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# 2020

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## SUMMARY OF THE YEAR



The picture shows Paxman's management and board prior to the introduction of pandemic-related restrictions.

## Summary of the year

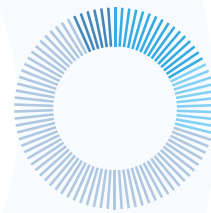
### Solid sales considering the pandemic, significant progress towards national reimbursement in the USA and R&D progress within both scalp cooling and CIPN prevention

In 2020, Paxman upheld its societal responsibility during the pandemic by continuing to be a strong source of support to both customers and patients, partly via novel digital solutions. Despite a stronger focus on increasing the patient utilisation numbers in the United States, the company sold and installed 345 (597) systems globally, which is an indication of the strong and growing underlying demand.

In the United States, Paxman's largest market, an important milestone was reached towards national reimbursement as the healthcare agency AMA decided to create CPT codes for scalp cooling. Paxman will be launching a strong effort to support the implementation of these codes by healthcare providers and payers when they become available on July 1, 2021.

In Europe, Paxman noticed a continued strong need among customers to upgrade their older systems, especially in the UK where 74 systems were sold despite the pandemic. This trend is expected to continue also in 2021 and thereafter, here as well as in other European countries.

In 2020, Paxman continued to advance its R&D projects together with its academic partners University of Huddersfield and NUH/NUS in Singapore. Some of the company's focus areas are improved scalp cooling efficiency and the development of a new miniature cryotherapy and compression device to prevent chemotherapy-induced nerve damage in hands and feet (CIPN).





## Selected events in 2020

- In Q2, the National Comprehensive Cancer Network® (NCCN®) in the United States updated its guidelines for ovarian cancer, fallopian tube cancer and primary peritoneal cancer with scalp cooling as a recommended category 2A treatment to reduce hair loss. Over 20,000 new ovarian cancer cases are discovered annually in the United States alone.
- In August, Paxman appointed TPC Korea as its new distributor in South Korea, a market with around 230,000 new cancer cases annually. Additionally, it was announced in Q3 that an open, randomised study of Paxman's PSCS system in connection with chemotherapy-induced hair loss in breast cancer patients was initiated at the prestigious Samsung Medical Center, with patient recruitment beginning in November 2020.
- In Q3, Cancer Australia updated its guidelines for early breast cancer so that they now include scalp cooling in connection with chemotherapy to reduce the risk of hair loss.
- In Q3, Paxman announced that patent applications had been filed for the company's upcoming cooling and compression product to prevent chemotherapy-induced nerve damage (CIPN). Additionally, Dr. Charles Loprinzi, one of the world's leading clinical opinion leaders within this field, was welcomed as a new member of Paxman's advisory board.
- In October, it was announced that the US healthcare authority AMA's editorial panel for CPT codes had decided to create category III codes for scalp cooling, which will become available on July 1, 2021. AMA's decision is important for patients across the United States, and it is expected to strengthen the role of scalp cooling in cancer care and support a substantially expanded access for patients.

- In the middle of December, it was announced that ESMO, the leading European professional organisation for medical oncology, had included scalp cooling as a category IIB recommendation to prevent hair loss in chemotherapy patients in its clinical practical guidelines. The recommendation is in line with the updates presented by the NCCN® in the United States and Cancer Australia.

## Summary of the year

- The group's turnover amounted to 78,053 (85,279) TSEK in 2020.
- The net profit/loss amounted to -19,186 (2,756) TSEK.
- Earnings per share amounted to -1.20 (0.17) SEK.
- Cash flow from operating activities amounted to -8,483 (3,305) TSEK.
- Net cash balance amounted to 77,011 (84,973) TSEK at the end of the period.
- Net liquid assets totaled -44,653 (-29,849) at the end of the period.
- Equity to assets ratio was 14.1 (33.4)% at the end of the period.

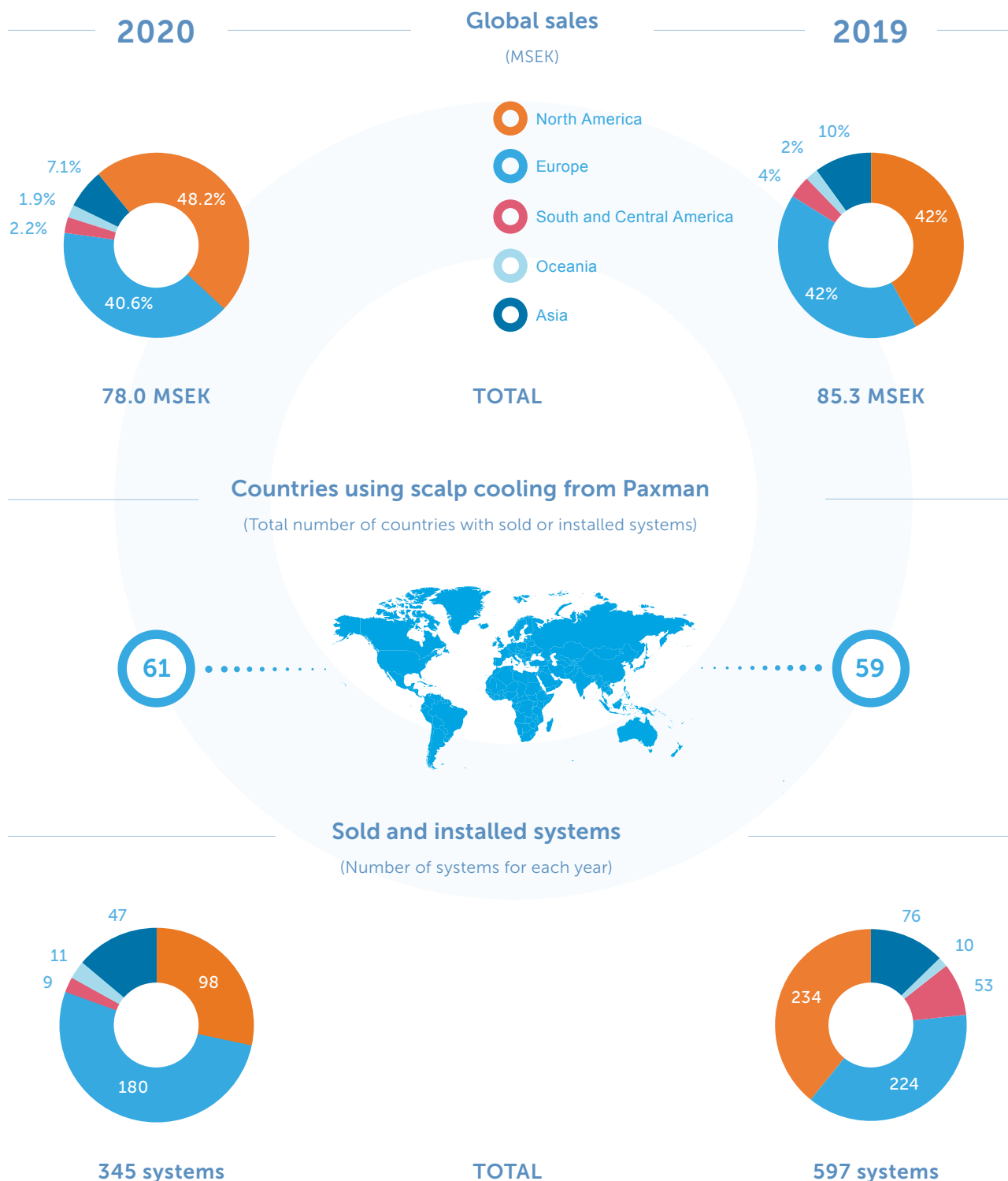
## Sold and installed systems in 2020

- Sold and installed systems in the USA: 97 (234) systems
- Sold and installed systems globally: 345 (597) systems

**SUMMARY OF THE YEAR**

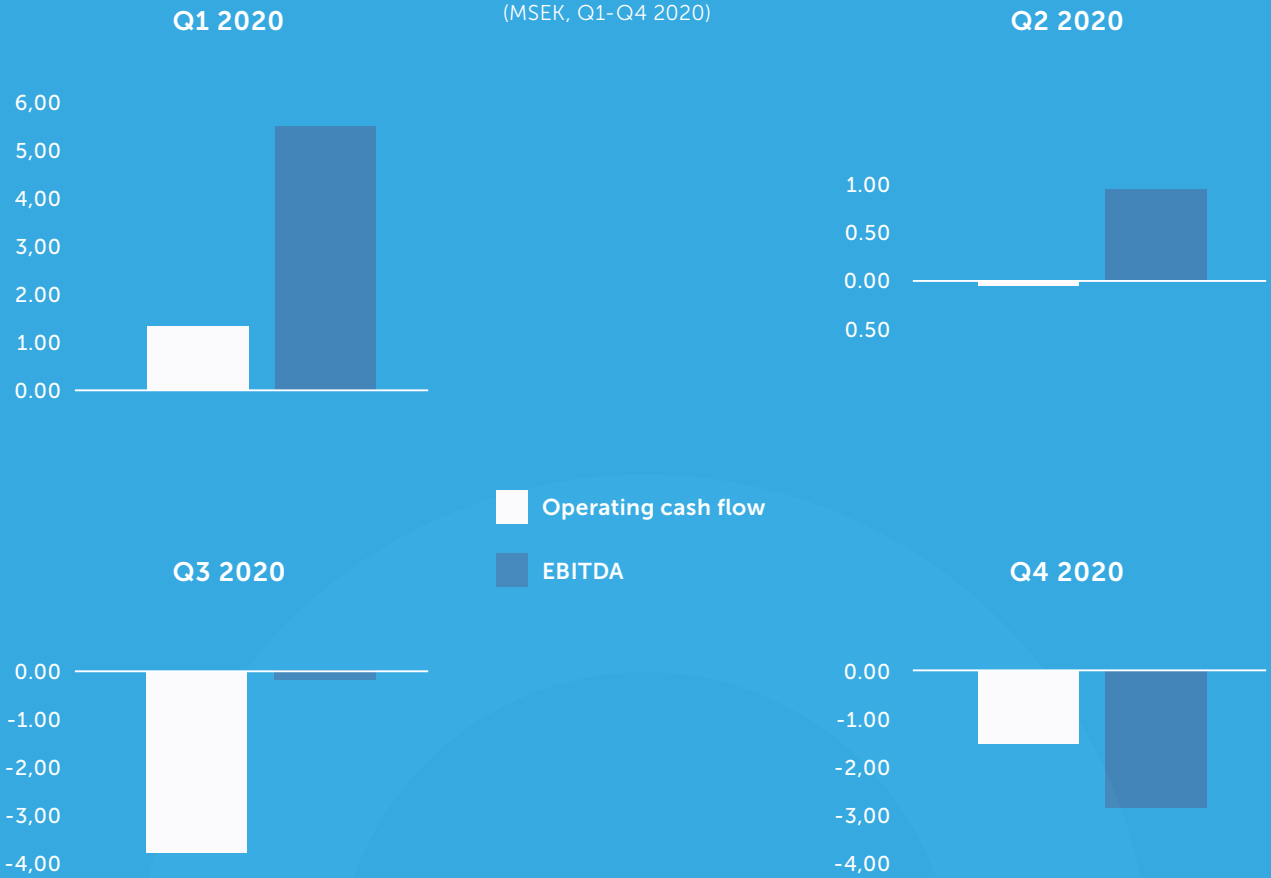
# Solid development in view of the COVID-19 pandemic

**P**axman exhibited excellent flexibility and resilience in 2020. The company was able to sell and install a large number of systems in several regions even though the healthcare systems were forced to focus almost entirely on COVID 19-related efforts during the most challenging periods of the year. In the important Japanese market, the company has now installed over 70 systems.



