWOG trial, has provided an opportunity to collect information beyond that which reflects on patient experience. Research teams have also taken the opportunity to gather highly valuable quantitative and qualitative device usability data from stakeholders (patients, nurses, device administrators). The enhanced product development that comes from this feedback will ensure that the product is not only effective but simple to use and will increase the likelihood of buy in and adoption from clinical teams and ensure that implementation of the device, once commercialised, is smooth and has longevity. Alongside this work, a clear regulatory strategy has been created with the correct timing of deployment in consideration.

2025 is set to be a busy year. After a design freeze commitment in February 2025, the transition from research and development to regulatory has begun. Work will now commence with a focus on key regulatory jurisdictions and subsequent commercialisation in the USA, Europe, the UK, and Singapore. Appropriate regulatory testing has now commenced with a completion date expected in Q3 2025. Following the medical device testing, submissions to both the US and European/UK authorities shall commence with an expected clearance date in February 2026 and April 2026 respectively. Product launches are currently being planned for Q2 2026 with a key focus on the USA.



Four sites have taken on additional devices to cater for their high recruitment volume and interest from patients to enrol on the study.

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Articles

Clinical Studies & Collaborations



# Clinical Studies & 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.

#### Importance of clinical trials

Clinical trials are essential for advancing medical science by testing new treatments, therapies, and interventions in a systematic and regulated manner. These trials are essential for determining the efficacy, safety, and potential side effects of new medical approaches. Trials have also been conducted to elucidate topics such as best protocols, determinants for efficacy, tolerance and more to give a deeper understanding of scalp cooling. Studies have also investigated the efficacy of scalp cooling beyond retention, notably the regrowth benefits and the prevention of persistent chemotherapy-induced alopecia – awareness of which is growing among patients. There are now over 80 published papers on scalp cooling via scalpcoolingstudies.com alone. As more clinical evidence becomes available, it is important that underrepresented populations are also studied

#### Recently published studies of significance

Recent months have seen the publications of two important studies into scalp cooling. Firstly, a South Korean paper titled 'Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial' by D. Kang et al., published in the Journal of Clinical Oncology, found that scalp cooling helped to prevent PCIA by increasing hair thickness and was found to be helpful in promoting qualitative hair regrowth. This study has significant implications, meaning that scalp cooling should be offered to patients who are eligible and despite any unwanted hair loss, should continue with treatment to preserve the follicles for regrowth.

Whilst not in a clinical setting, The Dutch Scalp Cooling Registry by T.S. Brook et al. And published in The Oncologist, is a valuable study that uses realworld data to fi nd determinants for the efficacy of scalp cooling. It is the largest global study of its kind. With data on 7,424 patients, it is highly valuable and found that only chemotherapy regimen and dosage affected patient outcomes, concluding that further study is required. In order to accelerate advances for individual patient care, the true determinants of scalp cooling efficacy need to be understood, which could be achieved through biomarkers such as scalp skin temperatures.

#### A full list of ongoing studies into scalp cooling and limb cryocompression can be found at scalpcoolingstudies.com

The Scalp Cooling Study Library unites key clinical research studies and data to provide an overview of global research and practice on scalp cooling and cryotherapy for chemotherapy side effect management.

#### Ongoing Clinical Trials

Aside from the ongoing clinical trials into CIPN, as outlined on page 48-50, there are currently a number of ongoing trials into scalp cooling.

### Scalp Cooling for Chemotherapy-Induced Alopecia in Patients of Color

Location: Montefiore Medical Center

This study evaluates the effectiveness of scalp cooling in patients of colour receiving chemotherapy for breast or lung cancer. Due to limited representation and reduced efficacy in prior studies, the research focuses on techniques to improve scalp cooling for hair types 3 and 4, aiming to increase contact with the cooling cap. It also investigates the molecular mechanisms behind persistent alopecia by following patients up to 6 months after completing final treatment. The study will enrol an estimated 30 participants.

#### Study of Cold Cap Therapy for Prevention of Hair Loss in Paediatric Patients

Location: St. Jude Children's Research Hospital

This study examines the safety and feasibility of using the Paxman scalp cooling device to prevent hair loss in paediatric patients receiving chemotherapy for non-cancerous conditions or solid tumours. The primary focus is on assessing hair loss incidence and intensity, with an estimated enrolment of 40 participants.

### Prevention of Alopecia in Patients With Localised Breast Cancer (ICELAND)

Location: Centre Francois Baclesse, Caen, France

This study aims to strengthen the evidence on preventing chemotherapy-induced alopecia (CIA) in France by evaluating the effectiveness of two scalp refrigeration techniques during anthracycline- and taxane-based chemotherapy. The study will assess not only the prevention of hair loss but also the impact on patients' quality of life, self-image, and satisfaction with care during and after treatment. Additionally, the study will analyse the cost-effectiveness of each refrigeration method, with the results intended to guide the selection of the most appropriate technique for CIA prevention. Estimated enrolment is 196 patients.



## Japan

Articles

As the world's second-largest market for cancer care, with over 1 million new cancer cases per year, Japan has continually delivered great results for the business with over 180 systems installed since launch and over 1,100 caps sold to the market in 2024. Paxman has maintained a presence within the country since 2019, working with Century Medical Inc. (CMI).

The Japanese business model revolves around capital equipment being provided to healthcare systems either via sales or a rental agreement through our distributor, with single patient caps sold to patients via hospitals or pharmacies.

CMI's parent company is Itochu, one of the largest Japanese general trading and investment companies, with a management philosophy of "Sampo Yoshi". It translates as "good for the seller, good for the buyer, and good for society." – a philosophy that draws its origins from the 13th and 14th centuries and one that aligns with Paxman's mission. Valued support from Itochu has resulted in a Paxman case study, featured in course material at Harvard Business School.

