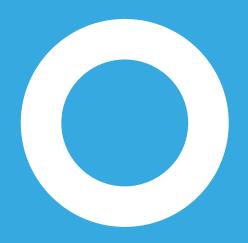


# INTERIM REPORT AS OF MARCH 31

2022



# Paxman AB (publ) First quarter 2022



#### Promising quarter but affected by strategic investments

- The Group's sales amounted to 27.9 (20.8) MSEK for the first quarter of the year.
- EBITDA amounted to -2.9 (0.4) MSEK and the Group's net result totaled -6.2 (-3.7) MSEK for the period.
- Earnings per share were -0.33 (-0.04) SEK for the period and cash flow before financing activities was -8.9 (-11) MSEK.
- Net liquid assets totaled 46.2 (2.9) MSEK at the end of the period.
- A total number of 99 (101) scalp cooling systems were installed around the world in the first three months of the year, with Q2 installs and order book containing an additional 215 systems.
- Average Daily Treatment Revenue (ADTR) amounted to 23.4 TUSD (219.2 TSEK) for Q1 2022, corresponding to an increase of 36.1% compared to 18.0 TUSD (151.3 TSEK) for Q1 2021. The figures in SEK have been converted from USD according to the actual exchange rate during each period.
- Recurring income increased from 11.3 MSEK in Q1 2021 to 16.6 MSEK for the same period in 2022.

ADTR includes pay-per-treatment revenue from patients and facilities in the United States. Lease revenue and disposable sales are not included.



# Significant events during the reporting period

- In February, Paxman appointed Rocol International SAS as the company's exclusive distribution partner for the new territory of Colombia. As an established medical device distributor in the oncology space, Rocol International SAS is well positioned to introduce scalp cooling to the Colombian market from its headquarters in Barranquilla, the capital of Colombia's Atlántico Department.
- Also in February, Paxman announced that the company has launched the Scalp Cooling Study Library, a digital library website with a comprehensive database which unites key published clinical research studies and data on scalp cooling and cryocompression therapy.
- o In March, Paxman announced that the company hosts the first ever Scalp Cooling Summit, where innovative leaders in the industry come together to talk all things scalp cooling, on 5 May 2022. This international, digitally hosted event included a series of talks, keynote discussions and live dialogue, with a speaker list containing representatives from institutions including Memorial Sloan Kettering Cancer Center, New York, USA; Tata Memorial Hospital, Mumbai, India; Dana Farber Cancer Institute, Boston, USA; Seattle Cancer Care Alliance, Washington, USA and Kyoto University, Japan.

# Significant events after the reporting period

- In April, the bill HB7322 was introduced to the House in the USA to require coverage for scalp cooling under group health plans and group and individual health insurance coverage, specified Federal health care programs, and the Federal Employees Health Benefits Program.
- In April, Paxman announced that it signed a letter of interest with a plan to enter into a distribution and marketing agreement with Guangzhou Concord Medical Sci-Tech Innovation Center Co., Ltd. (Concord Medical), a business subsidiary of Concord Medical Services Holdings Limited (NYSE: CCM), to jointly develop the market for the Paxman Scalp Cooling System within the Greater China territory, including Macau, Taiwan and Mongolia.
- In May, Paxman announced that the company signed its first contract under the new business model in the USA with a comprehensive healthcare system in New Jersey, and that the company has launched its enhanced Paxman HUB services.
- Paxman hosted the world's first Scalp Cooling Summit, a global and first of its kind conference with leading researchers and clinicians, in May. The Summit was a great success, with 50 speakers and over 1,400 delegates attending.

#### Comment by the CEO

The year has got off to a strong start, not only from a revenue and order book perspective, but other activity including on-boarding a growing team, developing our new buy and bill infrastructure, developing new markets and pushing ahead with our strong R&D pipeline. We started the year with a strong order book. Following some supply chain delays and COVID related staffing issues our fulfilment of those orders was slower than hoped, which was disappointing. Our production and warehousing team have continued to impress us in ensuring continuity throughout.