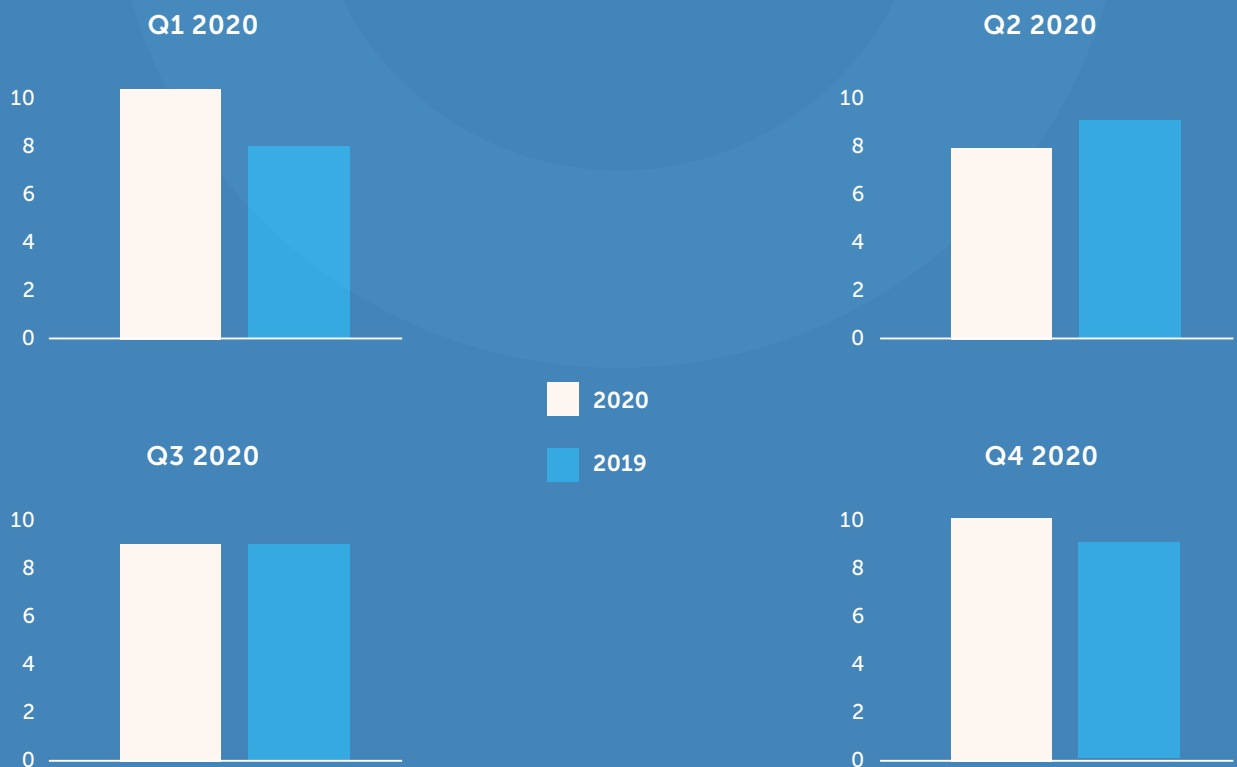
### Operating cash flow/EBITDA

(MSEK, Q1-Q4 2020)



### Revenues in the USA

(MSEK, Q1-Q4 2020)



# Chasing **Zero** Hair Loss During Chemotherapy

## Paxman's long-term vision:

### A world where all chemotherapy patients can avoid hair loss

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

**P**axman's long-term vision, and its efforts to achieve it, is condensed into the slogan "CHASING ZERO HAIR LOSS". This means aiming for a future where all chemotherapy patients worldwide are offered scalp cooling, with Paxman as the natural choice.

On a regulatory level, several important steps towards the realisation of this long-term vision were taken in 2019 and 2020. Paxman's purposeful work to achieve national reimbursement in the United States, the world's largest and leading market, led to the inclusion of scalp cooling as a recommendation for the prevention of chemotherapy-induced hair loss in breast cancer patients in the leading clinical guidelines published by the NCCN® in 2019. Inclusion for additional cancer types was added in 2020, and similar inclusions to a varying extent were made in guidelines published by ESMO in Europe as well as Cancer Australia in 2020. Additionally, the AMA in the United States announced in Q4 2020 that CPT codes for scalp cooling will be created and become ready to use from July 1, 2021.

Geographically, Paxman extended its outreach by establishing the company in Japan, the world's second largest market for cancer care with over 1 million new cancer cases per year, in 2019, and in South Korea in 2020. Additionally, a large clinical study was initiated in Q4 2020 that will support the company's continued expansion in Asia, including a greater presence in India and evaluation of go-to-market alternatives for China.

On the patient level, Paxman is aiming to achieve an even better scalp cooling efficiency, and in 2019 the company founded the Paxman Scalp Cooling Research Centre together with the University of Huddersfield. This multi-disciplinary effort constitutes the world's first scalp cooling-focused research and development centre. Information on Paxman's R&D progress in 2020 can be found on pages 26-34.

## Scalp cooling to prevent chemotherapy-induced hair loss included in leading clinical guidelines in 2020

### New cancer cases per year

**USA**  
**1,800,000**  
 (Expanded inclusion  
 in NCCN®'s clinical  
 guidelines)

**Europe**  
**3,700,000**  
 (Inclusion in ESMO's  
 clinical guidelines)

**Australia**  
**150,000**  
 (Inclusion in Cancer  
 Australia's guidelines for  
 early breast cancer)



“ In 2020, scalp cooling to prevent chemotherapy-induced hair loss was included in leading clinical guidelines developed by the NCCN® in the United States, ESMO in Europe and Cancer Australia in Australia. Additionally, the AMA in the United States decided to create CPT codes for mechanical scalp cooling, which will facilitate the cost reimbursement process.”

## A comment from our CEO Richard Paxman

2020 has been a year to remember for many reasons. Although it has been extremely challenging and many people around the world have experienced much loss, we have learned many lessons, which has led to the company being in a place of strength for the future, which is now where we must focus.

Some of the key learnings and outcomes in 2020 include the strength and resilience of the people at Paxman. From the moment the pandemic began to be a reality the whole team at Paxman worked closely to protect the business, ensuring we could still support our customers and most importantly our patients in a safe and effective way. Sacrifices were made by all for the greater good, something I shall not forget. We have also learned many new ways of working and embraced the world of digital perhaps sooner than we would have done otherwise. Our ability to reach our global partners, customers and patients virtually has been a great success, and in many ways, has been more collaborative and enabled a wider reach than historically. Although we are excited about the opportunity to take to the skies again and meet with our growing number of distributors, partners and customers, it is likely we will adapt to a more hybrid approach, dramatically reducing costs but also our carbon footprint.

Due to the pandemic we saw huge reductions or delays in cancer diagnosis and many restrictions on our activities but we were pleased to report that the company still performed during these unprecedented times, in fact the US business saw a 10% growth in patient revenues and we expanded our footprint into a total of 342 locations in 40 states by the end of the year. Our rest of world business reduced, albeit not to the extent we expected. In fact, the markets we had direct control over performed better, which is driving our strategy for greater internationalisation.

It is clear that the pandemic is still affecting many parts of the world and many people, but we can now begin to look to the future. 2021 started with some incredibly positive news with

the announcement that the American Medical Association (AMA) has issued two (2) separate CPT® codes for "mechanical scalp cooling". The CPT® Category III codes are: 0662T and 0663T and are effective July 1, 2021. The issuance of two Category III CPT Codes by the AMA is a key component to Paxman's reimbursement and business strategies.

With the announcement of the CPT codes Paxman are now forging ahead with accelerated efforts for reimbursement in the USA. Large investments have and will continue to be made in this area. Although the results will not be overnight, we are working on public and commercial payer engagement as well as developing new strategies with our partner McKesson along with our providers in 40 states across the country to work towards future reimbursement. This in the medium to long term is a step change in the business and our growth trajectory.

In February the board of directors, based on the authorization from the annual general meeting on 27 May 2020, resolved on a directed issue of 1,600,000 shares at a subscription price of SEK 36.60 per share. Through the Share Issue, the Company received approximately SEK 59 million before transaction costs. The subscribers in the Share Issue are the well reputable institutional investors Creades AB (publ) and Alcur Fonder and we are delighted to have them on board for our exciting journey ahead. This investment provides the growth capital the company needs to accelerate its investments in internationalisation, reimbursement and research and development. In addition, it provided the opportunity to reduce some of the company's debt whilst maintaining facilities for the future.

Throughout 2021 and beyond we shall focus on the internationalisation of the company. Although the USA will remain our number one focus, we have begun to make investments in direct personnel for markets including Europe, specifically Germany, India and Scandinavia initially. The company is also enhancing its global marketing proposition and providing further support to its international partners. China shall be a focus for 2021 with headway already being made in the first quarter of the year.

"The issuance of two Category III CPT Codes by the AMA is a key component to Paxman's reimbursement and business strategies."

Richard Paxman, CEO

Last but certainly not least, the investment will support our continued research and development plans, keeping Paxman as the leader in not only scalp cooling, but now the prevention of chemotherapy induced peripheral neuropathy.

Since 2019, Paxman has worked in partnership with the National University Cancer Institute, Singapore (NCIS) at the National University Hospital (NUH) and the N.1 Institute for Health at the National University of Singapore (NUS), in the research and development of a portable cooling and compression device to prevent chemotherapy-induced peripheral neuropathy (CIPN). CIPN is a severe side effect of taxane-based chemotherapy, used to treat common cancers such as breast, lung, ovarian and stomach cancer. CIPN affects about 1.4 million cancer patients globally every year. The potential of this development is vast, not only adding to our commercially and financially exciting business but as importantly having a huge social impact globally.

We would like to thank all our investors for joining our fight in changing the face of cancer globally. We are excited to forge ahead with our expansions plans ensuring cancer patients globally have access to this important treatment. Thank you team Paxman for all your support in 2020, we would not be where we are today without your resilience, passion and perseverance.

Huddersfield in May 2021

Richard Paxman, CEO  
Paxman AB (publ)





## About the company

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

Paxman was founded in the UK in 1996, and the company has installed around 4,000 scalp cooling systems globally. The company has a strong connection to Sweden as the CIMON group, an investment company with approx. 350 MSEK in annual turnover, became a large shareholder already in 1999.

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

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

### Market leading and personal scalp cooling

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

Today, the system is used at a large number of cancer centers and hospitals in Europe, North-, Central- and South America, Asia and Oceania,

and more installs are added continuously. The company is also developing a medical cooling and compression device to prevent chemotherapy-induced nerve damage in hands and feet (CIPN) with the aim to initiate clinical studies in Singapore in 2021.

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

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

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



## Paxman's history 1996 – 2019

### 1996

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

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

### 1999

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

CIMON Venture Trust AB based in Karlshamn, Sweden, invests in Paxman

### 2000

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

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

### 2003

The first clinical study is conducted with Paxman's system

### 2006

Paxman reaches 500 installed systems

### 2012

Paxman reaches 1 000 installed systems

### 2013

Richard Paxman is appointed as Paxman's CEO

### 2014

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

### 2015

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

Paxman reaches 2,000 installed systems

### 2016

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

### 2017

The company obtains FDA clearance in the USA

Paxman AB (publ) is listed at Nasdaq First North

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

Paxman obtains market approval in Taiwan and Argentina

### 2018

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

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

Paxman receives extended FDA clearance in the USA covering solid tumours

### 2019

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

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

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

Paxman obtains market approval for its scalp cooling system in Japan

Milestone of 500 installed systems in the USA achieved

### 2020

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

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

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

# How scalp cooling prevents hair loss

## A fundamentally simple yet highly effective method

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

### Scalp cooling in connection with chemotherapy works as follows:

#### Coolant is pumped through a cooling cap

During each treatment session, the patient puts on a cooling cap which is connected to the cooling system. The coolant is then pumped through the cap, cooling the hair follicles.

#### Lower amount of cytotoxin reaches the scalp

The cooling causes the blood vessels in the scalp to contract, which reduces the amount of cytotoxin that can attack the hair follicles by about 20-40 percent.

#### Dividing process of the hair follicles slows down

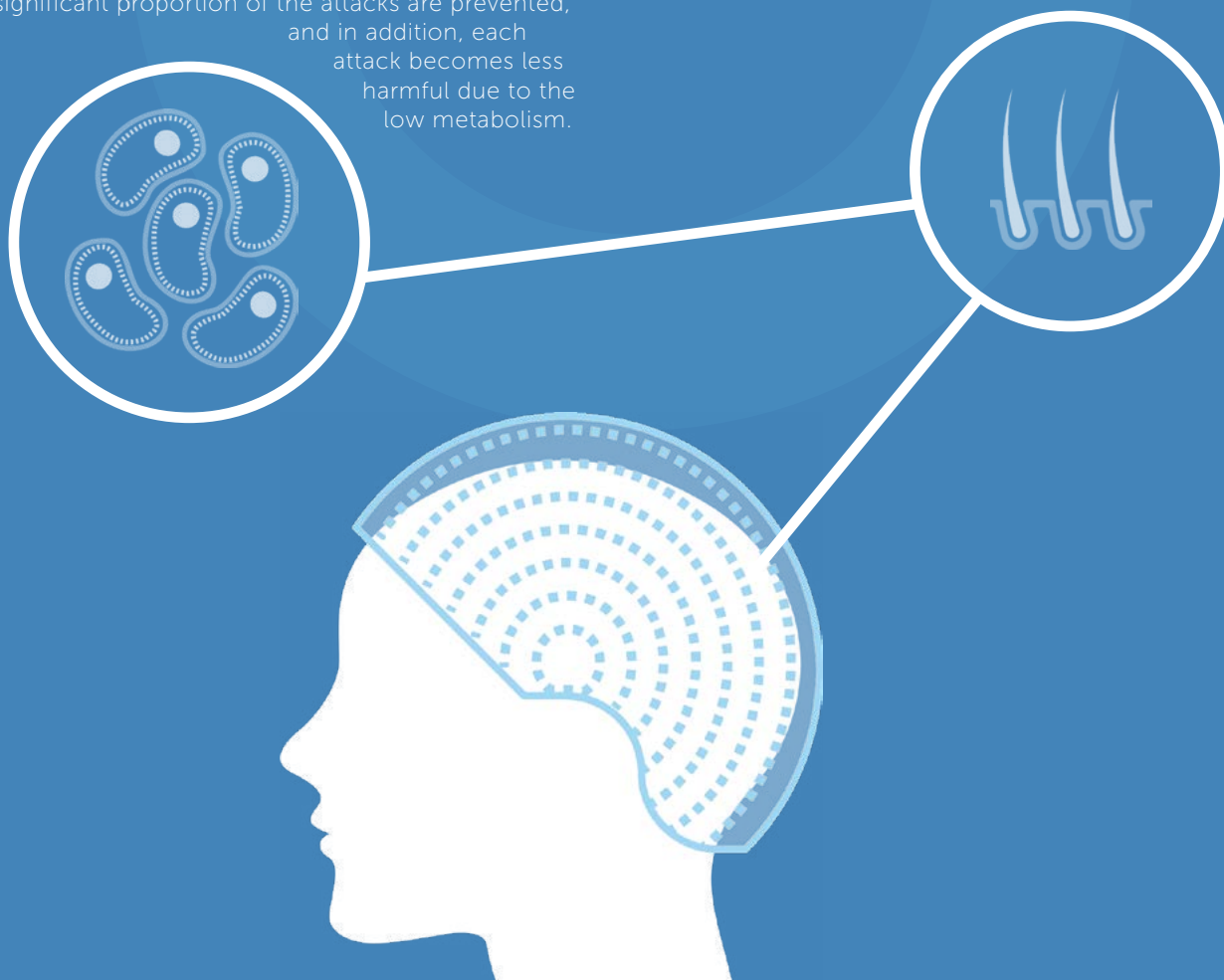
At the same time, the cooling slows down the metabolism and thus also the dividing frequency of the hair follicles (normally, 90 percent of the hair follicles are in an active division phase). As chemotherapy targets cells that divide frequently, a significant proportion of the attacks are prevented, and in addition, each attack becomes less harmful due to the low metabolism.

