Paxman

Sector: Medtech

Game Changer on the Horizon

Redeye initiates coverage of Paxman, a Swedish/English medical technology company. They develop, produce, and market their scalp cooling system that reduces hair loss (alopecia) associated with chemotherapy. We see an attractive case with significant upside potential. Strong clinical data and positive drivers for reimbursement in the US are the right ingredients for an exciting growth journey.

Addressing a USD 0,9bn market from a position of strength

With its strong growth, Paxman has taken a leadership position in the scalp cooling business with its large installed base and continued strong deliveries at the beginning of 2021 and a healthy order book. The potential for realizing the potential in this large market has never looked better, with reimbursement in the US coming closer in the second half of 2021.

Positive events and drivers during the last 12 months and H2 2021

Many positives have happened during 2020/21, even as the pandemic shut down the primary markets for Paxman. The AMA-issued CPT III codes to be implemented from 1 July in the US will be a game-changer regarding reimbursement and will make it more common practice.

- CPT III codes – reimbursement
- NCCN updated guidelines
- ESMO included scalp cooling as cat. IIB recommendation
- CIPN clinical study to start within 8-10 months – grant awarded
- New studies initiated – examples, pediatric patients, new countries – Argentina, etc.

DCF model and multiple-based valuation indicate substantial upside

We have used conservative assumptions (excluding CIPN, for example); our 20-year DCF model indicates a **Base case** fair value of **SEK 90 per share**. This is a potential upside of almost 60% from current levels. The Base case values Paxman at **10,9x** on our 2022 estimates. This represents a slight discount from the peer group of high-growth MedTech companies trading at a median of 14,2x on 2022 estimates.

SEKm	2019	2020	Q1	Q2	Q3	Q4	2021E	2022E	2023E
Net sales	**85**	**78**	**20,9**	**20,5**	**23,0**	**26,5**	**91**	**145**	**218**
Y/Y	*47%*	*-8%*					*16%*	*60%*	*50%*
EBITDA	**7**	**-1**	**0,4**	**0,8**	**0,5**	**1,1**	**3**	**13**	**33**
margin (%)	*8%*	*-1%*					*3%*	*9%*	*15%*
EBIT	**-1**	**-12**	**-2,4**	**-2,1**	**-2,2**	**-1,3**	**-8**	**3**	**24**
margin (%)	*-2%*	*-15%*					*-9%*	*2%*	*11%*
EV/Sales							**11,1**	**7,0**	**4,7**
EV/EBITDA							**376,7**	**79,3**	**30,6**
EV/EBIT							**-126,7**	**323,2**	**42,4**

Source : Redeye Research

FAIR VALUE RANGE

BEAR	BASE	BULL
45.0	90.0	130.0

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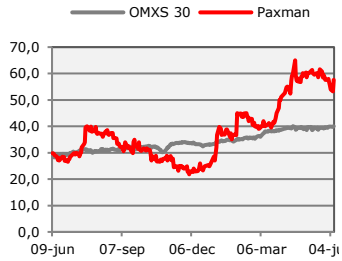
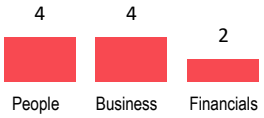


REDEYE RATING



KEY STATS

Ticker	PAX.ST
Market	First North
Share Price (SEK)	58
Market Cap (MSEK)	1022
Net Debt 21E (MSEK)	-9
Free Float	43%
Avg. daily volume ('000)	16

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Investment Thesis

Return of the growth story

The past year was, in terms of top-line growth, a difficult one. However, we firmly believe that all the positives in the last 12 months will make for a strong comeback for the Paxman growth story. The current year is still somewhat uncertain, but we believe that the medical devices market will start to show growth again in the second half of 2021. With easy comparables going into 2022, the growth outlook is appealing.

Addressing a USD 0,9bn market in a strong position

With its strong growth, Paxman has taken a leadership position in the scalp cooling business with its large installed base and continued strong deliveries at the beginning of 2021 and a healthy order book. The potential for realizing the potential in this large market has never looked better, with reimbursement in the US coming closer in the second half of 2021.

Positive events and drivers during the last 12 months and forward in 2021

Many positives have happened during 2020/21, even as the pandemic shut down the primary markets for Paxman. The AMA-issued CPT III codes to be implemented from 1 July in the US will potentially be a game-changer considering the reimbursement and to make it more common. In addition, the Texas legislation for mandatory scalp cooling decision and good headway has been made even if it did not pass the last house; the next step is further ahead into 2023; it's still progress.

- CPT III codes – reimbursement
- NCCN updated guidelines
- ESMO included scalp cooling as cat. IIB recommendation
- CIPN clinical study to start towards the end of 2021 - grant awarded
- New studies initiated – examples, pediatric patients, new countries – South Korea and Hong Kong.

CIPN could result in further upside to our estimates

Chemotherapy-induced nerve damage in hands and feet has the potential to be another important area for Paxman. The potential market is vast, and we believe that with the already established network by Paxman, be it the distributors or collaborating partners, time to market would be much shorter than for the scalp-cooling. The initiation of the clinical study and its completion will be closely monitored as it could be genuinely transformational for Paxman.

Key catalysts

We see the first **reimbursement** agreement as a key catalyst since it will make scalp cooling a much more used tool for patients undergoing chemotherapy treatment. The current system where patients mostly pay for their treatment limits the development of scalp cooling, the pricing for an individual at this point is prohibitive, and with reimbursement in place, the fundamentals for growth are improved vastly.

Improving growth in the second half of 2021, as the medical devices market has struggled during 2020/21, any sign that the growth is truly back will be well perceived. However, the pace of the recovery is still uncertain, and the **upcoming quarterly reports** are potential catalysts.

Even if the Texas legislation did not pass the last house, reapply will be in 2023. If Texas, in the end, makes this pass, other states may follow suit. This is an opportunity as we see it, but it is a long process and is a long-term catalyst.

