

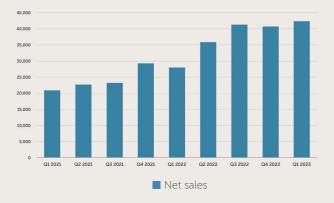


# Q1

## Strong sales growth and positive EBITDA

- The Group's sales amounted to 42.3 (27.9) MSEK for the first quarter of the year.
- The Group's net result totaled -2.5 (-6.2) MSEK for the period, and EBITDA amounted to 2.7 (-2.9) MSEK.
- Earnings per share were -0.13 (-0.33) SEK for the period.
- Cash flow before financing activities amounted to -8.3 (-8.9) MSEK for the first quarter of the year.
- Net liquid assets totaled 12.8 (46.2) MSEK at the end of the period.

- A total number of 140 (99) scalp cooling systems were installed around the world in the first three months of the year, with the order book containing an additional 162 systems.
- Average Daily Treatment Revenue (ADTR) amounted to 32.0 TUSD (333.9 TSEK) for Q1 2023, corresponding to an increase of 52,3% compared to 23.4 TUSD (219.2 TSEK) for Q1 2022. The figures in SEK have been converted from USD according to the actual exchange rate during each period.
- Recurring income increased from 16.6 MSEK in Q1 2022 to 23.7 MSEK for the same period in 2023.



#### Net sales (MSEK)

#### Recurring revenue (MSEK)



# Significant events during and after the reporting period...

## DURING THE PERIOD

In January the company announced that it received EU Medical Device Regulation (MDR) certification from its Notified Body, the British Standards Institution (BSI). Paxman is amongst the latest companies to achieve MDR approval, reaffirming its commitment to the market, its customers and, most importantly, the patients who will continue to benefit from the use of the Paxman Scalp Cooling System.

In January, the company incorporated Paxman Canada Inc., as a corporation in the province of Ontario. Following a successful pilot of the business through 2021 and 2022 the decision was taken to fully launch the company and incorporate. The company shall operate a hybrid business model offering pay for use services through Paxman personnel in large academic and high volume cancer centres and the sale of capital equipment to smaller regional cancer centres.

## AFTER THE PERIOD

#### Paxman attended its first exhibition in relation to the promotion

and marketing of the company and its products in China. Paxman, along with it's partner Concord Medical was exhibiting at BEYOND 2023 International Technology Innovation Expo in Macau. The exhibition took place at the Venetian Macao Convention and Exhibition Centre for 3 days from May 10-12 2023.

Paxman have shipped its first clinical trial Paxman Limb Crycocompression Systems (PLCS) to the USA in the months of April and May for the initiation of the ICE COMPRESS: Randomized Trial of Limb Cryocompression versus Continuous Compression versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy. Sites among the first to participate include Columbia University Medical Center, University of Washington Medical Center and Caromont Regional Medical Center.

#### Dear shareholders,

The year has got off to an excellent start. I cannot believe we are already approaching June and finally here in the UK a feeling of summer. We continue to feel confident about the rest of the year even with the backdrop of high inflation, slower growth expectations in some economies and other macro-economic challenges.

# Comment by the CEO

Richard Paxman has been CEO for 8 years. Under his leadership, Paxman has established its role as a global leader in scalp cooling to prevent hair loss in cancer patients.

At the start of the year we set out our 2023 vision for the company. A company that would deliver sustainable revenue growth, a positive and consistent EBITDA quarter on quarter, and most importantly drive towards cash flow positivity by the end of 2023. It is important to note the net cash position decreased from 46.2 MSEK Q1 2022 to 12.8 MSEK Q1 2023 but our cash availability at the end of Q1 2023 is 29 MSEK.

We are in a strong position to deliver, with our team and infrastructure in place, our investments in prior years paying dividends and a focus on a transition to the buy and bill model as opposed to new customer acquisition, therefore supporting a strong drive in utilisation which has been demonstrated by our early data from transitioning buy and bill sites. In the last 12 months we have invested heavily into our CIPN research and development programme, and most recently the manufacture of 200 devices for deployment in clinical trials. We shall now enter a period where minimal CIPN investment is required. Strong revenues and the reduction in high capital outlay in the USA and CIPN put the company in a good position.