#### 18-22 degrees – the temperature that provides optimal protective effect

Scientists like Gregory et al<sup>1</sup> and Bulow et al<sup>2</sup> have proven that it is optimal to cool the scalp to below 22 degrees, which equals cooling of the hair follicles to 18-22 degrees during the chemotherapy treatment. Paxman's scalp cooling system is developed to achieve this optimal cooling level throughout the treatment session.

1) Gregory RP, Cooke T, Middleton J, Buchanan RB, Williams CJ (1982) Prevention of doxorubicin-induced alopecia by scalp hypothermia; relation to degree of cooling. British Medical Journal 284, 1674.

2) Bulow J, Friberg L, Gaardsting O, Hansen M. Frontal subcutaneous blood flow, and epi and subcutaneous temperatures during scalp cooling in normal man. Scand J Clin Lab Invest 1985, 45, 505-508.



## The Paxman Scalp Cooling System (PSCS)

### Paxman's most effective, flexible and personal scalp cooling to date

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

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

To ensure optimal results as well as excellent comfort and hygiene, PSCS has the option to be used with personal cooling caps available in different sizes and versions. This opportunity is offered in most markets, and it is especially utilised in the United States and Japan. The personal 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. A more cost-efficient version is now also being developed to facilitate the use of this concept in more developing markets, as well as 3D-printed cooling caps based on the patient's head shape. More information on Paxman's R&D projects can be found on pages 26-34.

In addition to offering Paxman's best scalp cooling to date, PSCS offers the company the opportunity to customise its business model with an optimal balance between initial sales revenue and ongoing revenue based on the number of treatments and/or the number of personal caps sold. This allows Paxman 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.



**SCALABLE, HIGH-QUALITY MANUFACTURING WITH FACILITIES IN THE UK**

# Scalable, high-quality manufacturing with facilities in the UK

Paxman's scalp cooling systems are manufactured in the UK at the company's headquarters in Huddersfield. This enables Paxman to maintain high quality and stability in the production process, as well as to minimise prototyping lead times.

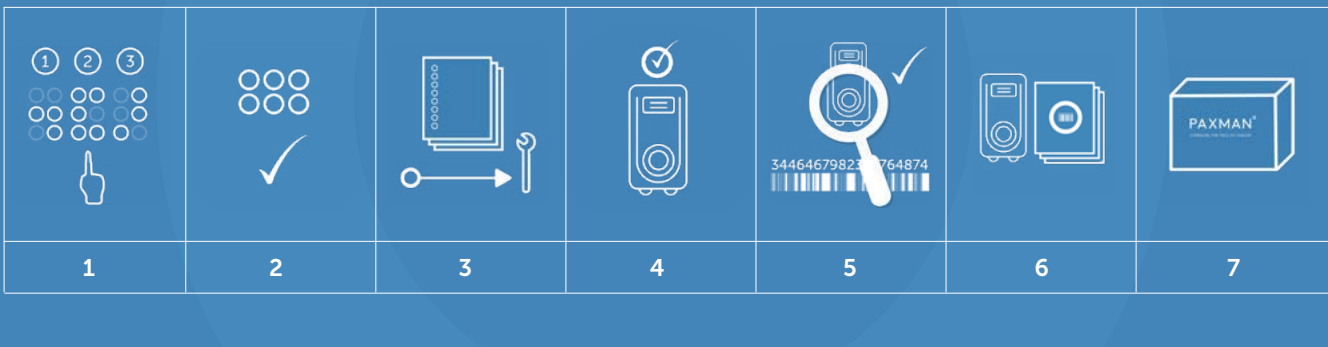
The benefits of in-house, local manufacturing capacity became even more evident during the COVID-19 pandemic. By quickly implementing new routines for social distancing and expanded control of the company's supply chain, production of the Paxman Scalp Cooling System could continue throughout 2020.

## Paxman aims to double its production capacity

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

To be able to handle this demand, Paxman has initiated efforts to double its production capacity in the UK. This new initiative will also facilitate the development of new and innovative products such as the upcoming cooling and compression device to prevent chemotherapy-induced nerve damage in hands and feet (CIPN).

### This is how a scalp cooling system is made



**1.** Parts are ordered and delivered from subcontractors and undergo quality tests before appropriately stored. The parts are divided into category 1, 2 and 3, with extended quality checks for category 1 parts.

**2.** The production plan is determined based on the order book in consultation with sales teams and the company's management.

**3.** The list of parts (BOM) is prepared, and all components are picked from stock and supplied to the production team that prepares them for assembly and production.

**4.** Production involves three stages, with quality assessments by the quality team at each step against strict criteria.

**5.** When a device is fully complete, a further quality inspection is undertaken which involves functionality testing and electrical safety testing. The device is then appropriately labelled with a unique serial number plate.

**6.** The fully tested equipment is allocated to a customer order, and the internal paperwork by UK Operations Coordinator/International Coordinators is then generated.

**7.** The customer order is finally packed and palletised with the required accompanying documentation and associated accessories, and the coordinator ensures that customer-specific and any export-related documentation is prepared and that the order is picked up and delivered to the customer by the shipping company.

# Interview on Paxman's production and its aim to double the manufacturing capacity

Jonathan Hallas, Paxman's Production & Training Manager, talks about how the company was able to sustain a reliable production in 2020 despite the COVID-19 pandemic, continuous improvements throughout the production process and the ongoing work to double the manufacturing capacity.

## What have been the main coronavirus-related challenges in this part of the business, and how have you handled them?

Supply chain has been affected by the pandemic and the obtaining of parts from suppliers was more challenging in 2020.

We swiftly mobilised to ensure social distancing was effectively integrated into our manufacturing processes by using skill set analysis to provide the right amount of transferable skills into the right areas to keep the Production department going to deliver our products to customers.

## Can you describe your overall efforts to improve the manufacturing and delivery chain and what progress you have made here in recent years?

We operate a continuous improvement system, where all staff are regularly encouraged to voice their opinions to help improve the smooth running of the Production department. Quality is paramount and any errors in manufacture are recorded, whether this be staff error or component issues. We have increased staffing in order to minimise disruption to production in the case of illness and have adequate holiday cover in place.

Improvement in the training of operatives is ongoing with examinations carried out for staged work on production stations and testing. Operatives attend external training courses in specific areas to ensure their skill sets are optimised.

Each production area has dedicated space for each manufacturing function with provision of all required tools to do the job efficiently. We operate a supplier Kanban system to ensure re-stocking of consumable parts on a weekly basis. This ensures regular

fulfilment of parts and components and shortages are minimal.

A spares parts tracking system has been introduced with a 'traffic light system' to follow spare parts orders from receipt through to fulfilment, ensuring internal communications are the best they can be. Furthermore, this optimised customer service for communication of accurate delivery lead times.

The processing of coolant orders for customers has been improved by the implementation of improved dispense pumps which also minimises wastage and therefore reduces cost.



## What are your future plans for improving the manufacturing/delivery part of the business?

We are in the early stages of implementing the installation of a second production and testing area, which will double production capability for the existing scalp cooling equipment whilst allowing extra capacity for future innovations.

Currently, the scalp cooling caps are assembled on two 'cap stations' which is adequate for current and future demands. It is anticipated that additional production staff will be required to join the existing team later in 2021 – a salary structure forecast has been produced to indicate costings for additional future staffing.

Warehouse expansion is planned to double the space for finished goods and component and part storage. This will incorporate a dedicated area for coolant dispense, spare parts, finished goods and Goods Inwards checking area. Additionally the area will include heating to provide a more comfortable working environment for the team.

# Patient enrolment growth in the USA

## Purposeful efforts aimed at patients, healthcare providers and payers

In 2020, increased patient utilisation in the United States has continued to be a key focus for Paxman. Activities to facilitate this include education aimed at patients and healthcare providers and virtual services for easy installation, training and support, as well as successful activities aimed towards achieving national reimbursement to minimise financial hurdles.

### The top five cancer centres in the USA uses Paxman

Paxman’s scalp cooling system has delivered positive results in several clinical studies and is also easy to use for patients as well as clinical staff. As a result, more than 363 US cancer centres are now using the system, including all of the five highest ranked cancer centres in the prominent US News & World Report’s annual evaluation. The list of clinics using scalp cooling from Paxman keeps growing every month.

### Successful activities towards national reimbursement in the United States

Paxman is working with the consulting firm Innovation Partners with the aim to facilitate national reimbursement in the US market. In 2020, the AMA healthcare authority decided to make new CPT codes for scalp cooling available from July 1, 2021, which will make it much easier for healthcare providers to apply for and get paid for treatments.

### Coldcap.com offers information and education for patients and relatives

Paxman has created the website coldcap.com, which constitutes a unique and valuable resource with information on the benefits of scalp cooling, how the method works and how the treatment is performed. The website is aimed at patients as well as their relatives and friends, and it has been very well received so far. The company is also initiating an effort to translate coldcap.com to additional languages in 2021.



### Educational program for important occupational groups

In 2019 and 2020, Paxman held the first instalments of its Paxman Clinical Pioneer Program in the United States, and the program is now offered virtually due to the COVID-19 pandemic. It is aimed at personnel at cancer centers, offering increased knowledge about optimal use of Paxman’s scalp cooling. The program has been very well received, and the goal is to scale up the number of events in 2021.

### High-quality patient support through the Paxman Hub

The service centre Paxman Hub & US HQ is the very core of the company’s operations aimed at cancer centres in the United States and their staff. From here, the company coordinates everything from installation and training to ongoing service and support, as well as updated information on the possibility for reimbursement from public or private healthcare entities.

### Virtual activation and training in connection with new installations

In 2019 and 2020, Paxman has implemented optimisations to minimise the time it takes before a newly installed system is used as much as an average system, including virtual training and activation of systems due to the COVID-19 pandemic. Although personal meetings cannot be replaced, virtual services have been proven to complement other solutions and will be used also after the pandemic.

## Introduction of CPT codes a further step towards broad reimbursement of scalp cooling in the United States

The inclusion of scalp cooling in NCCN®'s clinical guidelines in 2019 and 2020, and the AMA's decision to introduce CPT codes for scalp cooling from July 1, 2021, creates better conditions for making reimbursement more common in the United States.

Today, the vast majority of scalp cooling treatments in the United States are still paid for by the patients themselves. However, Paxman aims to eventually replace this payment model with a model where healthcare providers pay for the treatments and then receive reimbursements from public or private paying parties (healthcare programs or insurance companies).

For a large-scale transition to the new payment model to be possible, healthcare providers must be able to report performed treatments in a simple and efficient way, and the payers must also include the treatment in their compensation policies. The compensation must also be at a reasonable level. The introduction of CPT codes to facilitate reporting is thus an important step forward, as is the fact that scalp cooling is now recommended to prevent chemotherapy-induced hair loss in the leading organisation NCCN®'s clinical guidelines for breast cancer, as well as for additional types such as ovarian, fallopian tube and peritoneal cancer. The latter is important as NCCN®'s clinical guidelines usually form the basis for the payers' compensation policies.