Initiation of the CIPN clinical study is another potential catalyst, it is still early in the process, and the outcome is not certain. However, the potential in this field is excellent, and the start of the study will give an indicative timeline for market launch, given the study's positive outcome. The CIPN collaboration with NUHS in Singapore has also recently been awarded a translational grant of SGD 1,6 m. It is important to note as well that the ESMO and ASCO guidelines support the CIPN development.

Counter thesis – key risks

A less positive effect of reimbursement on sales

Even with reimbursement introduce in the US, there is a risk that the uptake is not as significant as we and the market expect. This could be due to several causes, such as skepticism from the healthcare providers or lower reimbursement levels than expected.

Lack of share catalysts

We see significant upside in the share, although as we see the upcoming quarterly reports as one of the catalysts for the share, there is a risk that the pandemic will dampen the positive news flow from the quarterly reports, and that growth could vary greatly due to this over the quarters.

Advances in cancer treatment

While chemotherapy is still the backbone of most cancers, biologics and targeted therapies have seen significant up-take in some indications. However, there are still many current trials that include chemotherapy. In addition, there are quite a few treatment approaches in late-stage development, and there is a possibility that this will decrease chemotherapy infusions during our forecast period. However, we do not believe that there will be any significant breakthrough in the short to mid-term and that advances will be gradual at best.

Potential increased competition

The installed base should be a deterrent to a certain degree and provide some protection against competition. However, the TAM is quite large and could intensify competition with price and margin pressure. Their solid clinical data should also protect the dominant players in mechanical scalp cooling in the medium term and, in Paxman's case, an interesting R&D pipeline through the Paxman Research Centre.

Company Description

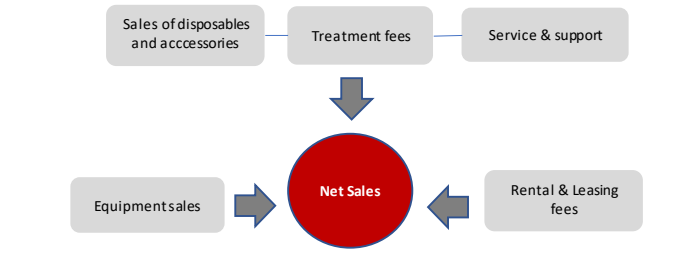
Paxman is an international medical technology group that develops, produces, and markets its Paxman Scalp Cooling System (PSCS). The system is intended to reduce the hair loss associated with chemotherapy. Paxman was founded in the UK in 1996 as a family company and had its headquarter in Huddersfield, with its parent company in Sweden. The company has installed over 4000 scalp cooling systems globally by the end of 2020. The company has 52 employees and has a revenue of about SEK 75 m during the last 12 months. Paxman has been listed on the Nasdaq First North Growth Market since 2017.

Business Model

Paxman has historically had a business model based on direct capital equipment sales to customers and a fixed price per system. In addition to this, the company has had some sales of cooling caps and accessories and some additional income from service and support. With this model, the recurring revenues were limited. However, this model has worked well in Great Britain and other markets. Recognizing the limitations of this model has Paxman gradually transferring to a business model based on recurring revenues. Instead of outright purchasing the system, clients pay a low rental fee, and Paxman receives compensation for each treatment or a monthly fee. We estimate that the new model is implemented to approx. 50% where the US is the primary driver with its strong growth.

We see that Paxman has several revenue streams; however, within a few years, the new model will be dominant, with the absolute majority consisting of treatment fees. This gives a solid recurring revenue stream and possibilities to strengthen profitability.

Paxman: Revenue streams



Source: Paxman & Redeye Research

Management, board, and ownership

Richard Paxman has been the CEO of Paxman since 2016 and as a board member since 2017. He has, however, been involved in the family business since 1999 while officially being hired in 2009. Before this, he had a leading position within Brewfitt Ltd. We believe that the management team has the experience to execute the company's goals and target setup.

Managment

Name	Position	Since	# of Paxman shares	
Richard Paxman	CEO	2016	1 281 000	Education; Management Science at University of Manchester. Active in Paxman since 1999 and employed since 2007. Previous management role in Brewfitt Ltd.
Emelie Gustafsson	CFO	2020	2 000	Education University of Kristianstad, business administration and tax law. CFO for the CIMEON Group since 2015. Board member of large number of companies in this group.
Claire Paxman	Director of Sales & Training	2010	7272 Warrants	Education from Huddersfield Technical College, many various leading roles within Paxman.

Source: Redeye Research, Paxman

Board of directors

Name	Position	Since	# of Paxman shares	
Per-Anders Johansson	Chairman of the Board	2016	1 578 992	Extensive experience from technology and development companies. Industrial experince from Karlshamns Group, Nordic and Ellos. Majority shareholder of CIMON AB. Other assigments on boards, CFS Medical AB TC TECH Sweden among others
Glenn Paxman	Board member & founder	2016	6 257 395	Founder and inventor of Paxman Scalp Cooler. Majority shareholder. Chairman of the Board of Webster Holdings Ltd.
Björn Littorin	Board member	2016	765 076	Experience as mangement consultant, CFO and board member of a number of companies in manufacturing and services industries. Been a board member in Paxman group companies since 1999.
Robert Kelly	Board member	2016	11 250	Attorney in corporate law. Extensive experience from business management in both public and private companies. Currently partner in Schofield Sweeney LLP.
Maria Bech	Board member	2016	4 200	Extensive experience from companies within biotech and pharma. Currently CEO of EpiEndo Pharma.

Source: Redeye Research,Paxman

We see that Paxman has extensive experience in their board of directors from various fields of business that is relevant to the operations of Paxman. In addition, the founder Glenn Paxman is important, and Björn Littorin has been with the company for a long time, indicating stability.

Ownership structure: attracting new institutional investors

The ownership structure is very much dominated by the founding family, Paxman. They control over 40% of the outstanding shares. In February of this year, Paxman made a direct issue towards two institutional investors that brought in SEK 59m before costs. The financial injection apart this is a good signal of increased interest from the institutional investor base. Both Creades and Alcur have an excellent reputation for finding companies with impressive growth and equity stories.