#### Clinical Pioneer Programme Rollout

The distribution partner in Japan began delivering Paxman's Clinical Pioneer Programme to Japanese clinical staff in 2024. The CPP enables individuals at cancer centres to become the subject matter expert on scalp cooling and a certified super user. This allows an individual to effectively lend best practice advice and disseminate key information to colleagues and peers on scalp cooling. By helping to increase the knowledge with which to execute scalp cooling correctly, it ensures the best possible patient outcomes. Working closely with Paxman, the distributor uses its valuable cultural perspective and in-market knowledge to localise this important training for a Japanese audience.



#### Exhibition at 32nd Annual Meeting of the Japanese Breast Cancer Society

Paxman and its partner, CMI, participated in the Japanese Breast Cancer Society Annual Meeting, held in Sendai in July 2024. Exhibiting Paxman's scalp cooling technology, the company engaged with the Japanese medical community, highlighting the benefits of the system in preventing chemotherapy-induced alopecia.

A seminar was held on Saturday, July 13th, a highlight of the event, attended by over 100 delegates. The seminar, titled "Chemotherapy and Prevention of Alopecia - Scalp Cooling and Prevention of Permanent Hair Loss," featured insightful presentations by Dr. Takao from Konan Medical Center, Dr. Kikuchi from Kitazato University, and Mrs. Maeda, an oncology nurse from Kami-lida Hospital. These experts shared their knowledge and experiences with scalp cooling, emphasising its importance in supporting the well-being of patients undergoing chemotherapy.

The conference in Sendai proved that scalp cooling is a hot topic in the oncology space. In addition to the seminar, there were seven poster presentations directly related to scalp cooling.

## China

China is, at current, a vast market with untapped potential for scalp cooling technology due to its high cancer burden. As the world's most populous country, it also has the world's highest incidence of cancer cases, with over 4.8 million reported in 2022. China's healthcare sector is rapidly expanding, with rising investment in innovative treatments and supportive care solutions. These factors create a compelling market landscape for scalp cooling technology.

Recognising this, Paxman signed a letter of intent with a Chinese marketing and distribution partner in April 2022, in order to effectively leverage their cultural and linguistic advantages in the market. A distribution agreement was subsequently finalised, and the company is now following the NMPA regulatory pathway, where testing is ongoing, and a clinical trial expected to follow.

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## South Korea

A presence in South Korea was established in 2020 with significant progress made in the years since. In December 2020, a large clinical study was initiated at the prestigious Samsung Medical Centre which led to market clearance being granted in November 2022. Working with our partner in the region, Humost, a new technology assessment was completed in January 2025, following a lengthy regulatory pathway which eventually resulted in trade approval from March

A press conference is planned for April 2025 and work on reimbursement options and determination of the business model will begin immediately afterwards. Paxman has plans in place to expand the indication of the device to all solid tumours, as the company has done in other markets across the world

#### A South Korean study into PCIA

In 2024, a study titled 'Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial', by D. Kang et al. was published in the Journal of Clinical Oncology. This randomised trial was conducted at the Samsung Medical Centre, Seoul, to evaluate the efficacy of scalp cooling in reducing persistent chemotherapy-induced alopecia (PCIA), 6 months after chemotherapy, using the PCSC2.

and August 2021, the study evaluated 139 patients who were randomly assigned groups, at a 2:1 ratio; scalp cooling or usual clinical practice (control group). Their hair thickness and density were

Conducted between December 2020 measured 6 months after chemotherapy. The study results were highly influential on the granting of market clearance in 2022.

For more information, and how Paxman used the study as the basis of a marketing campaign, see page 27-28.

Significantly reduced the incidence of PCIA

01.

02.

Promoted faster recovery of hair density & thickness

03.

Reduced psychological distress and improved quality of life

Results of the South Korean study

# Singapore

Paxman has developed close ties with Singapore through its collaboration with The National University of Singapore and has connections with a number of key opinion leaders and leading clinicians from the National University Cancer Institute, such as Dr. Joline Lim. Her and her team have been instrumental in the proliferation of public scalp cooling in the country, with 18 systems installed across 10 locations, including several Icon and Mount Elizabeth hospitals.

Working alongside Dr. Lim, Paxman's Regional R&D Manager, Dr. Aishwarya Bandla, is also a key figure in the development of Paxman's Limb Cryocompression System and the current trial taking place in Singapore. For more information on CIPN and the Singapore trial, see page 49.

#### A study into scalp cooling in Asian populations

The initial installation of the PSCS, and subsequent training, at the National University Cancer Institute, Singapore and Icon Cancer Centre has allowed the university to publish a study on scalp cooling efficacy in Asian patients. The study, published in 2024, aimed to address the underrepresented Asian population in scalp cooling efficacy clinical trials and focused on preventing chemotherapy hair loss in patients with breast or gynaecological cancers. The study used the Paxman Scalp Cooling System to deliver efficacy results with similarities with other publications such as The Dutch Registry.

Results show that 50% of patients achieved scalp cooling success, with patients on taxane regimens demonstrating a 64% success rate. With 94% of patients reporting a reasonable comfort score or above, and 91.7% experiencing more than 50% hair regrowth by the end of their chemotherapy, the study concluded that scalp cooling is a valuable option the management of chemotherapyinduced hair loss.



91.7%

of patients experienced more than 50% hair regrowth by the end of their chemotherapy

94%

of scalp cooled patients reported a resonable comfort score or aobve

Studies across different ethnic populations not only prove clinical efficacy and open up regulatory pathways but increase the confidence of customers and patients in the Paxman Scalp Cooling System, opening up more opportunities for business growth.

#### **ESMO** Asia

ESMO Asia is an annual congress specifically focused on multidisciplinary oncology in the Asian region. The event, held in Singapore for 2024, brings together oncologists, researchers, healthcare professionals, and industry representatives from Asia and around the world.