Going forward, Paxman will continue to work with specialised consultants and the company's

customers to further develop its operations in the United States. By doing so, Paxman can provide support to customers in the best possible way when they start using the CPT codes and at the same time move away from the current model where patients pay for their own treatment.

The company will also continue to work with commercial insurance companies and CMS to review reimbursement policies. Paxman expects to see positive decisions regarding reimbursement and payment from paying parties from July 1, 2021, when CPT codes for scalp cooling are introduced. Achieving large-scale reimbursement across the USA will however take much more time and investment.

In April 2021, Paxman announced that a bill making it mandatory for insurance companies to cover scalp cooling costs had been passed by the Texas House of Representatives following second and third reading. The bill now heads to the Texas Senate where it will need to be heard (and passed) within the next few weeks in order to make it law. This initiative shows that there is a good chance to achieve broad reimbursement for scalp cooling in the USA through state-level legislation.

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**"P**axman expects to see positive decisions regarding reimbursement and payment from paying parties from July 1, 2021, when CPT codes for scalp cooling are introduced.

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## Interview on Paxman's collaboration with Innovation Partners to achieve national reimbursement in the USA

Dave Melin, Founder & Managing Director at Innovation Partners LLC, talks about the successful collaboration with Paxman to facilitate and ultimately achieve national reimbursement for scalp cooling in the United States.

### Can you briefly describe Innovation Partners and your role in assisting Paxman towards achieving nationwide reimbursement for scalp cooling in the USA?

Innovation Partners is focused on serving biopharmaceutical, medical device/technology, and molecular diagnostic manufacturers to bring their healthcare innovations to a successful market launch and commercialization.

### Can you describe the strategy you have set up to reach this ultimate goal?

To meet the goal of achieving broad coverage and access for scalp cooling in the U.S., Innovation Partners is partnering with Paxman to broaden U.S. payer and provider relationships and engagement. Innovation Partners has evaluated Paxman's current business model and provided recommendations on how to create future revenue generating models in the US. Innovation Partners has helped to create a patient assistance program for scalp cooling to increase scalp cooling access. By working with health care policy advocates in Washington D.C., Paxman will be able to optimize or revise the current National Coverage Decision for scalp cooling. Additionally, it is important for scalp cooling to be listed in other clinical compendia sources which are referenced by providers and payers for product access of scalp cooling. Clinical compendia are summaries of drug information which affect coverage and reimbursement decisions for products.

In 2021, Innovation Partners submitted requests for scalp cooling to be included in the 4 other clinical compendia referenced by payers and providers. These compendia requests went to AHFS Drugs, Clinical Pharmacology, DrugDex, and Lexi Drugs

requesting Paxman Scalp Cooling System be listed as a supportive care treatment for the reduction and prevention of chemotherapy-induced alopecia (CIA) in patients with solid tumors.

### Which types of entities are you focusing on to raise awareness and influence towards positive change?

Innovation Partners is focusing on commercial and Medicare payer engagement and academic and community oncology provider relationships.

Accounts are prioritized in order of importance from having a current relationship/awareness of scalp cooling to naive to scalp cooling. We are utilizing the stakeholders who are aware of scalp cooling to pave the way for the new Paxman business model when the CPT III code is live on July 1, 2021. This will provide influence and momentum as more providers start to bill for scalp cooling. We are also partnering with a healthcare policy firm in Washington D.C. who is connecting Paxman to U.S. elected officials and other stakeholders who have been identified as influential in the healthcare policy space with the aim of increasing awareness of scalp cooling and connecting with Hill staff to gain support of re-opening the NCD and for the Hill to ultimately ask CMS to re-open the NCD.

### What are you focusing on going forward, and what do you see as the next probable milestone to reach?

In 2021, we are focused on preparing payers and providers to bill and receive claims for scalp cooling, setting up a patient assistance program and promoting the program to a broad set of healthcare stakeholders. Since it will still take time, even with the new CPT III code, for providers and payers to be billing and paying for claims, we are currently focused on making as many payers and providers



aware of the new scalp cooling CPT codes. We are engaging these stakeholders in preparatory meetings and requesting early test claim billing prior to the July 1 live date. Once the CPT III code is live, Innovation Partners will continue to work in partnership with Paxman to reach more academic and community oncology practices in the U.S. We anticipate our next milestone to be providers submitting claims and payers reimbursing those scalp cooling claims. We also anticipate scalp cooling being added into the clinical compendium and understanding a path forward with the CMS NCD language.

### Would you like to add anything else on this subject that could be of interest for Paxman's shareholders?

Innovation Partners has greatly enjoyed building a professional relationship with the Paxman team over the last 3+ years. It has not been an easy road navigating the U.S. healthcare landscape, but we have assisted Paxman with a few monumental changes which will increase access to scalp cooling for more patients, which is the ultimate goal!

### Innovation Partners has assisted Paxman with:

- Awareness and engagement with U.S. commercial and Medicare insurers for coverage and payment of scalp cooling.
- Awareness and engagement with NCCN institutions and community oncology networks and clinics to catalyse billing and payment process.
- Management of medical writing and submission process to NCCN for inclusion of scalp cooling into the NCCN Guidelines. Innovation Partners formally requested the inclusion of the Paxman Scalp Cooling System as a supportive care treatment for the reduction and prevention of chemotherapy-induced alopecia (CIA) to the NCCN Guidelines for Breast, Ovarian, Esophageal, and NSCLC.
- CMS National Coverage Determination (NCD) strategy. The Center for Medicare and Medicaid Services (CMS) makes National Coverage Determinations (NCD) for items and services that are reasonable and necessary for the diagnosis and treatment of an illness. Oftentimes, CMS NCDs help pave the way for private insurance coverage as well. While scalp cooling has received an NCD from CMS, and CMS has specifically recognized that keeping the scalp cool during chemotherapy has been noted to reduce the risk of hair loss, the current determination is ambiguous, unnecessarily causing concern for payers. The current NCD for scalp cooling states, "While ice-filled bags or bandages or other devices used for scalp hypothermia during chemotherapy may be covered as supplies of the kind commonly furnished without a separate charge, no separate charge for them would be recognized." This vague language is creating confusion from payers as to whether scalp cooling technology like the Paxman Cooling System is, indeed, covered, by conflating the issue of coverage and payment and referring to outdated technology.
- Innovation Partners has conducted research with payers to pressure test their reaction to the NCD and provided this feedback to our Healthcare Policy experts in Washington D.C. who are engaging elected officials to request their support in re-opening this NCD.
- CPT III application. To properly bill for services, specific billing codes are required. Innovation Partners managed the process of applying for CPT III codes and received approval from the AMA late fall of 2020 for two new CPT III codes related to scalp cooling. This process included writing a peer reviewed publication to support the physician work involvement that correlates to the scalp cooling process that supports the need for a CPT III code.
- Paxman business model strategy. Innovation Partners has provided Paxman with guidance for their U.S. business model to evaluate and develop different scenarios for future revenue generating models in the U.S. Innovation Partners assisted with evaluation of pricing structure and patient share of cost for scalp cooling.
- Patient assistance program. Innovation Partners has conducted research on multiple patient assistance program companies and is assisting Paxman with creating business rules related to setting up the program.
- Submitting scalp cooling to compendia organizations.

## Global expansion for short- and long-term revenue



### Regional business models is one of the keys to Paxman's success

With PSCS, the company's latest scalp cooling system, personal cooling caps are used to provide better results for patients and a more personal experience. Paxman is also able to use regionally adjusted business models with this latest model so that the company can receive payment for each treatment and/or sold personal cooling cap. The company is now developing a more cost-efficient version of the personal cooling cap for increased flexibility and potentially expanded utilisation of these business models in important growth markets.

**U**nited States, Paxman's largest market, became the first market where the company finances the full cost of the system in return for a payment per treatment and each personal cooling cap sold. With over 716 installed systems and a growing patient enrolment, this model is now showing its long-term strength, and when nationwide reimbursement becomes a reality a very powerful increase in sales in the United States is expected. A similar model is also used in Mexico with the license partner Teva. Paxman's investments in scalp cooling equipment in the US and Mexico has been successful so far, with a return on invested capital of 113 %.

### Balancing short- and long-term cash flows

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

### Strong business outlook in Japan and Mexico

In Mexico, the company is using a model that resembles the one in the United States together with its license partner Teva, and in Japan Paxman receives payment for each system sold and each personal cooling cap sold. The development in Japan is of key importance, as this is the world's second largest cancer market after the United States. Both of these markets have had a slower growth in 2020 due to the COVID-19 pandemic, but both Paxman and the company's regional partners had and continue to have a very positive outlook for the latter part of 2020 and thereafter.

# Paxman's expanded plan for international growth

## Focus on increased regional presence and digitalisation

The Paxman brand has a strong global position, but at the same time there is a need to increase the company's presence on a local level in important regions. This led Paxman to initiate an extended international effort, combining a continued use of traditional distribution networks with its own local presence in key markets.

**P**axman is also conducting a virtual overhaul to internationalise and expand its control over how the company's brand and communication is used. This international effort includes, but is not limited to, an update of digital and print-based communication, including translation to several languages, global stationing of personnel in key regional markets, extended market support from the UK and finally to proceed with the company's market registration and strategy for commercialisation in China. Recruitments have been completed or initiated in India, Germany, France and Sweden, as well as to the strengthening of the marketing department in the UK. The first phase of translations of [www.coldcap.com](http://www.coldcap.com) includes Arabic, France, German and Spanish, with additional languages following in phase two.

**"P**axman is now expanding its physical and digital presence in important regional markets.

## Paxman's regional business models

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



## Interview on Paxman's progress in Asia and planning for the upcoming years

Anna Parker, Paxman's Head of International Sales, talks about the progress in 2020 and the increased focus on important markets such as India and China.

### Can you mention some of the key progress achieved by Paxman in Asia in 2020?

Certainly. I want to begin by mentioning that we saw our best result ever in Q1 2020, prior to the pandemic restrictions, to the strong underlying demand shown in Asia in the beginning of the year, which is a strong and encouraging indicator of things to come.

In Japan, our partner CMI Medical has been working hard to follow up our Shonin approval with a market clearance for the Paxman Scalp Cooling System. Here we have also seen positive study publications and webinars.

In Singapore, following an internal product evaluation, the National University Health System (NUHS) in Singapore, purchased their first Paxman Scalp Cooling System (PSCS). This is a momentous conversion as it is the first public setting in Singapore to adopt scalp cooling technology and further cements the profile of the treatment in market.

Following regulatory clearance in South Korea, a randomised clinical trial commenced at the prestigious Samsung Medical Center in Seoul. This involved intensive support to initiate and treat the first patients in December 2020. Alongside the trial came the appointment of a new partner for the territory - TPC / Nokwon who began the important in-market regulatory clearance process to allow the future marketing of our product in South Korea.

We were also able to identify and engage a partner for Indonesia in late 2020, with the distributor agreement signed in 2021, and we installed our very first device in Pakistan at Khanum Memorial Trust hospital,

Pakistan's premier and most well reputed cancer hospital. Additionally, a large clinical study was initiated in Hong Kong at Prince of Wales Hospital.

### What main strategic changes did you implement in Asia in 2020 due to the pandemic?

2020 took everyone by surprise. Within a fortnight the world went into nearly a complete lockdown. As we navigated the unknown, we swiftly moved all international activities to the virtual space. We adapted by



finding new and effective ways of engaging with partners; from reviewing their performance and activities, to delivering our suite of training programmes, most of which were designed as interactive face-to-face activities, but we rapidly redeveloped to adjust to the new online way of working.

To an extent, the launch of coldcap.com was our silver lining as the launch had long-ago been planned for mid-March 2020. We could now truly leverage this tool – the world-first patient centric web resource hosting an abundance of scalp cooling materials,

patient tutorial videos, treatment and haircare best practice guides. The timing could not have been better! Looking back at that most challenging time when our contact with patients, partners and other key stakeholders became so difficult and restricted, we were fortunate to have all of these tremendous resources available at a click of a button.

This and our immediate action to adapt allowed us to support our partners effectively, to continue to drive sales in Asia and beyond.

### Looking specifically at Japan, can you describe the challenges you have been facing here and what your partner did in 2020, and the progress achieved?

2020 was a difficult year for any significant progress in Japan due to the pandemic. Reduced activity was unfortunately inevitable due to the wide scale disruption and state of emergency in Japan. Strict social distancing rules, along with no access to hospitals had a dramatic impact on performance. The key focus in Japan, as in the USA, is the need to focus on further utilisation of equipment in-market, which proved very difficult during the pandemic.

Despite this, Japan delivered a pleasing performance in 2020 as our leading Asian market based on the number of systems sold. We are optimistic for the future and remain confident. The regulatory clearance for PSCS is imminent, which means that we will be able to ramp up our sales efforts in Japan going forward.

**Looking forward, India and China are stated as Paxman's two main additional growth drivers in Asia in addition to Japan. What is your outlook for the Indian market?**

With a clear focus on innovative technology and drive for development, India does present huge opportunities to Paxman. The sheer size of the economy paired with its technological savviness, strong and highly competitive healthcare sector create an optimal environment for implementation of technological advances such as ours. Add to that the importance of supportive care in cancer therapy in India and we have a very strong proposition, in a market where solid foundations have been built over the past several years.