Ownership

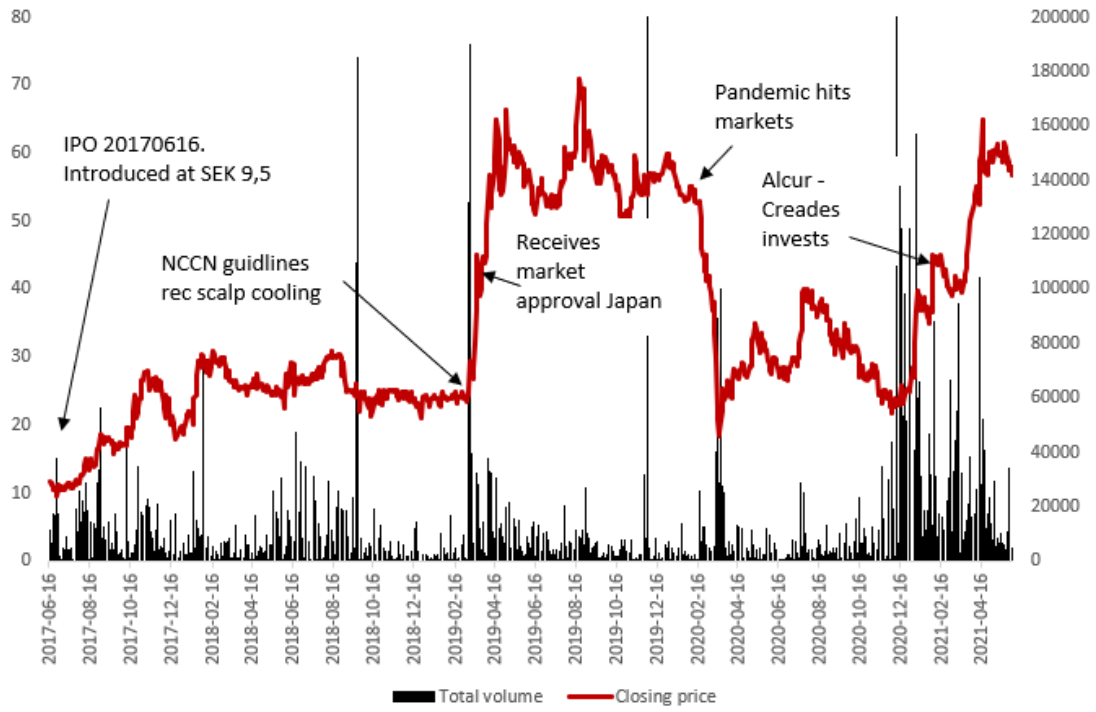
Rank	Shareholder		B-Shares	Total Shares	Share Capital	Voting Rights
1	Glenn Paxman		6,3	6,3	35,5%	35,5%
2	Per-Anders Johansson		1,6	1,6	9,0%	9,0%
3	Länsförsäkringar		1,4	1,4	8,0%	8,0%
4	Richard Paxman		1,3	1,3	7,3%	7,3%
5	Avanza Pension		1,2	1,2	7,1%	7,1%
6	Carl Ejler Rasmussen & Co, A/S		1,0	1,0	5,6%	5,6%
7	Björn Littorin		0,8	0,8	4,3%	4,3%
8	Alcur Fonder		0,8	0,8	4,3%	4,3%
9	Roger Johansson		0,3	0,3	1,4%	1,4%
10	CT Intressenter AB		0,2	0,2	1,2%	1,2%
11	Måns Flodberg		0,1	0,1	0,7%	0,7%
12	Max Lönner		0,1	0,1	0,7%	0,7%
13	Staffan Rasjö		0,1	0,1	0,4%	0,4%
14	Futur Pension		0,1	0,1	0,4%	0,4%
15	Jesper Bengtsson		0,1	0,1	0,3%	0,3%
	Total 15 Largest Shareholders	**0,0**	**15,2**	**15,2**	**86,3%**	**86,3%**
	Others		2,4	2,4	13,7%	13,7%
	Total Number of Shares	**0,0**	**17,6**	**17,6**	**100,0%**	**100,0%**

Source: Modular Finance AB as of 2021-03-31

Free Float	43,0%

Stock performance – bumpy road last 1,5 years

Since the introduction almost four years ago, the journey on the stock market has been volatile. The NCCN guidelines in 2019 and the market approval in Japan pushed the share upwards. However, like almost all the shares that are dependent on open clinics and hospitals, it was hit by the market jitters at the beginning of 2020. The share is now back at pre-pandemic levels, and it seems that the increased interest from institutions has sparked the latest revaluation. Many of the movements are news-driven, and relatively low volumes make for considerable swings in the share.



Product Overview

Paxman's scalp cooling system has been developed over a long time before the company was founded in 1996. The Paxman Scalp Cooling System (PSCS), the latest version, delivers strong clinical results for different chemotherapy treatments.

The system consists of a compact refrigeration unit containing a scientifically developed, low–temperature, non-viscous coolant with efficient heat transfer properties circulated through specially designed cooling caps. The PSCS is available in versions for one or two simultaneous users.

The cooling capability is instant after the 30 minutes to start up, allowing for a relatively fast start to treatment. The cooling cap gets scanned using pay for- use token in the cap; the session cost is then deducted from the patient's account. For specific markets, pre-loaded tokens or cards are used that can be swiped on the unit to make it function.

One of the more critical features of the PSCS system is the cooling caps. The caps are designed for flexibility and single-patient use. The cap is manufactured from a medical-grade soft silicone material. There are three different cap sizes developed after extensive anthropometric research regarding head shapes. The coolant passes through the cap to extract heat from the patient's scalp at a constant and even temperature. To accommodate the needs in the Asian market, there is also an Asian version of the Caps, which otherwise generally comes in three sizes.