With strong intentions to work on expansion into the region, Paxman attended the event for the first time with an exhibition stand, offering attendees to try the scalp cooling system, and providing important data on scalp cooling relevant to the Asian market.

The Paxman team crossed paths with Dr. Joline Lim of the National University Cancer Institute in Singapore, and a key figure in Paxman's development of the PLCS for peripheral neuropathy. Joline spoke about the recent study on scalp cooling in Asian populations conducted by the National University Cancer Institute, Singapore and its importance. Dr. Raghav Sundar, from the School of Medicine at Yale University, also shared his perspective on scalp cooling at the event, having worked with Paxman many times in the past. He endorsed Paxman's work to increase utilisation within Singapore and Asia as a whole, acknowledging the positive progress made to provide patients with better supportive care.

Paxman looks forward to pursuing the growth opportunities from this event and fostering the connections made with both potential new customers, distributors and key opinion leaders.

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General Targets & Outlook



# General Targets & Outlook

The company's long-term goal is that all patients undergoing chemotherapy shall have access to Paxman' chemotherapy side effect management technology, no matter their financial situation, gender, age or ethnicity, and that these devices will be the first choice for cancer patients all over the world.

Paxman is the superior global market leader for scalp cooling with over 6,000 sold and/or installed systems in Europe, North-, Central- and South America, Asia and Oceania.

#### For 2025 and beyond, Paxman's efforts are centred around the four following key targets:

#### Reimbursement in the US

With significant progress made in 2024 (see page 33) Paxman is placing a strong focus on the US market and reimbursement through the three key pillars of insurance: coding, coverage and payment. The reimbursement work will drive utilisation for 2025, but our key focus is preparing for 2026 onwards, when CPT I coding comes into effect (1 January 2026).

#### Coding

Applicable nationwide, this coding necessitates education, awareness and preparation. Initially, education and awareness will drive and/or expedite transitions from to the IBBM from either the self-pay model or to incorporate the new CPT I codes. It is important that clinical teams are well equipped to handle inevitable increases in utilisation as a result of the coding. Likewise, awareness and education for patients is equally important to ensure better and more equitable levels of scalp cooling access, less constrained by individual financial limitations.

#### Coverage

The company will be working closely with Centers for Medicare & Medicaid Services (CMS) and local Medicare Administrative Contractors (MACs) on securing further Local Coverage Determinations (LCDs) to expand coverage, alongside positive bulletins. Paxman will also work on commercial payer outreach to set clear coverage policies.

#### **Payment**

Paxman will again work with CMS to support appropriate pricing for the three codes (9X001, 9X002 and 9X003) following the AMA CPT meeting to ensure that insurance coverage provides sufficient reimbursement.

#### International Growth

In addition to the United States, expansion into other regions such as Asia and the Middle East have become increasingly important for the company whilst doubling down on our efforts in Europe and South America.

Paxman will continue to seek and develop new opportunities in its direct markets (UK, France, Spain, Germany, India and Scandinavia) whilst simultaneously working closely with our global distribution partners to drive growth, including key markets such as Japan and South Korea and the Middle East.

Japan has led the Asia market since 2019 through collaboration with the distributor CMI. Plans for South Korea are now coming to fruition after a new technology assessment was completed in January 2025 alongside the distributor, Humost, which resulted in trade approval, starting 1st March 2025. A distribution agreement with Concord Medical for a launch into the very large Chinese market has also been finalised. Paxman are now following the NMPA regulatory pathway, where testing is ongoing and a clinical trial is expected to follow, before full commercialisation in the market.

Paxman has welcomed further additions to its sales and marketing teams in pursuit of further international growth. Sales manager, Bryn Tudor-Owen, focused on growing sales in the Middle East was recruited in 2024, joined in 2025 by two regional sales managers: David Heathcoate will oversee European sales whilst Gregory Godeau will cover Latin America & the Association of Southeast Asian Nations. The team will also be supported by an International Marketing Manager who will take ownership of local marketing initiatives for individual distributor markets in line with Paxman's overarching marketing strategy.

#### CIPN Commercialisation

Paxman Limb Cryocompression System (PLCS) devices have been deployed to over 20 clinical study sites for efficacy studies in Singapore and the United States. Results for the trial in Singapore have shown promising results and suggest that concomitant scalp cooling is also possible (see page 49).

Paxman is now working to a timeline with which to commercialise a device

to prevent chemotherapy-induced peripheral neuropathy (CIPN) – a currently unmet need in cancer care.

The timeline is as follows:

#### 2025 - Preparation and Finalisation

- Finalising regulatory strategy and testing
- Preparing the market via communication and marketing strategies
- Development of branding, value proposition and messaging primed for launch
- Submissions to regulatory bodies later in 2025
- Finalisation of commercialisation strategy for the device

#### 2026 / 2027 - Launch

- A clear path for product rollout into the United States and the UK, with the potential for some European markets, from Q2 2026.
- Full commercialisation with launch to all other markets in 2027.

# Transition to a multi-product company

Paxman's ambitious research and development and dedication to improving cancer care interventions has led the company to explore new applications for our expertise in cryotherapy. With the launch of the device to prevent CIPN, Paxman no longer centres itself around a single product.

As a result, the year ahead requires the development of a clear and differentiated brand positioning towards the side-effect management space – an exciting challenge when combined with growth plans for scalp cooling. The new branding and positioning will also make considerations for additional medical device products in the future, whilst maintaining patient centricity at the core of the company.

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Paxman and its People



# Paxman and its people "Together, we have not only around shomethors around showether around

"Together, we have not only changed the conversation around chemotherapy-induced alopecia but have also advanced the broader mission to improve the overall experience of cancer treatment."

What began as a husband's goal to help his beloved wife, Sue, hold on to a part of herself during chemotherapy, has transformed into a global mission, offering privacy, normality, emotional wellbeing and a degree of control to hundreds of thousands facing the same battle.