Due to lower sales than hoped for and higher costs based on planned investments, our EBITDA and profitably have been affected. Sales of 28 MSEK were achieved, compared to 21 MSEK for the same period in 2021, a 34% growth, and only 1 MSEK lower than Q4 2021. US sales reached 15 MSEK, this is 41% higher than the same period in 2021, and is an increase from Q4 2021 with the ADTR also improving which is positive. Following two directed issues as promised we have invested heavily in the infrastructure and other key areas of development which will be required to enable the company to take advantage of the opportunities which include our CIPN development, greater USA access and internationalisation. These development costs which we expect to strengthen future performance have been expensed in the quarter.

As we enter into Q2 2022 we have an even stronger order book with 162 systems excluding the USA, compared to 115 systems at the end of Q4 2021. There are 53 systems on order for 28 new locations in the USA. We are still experiencing some delays and higher costs relating to both COVID and the problems in Ukraine but we are managing these effectively. The company is seeing some margin erosion, but this is manageable.

Our cash position remains strong with a cash balance of 62 MSEK. Significant investments have been made in the first quarter relating to the buy and bill model, R&D, exhibitions, marketing, personnel, reimbursement and investment in our working environment, which can be seen in the increase in external costs. These are investments in the future growth of our business and testimony to the activity and order book.

A large focus for the team here at Paxman this quarter has been the establishment of our new buy and bill model. This has been an intense period



with investment, both financially and time for personnel. We are incredibly proud to have launched our enhanced provider and patient assistance services, as well as offering a new business model to health systems. We announced our first signed contract under the new business model with a comprehensive healthcare system in New Jersey and the launch of the enhanced Paxman HUB services earlier this month. Since this time we are in the process of on-boarding a number of other health systems but we must be patient, this process will take some time. The more feedback we gather from New Jersey and others, the more traction we shall gain with the transition of other partners, gaining confidence with the payers.

In addition we have now signed an agreement with Unity and Onmark, considerably increasing our access to customers across the USA.

We were excited to announce the signing of a letter of interest with a plan to enter into a distribution and marketing agreement with Guangzhou Concord Medical Sci-Tech Innovation Center Co., Ltd. (Concord Medical) to jointly develop the market for the Paxman Scalp Cooling System within the Greater China territory, including Macau, Taiwan and Mongolia. This agreement marks an important first step towards the launch of Paxman Scalp Cooling in the very large Chinese market. We are looking forward to soon being able to reach a large number of cancer patients in the Greater China territory in collaboration with Concord Medical, and expect to be able to turn it into significant sales volumes in the coming years ahead. This is also an exciting further advancement of the company's vision to make scalp cooling technology available for all cancer patients worldwide. We hope to see traction through Q2 to formalise our approach.

Much focus for many of our team through Q1 has been on the world's first-ever Scalp Cooling Summit, which took place 5th May, 2022. The virtual event brought together global experts across the world of oncology to explore the future of scalp cooling and its benefits. This was a huge success and we were proud to host 50 speakers from around the World, leaders in their fields, presenting to over 1400 delegates.

More traction was made from a legislature perspective during the first part of the year. In connection with one of our partners, Infinite Strength, a bill, HB7322, was introduced to the House to require coverage for scalp cooling under group health plans and group and individual health insurance coverage, specified Federal health care programs, and the Federal Employees Health Benefits Program. The legislation was introduced by House Appropriations Committee Chair Rosa DeLauro and would require all health insurers to provide coverage for scalp cooling treatments for the prevention of chemotherapy-induced alopecia for cancer patients.

Finally, I am excited about the continued progression of our work with the University of Singapore. The phase 1 clinical trial has progressed well with a promising outlook. Work is now ongoing, planning for a larger phase 3 study in the USA, with a plan to manufacture up to 200 devices to satisfy clinical trials and other testing activities. There is a significant need and demand for this intervention with an impressive market potential, but above all strong clinical impact for the patient.