Paxmans first scalp cooling system has been available since 1996 in Great Britain, and in 1999 they installed the first system in Norway. By 2006 Paxman reached 500 installed systems. In 2017 the company received FDA clearance for the USA for the indicated use in the USA by breast cancer patients. The extended FDA clearance for all patients with solid tumours is passed in 2018. In 2018 Paxman also received market approval in Taiwan and Argentina. The scalp cooling system also obtained market approval in Japan in 2019.

In 2020 the AMA created CPT codes for mechanical scalp cooling to come into effect in July 2021, a key and crucial step for reimbursement in the USA. In addition, ESMO in Europe includes scalp cooling as a category IIB recommendation to prevent chemotherapy-induced alopecia in its clinical guidelines.

Company timeline, Paxman

1990's	R&D Scalp cooling. Paxman founded 1996. First system installed.
1999	First systems installed outside GB.
2000	Meets regulatory guidlines GB. International launch.
2003	First clinical study conducte with Paxman's system.
2012	Paxman reaches 1000 installed systems.
2014	First randomized multicenter study in USA
2015	Clinical studies intiated in Japan. 2000 installed systems.
2017	FDA clearance in USA. Paxman listed at First North.
2018	Extended FDA clearance for solid tumours in USA.
2019	NCCN in USA includes scalp coolingin guidelines. Market approval in Japan.
2020	AMA creates CPT codes for mechanical scalp cooling. ESMO cat IIB recommendation to prevent chemo induced alopecia.
2021	CPT codes in effect H2

Source: Paxman

Paxman PSCS process

The current PSCS is the latest version of Paxman's scalp cooling system. The main features are as follows:

- **Single or dual patient** unit that can be independently controlled. This allows for more effective use of the unit.
- **Compact size with touch screen visual display,** the small size requires less space in the clinic, and the touch screen makes for easier use by operators.
- **Scientifically developed, low-temperature non-viscous cooling** giving efficient heat transfer properties.
- **Instant cooling capability** when connected. More efficient use of machines and stable temperatures.

The systems have constantly been improved over the years, and the flexibility of the PSCS is key. The Pay-for-use token within the cap that gets scanned, which starts the system, makes it easy to charge the cost for the session.

The actual process can be described in three stages, as shown below. The start-up time for the machine is 30 minutes. The pay-for-use token is then scanned, so the session number is recorded. The patient will bring the personal cap, and the nurse can then help put the neoprene cover over the cap. Pre-cooling the scalp before the commencement of the drug infusion takes 30 minutes to ensure that the scalp has the right temperature before chemotherapy. Finally, the cap is worn throughout the administration of the chemotherapy and up to 90 minutes after.

Paxman PSCS treatment cycle

STAGE 1	STAGE 2	STAGE 3
Pre-cooling stage before Chemotherapy	**Infusion cooling stage during Chemotherapy**	**Post infusion cooling stage**
30 minutes	**XX - Infusion time**	**90 minutes**
- Time adj may have to be done due to patients hair thickness *- During pre-cooling no restroom use recommended*	*- Time varies depending on chemo duration*	*- Common post regimen is 90 min* *- Cooling cap removed 5-10min after Stage 3*

Source: Paxman

Scalp cooling as an answer to a high medical need

Hair loss (alopecia) is a widespread side effect of chemotherapy treatment or is referred to as chemotherapy-induced alopecia or CIA. The estimated incidence is up to 65 % (Trüeb RM, 2010), and almost 8% would decline chemotherapy due to fears of hair loss. Given the clear and severe impact on quality of life, this field has been studied to determine what patients rank hair loss as a side effect of the chemotherapy treatment. We have looked closer at some of the studies and can conclude that hair loss is ranked as one of the most severe side effects.

Patient ranking

Rank	Coates et al (1983) n=155	Griffin et al. (1993) n=155	Carelle et al. (2002) n=100	Ataseven et al. (2017)
1	Vomiting	Nausea	Affects on family	Difficulty sleeping
2	Nausea	Constantly tired	**Loss of hair**	Affects my family/partner
3	**Loss of hair**	**Loss of hair**	Constantly tired	**Loss of hair**
4	Thougth of coming for treatment	Thought of coming for treatment	Affect on work, home duties	Numbness in limbs
5	Length of treatmen at clinic	Vomiting	Affects on social activites	Shortness of breath

Source: Redeye Research

CIA occurs because of the systemic effects of chemotherapy. The chemotherapeutic agents exert their anticancer effect by targeting rapidly growing cancer cells. Unfortunately, this also affects other rapidly growing cells in the body, like hair cells. The scalp cooling process lowers the temperature in the scalp while administering chemotherapy, i.e., the blood flow to hair follicles is reduced, and the metabolic processes slow down. This prevents or reduces hair loss. Research done by Paxman is now establishing further mechanisms behind scalp cooling to provide insight into improving scalp cooling in the future.

Not all different chemotherapy treatments are the same, and some are more likely than others to cause alopecia. Of course, the results can vary depending on the dosage and duration of the treatment. The outcome can also vary; some patient's hair may fall out entirely or in sections and alter in the timeframe. In general, alopecia is reversible; however, the regrowth could be thinner. In some rare instances, the alopecia could be permanent. This has mainly been reported in cases with high-dose regimens with specific agents. It is believed that is due to a loss of hair follicle stem cells. Research has now shown that scalp cooling significantly reduces the risk of persistent chemo-induced hair loss.