Sue was the spark that ignited more than just a business, but a movement – one that never would have been possible without the passionate, dedicated and skilled people who have joined the Paxman family in a shared goal that began all those years ago.

Paxman is profoundly grateful for the many clinicians, patient advocates and researchers who have stood alongside us over the years, leading to the proliferation of scalp cooling awareness and adoption. Together, we have not only changed the conversation around chemotherapy-induced alopecia but have also advanced the broader mission to improve the overall experience of cancer treatment.

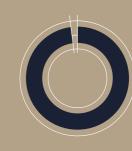
#### **Engagement survey**

Paxman is committed to fostering a vibrant, positive company culture and values the perspective of its teams. Consequently, the company regularly gains feedback from its people with an annual engagement survey, disseminated every November.

The surveys have been a useful tool in understanding the unique fabric of Paxman's organisational culture. Results can often lead to new company initiatives, aimed at supporting employees, growing their knowledge, and allowing them to thrive. The 2024 survey delivered an outstanding result of 90% engagement and allows the company to gauge the success of its initiatives and company culture. The national benchmark for similar sized companies is 73%, demonstrating a highly engaged business.

85% 88% 89% 90%

Overall engagement score



98% understand how their work contributes to Paxman's success

88% believe that senior

00000

9/10 are satisfied with Paxman's efforts to increase understanding of diversity  $\vartheta$  inclusion



89%

igree that Paxman cares about their wellbeing 91%

would recommend
Paxman as a great
place to work

4/5

agree that they are valued at **Paxman** 

91%

eel they belong at **Paxman** 

9/10 are satisfied with he flexibility they have in their work schedules

98%

agree that **Paxman** cares about their wellbeing



84%

agree that their manager supports and encourages their development



2025 Area of Focus

62%

feel there is good ommunication between different teams and departments 97%

are proud to wo for **Paxman** 



91%

agree that Paxman values and supports Diversity & Inclusion

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Section Artciles

Paxman and its People

**60** women employed

15 female managers including SLT

male managers including SLT



# Investing in people

Paxman is committed to learning and development within the organisation and is part of the West Yorkshire Combined Authority Fair Work Charter. It is designed to promote and recognise the positive impact of fair work on businesses and their people. Fair work can include good pay, fair and flexible working conditions, as well as greater wellbeing, diversity, and social mobility within the workplace. Its core pillars are centred around employee voice, fulfilment, opportunity, wellbeing and security.

Paxman believes strongly in investing in its people and continues to run its Paxman People Pathway (PPP) to allow individuals to deliver their best work, supporting them to achieve their personal career goals within the business. It is important that people at Paxman are valued and feel satisfaction in their roles and work. With the PPP, colleagues can see how their targets and professional development contribute to the wider business objectives.

Paxman has also invested in tools provided by Predictive Index that allow individuals and their managers to better understand their preferred methods of working, identify areas for self-improvement, minimise conflict, increase engagement and retain employees. The tools will also allow managers to more effectively identify a positive cultural fit for new and open roles, ensuring they have the ideal profile and aptitude to perform the role.

# Team building on an international scale

In November, the entire Paxman group came together for a week of learning, collaboration and celebration. It is the first time in the company's history that this many colleagues were present at the same time, with teams visiting Huddersfield from the United States.

Canada, France, Spain, Germany, India, Sweden and Singapore.

Alongside learning together in a large and informative session about the science behind breast cancer, the entire Paxman team participated in a day of team building activities that saw them navigate challenges requiring teamwork, communication and cohesive coordination. Activities such as this allow for a deeper connection between colleagues, giving individuals a chance to foster new connections, and ultimately increase collaboration and a sense of family – the very foundation on which Paxman was built.

With these new connections and a clearer understanding of the valuable role each individual plays within the business, the team celebrated another year at Paxman in the form of the annual Christmas party. This week in late November was incredibly valuable in bringing a physically distant team as close as they could be.

#### Supporting the community

Paxman allows its people to take a paid volunteering day once a year to give back to the community in a capacity that the individual feels passionate about. In addition to individual volunteering, the business assists Holmfirth High School in preparing their pupils for the world of work. Paxman colleagues have dedicated time to supporting pupils through mock interviews, helping them to gain important life skills and positively impacting future generations' careers.

Paxman hosts a number of students in work experience roles every year. Teams such as R&D also participate in presentations to students giving them valuable insight into what their studies can help them achieve in the workplace.

Paxman also supports local and national charities including Forget Me Not Children's Hospice, The Kirkwood Hospice, Project Youth Cancer and The Howarth Foundation.

#### Healthy body...

Healthy colleagues contribute to a healthy business. Paxman therefore understands that employee fitness is key to future prosperity and invests in initiatives to encourage the people at Paxman to challenge themselves and stay healthy.

2024 saw Paxman employees participate in the following:

- Yorkshire Three Peaks Challenge a 24-mile (38.6km) route which included 1,585m of ascent, raising over £3,800 for Paxman's affiliated charities.
- A company-wide challenge placing participants into teams to compete for the most combined distance covered (walking, running or cycling).
- Regular, organised lunchtime walks in the summer months

#### Healthy mind

Mental wellbeing is just as important as physical wellbeing. As such, the business has expanded on its duty of care to encompass mental health support. Monthly mental health drop-in sessions have been available for some time, and this continues to help people feel supported in the crossover between work and wellbeing.

In addition, the company benefits from quarterly seminars and support from external speakers, each session delivering relatable wellbeing support. In 2024, employees had the opportunity to learn more about developing healthy routines, managing anxiety and depression, sleep hygiene, healthy eating and how to deal with grief.