Thank you again to our existing and growing team. We have an exciting future and together we are making a real difference to so many patients and their families around the world.

Huddersfield, May 2022,

Richard Paxman, CEO

RNA

Paxman AB (publ)

## MARKET DEVELOPMENTS

#### **USA**

The average patient utilisation for the guarter was 23.4 TUSD per day, compared to 18 TUSD per day in Q1 2021. In Q1 2022, 38 systems were installed in 18 locations, with a total of 403 locations in 40 states now using the Paxman Scalp Cooling System. There are 53 systems on order for 28 new locations in the USA which will be delivered over the coming months. The main focus for the start of 2022 was the preparation and setup of the new buy and bill model, which went live early May, a little delayed due to finalising processes and training. This is an important step to allow the billing of CPT codes. The company has also launched its patient assistance program to ensure that we have an equitable approach to providing care across the USA. 8 locations have launched but the company is in discussions with a large number of cancer centers across America. Claims and appeals data will be critical to monitor and evaluate over the coming months.

#### Rest of the world

Key performing markets for the quarter included Australia, India, Japan, the Netherlands, and the UK. The company were pleased to receive the order of 5 systems from Japan and have further orders in the pipeline in addition to cap revenue. The company's order book is strong with over 160 systems to be installed and delivered to Australia, France, Germany, India, Italy, Japan, Switzerland, the Netherlands and the UK. New partnerships were signed in Columbia, Serbia and in April, Qatar. The company also signed a letter of interest with Concord in China, with a goal to finalise the agreement In Q2. Concord Medical Services Holdings Limited (NYSE: CCM) is a healthcare provider featuring a full cycle of premium oncology services including cancer diagnosis, treatment, education and prevention. The company focuses on providing a multidisciplinary cancer care approach in all areas of oncology services in its cancer hospitals and equipping its hospitals with technologically advanced equipment such as the state-of-the-art proton therapy system. Collaborating with domestic and international leading intelligence, they are striving to improve the quality and accessibility of cancer care. Their network of medically advanced cancer hospitals and clinics and partnered hospitals across China ensures the commitment to the highest standard of medical services for patients.

# MARKET DEVELOPMENTS, CONT.

# Global conferences during the period

Conference/Event	Event Type	Location	Conference Dates	Audience
Cleveland Clinic Florida, Best of SABCS	In person	Westin Fort Lauderdale	15 Jan	Clinicians
SABCS Highlights - Temple Health/Fox Chase	Virtual	Online	20 Jan	Clinicians
Best of Breast	Hybrid	West Palm Beach, Florida and online	22-23 Jan	Providers, MDs, APPs, nurses
Arab Health	In person	Dubai International Convention & Exhibition Centre	24-27 Jan	Business Development, Clinicians, Healthcare Professionals, Purchasing
SGO Winter Meeting	In person	Olympic Valley, CA	27-29 Jan	Physicians and residents
University of Kansas Post San Antonio Review	Virtual	Online	12 Feb	
ICCN	Virtual	Online	23-25 Feb	Oncology Nurses
MD Anderson Cancer Network Advanced Oncology Certified NP Review Course	Virtual	Online	24-26 Feb	Nurse Practitioners in the oncology setting
West Oncology Conference	Hybrid	Memphis and online	25-26 Feb	Providers, surgeons and oncologists, nursing
Women Rock - Drink for Pink	In person	Plano, Texas	28 Feb	
Miami Breast Cancer Conference	Hybrid	Fontainebleau Miami Beach and online	3-6 Mar	Medical, surgical and radiation oncologists, nurses, NP's, PA, HCP with an interest in breast cancer
Community Oncology Conference (COA)	Hybrid	Kissimmee, Fl	17-18 Mar	Physicians, Advanced Nurse Practitioners & Physician's Assistants, Nurses, Pharmacists, CFOs/CEOs, Self-Insured Employers & Employer Coalitions, Payers, Practice Administrators, Patient Advocates, Industry Partners
ESCTOX/UKASCC Conference	Virtual	Online	17-18 Mar	
Greater Baltimore Chapter ONS (GBCONS)	In person	Sheraton Baltimore North Hotel, Towson	19 Mar	