Furthermore, India has seen spectacular efficacy results: including further evidence of hair regrowth in a clinical trial carried out at the world-class Tata Memorial Hospital, Mumbai Cancer Centre. There are also strong scalp cooling advocates amongst key opinion leaders in the region, which will prove invaluable in developing and growing Paxman's presence in this market. The recruitment of an in-market Regional Manager for the Indian subcontinent will drive our growth in India and surrounding territories. This new member of the International team will be a Paxman ambassador who will work in close collaboration with our local longstanding partner Access Devices.

**In China, the situation is a bit different as you have not yet entered the market. Can you describe your status here and the company's outlook for 2021?**

China is a key market for Paxman. It has to be. Pre-COVID, the company had made significant efforts to evaluate the market but COVID put a stop to this, and our focus had to shift quickly. Discussions are in progress with a suitable prospective partner in China who will carry out all the in-market establishment work however we are collectively working on understanding the best regulatory route. As the leading global economy with unsurpassed potential, our efforts in 2021 will be focused on capitalising on the opportunities we have already created and identified in market.



## Research and development

Paxman is committed to an ambitious research and development program, allowing the company to continuously refine the efficiency and user-friendliness of its scalp cooling system. Since the beginning of 2019, a portable compression and cooling product aimed at preventing chemotherapy-induced peripheral neuropathy (CIPN), a related indication causing chronic nerve damage in hands and feet, is also under development with the aim to initiate clinical studies in 2021.

### Paxman Scalp Cooling Research Centre – the world's first multidisciplinary research centre focused on scalp cooling

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

Cooling Centre, the world's first multidisciplinary research centre focused on scalp cooling.

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



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

# Selected research and development projects at the Paxman Scalp Cooling Research Centre

## • Biological research with cultivated human hair follicles

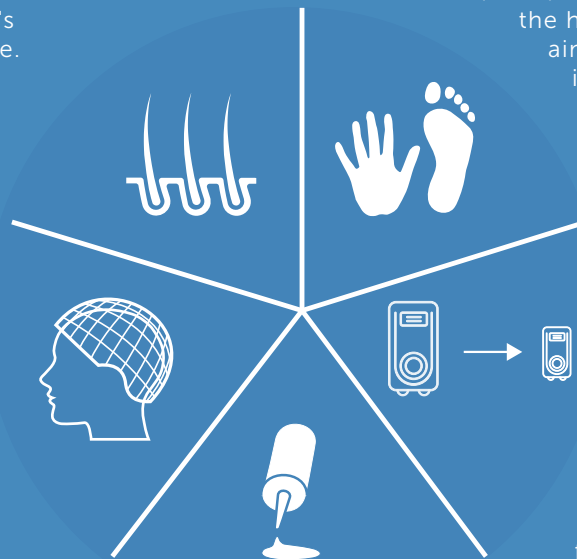
By examining cultivated human hair follicles in connection with chemotherapy treatment and scalp cooling under different conditions, researchers can deepen their knowledge of underlying biological and chemical mechanisms. This research is used in the further development of Paxman's current and future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

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

Researchers at Paxman Scalp Cooling Centre are collaborating with the National University Hospital in Singapore (NUH) within the project to develop a new product in chemotherapy-induced peripheral neuropathy (CIPN) that causes nerve damage to the hands and feet. The parties aim to initiate clinical studies in Singapore in 2021.

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

Individual 3D-printed cooling caps have the potential to increase the efficiency of Paxman's scalp cooling on markets where the company currently uses personal cooling caps, including the USA, Japan and Mexico. Test versions of 3D-printed cooling caps for internal evaluation were finalised during the spring of 2021.



## • Development of a miniaturised cooling and compression system

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

## • Topically applied product to enhance the effect of scalp cooling

The biology team has already shown that their first substance being developed for topical use can enhance the effect of scalp cooling in connection with specific chemotherapy treatments. Additional possible substances and chemotherapy types are now tested, which is expected to provide stronger evidence for the concept and to clarify if the most optimal route is to aim for a general topical product or several cytotoxic-specific topical products. The product can be applied directly onto the head of the patient, which means that it can be used together with Paxman's current scalp cooling systems. This means that the customers do not need to upgrade their systems, allowing a faster and broader market launch.

## Interviews on Paxman's scalp cooling R&D projects

Dr. **Nikolaos Georgopoulos** and Dr. **Andrew Collett** at the Department of Biological and Geographical Sciences, University of Huddersfield, research the biological effects of scalp cooling on hair follicles, and develop a topically applied product to enhance the effect of scalp cooling.



### Your PLOS ONE article confirms a more direct and complex relationship between scalp cooling and the uptake of chemotherapy agents by human hair follicles. How important are these findings for your biological research focus going forward?

Our PLOS ONE article has for the first time provided biological evidence that cooling directly inhibits the ability of chemotherapy drugs to enter keratinocytes thus dramatically reducing the amount of drug inside cells. The ability to suppress drug entry to cells is certainly one of the mechanisms by which cooling protects. These findings a) make us more confident that when optimal temperature is achieved during cooling the patients will maintain their hair and b) strengthen our drive to identify new ways to enhance the protective ability of cooling. By reaching a deeper understanding of how cooling works or, more importantly, why it is not always effective enough, then we can design better ways to enhance its efficacy.

### Could you mention some specific and important progress in 2020 and so far in 2021 in your biological scalp cooling research?

Our 2020-2021 studies using human hair follicles as 'mini-organ' cultures, have provided more extensive evidence that achieving optimal cooling conditions (adequately low temperature) is key, as optimal cooling can provide near-full protection from drug toxicity, which is an incredible biological observation. We believe that our findings using

such physiologically relevant biological models, provide the strongest and most unequivocal evidence that supports the ability of cooling to protect.

Moreover, we have reached a better understanding of how different chemotherapy drugs cause toxicity inside cells and how cooling suppresses these cellular processes, and our aim is to prepare these findings for publication. This will add to the extensive biological findings we now have and conclude a large piece of laboratory research that we have been working on for several years.

Finally, and probably most importantly, we have made further progress with our biological work on using combination of cooling together with 'protective agents' (antioxidants) as a powerful approach to prevent cell toxicity. The agents tested utilize different mechanisms of action to protect from toxicity and it is important for us to understand the underlying biology of this protective effect in order to optimize the efficacy of our approach.

### Can you describe your progress in 2020 and so far in 2021 for your topical product to improve the effects on scalp cooling?

Despite the difficulties that we have encountered whilst working through a pandemic (which limited our research capacity for several months), we have made good progress in what is an area of priority for our work.

Following some very promising initial results using a 'lead' antioxidant agent showing good

ability to enhance the effect of cooling to protect both keratinocytes and, more importantly, hair follicles, we have now expanded our panel of agents significantly. In fact, we have shown that some of the new agents tested are even better at protecting hair follicle-derived keratinocytes from drug toxicity in combination with cooling. This is a significant discovery, as the agents we have tested have different physical and chemical properties. This means that we have several potential 'candidates' for formulation, i.e. preparation for delivery onto skin as a topical application and we aim to select the specific agents that are best at targeting the hair follicle clinically.

### What are the next steps for the development of this topical agent?

Having tested the ability of the panel of our candidate agents for their efficacy, we are now aiming to make rapid progress on their delivery to skin. In fact, the Paxman Research Centre is in the process of recruiting a post-doctoral scientist who will work exclusively on developing novel formulations for targeted delivery of these protective agents to human hair follicles. The aim of the work is to utilize our new panel of agents and design the most effective formulation that will allow entry through the skin and delivery to the follicles in combination with cooling.

This is an exciting step, and it will allow us to make significant progress in our efforts to create a powerful topical agent. We

will be working closely with senior staff in the Department of Pharmacy (in our School of Applied Sciences), who have strong expertise in formulation development for human skin delivery. Our aim is to design the most optimal delivery tools for the protective agents we have tested and to confirm both their delivery and efficacy in combination with cooling. Once we have the results from these studies, we will certainly

have more clarity on timescales regarding the route to the clinic for testing on patients.

**Will you be aiming for a range of topical products based on the chemotherapy agent used, or is a universal product to boost scalp cooling efficiency regardless of chemotherapy agent the most likely scenario?**

That is a very important question

and focal point for our research. It is possible that chemotherapy drug-specific topical products might be designed, however ideally we would like to create a topical product that can enhance the protective effect of cooling against multiple chemotherapy drugs. However, this will depend on the specific chemical properties of these agents and it is something that we will need to test specifically in the laboratory.

Dr. **Ertu Unver** at the Department of Architecture and 3D Design, University of Huddersfield, works with research and development in product design, including 3D-printed personal cooling caps, a substantially smaller version of the scalp cooling system, and Paxman's new product to prevent nerve damage in hands and feet in connection with chemotherapy (CIPN).

**Could you describe the progress you have made in 2020 and so far in 2021 with the 3D-printed cooling caps project?**

We are extremely pleased with the progress made throughout 2020 even with the challenges the pandemic posed. This is an ongoing five-year project aimed at the development of a novel, environmentally friendly ecosystem for 3D-printed individual cooling caps ready for mass production.

New product design and development requires research, analysis, data collection, critical review, alpha prototypes and beta prototypes. We have made great headway here, developing early computer models and various prototypes: the closest we have been to printing a 3D cooling cap made from sustainable materials. We are currently working on the development of alpha prototypes.



**Are you still aiming for having printed samples of the personal cap ready in spring 2021?**

We have already achieved these first printed samples in 2021. Currently we are focusing our attentions on other key projects that are more of a priority for the direction of the business.

**What regulatory requirements and hurdles do you foresee before getting these caps onto the heads of patients?**

This still very much depends on how different the cooling cap is from our existing model. The Indication for use is of course the same however, the design materials and manufacturing

processes will be different.

In certain cases, internal and external testing of functionality will be required as well as other assessments such as biocompatibility tests. We do not expect that clinical trials will be required, and we will collect post market surveillance data, as we currently do.

**Can you describe the progress you have made in 2020 and so far in 2021 with the miniaturised cooling and compression system for the new CIPN product?**

Paxman has made vast progress with the CIPN development project. We expect to have a number of prototype devices available for both testing on healthy volunteers along with a small pilot trial in Singapore by the summer of 2021.

**What are the next steps, and what is your end goal? Will this become a completely new product line, or more of a continuation of your current offering?**

Following a successful pilot, the company will plan a large randomised controlled trial to confirm both the efficacy and safety of the product prior to commercialisation. The new product will form a part of the PSCS family, although it will have additional functionality and be in miniature form.

# Development of a new cooling and compression device to prevent chemotherapy-induced nerve damage

Paxman is well aware of the fact that chemotherapy can cause other serious side effects in addition to hair loss, including nerve damage in hands and feet (chemotherapy-induced peripheral neuropathy, CIPN). CIPN can cause several different symptoms from tingling and sensory impairment to severe pain and temperature sensitivity.

## Research in collaboration with the National University Hospital in Singapore, (NUH)

In January 2019, Paxman signed a research collaboration agreement with the National University Hospital in Singapore, (NUH) for the development of a portable cooling and compression system to prevent CIPN. The parties are aiming to initiate clinical studies in Singapore in 2021.

The research team at NUH is led by Dr. Raghav Sundar, who has examined the possibility of using cooling and compression to prevent CIPN for some time. Dr. Sundar sees Paxman as an ideal partner to take the product to market and distribute it to healthcare providers worldwide. The development of the actual device is conducted in collaboration with researchers from Paxman Scalp Cooling Research Centre at the University of Huddersfield. Ten cooling and compression systems will be produced for the clinical studies in 2021.

Paxman has further developed its relationships with key clinical opinion leaders in 2020, including the renowned Prof. Charles Loprinzi, who was appointed as a member of the company's advisory board in 2020. He is now involved in the work of designing the upcoming clinical studies in Singapore.

## Paxman holds the exclusive right to commercialise the technology

Any patents and additional intellectual properties conceived from the partnership will be jointly owned by the two parties, while Paxman receives exclusive rights to commercialise and sell market-approved products. The first patent applications for the cooling and compression system, and the limb wraps, were filed in 2020.

The goal is to launch a cooling and compression product used to reduce the amount of cytotoxin that reaches hands and feet, as well as minimising its harmful effects by slowing down the metabolic activity in the nerve cells.



# Interview on the development of a novel Paxman product to prevent CIPN

**Dr. Raghav Sundar** at NUH is head of the project for the development of a cooling and compression device to prevent CIPN, in collaboration with Paxman.

## Can you update on the general progress made in this project in 2020 and so far in 2021?

The Paxman-Singapore team has made good progress with respect of device development and clinical study design. The device development has moved forward from design stage to prototyping, currently at beta prototyping stage. The teams have filed two provisional patents covering design of the device and wraps. Regarding the aspect of clinical studies, we have established important collaborations with clinical experts from the USA such as Prof. Charles Loprinzi who has shown great interest in co-developing the clinical study design.