Net revenues for the quarter reached 42 MSEK, compared to 28 MSEK for the same period in 2022, an impressive growth of 51% and our highest level of sales to date. Taking a look at this from an entity view, our UK entity posted sales of 2.4 million GBP for the quarter, which is on the same level as the prior quarter. In the USA, sales of 2.18 million USD were achieved, compared to 1.93 million USD for the prior quarter. We continue to maintain our gross margins with the expectations that price increases will improve this position or at least reduce any marginal impact. We continue to see our operating expenses and personnel costs stable.



The company delivered a 6% EBITDA of 2.7 MSEK, and we are confident in driving this margin in the coming quarters. An operating loss of 1.7 MSEK was achieved, due to high levels of depreciation based on our capital investments in the USA.

Our buy and bill business model continues to gain momentum but we have learned that contracting and the implementation can take some time due to the additional steps the providers now have to undertake, along with the different stakeholders that must be involved to initiate a successful launch. We know and understand that the patient experience is improved substantially, not only through improved access, but also through improved simplicity in obtaining access to scalp cooling without the financial burden. We have a large number of discussions and contracting negotiations in place. As you will have seen the success of the programme has been beyond our expectations in terms of coverage. Buy and bill income for the quarter reached 3 MSEK, above our expectations, a growth of 1.6 MSEK from Q4 2022. Looking

specifically at locations which use our Hub services, in 2023 through to April we have seen 203 Benefits Investigations (BI) completed with a coverage of 80% seen, and 35 patients supported through our Patient Assistance Programme. Our pilot programme with a community oncology location in Texas is progressing well with 20 patients now enrolled and early signs of claims data are looking good.

In the month of May I was with Concord Medical in Macau at the BEYOND 2023 International Technology Innovation Expo, showcasing our technology for the first time. We shall be working hard to understand the next steps of our collaboration with Concord, ensuring we can now build some momentum throughout 2023 and 2024.

We are excited for a busy June, where we shall be attending ASCO, exhibiting and hosting our network of providers throughout the Conference, as well as attending the Annual Conquer Cancer Dinner. We shall end the month in Japan for the joint MASCC and JASCC Conference in Nara where we shall be presenting the latest in cryotherapy for hair loss and peripheral neuropathy in a sponsored session. This sponsored session is conducted alongside Dignitana.

Although there have been some delays, not Paxman related, in the initiation of our clinical trials in the USA with SWOG, we are now deploying devices across the 25 sites hoping to see our first patients in May and June. This market represents a huge opportunity both commercially and to make an incredible difference to the patients potentially suffering from this debilitating side effect.

We are looking forward to delivering our vision through 2023. Thank you to all my team and our partners for continuing to make Paxman a success. We have a good year ahead.

Huddersfield, May 2023, **Richard Paxman, CEO** Paxman AB (publ)

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We are excited for a busy June, where we shall be attending ASCO, exhibiting and hosting our network of providers throughout the Conference, as well as attending the Annual Conquer Cancer Dinner. We shall end the month in Japan for the joint MASCC and JASCC Conference in Nara where we shall be presenting the latest in cryotherapy for hair loss and peripheral neuropathy in a sponsored session.

# Recurring revenue and new US business model update

Increasing recurring revenues is a focus for Paxman. In Q1 2023 recurring revenues reached 23.6 MSEK an 38% increase from Q1 2022.

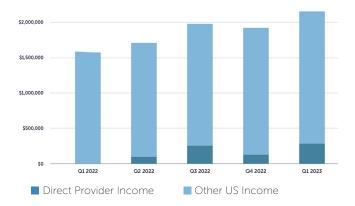
#### New US business model

The new business model in the United States is now gaining some momentum. The success of the model is measured in both direct provider income and coverage success for patients.



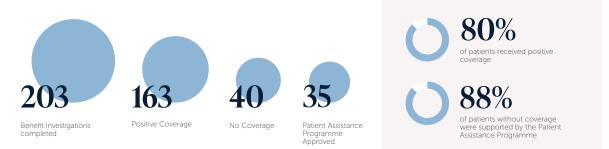
#### Recurring revenue (MSEK)





#### Direct Provider Income

#### Results for providers using Paxman Hub Services



Only providers using the full hub services are included in this data set - June 22, 2022 to April 23, 2023.