# A diverse and inclusive place to work

At Paxman, we believe in the power of inclusivity and representation and wish to ensure that anyone who wishes to access to scalp cooling can. That belief extends to our internal activities, fostering an inclusive environment where diversity is embraced and celebrated. Gender equality is a core element of the Paxman ethos, as we continually strive to recognise and celebrate the achievements of women within the business. Currently, 60 women contribute to our success, led by a female-majority Senior Leadership Team (SLT) and management.

Throughout 2024, Paxman was proud to facilitate a number of presentations by guest speakers around diversity and inclusion with topics on Pride and the LGBTQ+ community as well as how our values, morals and opinions can affect the workplace.

2024 saw the launch of a quarterly support group aimed at neurodivergence, introducing colleagues to its many forms such as autism, ADHD, dyslexia and dyscalculia, how these impact people in the workplace and how to support them best.

Initiatives such as these help refine our culture of respect and acceptance and allow the company to work more cohesively as an international team. It opens us up to new perspectives and improves decision-making capabilities. Moreover, diversity  $\vartheta$  inclusion initiatives make Paxman a more attractive place to work and do business with. The business is already reaching out to other guest speakers for further diversity and inclusion education sessions in 2025.

#### Cultural insights

As an international business, our colleagues often communicate across both geographical borders and cultural or linguistic boundaries, to achieve success. In 2024, we continued to our initiatives that allow employees to deepen their understanding of the cultures that are represented within Paxman.

# More responsible manufacturing

In alignment with the company's environmental and social commitments, the Paxman design team continue to explore new and innovative approaches to manufacturing, emphasising the use of sustainable and recyclable materials. This collaborative effort, spanning two years and conducted in partnership with the University of Huddersfield, is nearing a promising and positive outcome. Paxman anticipate that the results will not only advance the sustainability of production processes but also enhance the cap quality for the benefit of patients in the future.

Paxman works very closely with the UK's National Health Service (NHS) with 99% coverage in the country. The company is therefore working towards an environmental policy that aligns with the NHS Carbon Footprint targets. Their targets are as follows:

- For emissions under direct control, the NHS will reach net zero by 2040, with an ambition to reach an 80% reduction by 2028 to 2032.
- For the emissions under their influence, the NHS will reach net zero by 2045, with an ambition to reach an 80% reduction by 2036 to 2039.

Paxman is addressing manufacturing and sustainability challenges through innovative approaches such as a focus on eco-design and circular economy principles to advance technological limitations and help reach the outlined targets. Paxman has also undertaken building and renovation works where possible to improve energy efficiency and accessibility to manufacturing and office premises.

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Yearly Reporting



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

# Management Team



Richard Paxman, OBE

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 H

Holding: 1,268,000 shares



**Emelie Gustafsson** 

CFO since March 1st, 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

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Our People

# **Board of Directors**







#### Per-Anders Johansson

Member 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: 941,809 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: 33,212 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 servicebased 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

Born: 1947 Holding: 347,865 shares

#### 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: 4,356,386 shares





#### Richard Paxman, OBE

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: 1,268,000 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. She 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 Hoseth Biocare AS, and CEO in EpiEndo Pharmaceuticals.

Born: 1968 Holding: 4,200 shares held directly and 4,500 held

through the company Bech Pharma Consulting AB Karen Clakeley

Member of the board since May 23rd, 2024

Karen Clakeley has a distinguished career of over 35 years as a senior sales executive and turnaround leader, most recently serving as Executive Director of Market Development at Hart InterCivic. She has extensive experience in sales strategy, customer experience, marketing, product management, and organisational development. Previously, she held the position of Vice President of North American Sales at Evervone Counts and managed a \$170M+ portfolio of business at DST Systems. She also has notable experience from her roles at Reynolds and Revnolds and Gaunt, Dore, Snyder, Clakeley.

Born: 1960 Holding: 25,256 shares

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Directors Report

# DIRECTORS REPORT 2024

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 2024.

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

#### Multi-year Summary for the Group

	2024	2023	2022	2021
Total operating income	263,195	220,608	156,745	104,708
EBITDA <sup>1)</sup>	49,726	31,229	16,175	2,882
Operating profit/loss	33,508	12,619	-1,243	-10,587
Profit/loss after net financial items	41,500	7,969	-8,562	-12,670
Balance sheet total	227,231	167,124	173,960	166,341
Assets as percentage of equity 2)	72.2%	73.4%	65.6%	75.6%
Number of employees at end of period	105	91	78	56

## Multi-year Summary for the Parent Company

	2024	2023	2022	2021
Total operating income	2,033	2,207	1,295	244
EBITDA <sup>1)</sup>	-4,347	-3,851	-4,042	-4,171
Operating profit/loss	-4,363	-3,874	-4,065	-4,179
Profit/loss after net financial items	-1,509	-1,151	-2,850	-4,676
Balance sheet total	159,039	160,716	162,320	165,010
Assets as percentage of equity 2)	99.7%	99.6%	99.3%	99.3%
Number of employees at end of period	1	1	1	1

<sup>1)</sup> Earnings before interest income, interest expenses, tax and depreciation.

# Corporate Information

#### The Company

PAXMAN AB (publ), with corporate identity number 559079-3898, was formed as a stock company in October 2016, and its current name and operations were registered on 14 December 2016. The company is a public limited company, and its form of association is governed by the Swedish Companies Act (2005:551). The parent company has its registered office in Karlshamn at Pirgatan 13, 374 35 KARLSHAMN, Sweden. Production and sales are handled by the English subsidiary Paxman Coolers Ltd, International House, Penistone Road, Fenay Bridge, HD8 OLE HUDDERSFIELD, England. The Group also has a subsidiary in the USA, Paxman US, Inc, based in Houston, Texas, and in Canada, Paxman Canada, based in Toronto. All are wholly owned subsidiaries of Paxman Group Ltd, which in turn is a wholly owned subsidiary of PAXMAN AB (publ)

PAXMAN AB has appointed FNCA Sweden AB (tel 08 - 528 003 99, info@fnca.se) as its Certified Adviser.