## Can you elaborate on Prof. Charles Loprinzi's involvement and the scope of the study?

Prof. Charles Loprinzi, a key opinion leader in the CIPN field, has been an integral part of the planning and design of the clinical study, which will potentially be a multi-centre large-scale clinical trial investigating the efficacy of the limb cryocompression device.

## How far have you progressed when it comes to the development of the cryocompression device and the wraps?

In spite of the evolving pandemic situation globally, the team continued to make good progress in design and development of the limb cryocompression prototypes

in 2020. We have successfully conducted a user experience testing at the Leeds teaching hospital with the developed alpha prototypes. This was further improved to beta prototype stage incorporating inputs from the Leeds user study. The cryocompression device and wrap design and development have been filed as provisional patents.

## Are you working together with the R&D team in Huddersfield on this project?



We are collaborating with the University of Huddersfield R&D team for design and development of the limb cryocompression devices. The team's expertise and experience from the scalp cooling device development has helped accelerate the limb cryocompression device development, however the two projects are distinct at this stage.

## Looking ahead, how far are you hoping to progress in 2021?

The Paxman and Singapore teams are working with Prof. Loprinzi to design clinical studies to investigate safety and efficacy of the cryocompression devices in preventing CIPN, potentially a multi-centre large-scale clinical trial. The pilot study for this will commence in Singapore to investigate device safety.

## With regards to producing devices ready for the study, what are your goals for 2021?

The team is working towards ten beta prototypes to be sent to Singapore for pilot studies in healthy volunteers and cancer patients to investigate safety and effectiveness in 2021.

## Clinical studies and collaborations

The Paxman Scalp Cooling System is continuously evaluated with different types of chemotherapy treatments and patient groups, hair types and ethnicities from around the world in order to gain further knowledge, improve patient experience and efficacy and ensuring a diverse and inclusive approach to provide the best possible outcome and patient education.

### Some of the studies that were initiated or completed in 2020 or early in 2021

#### Large open randomized breast cancer trial in South Korea

An open label randomized controlled trial of Paxman's PSCS system with chemotherapy-induced alopecia in breast cancer patients was initiated in South Korea in December 2020. The trial will study stage I-III breast newly diagnosed cancer patients, aged 20-69 who will receive Adriamycin and/or Taxane as neoadjuvant or adjuvant treatment.

Paxman, along with their partner TPC (part of the Nokwon Group) will continue to collaborate closely with the study's principal investigator Jin Seok Ahn, MD, PhD and its co-principal investigator Juhee Cho, PhD of the prestigious Samsung Medical Center, during the trial period. Patient recruitment began in November 2020, with 100 patients anticipated to join the trial in the first year, with publication of the data planned for early 2023.

The primary objective of the trial is to demonstrate that the PSCS system is effective in reducing permanent chemotherapy-induced alopecia in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy. The demonstration that the PSCS is effective in reducing distress due to chemotherapy-induced alopecia and increasing quality of life in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy is the important secondary objective.

#### Study with 100 participants in Hong Kong

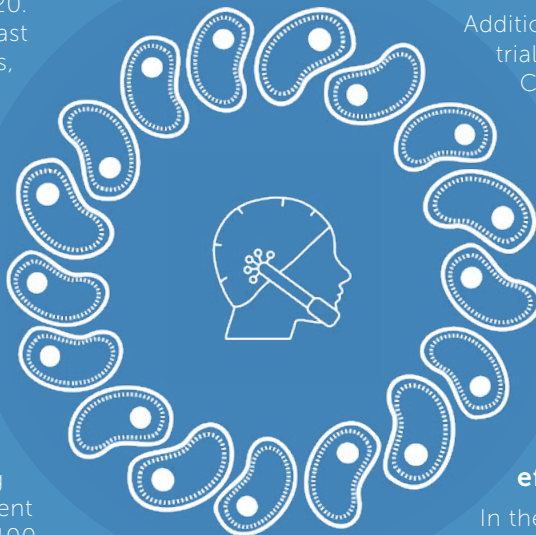
In December 2020, the "Alopecia Prevention Scalp Cooling in Chinese Breast Cancer Patients" study was initiated at the Prince of Wales Hospital, Hong Kong and is expected to be concluded towards the end of 2023. The trial will aim to enrol 100 patients and measure the success rate of scalp cooling, the rate of perceived hair preservation, quality of life, and the incidence of treatment-emergent adverse events of scalp cooling.

Additionally, the ongoing independent trial "Scalp Cooling in Gynecologic Cancer Patients" continues at the University of Hong Kong, Queen Mary Hospital. This trial will measure levels of anxiety / depression, quality of life, incidence and grading of CIA, and incidence and grading of treatment-related adverse events. Mid-2022 is the anticipated end date.

#### Clinical study in Japan shows strong scalp cooling efficacy in Asian patients

In the middle of 2020, data from a clinical prospective study at the Shikoku Cancer Center concluded that efficacy in Asian breast cancer patients is comparable to Caucasian patients. This is an important finding following weaker data for Asian patients that was published in 2019. The article is available to read online. The study included 143 female breast cancer patients with an average age of 50 who planned to receive (neo) adjuvant chemotherapy. Its primary aim was to evaluate patients with grade 3 alopecia (>50%) and use of a wig one month after chemotherapy.

The author followed up with these patients and recently published further data in the Supportive Care in Cancer Journal in a publication named



'Prospective study of hair recovery after (neo) adjuvant chemotherapy with scalp cooling in Japanese breast cancer patients (Ohsumi et al 2021)'.

In this study, all the women were assessed for the following year and it was found that objective hair regrowth was better at all time points for the SC group compared to the control. The patient's own (subjective) assessment of hair regrowth was significantly better after SC at 4 and 7 months. In addition, the objective increase in the rate of hair growth in the SC group occurred in both those that experienced Grade 3 alopecia 1 month after treatment and those that did not, thus scalp cooling could reduce hair follicle damage even in those who suffer Grade 3 alopecia. This theory is supported by the fact that the study also showed that persistent alopecia, defined as hair loss at 13 months, occurred in 1.4% of the SC group compared to 18.4% in the control group.

### Indian study on the psychosocial impact of hair loss

An Indian study, "A Descriptive Study to Analyse Chemotherapy Induced Hair Loss and its Psychosocial Impact in Adults: Our Experience from a Tertiary Care Hospital" (2021) claims 'A total of 101 (56.4%) patients felt that hair loss was the worst side effect of chemotherapy, while 29 (16.2%) had to continue because it was life saving.'

### The first clinical data report of scalp cooling in Argentina

Paxman's distribution partner in Argentina, Xeikon DIAGNO SA, has been working closely with the prestigious The Sanatorio Parque, Rosario, in the Province of Santa Fe on the first clinical data report of scalp cooling in Argentina, which is now published.

The overall success rate in the prevention of chemotherapy-induced alopecia was 78% in the population analysed, being 90% with taxanes, 71% with anthracycline-taxane and almost 61% with taxanes-platinum and dose-dense anthracyclines /

taxanes. The most common adverse events were headache and chills, while no serious adverse effects were recorded. 11.4% of the patients discontinued the scalp cooling treatment program due to intolerance.

### First non-cancer scalp cooling study in pediatric patients

In February 2021, Paxman announced that that the "Pilot Study of Cold Cap Therapy for Prevention of Hair loss in Pediatric Patients Receiving Chemotherapy for Non-Malignant Indications" will be the first study undertaken with Paxman in pediatric patients, and also the first-time scalp cooling has been investigated as a therapy for the prevention of hair loss for patients receiving chemotherapy for non-malignant indications.

High dose conditioning chemotherapy and subsequent hematopoietic stem cell transplant (HSCT) has been associated with permanent chemotherapy induced alopecia. The incidence of permanent alopecia ranges from 0.9% to 43% in adults and 24% in pediatric patients.

The primary aim of the study is to assess the safety and feasibility of the use of scalp cooling in pediatric and young adult patients receiving chemotherapy for non-malignant disorders.

Comparisons will be made of hair loss experienced by the scalp-cooled patients receiving chemotherapy and those patients who do not use scalp cooling during their chemotherapy treatment. The incidence and intensity of chemotherapy induced hair loss in patients receiving chemotherapy for non-malignant conditions who have used a scalp-cooling device will also be assessed.

The recruitment of up to 40 participants began in mid-March with an anticipated primary end date of December 2024. Conclusion of the study is expected by the end of 2025.



RESEARCH AND DEVELOPMENT

## International and digital presence at scientific conferences and industry events

Research conferences and industry events are two of Paxman’s most important forums for raising awareness and knowledge of scalp cooling, and to create credibility and enthusiasm for its activities among leading researchers and clinicians. Numerous events were cancelled in the second quarter due to the pandemic, but then many started to use virtual solutions.

Prior to the social restrictions that were implemented in many regions, Paxman was able to attend events including Arab Health, Best of Breast in Florida and the Miami Breast Cancer Conference. The company also held its own and much appreciated educational event in Washington DC, the Clinical Pioneer Program.

During the third and fourth quarter, Paxman virtually attended events including the Oncology Nursing Society (ONS) first Virtual Bridge-event, the 12th European Breast Cancer Conference, London Global Cancer Week, UK Oncology Nursing Society

(UKONS) annual conference and San Antonio Breast Cancer Symposium (SABCS).

Paxman also extended its own range of digital activities and events substantially in 2020. Among others, the company launched the successful Conversations with the CEO series where Richard Paxman invites experts to conversations on cancer treatments and various aspects of scalp cooling, and a virtual version of its Clinical Pioneer Program. The first instalments of these virtual educational days were held on March 16 and 25.

# NATIONAL MANUFACTURING CONFERENCE

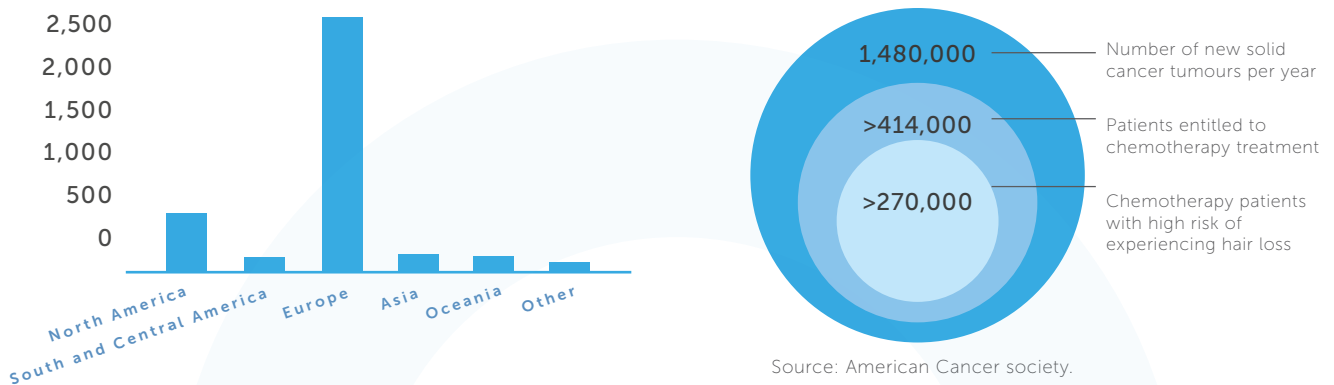


## Markets and sales

### Scalp cooling to prevent hair loss in connection with chemotherapy – a global growth market

Paxman develops and offers complete scalp cooling solutions used to prevent chemotherapy-induced hair loss. In addition, a medical compression and cooling device is under development to prevent chemotherapy-induced nerve damage in hands and feet (CIPN). As cancer affects people in all countries and continents, the market for scalp cooling is truly global and currently Paxman has customers in Europe, North-, Central- and South America, Asia and Oceania.

**Total number of delivered systems per region    The North American market**



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

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

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

As the knowledge on the benefits of scalp cooling increases, and thus the demand from both healthcare providers and patients, the scalp cooling market is growing at a strong rate. The inclusion in the NCCN® guidelines in the USA, ESMO guidelines in Europe and Cancer Australia's guidelines, and the AMA's decision in the USA to create CPT codes for scalp cooling with availability from July 1, 2021, will also further contribute to the use and acceptance of scalp cooling. Paxman had installed around 4,000 scalp cooling systems at the end of 2020, which

means that only a fraction of all the patients who could benefit from scalp cooling has access to the technology at present.

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

Consequently, the USA is one of Paxman's most important individual markets. In Japan, where Paxman received market approval in March 2019, about 1 million new cancer cases are discovered each year. Japan is expected to become one of Paxman's most important markets in the coming years, and the company is also aiming to increase its presence in markets such as India, while also evaluating possible go-to-market strategies for China.