## **Installed systems January–March 2023**

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



Armenia	1	Israel
Australia	10	Netherlands
Austria	1	Romania
Brazil	12	Singapore
Bulgaria	1	Spain
Canada	1	Sweden
Colombia	1	United Arab Emirates
France	6	United Kingdom
India	3	USA
Ireland	2	



#### Total systems: 140

## **Installed systems January–March 2023**

## plus confirmed orders so far in 2023

The total number for the business operations so far in 2023 (up until May 22). This includes installed systems and confirmed orders that are yet to be installed. 302



Argentina	4	Hong Kong	1	Singapore	1
Armenia	1	India	10	South Korea	6
Australia	20	Ireland	5	Spain	3
Austria	2	Israel	8	Sweden	2
Bulgaria	1	Italy	10	Switzerland	2
Brazil	12	Japan	5	United Arab Emirates	6
Canada	2	Netherlands	8	United Kingdom	77
Columbia	1	Poland	1	Uruguay	1
Greece	1	Romania	1	USA	93
France	8	Russia	10		

#### Total systems: 302

# Comments to the financial statements

#### Sales and earnings

Net sales in Q1 2023 totalled 42.3 MSEK, compared to 27.9 MSEK in Q1 2022, corresponding to a 51% increase in revenue. US revenue is up 35% on Q1 2022.

In Q1 2023, EBITDA is recorded at a profit of 2.7 MSEK. This compares to an EBITDA loss of -2.9 MSEK for Q1 2022. This is due to the increase in revenue as a result of previous cost investment which is now being maintained.

Operating loss in Q1 was -1.7 MSEK. Operating earnings are of course also heavily impacted by depreciation, a consequence of strong investments in the US where the scalp cooling systems are reported as fixed assets in the Group's balance sheet of 34 MSEK.

Included within the financial costs is a currency loss of -582 TSEK, compared to a gain of 877 TSEK in Q1 2021.

There have been no transactions with related parties in the reporting period.

#### Cash flow

Cashflow from operating activities has improved to -1,8 MSEK compared to -3,4 MSEK Q1 2022, and is a consequence of the increased turnover.

#### **Financial position**

There is an increase in the group's liabilities to 55.7 (41.1) MSEK on 31 March, of which 16.3 (15.7) MSEK is interest bearing. The increase is due to an increase in trade payables due to increase in trading activity.

Cash on hand has decreased to 29 MSEK due to investing activities including Reimbursement and Research and Development.

#### **Employees**

As of 31 March 2023, the Group had a total of 79 employees, 1 by Paxman AB, 67 by Paxman Coolers Ltd and 11 by Paxman US, Inc. As of 31 March 22, the Group had a total of 67 employees, 1 by Paxman AB 57 by Paxman Coolers Ltd and 9 by Paxman US, Inc.



#### EBITDA (MSEK)



#### Parent company

Paxman AB (publ) is the parent company of the Paxman Group. Its operations include Group functions such as finance, legal and communications. The parent company has its headquarters in Karlshamn, in the south of Sweden.

#### Accounting principles

Paxman AB (publ) applies the accounting principles of BFNAR 2012:1 (K3), which are also the accounting and reporting principles used in the Group's annual report.

No adjustments have been made to these accounting principles since PAXMAN's latest annual report was published. This interim report has not been reviewed by the Group's auditors.

## AFFIRMATION

Paxman AB (publ)'s Board of Directors and CEO hereby assure that these summarized financial statements give a true and fair view of the Group's operations, financial position and performance.

Karlshamn, 24 May 2023

Paxman AB (publ)

Per-Anders Johansson	Chairman of the Board
Maria Bech	Director of the Board
Robert Kelly	Director of the Board
Björn Littorin	Director of the Board
Glenn Paxman	Director of the Board
Richard Paxman	CEO and Director of the Board

For further information, please contact Richard Paxman, CEO, Paxman AB (publ)

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This is information that Paxman AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, and will be published at 08:00 CEST on 24 May 2023.