The main categories of commonly used anticancer compounds

	Usually causes CIA	Occasionlly causes CIA	Unlikely to cause CIA
DNA replication (S phase)	***Topoisomerase inhibitors*** Doxorubicin, epirubicin, daunorubicin irinotecan, toptecan etoposide, tenoposide	***Amsacrine***	-
	Alkylating agents Cyclophosphamide, ifosfamide	Busulfan, melphalan, lomustine	Carmustine, procarbazine, streptozocin
	Antimetabolites -	Cytatarbine, gemcitabine, 5-FU	6-MP, methotrexate, hydroxyurea, mitoxantrone, fludarbine, raltitrexed, capecitabine, idarubicin
	Platinum-based heavy metal alkylators -	-	Cisplatin, carboplatin
	Anticancer antibiotics -	-	Mitomycin C
Mitosis (M phase)	***Antimicrutubale agents*** Docetaxel, paclitaxel, vindesine, vinorelbine	Vincristine, vinblastine	-

Source: The Oncologist, 2017 ;Redeye Research
Abbreviations: -, No data, 5-FU, 5-fluorouracil; 6-MP, 6-mercarptopurine

Broaden the offering within Chemotherapy-Induced Peripheral Neuropathy (CIPN)

Chemotherapy-induced peripheral neuropathy (CIPN) is one of the most frequent side effects caused by antineoplastic agents, with a prevalence from 19-85%. CIPN is generally a sensory neuropathy accompanied by motor and autonomic changes of different degrees of severity. With such a high prevalence, it is a big problem for both patients and providers. The six main substance groups that cause this damage is; platinum-based antineoplastic, vinca alkaloids, epothilones, taxanes, proteasome inhibitors, and immunomodulatory drugs. The most neurotoxic are platinum-based agents, taxanes, ixabepilone, and thalidomide. (R Zajaczkowska et al., 2019)

Generally, the risk of developing CIPN is higher with higher doses, multiple courses, and combination chemotherapy. The risk is also increased if patients have diabetes, vitamin deficiencies, or preexisting peripheral neuropathy. To date, there have been no proven interventions to prevent CIPN, and options to treat CIPN are limited. The theory behind the benefits of applying cooling or cryotherapy is that cooling protects against side effects of chemotherapy. This is done by reducing drug distribution at the cooled area through vasoconstriction, thus decreasing cellular uptake. (Bandla et al., 2016)

Paxman has collaborated with the National University Hospital in Singapore (NUH) to develop a portable cooling and compression system to prevent CIPN. Clinical studies are to be initiated in 2021/22, which is most likely to be in 2022.

This is an exciting R&D project undertaken by Paxman, and their expertise within the cooling field and collaboration with the University of Huddersfield shows promise. With the high prevalence and severity of CIPN, it would be of high interest for health care providers and would be a vast and interesting market to develop.

If the clinical trials show positive outcomes, this device could reach the market already in 2024. We believe that the time to market would be shorter than Paxmans other products due to an already set up distribution network. In addition, the method is already included and being discussed in several guidelines.

Paxman CIPN device

Source: Paxman

We have decided not to include this potential in our estimates; however, we will view the trial outcome with great interest. This could mean a great addition to the total available market for Paxman.

Clinical experience with (Paxman)

Paxman has since the 1990s been pioneers in scalp cooling. The ongoing collaboration with the University of Huddersfield was initiated in 2011 and has involved extensive laboratory research in understanding how cooling prevents CIA. These laboratory findings demonstrated that cooling blocks drug toxicity due to reduced drug accumulation within the cells. In addition, the concentration in cooled cells is over five times lower than in non-cooled cells. (Dunnil et al., 2018 conducted a clinical and biological guide into the CIA and its prevention that further highlights the causes and benefits of scalp cooling.)

During the last decade, there have been several successful clinical studies with leading clinics and cancer centers worldwide that have strengthened and given further clinical evidence of the high efficacy and safety of the system. The world's first **randomized** multi-center study was conducted in the US in 2017. (Nangia et al., 2017)

We have chosen two of the most important clinical studies to dig into deeper.

The US (SCALP) randomized clinical trial in breast cancer

The FDA cleared the Paxman Scalp Cooler (Orbis) by a 510K approval in April 2017. We see this clinical trial design as rigorous and the successful treatment outcome of most patients. The result showed success rates statistically higher in the scalp cooling group than the control group. The difference in success rate between the groups was 50,5%, giving patients a significantly better chance of retaining their hair if scalp cooling was used with chemotherapy treatment. The success rates between drug regimens varied significantly.

The trial was initiated towards the end of 2013 and run to September 2016. It was a randomized, non-blinded, multi-center (7 sites) clinical trial for women planning to undergo neoadjuvant or adjuvant chemotherapy.
The overall objective was to assess whether a scalp cooling device effectively reduces chemotherapy-induced alopecia (CIA) and asses adverse treatment effects.

The primary efficacy endpoints were successful hair preservation assessed using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. Success was defined as CTCAE grade 0 (no hair loss) or grade 1 (<50% hair loss not requiring a wig). Failure was grade 2 (>50% hair loss requiring a wig). The primary efficacy endpoint was assessed by independent clinicians unaware of study treatment. Withdrawals of a patient were deemed a treatment failure.

The secondary endpoint success in hair preservation was assessed by the participant's clinician and by the participant by using wigs/head wraps, reported comfort, and quality of life. The quality of life was assessed by the EORTC QLQ-C30 (Emotional functional and Social scale), HADS (anxiety and depression summary), and BIS (body image scale).

The primary safety endpoint was anticipated adverse device effects, based on already know complications in conjunction with this type of device. The anticipated effects included cold discomfort, headaches, dizziness, and nausea described in the CTCAE v4.0. The secondary safety endpoint was participant reported comfort, categorized into five levels from very comfortable to very uncomfortable. The participants will be followed up for five years for overall survival, recurrence, and scalp metastases.