#### Earnings and Financial Position

- The group's turnover amounted to 253,007 (210,117) TSEK.
- The group's net profit was 40,196 (8,330) TSEK, with profit per share amounting to 2.11 (0.44) SEK
- Consolidated equity as of 31 December totalled 163,994 (122,616) TSEK. The equity/assets ratio for the group was 72.2 (73.4)%.
- The cash and bank balances for the group was 40,310 (24,981) TSEK.
- At year end, the group had 19,969 (17,531) TSEK in external interest bearing liabilities, of which 13,485 (11,038) TSEK were current.
- Cash flow from operating activities amounted to 39,104 (15,632) TSEK, and this year's net investments affecting cash flow to -24,496 (-25,329) TSEK. Cash and cash equivalents increased by 15,329 (-13,111) TSEK during the year.

#### The Parent Company

- The company's turnover amounted to 2,033 (2,207) TSEK.
- The parent company's cash and bank balances amounted to 13,830 (18,013) TSEK on 31 December
- Cash flow from operating activities was -1,341 (-1,664) TSEK. Net investments affecting cash flow for the year
  amounted to 0 (0) TSEK.
- The parent company had 1 (1) employee on the balance sheet date.

 $^{68}$ 

<sup>2)</sup> Adjusted equity as a percentage of total assets.

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#### Significant developments in 2024

In February the Paxman Group has increased its investment from 20% to 49% in Paxman GmbH, working our partner Novidion to relaunch Paxman in the German Direct market. The German market is an excellent opportunity for the company and with the UK company's increased involvement traction is expected to improve through 2024.

In March, Paxman was honoured to receive the Export Achievement Award during the prestigious Medilink North of England Healthcare Business awards, recognising our outstanding growth and success in international markets. Paxman's R&D team were also runnersup for the Partnership with Academia category for our collaborative efforts with academic institutions.

Also in May, the partnership between the University of Huddersfield and Paxman was awarded an outstanding grade from UK Research and Innovation. The award is the culmination of a two-year Knowledge Transfer Partnership (KTP) that designed and developed the Paxman device for the unmet clinical need of chemotherapy-induced peripheral neuropathy (CIPN).

In June, an important paper on persistent chemotherapy-induced alopecia (PCIA) was published. The study showed that scalp cooling reduced the incidence of PCIA primarily by increasing hair thickness and was found to be helpful in promoting qualitative hair regrowth.

In the same month, The Dutch Scalp Cooling Registry was published in The Oncologist – the world's largest realworld study into the determinants of scalp cooling efficacy. The cumulative study now has data from 7,424 scalp cooling patients across 68 hospitals in The Netherlands. You can find out more about this valuable study at:

scalpcoolingstudies.com/dutchregistry

In July, it was announced that Paxman had secured a contract for the provision of scalp cooling systems to the U.S.

Department of Veterans Affairs (VA) for the National Precision Oncology

Program (NPOP). Paxman is partnering with Capri Construction 426 LLC, who were awarded an Indefinite Delivery, Indefinite Quantity (IDIQ) contract, with Paxman as the sole subcontractor. It is projected to be worth \$2.7 million over the contract period which has a base year and four option years spanning 1st July 2024 to 30th June 2029.

Paxman won the SMART award from Innovate UK for its work on a device for the prevention of chemotherapy-induced peripheral neuropathy (CIPN). The project will build on previous highly successful collaborations, between Paxman and the University of Huddersfield whilst also integrating expertise from University of Leeds, extending the collaboration network and strengthening Paxman's developing R&D

team. The project started successfully on

1st October 2024.

Paxman attended the ESMO Congress 2024 & EONS17 along with 34,000 participants from 149 countries in September. As part of EONS17, Paxman sponsored a symposium on 'Achieving successful scalp cooling – the importance of nursing in chemotherapy side effect management'. Filled to capacity, the auditorium heard from nursing professionals, scalp cooling expert Dr. Corina van den Hurk, and Paxman's regional representative in Spain, Begoña Parrado.

In October, Paxman successfully passed its recertification audit. The dedication of Paxman's quality team plays a pivotal role in ensuring we remain compliant with global regulatory standards. This

thorough audit assessed our documented management system processes, as well as documents and records related to the design, development, manufacture, inspection, and servicing of our Scalp Coolers, aligning with key standards such as ISO 13485, MDSAP, and EU MDR.

Later in October the American Medical Association (AMA) issued 3 CPT®
Category I codes for mechanical scalp cooling, effective from January 1st, 2026. This issuance of a permanent CPT® I codes is one of the most significant breakthroughs in Paxman's efforts towards widespread adoption of Paxman's insurance-based billing model.

OPPS Final Rule, this is the Hospital Outpatient Prospective Payment System. Based on the updated claims data available since the proposed rule earlier in the year, the payment rate calculated using their methodology falls within the cost band for New Technology APC 1519 (New Technology - Level 19 (\$1701-\$1800)). Therefore, they are assigning CPT code 0662T to APC 1519 for 2025 as opposed to APC 1515, which was \$1350.50.

On November 1st, CMS published the

On 5th December, Paxman announced that founder and board member Glenn Paxman, CIMON Venture Trust AB (represented by the chairman Per-Anders Johansson) and board members and the board members Björn Littorin and Robert Kelly sold shares in the **company.** All selling parties entered a lock-up agreement for 180 days. In total, the transaction amounted to 2 000.000 shares. Among the new owners are SEB Investment Management, Carnegie Fonder, Aktia Asset Management, and Adrigo Asset Management. The high level of interest in the company is a clear signaller of performance, but more importantly a future opportunity to build a strong profitable business providing a

clear impact socially.