## Consolidated income statement (condensed)

ТЅЕК	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Net sales	42,320	27,944	145,920
Capitalized expenses	3,407	1,708	10,825
Total operating income	45,727	29,652	156,745
Raw materials and consumables	-16,109	-11,320	-55,310
Other operating expenses	-13,472	-10,868	-35,788
Personnel costs	-13,461	-10,347	-49,472
Total operating costs	-43,042	-32,535	-140,570
EBITDA	2,685	-2,883	16,175
Depreciation	-4,346	-4,010	-17,418
Operating profit/loss	-1,661	-6,893	-1,243
Net financial items	-858	703	-7,319
Profit/loss after net financial items	-2,519	-6,190	-8,562
Tax	-12	-16	-1,761
Net profit/loss for the period	-2,531	-6,206	-10,323

## Consolidated balance sheet (condensed)

тѕек	31-Mar-23	31-Mar-22	31-Dec-22
Assets			
Intangible fixed assets	24,773	16,975	22,701
Tangible fixed assets	47,951	36,691	47,822
Financial fixed assets	7,366	6,574	7,426
Total fixed assets	80,090	60,240	77,949
Inventories	28,632	19,204	27,161
Current receivables	31,166	20,056	30,758
Cash and bank balances	29,126	61,974	38,092
Total current assets	88,924	101,234	96,011
Total assets	169,014	161,474	173,960
Equity and liabilities			
Shareholders' equity	111,770	119,423	114,198
Total equity	111,770	119,423	114,198
Provisions for taxes	1,479	938	1,451
Total provisions	1,479	938	1,451
Liabilities to credit institutions	3,887	5,395	4,257
Non-current liabilities	3,887	5,395	4,257
Liabilities to credit institutions	12,450	10,324	12,728
Accounts payable	24,080	13,905	24,170
Other current liabilities	15,348	11,489	17,156
Current liabilities	51,878	35,718	54,054
Total equity and liabilities	169,014	161,474	173,960

## Consolidated statement of cash flows (condensed)

ТЅЕК	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Cash flow from operating activities	-1,772	-3,430	1,688
Cash flow from investing activities	-6,547	-5,427	-35,692
Cash flow from financing activities	-647	-1,435	-170
Cash flow for the period	-8,966	-10,292	-34,174
Cash and cash equivalents, opening balance	38,092	72,266	72,266
Cash and cash equivalents, closing balance	29,126	61,974	38,092

## Consolidated changes in equity (condensed)

ТЅЕК	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Opening balance as of 1 January	114,198	125,755	125,755
Translation gains/losses on consolidation	103	-244	-1,470
Equity-settled share-based payment transaction		118	236
Profit/loss for the period	-2,531	-6,206	-10,323
Closing balance	111,770	119,423	114,198

## Key ratios

ТЅЕК	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Operating margin, %	Neg	Neg	Neg
EBITDA (TSEK)	2,685	-2,883	16,175
Equity/assets ratio, %	66.1%	74.0%	65.6%
Liquid assets, net (TSEK)	12,789	46,255	21,107
Market capitalization (TSEK)	673,043	1,087,515	819,439

## Parent company income statement (condensed)

ТЅЕК	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Net sales	480	27	219
Other operating income	-	-	25
Total operating income	480	27	244
Raw materials and consumables	-455	-9	-
Other external costs	-931	-936	-3,526
Personnel costs	-333	-272	-890
Total operating costs	-1,719	-1,217	-4,416
EBITDA	-1,239	-1,190	-4,172
Depreciation	-6	-6	-8
Operating profit/loss	-1,245	-1,196	-4,180
Net financial items	630	254	-496
Profit/loss after net financial items	-615	-942	-4,676
Net profit/loss for the period	-615	-942	-4,676

## Parent company balance sheet (condensed)

ТЅЕК	31-Mar-23	31-Mar-22	31-Dec-22
Assets			
Tangible fixed assets	33	56	39
Investments in Group companies	26,937	26,819	26,937
Total fixed assets	107,494	75,931	97,864
Receivables from Group companies	134,464	102,806	124,840
Accounts receivable	595	-	-
Other current receivables	1,021	733	1,080
Cash and bank balances	26,035	60,230	36,400
Total current assets	27,651	60,963	37,480
Total assets	162,115	163,769	162,320
Equity and liabilities			
Shareholders' equity	160,597	163,001	161,211
Total equity	160,597	163,001	161,211
Other current liabilities	1,065	244	444
Accrued costs and prepaid income	453	524	665
Total current liabilities	1,518	768	1,109
Total equity and liabilities	162,115	163,769	162,320