# MARKET DEVELOPMENTS, CONT.

# Global conferences after the end of the period

Conference/Event	Event Type	Location	Conference Dates	Audience
Infinite Strength - An Evening in Pink	In person	Madison Beach Hotel, CT	2 Apr	
AFSOS - Référentiels en Soins Oncologiques de Support	Virtual	Online	6-7 Apr	HCP's and patients to pool knowledge, improve reasearch, training and protocols between French speaking cancer communities and Oncological Supportive Care Groups
Midwest Womens Cancer Conference	Hybrid	Kansas City, MO	9 Apr	HCP's with a focus on women treating women's cancers
ONS	In person	Anaheim, CA	27 Apr-1 May	Oncology Nurses
Scalp Cooling Summit	Virtual	Online	5 May	Researchers and clinicians
Sanford Health Cancer Symposium	In person	Sioux Falls, SD	13 May	Physicians, Nurses, APP, research staff, radiation therapists, gen HCP's
Art Bra Austin - Breast Cancer Resource Center of Texas	In person	JW Marriott, Austin	20 May	
Oncology Professional Care	In person	ExCel, London	24-25 May	Oncologists, specialist nurses, radiographers, cancer service managers and pharmacy professionals
ASCO 2022	Hybrid	McCormick Place, Chicago	3-7 Jun	Oncologists, specialist nurses, radiographers, cancer service managers and pharmacy professionals
MASCC	In person	Westin Harbour Castle, Toronto	23-25 Jun	HCP's with an interest in supportive care
Deutsche Gesellschaft fur Senologie	In person	Stuttgart	30 Jun-2 Jul	HCP's with an interest in diagnosis and treatment of breast diseases

## Installed systems January-March 2022

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).



# Installed systems January-March 2022 + confirmed orders so far in 2022

The total number for the business operations so far in 2022 (up until May 24). This includes installed systems and confirmed orders that are yet to be installed.



## **COMMENTS TO THE FINANCIAL STATEMENTS**

#### Sales and earnings

Net sales in Q1 2022 totalled 27.9 MSEK, compared to 20.9 MSEK in Q1 2021 a 34% increase in revenue. The company is still seeing the effects of COVID-19 globally but mainly relating to supply chain as opposed to sales activity. Revenues are now stronger than before the pandemic. US revenue is up 41% on Q1 2021.

In Q1 2022 EBITDA is recorded at a loss of -2.8MSEK. This compares to an EBITDA profit of 409 TSEK for Q1 2021. This is due to significant investments made in the first quarter relating to the buy and bill model, R & D, exhibitions, marketing, personnel, reimbursement and investment in our working environment, which can be seen in the increase in external costs.

Operating loss in Q1 was -6.9 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 32 MSEK.

Included within the financial costs is a currency gain of 877 TSEK compared to a gain of 2.1 MSEK in Q1 2021. Due to the decrease in debt levels in the group this has in turn led to a decrease in external finance costs.

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

#### Cash flow

The increase of activities relating to the buy and bill model, R&D, exhibitions, marketing, personnel, reimbursement and investment in the working environment during the quarter led to an operational cash outflow in Q1 of -3.4 MSEK.

#### Financial position

There is a decrease in the group's liabilities to 41.1 (54.3) MSEK on 31 March, of which 15.7 (36.7) MSEK is interest bearing. These will continue to be reduced.

Cash on hand has increased to 62 MSEK from Q1 2021.