#### Competitors

Scalp cooling using gel caps is a method that has been used for many years. However, gel caps require careful and correct handling to work optimally and lack approval from important government bodies such as the FDA in the USA. Consequently, Paxman does not expect any meaningful competition from companies using this method. In the liquid-based scalp cooling sector, Dignitana is the most prominent competitor. The company has had some success globally and in the USA, and has sold hundreds of systems in total. However, Paxman has sold several times more systems and is the only company to have received market approval in Japan, giving Paxman a head-start of 1-2 years on the world's second largest market.

# Chemotherapy-induced nerve damage in hands and feet (CIPN)

## – a global and under-treated health problem

Many people know that chemotherapy treatment can cause hair loss, but nerve damage in hands and feet (chemotherapy-induced peripheral neuropathy, CIPN) is also a severe and common side effect. In early 2019, Paxman started a collaboration with the National University Hospital in Singapore (NUH) with the aim of developing a portable compression and cooling device to prevent CIPN. The parties are planning to initiate clinical studies in 2021.

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

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

### Competitors

To date, there is no market-approved cooling product to prevent CIPN. However, other companies are conducting research and development in this field of which the Swedish company Braincool, listed on

Nasdaq First North, is considered the most important competitor. Paxman believes that the company's solid experience from developing market leading scalp cooling equipment, collaborations with world-leading scientists at NUH, excellent relationships and collaborations with leading key opinion leaders in the clinical field, a strong global customer base and an exclusive focus on oncology-related applications constitute substantial advantages over this competitor.

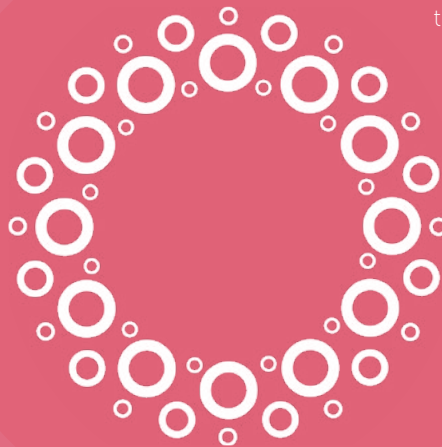
In addition to the United States, Paxman considers Japan, India and then China as three of the most important markets for its future growth.

## Targets and outlook

Paxman's long-term goal is that all patients undergoing chemotherapy shall have access to scalp cooling, and that the Paxman Scalp Cooling System is the obvious first choice for cancer patients all over the world. In 2020, the company solidified its position as the superior global market leader by selling and/or installing 345 systems in Europe, North and South America, Asia and Oceania despite severe challenges due to the COVID-19 pandemic.

In addition to the United States, Asia is becoming an increasingly important region for Paxman. Japan is the company's leading single Asian market, with India and then China (where Paxman is evaluating go-to-market strategies but not yet established) expected to become additional important contributors of growth. Paxman is also established in other Asian markets such as Malaysia, Singapore and Pakistan. So far, the company has delivered over 70 systems to Japan.

To further increase its global growth rate, Paxman is planning to expand its outreach to additional markets going forward, including China as stated above, and this may also include additional collaboration agreements with the large pharmaceutical company Teva Pharmaceuticals in addition to the existing licensing agreement for Mexico. Paxman has also initiated efforts to increase its physical and digital presence in important regional markets, as well as a strengthening of the marketing function in



the UK. Additionally, the project for the development of a new product to prevent chemotherapy-induced nerve damage in hands and feet (CIPN) constitutes a promising opportunity to broaden the product portfolio in the future.

The company will also continue the transition to regional business models, with income generated for each personal cooling cap that is sold and/or each treatment. This business model is fully implemented in the United States, and a similar model is used in Mexico in collaboration with the licensing partner Teva. A modified model is used in Japan where the company sells scalp cooling systems to the distributor and receives payment for each personal cooling cap sold. This model is also gradually implemented in additional markets when the company is able to start offering its latest PSCS model.

# PAXMAN<sup>o</sup>

CHANGING THE FACE OF CANCER

## Systems installed in 2020

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



Australia	11	Hungary	1	Russia	12
Bahrain	1	India	3	Saudi Arabia	2
Brazil	8	Israel	1	Singapore	1
Canada	1	Italy	20	Slovakia	1
Cayman Islands	1	Japan	21	Spain	2
Cyprus	3	Malaysia	1	Sweden	5
Czech Republic	1	Netherlands	33	Switzerland	12
France	19	Pakistan	1	UK	74
Germany	4	Poland	4	United Arab Emirates	1
Greece	1	Portugal	3	USA	97
				<b>Total</b>	<b>345</b>

# PAXMAN<sup>o</sup>

CHANGING THE FACE OF CANCER

## Systems installed in 2019

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



Argentina	8	Japan	50	Spain	10
Australia	10	Jordan	2	Sweden	3
Brazil	19	Lithuania	2	Switzerland	20
Bulgaria	2	Malaysia	5	Turkey	5
France	7	Mexico	25	UK	84
Georgia	4	Netherlands	39	United Arab Emirates	1
Germany	20	Poland	5	USA	234
India	13	Puerto Rico	1	<b>Total</b>	<b>597</b>
Ireland	7	Russia	5		
Italy	15	Slovakia	1		

# The people behind Paxman

## Management team



### Richard Paxman

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

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

**Born: 1983**

**Holding: 1,281,000 shares**



### Emelie Gustafsson

**CFO since March 1, 2020.**

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

**Born: 1980**

**Holding: 2,000 shares**

## The Board



### Per-Anders Johansson

**Chairman of the board since December 1st, 2016.**

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

**Born: 1954**

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

\* This refers to the holding at the time of publication for this annual report.



### 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: 0 shares**

### Björn Littorin

**Member of the board since December 1st, 2016.**

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

**Born: 1947**

**Holding: 765,076 shares**



**THE PEOPLE BEHIND PAXMAN**

## The Board



### Glenn Paxman

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

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

**Born: 1956**

**Holding: 6,268,645 shares**



### Richard Paxman

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

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

**Born: 1983**

**Holding: 1,281,000 shares**



### Maria Bech

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

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

**Born: 1968**

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

## Directors' report 2020

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 2020.

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

### Corporate information

#### The company

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

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

#### Earnings and financial position

- The group's turnover amounted to 78,053 (85,279) TSEK.
- The group's net profit/loss was -19,186 (2,756) TSEK, with profit/loss per share amounting to -1.2 (0.17) SEK.
- Consolidated equity as of 31 December totalled 10,889 (28,361) TSEK. The equity/assets ratio for the group was 14.1 (33.4) %.
- The group's cash and bank balances totalled 3,577 (1,603) TSEK at year end.
- On 31 December 2020, the group's external interest-bearing liabilities amounted to 48,230 (31,452) TSEK, of which 31,817 (17,344) TSEK were current liabilities.
- Cash flow from operating activities was -8,484 (3,305) TSEK for the year, with total net investments amounting to -6,320 (-20,827) TSEK. Cash and bank balances increased by 1,974 (1,155) TSEK in 2020.

#### The parent company

- The parent company's operations include only group functions such as finance, legal and communication. Thus, the parent company reports no sales.
- The parent company's cash and bank balances amounted to 50 (50) TSEK on 31 December.
- Cash flow from operating activities was -4,974 (-4,184) TSEK. The parent company made no investments that affected cash flow in the financial year 2020 or 2019.
- The parent company had 0 (1) employee on the balance sheet date.

#### Two-year summary for the group

	2020	2019	2018	2017
Operating income, TSEK	85,478	95,670	68,563	36,285
EBITDA <sup>1)</sup>	-1,045	2,438	-95	-5,198
Operating profit/loss, TSEK	-11,690	-5,960	-4,782	-6,796
Profit/loss after financial items, TSEK	-20,096	-2,674	-5,164	-6,853
Total assets, TSEK	77,011	84,973	55,739	45,606
Equity/assets ratio, % <sup>2)</sup>	14.1	33.4	45.6	71.8
Total number of employees at year end	51	48	41	35

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

2) Adjusted equity as a percentage of total assets.

**DIRECTORS' REPORT****Significant developments in 2020**

At the beginning of the year, Paxman appointed Emelie Gustafsson as its new CFO, effective March 1, 2020. Paxman's previous CFO Eva Jonasson left the company on her own request to retire.

In February, an additional credit facility of 20 MSEK was secured to guarantee Paxman's continued expansion in the important US market.

During the first quarter, the new patient-focused website [www.coldcap.com](http://www.coldcap.com) and a blog that will offer comprehensive information on scalp cooling and its benefits was launched. Additionally, Paxman announced that it will also update its company website.

In late March, the National Comprehensive Cancer Network® (NCCN®) in the United States updated its guidelines for ovarian cancer, fallopian tube cancer and primary peritoneal cancer with scalp cooling as a recommended category 2A treatment to reduce hair loss. Over 20,000 new ovarian cancer cases are discovered annually in the United States alone.

Considering the Covid-19 pandemic, Paxman implemented substantial cost-reducing measures during the first half of the year. The company also received a Corona Business Interruption Loan of 700,000 GBP and an extended credit of 400,000 GBP. Additionally, the company was granted access to the Small Business Paycheck Protection Program in the United States and the Coronavirus Job Retention Scheme in the UK.

In August, Paxman appointed TPC Korea as its new distributor in South Korea, a market with around 230,000 new cancer cases annually. Additionally, Claes Médical Service was appointed as the company's distributor in Morocco, a market with approx. 50,000 new cancer cases per year.

In the third quarter, two clinical guidelines of importance to Paxman were updated. European Society for Medical Oncology (ESMO) together with European Oncology Nursing Society (EONS) and European Association of Neuro-Oncology (EANO) updated their clinical guidelines for chemotherapy-induced peripheral neuropathy (CIPN) with cooling therapy as a recommended pre-emptive measure, which is positive for Paxman's ongoing development of a product to prevent CIPN. Cancer Australia updated its guidelines for early breast cancer treatment so that they now include scalp cooling in connection with chemotherapy.

In the third quarter, Paxman announced that patent applications had been filed for the cooling and compression product that the company is developing to prevent chemotherapy-induced nerve damage (CIPN) together with National University of Singapore. The company also applied for financing of clinical studies and the continued commercialisation of the product. Prof. Charles Loprinzi, one of the world's leading clinical opinion leaders within this field, was welcomed as a new member of Paxman's advisory board.

In October, regulatory approval was achieved in South Korea for an open, randomised study of Paxman's PSCS system in connection with chemotherapy-induced hair loss in breast cancer patients at the prestigious Samsung Medical Center. The patient recruitment was initiated in November, 2020 with the aim to recruit 100 patients during the first year of the study.

In late October, it was announced that the US healthcare authority AMA had decided to create so-called CPT codes for scalp cooling. AMA's decision is important for patients across the United States, and it is expected to strengthen the role of scalp cooling in cancer care and support a substantially expanded access for patients. The two new CPT codes will be available to use from July 1, 2021.

In the beginning of December, Paxman announced that Praesidia s.r.l, the company's distributor in Italy, had received an order of 10 PSCS2 systems to the hospital Institute G.Pascale in Naples. The hospital is a new user of Paxman's scalp cooling.

In the middle of December, it was announced that ESMO, the leading European professional organisation for medical oncology, had included scalp cooling as a category IIB recommendation

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

## Employees

As of 31 December 2020, the Paxman group had a total of 51 employees, of whom 44 in Huddersfield, England and 7 in Houston, USA.

As of 31 December 2019, the Paxman group had a total of 48 employees, of whom 1 employed by the parent company, 40 in Huddersfield, England and 7 in Houston, USA.

## Incentive programmes

At the Annual General Meeting on May 23, 2019, it was resolved to issue warrants to employees of the subsidiary Paxman Coolers Ltd. A total of 68,478 warrants have been issued, with the right to subscribe for a maximum of 68,478 new shares in Paxman AB. The warrants entitle the holder to subscribe for shares from June 2020 until June 2029, at a subscription price of SEK 65.37 per share. Upon full subscription, the dilution effect amounts to 0.4% of the total number of shares in the company.

## Environment

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

## Proposed appropriation of retained earnings

### Retained earnings at the disposal of the Annual General Meeting:

Retained earnings	28,947 TSEK
Profit/loss for the year	-5,284 TSEK
	23,663 TSEK

### The Board of Directors proposes that the retained earnings are to be appropriated as follows:

Carried forward	23,663 TSEK
	23,663 TSEK

Paxman's net profit/loss for the accounting year 2020, as well as the company's financial position as at 31 December 2019, are disclosed in the following income statements, balance sheets and cash flow statements.