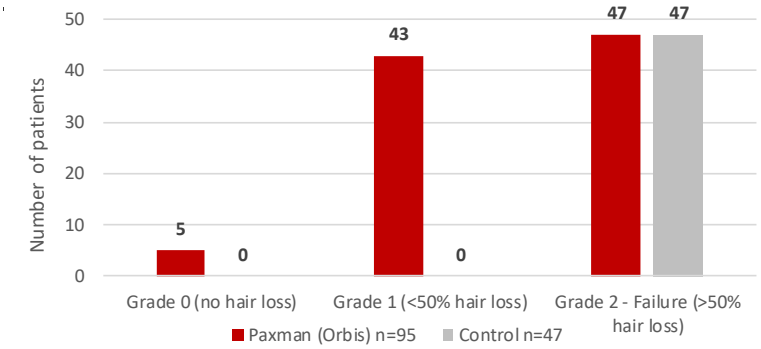
The study enrolled 229 participants, of which 182 were randomized to scalp cooling or control. Of the 182 randomized participants, 142 participants who completed at least one cycle of chemotherapy were evaluable for the primary endpoint. The mean age of the ITT (intent-to-treat) population of 142 was 52,6, with an 81,7% white group. The participants were all (100%) graded at 0 according to the CTCAE alopecia grade at baseline. The regimen included in the trial were:

- Doxorubicin (60 mg/m2) with cyclophosphamide (600 mg/m2)
- Doxorubicin (50 mg/m2) with fluorouracil (500 mg/m2) and cyclophosphamide (500mg/m2)
- Paclitaxel (80-90 mg/m2) weekly, (every 3wk constitutes a cycle) or (175 mg/m2) every 2-3 weeks as a single agent
- Paclitaxel (80-90 mg/m2) weekly, with carboplatin target AUC of 6mg – min/ml every 3 weeks

- Docetaxel (100mg/m2) as a single agent
- Docetaxel (75-100 mg/m2) with pertuzumab and trastuzumab at standard dose
- Docetaxel (75 mg/m2) with cyclophosphamide (600 mg/m2)
- Docetaxel (75 mg/m2) with carboplatin target AUC of 6 mg – min/ml and trastuzumab at standard dose

In the modified ITT population, 64% (n=91) of the participants received taxane-based chemotherapy, and 36% (51) were treated with anthracycline-based chemotherapy. In the interim analysis, 95 patients in the cooling group and 47 patients in the non-cooling group were evaluable with four cycles of chemotherapy completed. Overall, 48 (50,5%) patients in the cooling group demonstrated treatment success out of the 95 included. In the control group, 0 out of 47 had hair preservation. Grade 0 and 1 were considered a success. The success rate difference between the 2 groups in were 50,5% (Grade 0 – 5,3%, Grade 1 - 45,3%).

Summary of success in Hair preservation

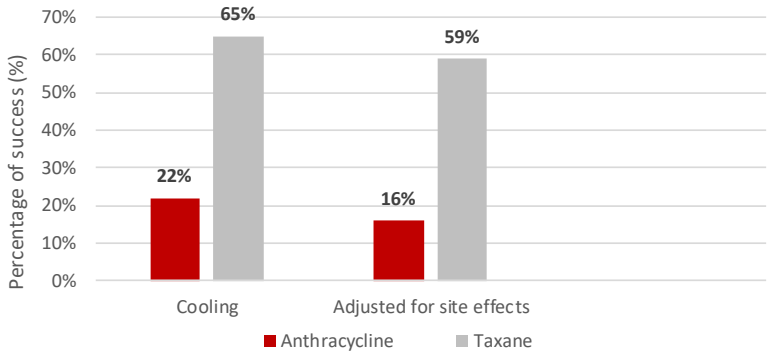


Source: Nangia et al., 2017 & Redeye Research

In September 2016, the recommendation from the data and safety monitoring board to stop accrual to the study early and release the results to the principal investigator due to the superiority of hair retention in the participants who received scalp cooling. This early stop shows the strength of the scalp cooling in this area.

As expected, there were substantial differences in the success of hair preservation by both sites and by drug group (taxane vs. anthracycline). The success range from 0% (n=1) to 68,6% (n=51) in the cooling group.

Paxman - Effectivess by chemotherapy regimen



Source: Nangia et al., 2017 & Redeye Research

The rates for oncologist-graded hair preservation were higher, and 53 out of the 95 in the cooling group showed hair preservation, i.e., 55,8% and 0% in the control group. In addition, wigs and headwraps were used by 63% in the cooling group vs. 100% in the control group.

Patient assessment regarding the quality of life showed no significant change in emotional and social functioning and patient body image between the groups after four cycles of chemotherapy. These were evaluated using EQRTC and HADS, while we would have expected a difference while these tools are not fully useful for such an analysis and new tools are being developed and are in use.

In total, there was no serious adverse event that was reported. There were 54 minor adverse events reported. The majority are in order headaches, nausea, dizziness, and chills. 48% of the reported adverse events were related to headaches. These negative effects are in line with what could be expected, with the majority coming from headaches.

Paxman - Adverse device effects in safety analysis

	Participants by Chemo cycle, No (%)			
Adverse Device event	1 (n=101	2 (n=84)	3 (n=66)	4 (n=62)
Headache	12 **(11,9)**	9 **(10,7)**	1 **(1,5)**	4 **(6,5)**
Nausea	4 **(4,0)**	2 **(2,4)**	1 **(1,5)**	1 **(1,6)**
Dizziness	3 **(3,0)**	1 **(1,2)**	0	0
Chills	1 **(1,0)**	0	0	0
Pruritus	1 **(1,0)**	0	0	0
Sinus pain	0	0	1 **(1,5)**	0
Skin a subcutaneous tissue disord.	1 **(1,0)**	0	0	0
Skin ulceration	1 **(1,0)**	0	0	0
Dry skin	1 **(1,0)**	1 **(1,2)**	1 **(1,5)**	0
Scalp pain	1 **(1,0)**	2 **(2,4)**	1 **(1,5)**	1 **(1,6)**

Source: Nangia et al., 2017 & Redeye Research

Link to study: https://paxmanscalpcooling.com/wp-content/uploads/2020/03/JAMA-SCALP-DATA-PUBLICATION-14.2.17-do-not-share-with-customers-only-provide-link-to-JAMA.pdf

German study – observational to assess success rates of scalp cooling

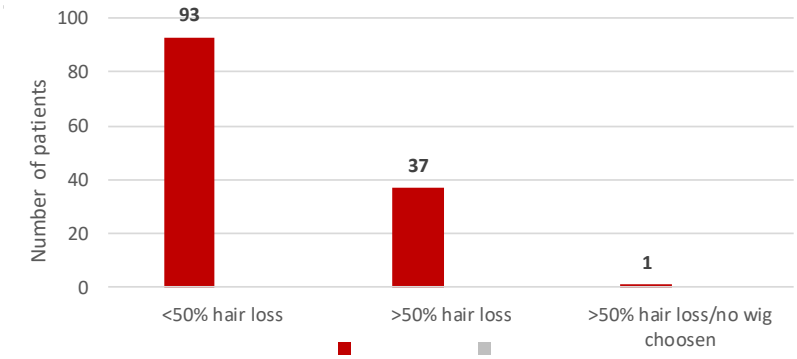
This German study was set up to determine if a scalp cooling device effectively reduces chemotherapy-induced alopecia (CIA) and asses adverse treatment effects.