#### **Employees**

Employees 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. As of 31 March 2021, the Group had a total of 51 employees, 45 by Paxman Coolers Ltd and 6 by Paxman US, Inc.

#### **Parent company**

Paxman AB (publ) is the parent company of the Paxman Group. Its operations include Group functions such as finance, legal and communications, as well as sales in Scandinavia. 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 C.E.O. hereby assure that these summarized financial statements give a true and fair view of the Group's operations, financial position and performance.

Karlshamn, 25 May 2022
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 C.E.O. and Director of the Board

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

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Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, and will be published at 12:00 CET on 25 May 2022.

# **Consolidated income statement (condensed)**

TSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Net sales	27,944	20,857	96,202
Capitalized expenses	1,708	2,049	8,506
Total operating income	29,652	22,906	104,708
Raw materials and consumables	-11,320	-8,241	-40,190
Other operating expenses	-10,868	-7,256	-29,083
Personnel costs	-10,347	-7,000	-32,553
Total operating costs	-32,535	-22,497	-101,826
EBITDA	-2,883	409	2,882
Depreciation	-4,010	-2,759	-13,469
Operating profit/loss	-6,893	-2,350	-10,587
Net financial items	703	1,622	-2,083
Profit/loss after net financial items	-6,190	-728	-12,670
Tax	-16	0	-106
Net profit/loss for the period	-6,206	-728	-12,776

## Consolidated balance sheet (condensed)

TSEK	2022-03-31	2021-03-31	2021-12-31
Assets			
Intangible fixed assets	16,975	13,354	16,364
Tangible fixed assets	36,691	32,237	35,886
Financial fixed assets	6,574	6,185	6,426
Total fixed assets	60,240	51,776	58,676
Inventories	19,204	14,509	18,111
Current receivables	20,056	15,037	17,288
Cash and bank balances	61,974	39,656	72,266
Total current assets	101,234	69,202	107,665
Total assets	161,474	120,978	166,341
Equity and liabilities			
Shareholders' equity	119,423	65,945	125,755
Total equity	119,423	65,945	125,755
Provisions for taxes	938	725	939
Total provisions	938	725	939
Liabilities to credit institutions	5,395	27,502	5,826
Non-current liabilities	5,395	27,502	5,826
Liabilities to credit institutions	10,324	9,211	11,328
Accounts payable	13,905	11,288	16,506
Other current liabilities	11,489	6,307	5,987
Current liabilities	35,718	26,806	33,821
Total equity and liabilities	161,474	120,978	166,341

# Consolidated statement of cash flows (condensed)

TSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Cash flow from operating activities	-3,430	-4,537	-4,792
Cash flow from investing activities	-5,427	-6,427	-23,796
Cash flow from financing activities	-1,435	47,043	97,277
Cash flow for the period	-10,292	36,079	68,689
Cash and cash equivalents, opening balance	72,266	3,577	3,577
Cash and cash equivalents, closing balance	61,974	39,656	72,266

# Consolidated changes in equity (condensed)

TSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Opening balance as of 1 January	125,755	10,889	10,889
New share issue	-	58,560	135,560
Share issue costs	-	-2,928	-7,206
Translation gains/losses on consolidation	-244	34	-1,184
Equity-settled share-based payment transaction	118	118	472
Profit/loss for the period	-6,206	-728	-12,776
Closing balance	119,423	65,945	125,755

# **Key ratios**

TSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Operating margin, %	Neg	2%	3%
EBITDA (TSEK)	-2,883	409	2,882
Equity/assets ratio, %	74.0%	54.5%	75.6%
Liquid assets, net (TSEK)	46,255	2,943	55,112
Market capitalization (TSEK)	1,087,515	880,625	1,235,813