A legislative bill (A38-A/S2063-A) in the State of New York was signed into law on 13th December 2024, requiring insurance coverage of scalp cooling systems to prevent hair loss. The bill is an acknowledgement of the importance of scalp cooling to help reduce and manage chemotherapy-induced alopecia and will highlight and narrow the disparities in access to a treatment.

#### Employees

As of 31 December 2023, the Group had a total of 91 employees, 1 by Paxman AB 68 by Paxman Coolers Ltd, 12 by Paxman US Inc and 10 by Paxman Canada Inc.
As of 31 December 2022, the Group had a total of 78 employees, 1 by Paxman AB, 65 by Paxman Coolers Ltd and 12 by Paxman US, Inc.

#### 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.

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# Proposed Appropriation of Retained Earnings

Retained earnings at the disposal of the annual general meeting

141,048
Retained earnings (TSEK)

-1,509
Profit/loss for the year (TSEK)

The board of directors and the CEO proposes that the retained earnings are to be appropriated as follows

139,539

Caried forward (TSEK)

Paxman's net profit/loss for the accounting year 2024, as well as the company's financial position as at 31 December 2024, are disclosed in the following income statements, balance sheets and cash flow statements.

#### Consolidated Income statement

TSEK	JAN-DEC 2024	JAN-DEC 2023
Operating income		
Net sales	253,007	210,117
Capitalized expenditure	10,188	10,491
Total operating income	263,195	220,608
Operating expenses		
Raw materials and consumables	-87,775	-74,189
Other operating costs	-57,582	-55,849
Personnel costs	-68,112	-59,343
Depreciation and write-downs	-16,218	-18,610
Total operating costs	-229,687	-207,989
Operating profit/loss	33,508	12,619
Results from financial investments		
Other interest income and similar profit/loss items	9,140	13
Interest expense and similar profit/loss items	-1,148	-4,663
Total result from financial investments	7,992	-4,650
Profit/loss after financial items	41,500	7,969
Tax	-1,304	363
Net profit/loss for the year	40,196	8,330
Earnings per share*	2.11	0.44

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

## **Consolidated Balance Sheet**

TSEK	31-DEC 2024	31-DEC 2023
Assets		
Fixed Assets		
Intangible fixed assets		
Development expenditure	38,926	34,157
Total intangible fixed assets	38,926	34,157
Tangible fixed assets		
Plant and machiner	38,355	35,878
Equipment, tools, fixtures and fittings	6,859	7,207
Total tangible fixed assets	45,214	43,085
Financial fixed assets		
Deferred tax asset	7,798	7,072
Shares in associated companies and jointly controlled companies	1,430	49
Long-term receivable	3,632	2,108
Total financial fixed assets	12,861	9,229
Total Fixed Assets	97,000	86,471
Current Assets		
Inventories etc		
Finished products and goods for resale	29,688	19,999
Total inventories etc	29,688	19,999
Current Receivables		
Accounts receivable - trade	42,713	27,060
Receivables from associated companies	402	1,282
Other reciveables	3,364	2,141
Prepayments and accrued income	13,754	5,190
Total receivables	60,233	35,673
Cash and bank balances	40,310	24,981
Total current assets	130,231	80,653
Total Current assets		

TSEK	31-DEC 2024	31-DEC 2023
Equity and Liabilities		
Equity		
Share capital (19,012,500 shares)	19,012	19,012
Non-restricted equity	104,786	95,274
Result for the year	40,196	8,330
Total equity	163,993	122,616
Provisions		
Provisions for taxes	1,454	1,660
Total provisions	1,454	1,660
Liabilities		
Non-current liabilities		
Liabilities to credit institutions	808	2,532
Accrued costs and prepaid income	5,676	3,961
Total non-current liabilities	6,483	6,493
Current liabilities		
Liabilities to credit institutions	13,485	11,038
Accounts payable - trade	26,696	15,145
Income tax liability	1,163	-
Other liabilities	2,939	2,971
Accrued costs and prepaid income	11,017	7,200
Total non-current liabilities	55,300	36,355
Total liabilities	61,784	42,848
Total non-current liabilities	227,231	167,124

## **Consolidated Statement of Cash Flows**

ТЅЕК	JAN-DEC 2024	JAN-DEC 2023
Cash Flow from Operating Activities	_	
Results before financial items	33,508	13,028
Financial items	7,992	-4,650
Income tax paid	-1,304	555
Adjustments for:		
Depreciation and write-downs	16,218	18,610
Other non-cash items	-5,067	-
Cash flow before changes in working capital	51,348	27,543
Cash flow from changes in working capital:		
Inventories, etc	-9,689	7,162
Operating receivables	-26,084	-7,025
Operating debts	17,049	-12,048
Cash flow from operating activities	-18,723	-11,911
Cash flow from operating activities??????	32,625	15,632
Investing Activities		
Investments in intangible fixed assets	-4,457	-13,605
Investments in tangible fixed assets	-12,768	-11,724
Investments in financial fixed assets	-1,381	-
Cash flow from investment activities	-18,606	-25,329
Financing Activities		
Loans taken (+)/repayment of loans (-)	721	-3,414
Cash flow from financing activities	721	-3,414
Cash flow for the year	14,740	-13,111
Cash and cash equivalents, opening balance	24,981	38,092
Exchange rate difference in cash and cash equivalents	589	-
Cash and cash equivalents, closing balance	40,310	24,981

# Parent Company Income Statement

TSEK	JAN-DEC 2024	JAN-DEC 2023
Operating income		
Net sales	2,033	2,207
Total operating income	2,033	2,207
Operating expenses		
Raw materials and consumables	-774	-932
Other external expenses	-4,318	-3,736
Personnel costs	-1,288	-1,390
Depreciation and write-downs	-16	-23
Total operating costs	-6,396	-6,081
Operating profit/loss	-4,363	-3,874
Results from financial investments		
Interest income and similar profit/loss items	2,854	2,735
Interest expenses and similar profit/loss items	-	-12
Total result from financial investments	2,854	2,723
Profit after financial items	-1,509	-1,151
Tax	-	-
Net profit/loss for the year	-1,509	-1,151