Although smaller than the US SCALP study, the results showed strong results with a success rate of 88% with paclitaxel and an overall success rate of 71%, indicating a high efficacy and a beneficial safety profile.

In total, the prospective, single-center study recruited 131 patients with a mean age of 49,8 years. The patients underwent chemotherapy with either anthracycline/taxane-based or taxane-monotherapy and had stage I-III breast cancer.

The primary efficacy endpoint, success, was defined as no hair loss, <30% hair loss requiring no wig, or <50% hair loss and not requiring a wig. On the other hand, failure was >50% hair loss and/or requiring a wig per patient preference. This was assessed by empirical visual evaluation by the oncology study nurse. The eventual decision to wear a wig was up to the patient independently.

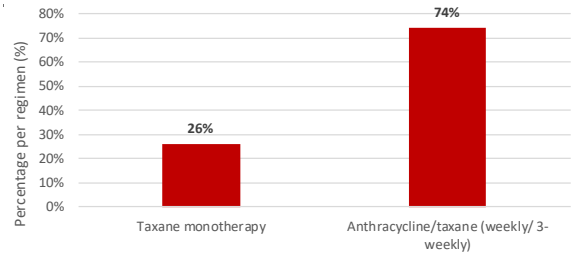
Summary of success in Hair preservation



Source: Vassconcelos, Wiesske & Schoenegg, 2018 & Redeye Research

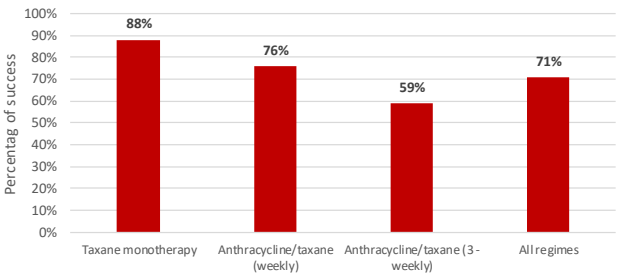
As seen in other studies, the success rate was significantly different depending on the chemotherapy regimen. The highest success rates were among those receiving taxane-monotherapy with a 88% success rate. The weekly administered anthracycline/taxane-based therapy received a rate of 76% and 59% by the three-weekly administration of the same drug.

Paxman : Received treatment regimen (%)



Source: Vassconcelos, Wiesske & Schoenegg, 2018 & Redeye Research

Paxman : Success rate per treatment regimen (%)



Source: Vassconcelos, Wiesske & Schoenegg, 2018 & Redeye Research

We conclude that the high success rates in both the US and German studies are strong and reiterate the high impact that Paxman's scalp cooling has on patients' quality of life. The more substantial success rate for the German study is most likely because the US study is randomized, and the intrinsic hair follicle characteristics of the German population and adjuvant haircare measures are recommended. In all respects, this is a very strong study with no serious adverse device events and clearly shows the positive effects in reducing the severity of alopecia. It is also worth noting that in the German study, they were well versed in using the scalp cooling devices.

There is also another study that is of interest, both because of the preliminary results but also the sheer size. It is a Dutch study comprising more than 7000 patients with solid tumors between 2006 and 2017. The Dutch Scalp Cooling Registry collected data on scalp cooled patients in 28 hospitals. Overall, 50% of the scalp cooled patients did not wear a headcover during the last chemotherapy session. There were, as in other studies, differences between types of dose of chemotherapy as the outcome. We believe that the primary scalp cooling device used was from Paxman.

We recognize that both studies fall nicely in the range with other studies' success rates made in the field, both for Paxman and other studies made for scalp cooling devices. (See table below for a number of studies.)

Paxman: Summary of clinical evidence in breast cancer

Authors	Type of study	Chemotherapeutic agents used in trial	Purpose of study/ Follow-up schedule for alopecia	Paxman arm sample size (control arm)	Paxman pts completed cooling (%)	Paxman pts with <50% hair loss (%)
Lemieux et al., 2014	Retrospective	Anthrcycline and taxanes	Survival rates study	553 (817)	N/M	N/M
Nangia et al., 2017	Prospective, randomized	Anthrcycline (36%) and taxanes (64%)	CTAE v4.0 Grade 1 or 0	119 (63)	100	48 (50,5)
Rugo, Melin & Voigt, 2017	Retrospective, systematic review	N/A	Risk of scalp metastases	3197	N/M	N/M
Martin et al., 2018	Prospective, non randomized	Docetaxel > = 400mg/m(2)	Grade: 1 (weakening of hair or partial alopecia); 2 (complete alopecia)	492	100	100
Vasconcelos, Wiesske & Schoenegg, 2018	Prospective, non randomized	Anthracycline/taxane (74%) and Taxane - monotherapy (26%	Preventing alopecia with scalp cooling. Patient rating - wearing wig/headcover or not	131	100	93 (71)
Komen et al., 2018	Prospective, randomized	FEC, epirubicin - 90-100mg/m(2)	Post infusion duration study WHO scale for alpecia. Patient self assement VAS score	102	100	N/M
Kinoshita et al., 2019	Prospective, non-randomized	Taxane or anthracycline	Efficacy of scalp cooling, CTAE v4.0	43 (13)		18/30 (60)
Bajpai et al., 2020	Prospective, randomized	Taxane or anthracycline	Efficacy of scalp cooling, CTCAE v4.0	34 (17)	100	19 (56,3)
Ohsumi et al., 2020	Prospective non-randomized	Taxane and/or anthracycline	Efficacy of scalp cooling, WHO scale 1-3	122	64	56 (54)