# Parent company income statement (condensed)

TSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Net sales	27	0	219
Other operating income	0	0	25
Total operating income	27	0	244
Raw materials and consumables	-9		
Other external costs	-936	-1,031	-3,526
Personnel costs	-272	-88	-890
Total operating costs	-1,217	-1,119	-4,416
EBITDA	-1,190	-1,119	-4,172
Depreciation	-6		-8
Operating profit/loss	-1,196	-1,119	-4,180
Net financial items	254	-298	-496
Profit/loss after net financial items	-942	-1,417	-4,676
Tax	-	-	-
Net profit/loss for the period	-942	-1,417	-4,676

# Parent company balance sheet (condensed)

TSEK	2022-03-31	2021-03-31	2021-12-31
Assets			
Tangible fixed assets	56		62
Investments in Group companies	26,819	26,347	26,701
Total fixed assets	26,875	26,347	26,763
Receivables from Group companies	75,931	50,543	67,677
Other current receivables	733	696	1,151
Cash and bank balances	60,230	37,537	69,419
Total current assets	136,894	88,776	138,247
Total assets	163,769	115,123	165,010
Equity and liabilities			
Shareholders' equity	163,001	94,009	163,825
Total equity	163,001	94,009	163,825
Liabilities to credit institutions (non-current liabilities)	-	20,000	0
Total long-term liabilities	-	20,000	0
Liabilities to credit institutions	-	0	0
Other current liabilities	244	778	404
Accrued costs and prepaid income	524	336	781
Total current liabilities	768	1,114	1,185
Total equity and liabilities	163,769	115,123	165,010

#### Data per share

	Jan–Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Earnings per share, SEK <sup>1)</sup>	-0.33	-0.04	-0.73
Earnings per share, SEK, diluted <sup>2)</sup>	-0.33	-0.04	-0.73
Equity per share, SEK <sup>1)</sup>	6.28	3.74	6.61
Cash flow from operating activities per share, SEK <sup>1)</sup>	-0.18	-0.27	-0.27
Share price on closing day, SEK	57.20	50.00	65.00
Number of shares on closing day	19,012,500	17,612,500	19,012,500
Number of shares on closing day, diluted <sup>2)</sup>	19,080,978	17,680,978	19,080,978
Number of shares, weighted average in the period	19,012,500	16,812,500	17,470,833
Number of shares, weighted average in the period, diluted <sup>2)</sup>	19,080,978	16,880,978	17,539,311

- 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, 2022, 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.

The options entitle the holders to subscribe for shares from and including June 2020 and up to and including June 2029, at a subscription price of SEK 65.37 per share. Upon full utilization, the dilution effect amounts to 0.4% of the total number of shares in the company. The warrants have been issued free of charge and the benefit has thus, in accordance with current accounting principles, been valued at market value. In total, Paxman Coolers Ltd's personnel costs will thus be charged with SEK 1.4 million over three years (without any cash flow effect).

## OTHER INFORMATION

#### **About Paxman**

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.

Presently, 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 nerve damage in hands and feet in connection with chemotherapy (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 decades, Paxman has invested substantially in research and development, and then also on a target-focused global expansion. The company has conducted several successful clinical studies with leading clinics and cancer centers all over the world, including the world's first randomised multicenter study with a scalp cooling system.

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

Paxman's research collaboration agreement with National University Hospital, Singapore for the development of a portable cooling and compression device to prevent CIPN continued to achieve substantial progress in 2021. In May, 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. This pilot trial in Singapore has now completed recruitment, and data should be available by Q4 2022, however we expect to expand the study to include additional sites in Singapore. A larger randomized phase 3 efficacy study is being planned to open in the USA. The data from the trials will be used in regulatory documentation to support the cryo-compression system as a new medical device, initially in Singapore, and then the United States.

#### 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. Some of the studies that were active or saw results published 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. Publication of the data from the trial is 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 in 2021 further data was published 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. For 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 lifesaving.'

#### Clinical studies and collaborations, cont.

# 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 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 will begin in mid-March with an anticipated primary end date of December 2024. Conclusion of the study is expected by the end of 2025.