### Data per share

	Jan – Mar 2023	Jan – Mar 2022	Jan – Dec 2022
Earnings per share, SEK <sup>1)</sup>	-0.13	-0.33	-0.54
Earnings per share, SEK, diluted <sup>2)</sup>	-0.13	-0.33	-0.54
Equity per share, SEK <sup>1)</sup>	5.88	6.28	6.01
Cash flow from operating activities per share, SEK $^{\mbox{\tiny 1)}}$	-0.09	-0.18	0.09
Share price on closing day, SEK	35.4	57.2	43.1
Number of shares on closing day	19,012,500	19,012,500	19,012,500
Number of shares on closing day, diluted <sup>2)</sup>	19,080,978	19,080,978	19,080,978
Number of shares, weighted average in the period	19,012,500	19,012,500	19,012,500
Number of shares, weighted average in the period, diluted $^{2\mathrm{i}}$	19,080,978	19,080,978	19,080,978

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

2) As of March 31, 2023, the company had an outstanding option program, aimed at employees at the subsidiary Paxman Coolers Limited in Huddersfield. The decision to issue warrants was made at the Annual General Meeting on May 23, 2019, and the warrants were issued immediately thereafter. A total

of 68,478 warrants have been issued, with the accompanying right to subscribe for a maximum of 68,478 new shares in the company.

# OTHER INFORMATION

### **About Paxman**

We are global leaders in scalp cooling and cryotherapy, on an ambitious journey to change the face of cancer. Together, we can make a difference.

Paxman have been pioneering scalp cooling technology to help prevent chemotherapy-induced alopecia worldwide for over 20 years. The Paxman Scalp Cooling System is the market leading scalp cooling system. Presently, the system is used at a large number of cancer centres and hospitals in Europe, North-, Central- and South America, Asia and Oceania, and more installs are added continuously. The company is also developing a medical cooling and compression device to prevent chemotherapy-induced peripheral neuropathy (CIPN).

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 as the company's Brand Ambassador & Director of Global Training.

Their understanding of how important it is for cancer patients to keep their hair, and thereby a certain amount 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.

During the last ten years, Paxman has invested substantially in research and development, and then also on a targetfocused global expansion. The company has conducted many successful clinical studies with leading clinics and cancer centres all over the world, including the world's first randomised multicentre study with a scalp cooling system.

#### **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 is also under development. This product is aimed at preventing chemotherapy-induced peripheral neuropathy (CIPN), a related indication causing chronic nerve damage in hands and feet.

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 Research and Innovation Centre, the world's first multidisciplinary research centre focused on scalp cooling. During the first five years, the Paxman has an ongoing research collaboration agreement with National University Hospital, Singapore for the development of a portable cooling and compression device, to prevent CIPN. In May 2021, the project received a research grant of 1.57 million SGD from National Research Foundation (NRF) in Singapore. Thereafter, a clinical trial was initiated with National University Hospital, Singapore, in collaboration with The N.1 Institute for Health, National University of Singapore to evaluate the system with healthy volunteers and cancer patients. The first phase of this trial in Singapore was completed in 2022. Results from the first phase have been positive - patients have reported efficacy of the Paxman Limb Cryocompression System (PLCS) in helping to prevent chemotherapy-induced peripheral neuropathy, and there have been no chemotherapy dose reductions due to the onset of CIPN in any of the 15 cancer patients. Later in 2022, the study initiated the second expansion phase to recruit a larger patient population in preparation for plans to obtain Health Science Authority approval for the PLCS device in Singapore.

## "The company's vision is to make the technology available for all cancer patients worldwide."

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. In 2021, a further 600,000 GBP (7.1 MSEK) grant was awarded to the centre.

Together, the University of Huddersfield and Paxman are leading exciting and important multi-disciplinary scalp cooling and hair follicle research.

The aim of the Research and Innovation Centre is to be a global leader in its field, pushing the boundaries of human knowledge, while also developing cutting-edge products. Creating the best possible outcome for the patient will always be its first priority.