# Parent Company Balance Sheet

TSEK	31-DEC 2024	31-DEC 2023
Assets		
Fixed Assets		
Tangible fixed assets		
Machinery and other technical facilities	-	16
Total tangible fixed assets	-	16
Financial assets		
Participations in group companies	26,937	26,937
Receivables from group companies	117,429	114,586
Total financial assets	144,366	141,523
Total Fixed Assets	144,366	141,539
Current Assets		
Current Receivables		
Accounts receivable	73	631
Other receivables	676	464
Prepayments and accrued income	95	70
Total current receivables	843	1,165
Cash and bank balances	13,830	18,013
Total current assets	14,673	19,178
Total assets	159,039	160,717

TSEK	31-DEC 2024	31-DEC 2023
Equity and liabilities		
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	141,048	142,199
Profit/loss for the year	-1,509	-1,151
Total non-restricted equity	139,539	160,060
Total equity	158,550	160,060
Liabilities		
Current liabilities		
Accounts payable - trade	54	60
Accounts payable - group companies	86	83
Other liabilities	34	41
Accrued costs and deferred income	315	473
Total current liabilities	488	657
Total liabilities	488	657
Total equity and liabilities	159,039	160,717

## Parent Company Cash Flow Analysis

TSEK	JAN-DEC 2024	JAN-DEC 2023
Carlo Flavor Constant Astronomy		
Cash Flow from Operating Activities		
Profit/loss before financial items	-4,363	-3,874
Adjustments for:		
Financial items	2,854	2,723
Depreciation and write-downs	16	23
Other non-cash items	-2 853	-
Cash flow from changes in working capital:		
Current receivables	322	-84
Current liabilities	-169	-452
Cash flow from operating activities	-4,183	-1,664
Investing Activities		
Investments in intangible fixed assets	-	-
Cash flow from investment activities	-	-
Financing Activities		
Loans to group companies	-	-16,722
Cash flow from financing activities	-	-16,722
Change in Liquid Funds	-4,183	-18,386
Cash and cash equivalents at the beginning of the period	18,013	36,400
Cash and cash equivalents at the end of the period	13,830	18,013

## Change in Equity

#### The Group

TSEK	Share capital	Non-restricted equity	Profit/loss for the year	Total equity
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	105,510	-10,324	114,198
Profit/loss carried forward	-	-10,324	10,324	-
Translation gains/losses on consolidation	-	88	-	88
Profit/loss for the year	-	-	8,330	8,330
Total equity as of 2023-12-31 (19,012,500 shares)	19,012	95,274	-8,330	122,616
Profit/loss carried forward	-	8,330	8,330	-
Translation gains/losses on consolidation	-	1,182	-	1,182
Profit/loss for the year	-	-	40,196	40,196
Total equity as of 2024-12-31 (19,012,500 shares)	19,012	104,786	40,196	163,994

#### **Parent Company**

TSEK	Share capital	Share premium reserve	Profit/loss for the year	Total equity
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	145,049	2,850	161,211
Profit/loss carried forward	-	-2,850	2,850	-
Change in translation difference regarding subsidiaries	-	-	-	-
Share related remuneration regulated by equity instruments	-	-	-	-
Profit/loss for the year	-	-	-1,151	-1,151
Total equity as of 2023-12-31 (19,012,500 shares)	19,012	142,199	-1,151	160,060
Profit/loss carried forward	-	-1,151	1,151	-
Change in translation difference regarding subsidiaries	-	-	-	-
Share related remuneration regulated by equity instruments	-	-	-	-
Profit/loss for the year	-	-	-1,509	-1,509
Total equity as of 2024-12-31 (19,012,500 shares)	19,012	141,048	-1,509	158,550

#### The Shar

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 shareissue 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 65.6 (2023: SEK 36.8, 2022: SEK 43.1. 2021: SEK 65.00, 2020: SEK 25.40, 2019: SEK 60.00, 2018: SEK 24.10, 2017: SEK 19.50).

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## Shareholders

The company's 10 largest shareholders as of 2024-12-30 (Source: www.paxman.se 2024-12-30).

Name	Number of share held	Shareholding in %
Paxman, Glenn	4,356,386	23
Paxman, Richard	1,268,000	7
Per-Anders Johansson	1,256,806	7
Länsförsäkringar Blekinge	1,121,626	6
Avanza Pension	1,112,005	6
Carl Ejler Rasmussen & Co. A/S	1,054,809	6
Second Swedish National Pension Fund	666,617	4
SEB Investment Management	600,000	3
Måns Flodberg	525,000	3
Alcur Funds	444,186	2

On 31 December 2024, the company had a total of 1,703 (2023: 1,163) shareholders, of which the ten largest represented 65 (75)%.

Data per share	2024	2023
Earnings per share, SEK <sup>1)</sup>	2.11	0.44
Earnings per share at full dilution, SEK <sup>2)</sup>	2.11	0.44
Equity per share, SEK , <sup>1)</sup>	8.63	6.45
Cash flow from operating activities per share, SEK <sup>1)</sup>	2.06	0.82
Share price at the end of the period, SEK	65.6	36.8
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 <sup>2)</sup>	19,080,978	19,080,978
Number of shares, weighted average during the year	19,012,500	19,012,500
Number of shares, weighted average during the year at full dilution 2)	19,080,978	19,080,978



<sup>1)</sup> Earnings and cash flow per share are calculated on the average number of shares during the period. Equity per share is calculated on the number of shares outstanding at year-end.

<sup>2)</sup> As of December 31, 2024, 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, 2024, there was no dilution effect to











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