## CONSOLIDATED INCOME STATEMENT

## Consolidated income statement

TSEK	Note	2020	2019
<b>Operating income</b>			
Net sales	4,5	78,053	85,279
Work performed by the company for its own use and capitalized		5,084	10,391
Other income	6	2,341	-
<b>Total operating income</b>		<b>85,478</b>	<b>95,670</b>
<b>Operating expenses</b>			
Raw materials and consumables		-32,449	-31,631
Other external costs	7,9	-30,098	-37,347
Personnel costs	8	-23,976	-24,254
Depreciation and write-downs	10	-10,645	-8,398
<b>Total operating costs</b>		<b>-97,168</b>	<b>-101,630</b>
<b>Operating profit/loss</b>		<b>-11,690</b>	<b>-5,960</b>
<b>Result from financial investments</b>			
Other interest income and similar profit/loss items	11	13	4,667
Interest expense and similar profit/loss items	12	-8,419	-1,381
<b>Total result from financial investments</b>		<b>-8,406</b>	<b>3,286</b>
<b>Profit/loss after financial items</b>		<b>-20,096</b>	<b>-2,674</b>
Tax	13	910	5,430
<b>Net profit/loss for the year</b>		<b>-19,186</b>	<b>2,756</b>
Net profit/loss per share*		-1.20	0.17

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

# Consolidated balance sheet

TSEK	Note	2020-12-31	2019-12-31
<b>Assets</b>			
<b>Fixed assets</b>			
<b>Intangible assets</b> 14			
Concessions, patents, licences, trademarks and similar rights		12,424	12,329
<b>Total intangible assets</b>		<b>12,424</b>	<b>12,329</b>
<b>Tangible assets</b> 15			
Plant and machinery		26,551	30,956
Equipment, tools, fixtures and fittings		2,947	2,961
<b>Total tangible assets</b>		<b>29,498</b>	<b>33,917</b>
<b>Financial assets</b>			
Deferred tax asset	13	5,735	6,500
Participations in associated companies	16	42	47
<b>Total financial assets</b>		<b>5,777</b>	<b>6,547</b>
<b>Total fixed assets</b>		<b>47,699</b>	<b>52,793</b>
<b>Current assets</b>			
<b>Inventories etc.</b>			
Finished products and goods for resale		13,746	11,861
<b>Total inventories etc.</b>		<b>13,746</b>	<b>11,861</b>
<b>Current receivables</b>			
Accounts receivable – trade	19	6,271	11,509
Receivables from associated companies	20	527	484
Other receivables		1,618	2,461
Prepaid expenses and accrued income	21	3,573	4,262
<b>Total current receivables</b>		<b>11,989</b>	<b>18,716</b>
Cash and bank balances		3,577	1,603
<b>Total current assets</b>		<b>29,312</b>	<b>32,180</b>
<b>Total assets</b>		<b>77,011</b>	<b>84,973</b>

**CONSOLIDATED BALANCE SHEET****Consolidated balance sheet**

TSEK	Note	2020-12-31	2019-12-31
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital (16,012,500 shares)		16,012	16,012
Non-restricted equity		14,063	9,593
Profit/loss for the year		-19,186	2,756
<b>Total equity</b>		<b>10,889</b>	<b>28,361</b>
<b>Provisions</b>			
Provisions for taxes	13	667	663
<b>Total provisions</b>		<b>667</b>	<b>663</b>
<b>Non-current liabilities</b>			
Liabilities to credit institutions	22	16,413	14,108
<b>Total non-current liabilities</b>		<b>16,413</b>	<b>14,108</b>
<b>Current liabilities</b>			
Liabilities to credit institutions	22	31,817	17,344
Accounts payable – trade		10,957	19,895
Income tax liability		-	1,037
Other liabilities		2,808	1,562
Accrued expenses and deferred income	23	3,460	2,003
<b>Total current liabilities</b>		<b>49,042</b>	<b>41,841</b>
<b>Total liabilities</b>		<b>65,455</b>	<b>55,949</b>
<b>Total equity and liabilities</b>		<b>77,011</b>	<b>84,973</b>

For changes in equity for the group, see page 55.

# Consolidated cash flow statement

## - Note 25

TSEK	2020	2019
<b>Cash flow from operating activities</b>		
Profit/loss before financial items	-11,690	-1,293
Financial items	-8,405	-1,381
Income tax paid	735	-1,205
<b>Other non-cash items</b>		
Depreciation and write-downs	10,645	8,398
Unrealised currency effects	1,714	-
<b>Cash flow before working capital changes</b>	<b>-7,002</b>	<b>4,519</b>
<b>Cash flow from changes in working capital:</b>		
Inventories etc.	-1,885	-4,042
Current receivables	7,675	-5,108
Current liabilities	-7,272	7,936
<b>Cash flow from operating activities</b>	<b>-1,482</b>	<b>-1,214</b>
<b>Cash flow from operating activities</b>	<b>-8,484</b>	<b>3,305</b>
<b>Investing activities</b>		
Investments in intangible fixed assets	-1,646	-3,834
Investments in tangible fixed assets	-4,674	-16,993
Investments in financial fixed assets	-	-
<b>Cash flow from investing activities</b>	<b>-6,320</b>	<b>-20,827</b>
<b>Financing activities</b>		
New loans	16,778	18,677
<b>Cash flow from financing activities</b>	<b>16,778</b>	<b>18,677</b>
<b>Cash flow for the year</b>	<b>1,974</b>	<b>1,155</b>
Cash and cash equivalents, opening balance	1,603	448
Cash and cash equivalents, closing balance	3,577	1,603

## PARENT COMPANY INCOME STATEMENT

## Parent company income statement

TSEK	Note	2020	2019
<b>Operating income</b>			
Net sales		-	-
<b>Total operating income</b>		-	-
<b>Operating costs</b>			
Other external costs	7	-3,110	-2,110
Personnel costs	8	-512	-1,355
<b>Total operating costs</b>		<b>-3,622</b>	<b>-3,465</b>
<b>Operating profit/loss</b>		<b>-3,622</b>	<b>-3,465</b>
<b>Result from financial investments</b>			
Interest income and similar profit/loss items	11	717	588
Interest expense and similar profit/loss items	12	-2,379	-1,208
<b>Total result from financial investments</b>		<b>-1,662</b>	<b>-620</b>
<b>Profit/loss after financial items</b>		<b>-5,284</b>	<b>-4,085</b>
Tax	13	-	-
<b>Net profit/loss for the year</b>		<b>-5,284</b>	<b>-4,085</b>

## Parent company balance sheet

TSEK	Note	2020-12-31	2019-12-31
<b>Assets</b>			
<b>Fixed assets</b>			
<b>Financial assets</b>			
Participations in group companies	17	26,228	25,756
<i>Total financial assets</i>		<i>26,228</i>	<i>25,756</i>
<b>Total fixed assets</b>		<b>26,228</b>	<b>25,756</b>
<b>Current assets</b>			
<b>Current receivables</b>			
Receivables from group companies	18	46,867	45,901
Other receivables		600	491
Prepaid expenses and accrued income	21	54	73
<i>Total current receivables</i>		<i>47,521</i>	<i>46,465</i>
Cash and bank balances		50	50
<b>Total current assets</b>		<b>47,571</b>	<b>46,515</b>
<b>Total assets</b>		<b>73,799</b>	<b>72,271</b>

## PARENT COMPANY BALANCE SHEET

## Parent company balance sheet

TSEK	Note	2020-12-31	2019-12-31
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital (16,012,500 shares)		16,012	16,012
<i>Total restricted equity</i>		<i>16,012</i>	<i>16,012</i>
<b>Non-restricted equity</b>			
Share premium reserve		28,947	32,560
Profit/loss for the year		-5,284	-4,085
<i>Total non-restricted equity</i>		<i>23,663</i>	<i>28,475</i>
<b>Total equity</b>		<b>39,675</b>	<b>44,487</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Liabilities to credit institutions	22	9,480	13,740
<b>Total non-current liabilities</b>		<b>9,480</b>	<b>13,740</b>
<b>Current liabilities</b>			
Liabilities to credit institutions	22	23,840	13,640
Accounts payable – trade		136	76
Other liabilities		Ta bort	106
Accrued expenses and deferred income	23	668	222
<i>Total current liabilities</i>		<i>24,644</i>	<i>14,044</i>
<b>Total liabilities</b>		<b>34,124</b>	<b>27,784</b>
<b>Total equity and liabilities</b>		<b>73,799</b>	<b>72,271</b>

For changes in equity for the parent company, see page 55.

# Parent company cash flow statement

## - Note 25

TSEK	2020	2019
<b>Cash flow from operating activities</b>		
Profit/loss before financial items	-3,622	-3,465
Adjustments for:		
Financial items	-1,662	-620
<b>Cash flow from changes in working capital:</b>		
Current receivables	-90	-88
Current liabilities	400	-11
<b>Cash flow from operating activities</b>	<b>-4,974</b>	<b>-4,184</b>
<b>Financing activities</b>		
New loans	5,940	17,677
Loans to group companies	-966	-13,493
<b>Cash flow from financing activities</b>	<b>4,974</b>	<b>4,184</b>
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>
Cash and cash equivalents, opening balance	50	50
Cash and cash equivalents, closing balance	50	50

## CHANGES IN EQUITY

## Changes in equity

The group TSEK	Share capital	Non-restricted equity	Profit/loss for the year	Total equity
<b>Total equity as of 2018-12-31 (16,012,500 shares)</b>	16,012	16,483	-7,101	25,394
Profit/loss carried forward		-7,101	7,101	-
Translation gains/losses on consolidation		-25		-25
Share related remuneration regulated by equity instruments		236		236
Profit/loss for the year			2,756	2,756
<b>Total equity as of 2019-12-31 (16,012,500 shares)</b>	16,012	9,593	2,756	28,361
Profit/loss carried forward		2,756	-2,756	
Translation gains/losses on consolidation		1,242		1,242
Share related remuneration regulated by equity instruments		472		472
Profit/loss for the year			-19,186	-19,186
<b>Total equity as of 2020-12-31 (16,012,500 shares)</b>	16,012	14,063	-19,186	10,889

Parent company TSEK	Share capital	Share premium reserve	Profit/loss for the year	Total equity
<b>Total equity as of 2018-12-31 (16,012,500 shares)</b>	16,012	35,126	-2,802	48,336
Profit/loss carried forward		-2,802	2,802	-
Translation gains/losses on consolidation				
Share related remuneration regulated by equity instruments		236		236
Profit/loss for the year			-4,085	-4,085
<b>Total equity as of 2019-12-31 (16,012,500 shares)</b>	16,012	32,560	-4,085	44,487
Profit/loss carried forward		-4,085	4,085	
Translation gains/losses on consolidation				
Share related remuneration regulated by equity instruments		472		472
Profit/loss for the year			-5,284	-5,284
<b>Total equity as of 2020-12-31 (16,012,500 shares)</b>	16,012	28,947	-5,284	39,675

## The share

Paxman has issued a total number of 16,012,500 shares, all fully paid for. Each share has a quota value of 1 SEK, and a voting right of 1. There are no pre-emption clauses, refusal clauses or other restrictions on the transfer of shares in the company. Up to 12 March 2018, the company's four original shareholders were bound by a so-called lock-up agreement, entered into in connection with Paxman's listing on Nasdaq First North Growth Market. By this agreement, these shareholders committed themselves to refrain from selling shares (directly or indirectly) in a nine-month period from the first day of trading on Nasdaq First North. In all, 12,810,000 shares were bound by the lock-up agreement. Prior to the listing this corresponded to 100 % of all issued shares; after the listing and the new share issue to 80 %.

## The share price

The listing price for Paxman's share on 12 June 2017 was SEK 9.50. The closing price at year-end was SEK 25.40. (2019: SEK 60.00, 2018-12-31: SEK 24.10, 2017-12-31: SEK 19.50).

## Shareholders

The company's 10 largest shareholders as of 2020-12-30 (Source: Euroclear 30/12/2020).

Name	Number of shares held	Shareholding in %
Paxman, Glenn	6,268,645	39.15
Paxman, Richard	1,281,000	8
CIMON Venture Trust AB	1,263,992	7.89
BNY Mellon SA/NV	994,584	6.21
Littorin, Björn	765,076	4.78
Länsförsäkringar Blekinge	585,000	3.65
Länsförsäkringar Kalmar län	545,185	3.4
Försäkringsaktiebolaget Avanza Pension	321,941	2.01
NOMIC AB	310,000	1.94
Johansson, Roger	250,000	1.56

On 30 December 2020, Paxman had a total of 963 (2019: 900) shareholders. The 10 largest of these held 78.6 (79.5) % of all issued shares.

Data per share	2020	2019
Earnings per share, SEK <sup>1)</sup>	-1.2	0.17
Earnings per share at full dilution, SEK <sup>2)</sup>	-1.2	0.17
Equity per share, SEK, <sup>1)</sup>	0.68	1.77
Cash flow from operating activities per share, SEK <sup>1)</sup>	-0.53	0.21
Share price at the end of the period, SEK	25.4	60
Number of shares at the end of the period	16,012,500	16,012,500
Number of shares at the end of the period at full dilution <sup>2)</sup>	16,080,978	16,080,978
Number of shares, weighted average during the year	16,012,500	16,012,500
Number of shares, weighted average during the year at full dilution <sup>2)</sup>	16,080,978	16,080,978

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

2) As of December 31, 2020, 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, 2020, there was no dilution effect to report.



**PAXMAN**<sup>o</sup>  
PIONEERS IN SCALP COOLING



**This annual report was made by Honeybadger together with Paxman**

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