The Centre's three main areas of focus are:

1. Biological research using the most clinically relevant in vitro models, specifically cultivated human hair follicles. Learn more about the mechanisms of scalp cooling.

2. Development of a topical product with the potential to substantially enhance the effect of scalp cooling.

3. Development of an individual 3D-printed eco-friendly cooling cap, ready for mass production.

A larger randomized phase 3 efficacy study has been approved in the USA. The study, S2205, Ice Compress: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy will take place with the Paxman Limb Cryocompression System across the USA in a minimum of 25 locations and begin in 2023. This trial is part of the National Clinical Trials Network (NCTN) program, which is sponsored and funded by the National Cancer Institute (NCI). The trial will be led by SWOG with the participation of the network of NCTN organisations: Alliance for Clinical Trials in Oncology; ECOG-ACRIN Cancer Research Group; and NRG.

### Clinical studies and collaborations

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

#### Scalp Cooling in Metastatic Breast Cancer

Location: Dana-Farber Cancer Institute

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

Full text (ClinicalTrials.gov)

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

Location: Montefiore Medical Center

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

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

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

Full text (ClinicalTrials.gov)

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

Location: Memorial Sloan Kettering Cancer Center

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

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

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

Full text (ClinicalTrials.gov)

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

Location: Samsung Medical Center, Seoul

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

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

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

Full text (ClinicalTrials.gov)

## Alopecia Prevention Scalp Cooling in Chinese Breast Cancer Patients

Location: Chinese University of Hong Kong

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

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

Full text (ClinicalTrials.gov)

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

Location: St. Jude Children's Research Hospital

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

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

Estimated enrolment of 40 participants.

Full text (ClinicalTrials.gov)

## Reimbursement and related activities

Paxman is working intensely with specialised reimbursement consultants to influence major insurance companies and decision-making bodies. These include the AMA, and in October 2020 Paxman was able to announce that the AMA implemented a specific CPT code for scalp cooling that was available to use from July 2021. The company was also engaged in efforts to include scalp cooling in the NCCN's national cancer care guidelines in the USA, which was achieved in March 2019. In March 2020, NCCN included scalp cooling in their guidelines for ovarian cancer, fallopian tube cancer and primary peritoneal cancer. At the beginning of January 2021, it was announced that the AMA had issued two separate CPT<sup>®</sup> codes for "mechanical scalp cooling". The CPT® Category III codes are 0662T and 0663T, and they came into effect on July 1, 2021. These achievements are expected to quickly and efficiently increase the number of patients offered access to scalp cooling. Additionally, Paxman is supporting initiatives to promote legislation on the state level which makes it mandatory for health care plans to cover scalp cooling costs.

As Paxman announced in its 2 November, 2021 press release, the Centers for Medicare & Medicaid Services (CMS) issued its Medicare CY 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule ("HOPPS Final Rule"). In this HOPPS Final Rule, CMS announced that it was reassigning CPT code 0662T, which is for "Scalp cooling, mechanical; initial measurement and calibration of cap," to a higher reimbursement Ambulatory Payment Classification for hospitals. As of 1 January 2022, hospitals can bill for their services of "Scalp cooling, mechanical; initial measurement and calibration of cap" once per chemotherapy treatment period using CPT Code 0662T and they should be reimbursed under APC 1520 at a rate of 1,850.50 USD, with 80% being paid by Medicare and 20% being paid by the patient. In November 2022, CMS reconfirmed this decision for calendar year 2023.

In May 2022, Paxman launched its new buy and bill business model in the USA. This is an important step to allow the billing of CPT codes and reimbursement. With Paxman now offering full hub services the Paxman Hub will assist providers to bill their patients' insurance company. Providers under this new business model will receive support via the Paxman Hub to:

1) Verify patient insurance benefits,

2) Identify information if required for a Prior Authorization Submission and Appeal, and

3) Determine patient eligibility for the company's Patient Assistance Program (please see below for more detail).