# Assessing the impact of scalp cooling in connection with metastatic breast cancer

November saw the opening of a new clinical trial at the Dana Farber Cancer Institute. This is a prospective, controlled, pivotal clinical investigation to assess the efficacy of the Paxman Scalp Cooling System (PSCS) at preventing hair loss in women undergoing treatment for metastatic breast cancer with Sacituzumab govitecan (IMMU-132 or Trodelvy™), trastuzumab deruxtecan (DS-8201a or Enhertu®), or Eribulin (Halaven®). 40 participants will be recruited into each treatment arm. In each treatment arm, 20 participants will receive scalp cooling and 20 participants will receive no scalp cooling, for a total of 120 participants. Hair loss and quality of life (QOL) will be measured in participants at baseline, C3D1, and C5D1by CTCAE criteria.

# 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 Paxmar was able to announce that the AMA will implement a specific CPT code for scalp cooling that was available to use in 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, it was announced that the AMA has issued two separate CPT® codes for the "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. Hospitals, as of 1 January 2022 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 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. The company has also launched its patient assistance program to ensure that there is an equitable approach to providing care across the USA.

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 have started a separate fund in her name specifically aimed at mothers with very low income.

#### General 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.

The company is the superior global market leader with over 4,400 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 Paxman, with Japan as the single leading market. Paxman received market approval (Shonin) in Japan for use in connection with treatment of solid tumours like breast cancer in March 2019, and extensive marketing activities were then initiated together with the distributor CMI. 50 systems were delivered to Japan in 2019, and when the coronavirus situation is under control the company sees great potential to deliver continued strong sales in Japan in the coming years. In addition to Japan, Paxman is already established in additional Asian markets such as India, Malaysia, Singapore and Pakistan, and the company has signed a letter of interest with Concord Medical for a possible market launch on the very large Chinese market.

To further increase the global growth rate, Paxman's commercialisation strategy for 2022 focuses on strengthening the company's sales organization 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, capitalising on the recent positive CPT III code publication, and continue to invest in its R&D pipeline.

Paxman will also continue the transition from selling equipment to clinics to the new business model that generates income for each treatment. The business model is fully implemented in the United States, and a similar model is used in Mexico in collaboration with the licensing partner Teva, as well as in Canada. 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.

# Chasing **Zero** Hair Loss During Chemotheraphy

#### **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 2021 (pages 51-53). 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 549300OT2V7Q4IDX8X68. The share capital in the company amounted to SEK 19,012,500 split on 19,012,500 shares on March 31, 2022, 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 2022, the 10 largest shareholders held 76.64% of all issued shares. At this time, Paxman had a total of 1.199 individual shareholders.

#### **Annual general meeting 2022**

The next AGM of Paxman AB (publ) will be held in Karlshamn, Sweden, on 25 May 2022 at 15:00 CEST. The AGM will be held in premises adjacent to the company's head office at Pirgatan 13, NetPort, Karlshamn.

#### Nomination committee

For the 2022 AGM, the following three members have been appointed to the Nominating Committee:

- Lene Håkansson, representing Björn Littorin
- Glenn Paxman, Board member and majority shareholder
- Roger Johansson, Committee Chairman representing CIMON Venture Trust AB

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 0LE 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).

E-mail: info@paxmanscalpcooling.com www.paxmanscalpcooling.com www.paxman.se www.coldcap.com

Paxman AB (publ) has appointed FNCA Sweden AB its Certified Adviser. FNCA can be reached at +46 (0)8 – 528 003 99 or email info@fnca.se.

## Financial calendar

Interim report as of 30 June 2022 | 24 August 2022

Interim report as of 30 September 2022 | 18 November 2022

Year end report 2022 24 February 2023

Paxman's interim reports and annual reports are available on www.paxman.se. Here you will also find Paxman's newsletter, published on a monthly basis.









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