#### The Paxman Patient Assistance Program

The company has also launched its Patient Assistance Program to ensure that there is an equitable approach to providing care across the USA. The Paxman Patient Assistance Program (PAP) is available when facilities are contracted under the new business model. The PAP assists patients who:

- Are uninsured or underinsured
- Live in the United States
- Live in a household with a combined income at or below a generous percentage of the US Federal Poverty Level

In addition to promoting payer coverage, Paxman is also supporting other initiatives to finance scalp cooling for patients who are unable to pay for their own treatment. This includes a close collaboration with HairToStay, an organisation that contributes financially to patients who cannot afford to pay for scalp cooling themselves. In honour of Sue Paxman, the parties also initiated a separate fund in her name specifically aimed at mothers with very low income.

### General targets and outlook

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

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

Market approval (Shonin) in Japan for use in connection with treatment of solid tumours like breast cancer was received in March 2019, and extensive marketing activities were then initiated together with the distributor CMI. With a recurring revenue model launched, Japan is set to be a strong growth market in the future. In addition to Japan, Paxman is already established in additional Asian markets such as India, Malaysia, Singapore and Pakistan, and the company is finalising a distribution agreement with Concord Medical for a market launch on the very large Chinese market. To further increase the global growth rate, Paxman's commercialisation strategy continues to focus on strengthening the company's sales organisation with direct presence as well as new and established distribution partners in key regional markets including China, India, Europe and the Middle East, supported by enhanced marketing support based in the UK. Paxman will also advance the company's reimbursement strategy in the USA, where customers started to implement the new buy and bill model in 2022 to facilitate reimbursement using established CPT III codes, and continue to invest in its R&D pipeline in both scalp cooling and cryotheraphy to prevent chemotherapy-induced peripheral neuropathy (CIPN).

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

## **Risks and uncertainties**

Information on current risks and uncertainties, as well as on how the company acts to mitigate them, can be found in the annual report for 2022 (pages 58-60). An English translation of this segment is available upon request.

## The share

The Paxman share is listed on Nasdaq First North Growth Market since 12 June 2017. The share's trading name is PAX, its ISIN code SE0009806284 and its LEI code 5493000T2V7Q4IDX8X68. The share capital in the company amounted to SEK 19,012,500 split on 19,012,500 shares on March 31, 2023, each with a quota value of SEK 1. Paxman has only one class of shares.

### Ownership structure

A list of Paxman's 10 largest shareholders is available on www.paxman.se and is updated at the end of each quarter. As of 31 March 2023, the 10 largest shareholders held 76.5% of all issued shares. At this time, Paxman had a total of 1,173 individual shareholders.

## Annual general meeting 2023

The next AGM of Paxman AB (publ) will be held in Karlshamn, Sweden, on 24 May 2023 at 10:00 CEST. The AGM will be held in premises adjacent to the company's head office at Pirgatan 13, NetPort, Karlshamn.

### Nomination committee

For the 2023 AGM, the Nominating Committee was appointed during the autumn of 2022 based on the 5 largest shareholders on the last business day of September 2022. For the 2023 AGM, the Nominating Committee is comprised of the following three members:

- Roger Johansson, Committee Chairman representing CIMON Venture Trust AB
- Glenn Paxman, Board member and majority shareholder
- Daniel Albin, representing Creades

Their contact details, as well as full guidelines for their appointment and responsibilities, are available on www.paxman.se.

## Corporate information

Paxman AB (publ), corporate identity number 559079-3898, has its statutory seat in Karlshamn, Sweden, at Pirgatan 13, SE-374 35 KARLSHAMN. Production and sales are carried out by the UK subsidiary Paxman Coolers Limited, International House, Penistone Road, Fenay Bridge, HD8 OLE Huddersfield, United Kingdom. The Group also has a subsidiary in the US; Paxman US, Inc, based in Houston, Texas. Paxman Coolers Limited and Paxman US, Inc are both wholly owned subsidiaries of Paxman Group Limited, in its turn a fully owned subsidiary of Paxman AB (publ).

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# TOGETHER, WE CAN MAKE A DIFFERENCE



## FINANCIAL CALENDAR

Annual general meeting 2023		24 May 2023
Interim report as of 30 June 2023		24 August 2023
Interim report as of 30 September 2023		17 November 2023
Year-end report 2023		23 February 2024

Paxman's interim reports and annual reports are available on www.paxman.se.

## PAXMAN<sup>°</sup> PIONEERS IN SCALP COOLING



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