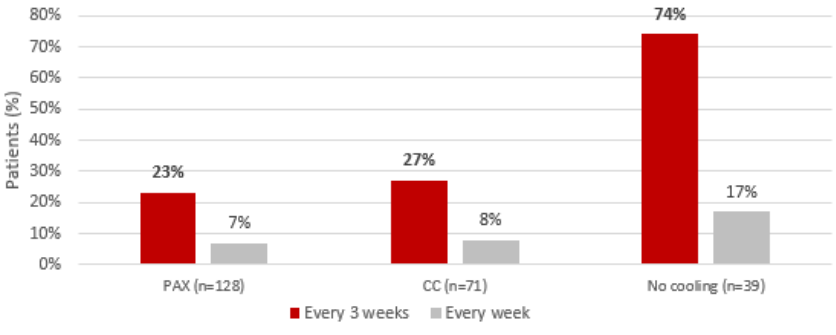
Source: Paxman & Redeye Research

Paxman in patients with solid tumors

The number of studies made for solid tumors is not as large as for breast cancer, naturally so since the scalp cooling systems initially targeted breast cancer indications. In general, the system has shown results in the same range as for the previously discussed area of breast cancer. In the largest trial conducted (Betticher et al., 2013), the prospective, non-randomized trial done were done with 238 patients. The purpose was to investigate two different methods of scalp cooling that can prevent hair loss. In the study, 128 patients were with the Paxman system, 71 with cold cap, and 39 patients with no cooling.

In this study, the primary endpoint was the WHO grade III or IV alopecia incidence assessed by the treating physician or wearing a wig. There were additional endpoints, such as discontinuation of the chosen method, received number of cycles, and patient perception of scalp cooling procedures. As seen in the graph below, there are clear benefits to scalp cooling. In addition, the risk of developing alopecia was lower if docetaxel was given weekly rather than every three weeks.

Paxman: Incidence of combined end point (alopecia), by docetaxel treat.sched.

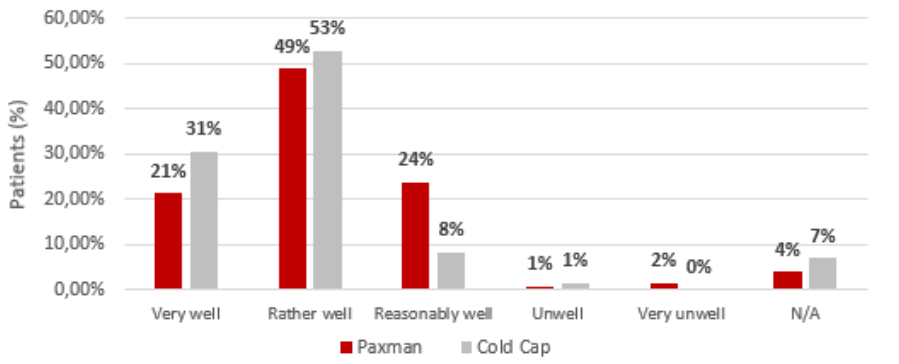


Source: Betticher et al., 2013 & Redeye Research

The time pattern showed that the no cooling group declined steeply while the PAX and CC remained over 80% and combined significantly reduced the risk of alopecia by 78%.

The tolerability number stands out as a clear positive, with 93,7% of patients reported feeling reasonably well or better with Paxman Scalp cooler. A patient questionnaire did this. The results indicated in the table below show an excellent rating for scalp cooling.

Paxman: Overall assement of cooling therapy cycle 1



Source: Betticher et al., 2013 & Redeye Research

Paxman: Summary of clinical evidence in solid tumours

Authors	Type of study	Chemotherapeutic agents used in trial	Purpose of study/ Follow-up schedule for alopecia	Paxman arm sample size (control arm)	Paxman pts completed cooling (%)	Paxman pts with <50% hair loss (%)
van den Hurk et al., 2013a	Prospective, randomized	Taxane and/or anthracyline	Use of wig/headcover - WHO scale 0-4	160 (86)	97	N/M
Komen et al., 2016	Prospective, randomized	Docetaxel 75-100mg/m2	Post infusion study time difference WHO scale 0-4	134	72	N/M
Betticher et al., 2013	Prospective, non-randomized	Docetaxel palliative	Efficacy/ tolerability study, WHO scale 0-4	128 (38) (238 total)	90	77

Source: Paxman & Redeye Research

Summarizing Paxman Scalp Cooling clinical documentation

To summarize, we view the Paxman scalp cooling system's clinical documentation as solid. Results clearly show that the system is efficacious in inhibiting CIA for a majority of patients. Apart from the solid clinical documentation, it is strengthened by similar findings from other groups of researchers investigating the effect of scalp cooling on CIA.

We view the success rates as good, while they are relatively broad in range; however, this is most likely due to the design of the studies and the small sample sizes, and the different follow-up methods. For example, in the US study (Nangia et al., 2017), the cost issue regarding scalp cooling is discussed as an important factor as the reimbursement is not yet in place. However, this is on its way to be remedied. It is also important to recognize that scalp cooling positively affects a patient's quality of life and the reported side effects are mainly mild in severity. Therefore, we see a convincing offer for patients to use scalp cooling when undergoing chemotherapy.

The fear of scalp metastases has held back development in the US

There have been concerns about the risk of scalp metastases, especially in the US, and have hampered the acceptance of the technology in the market. As far as we can see, these fears seem exaggerated with a low incidence of scalp metastases and not increased by scalp cooling.

As far as we can tell, there have been no scalp metastases in the clinical trials conducted with Paxman's devices. There is further support given by Rugo et al.(2017) which reviewed ten studies analyzing the incidence of scalp metastasis with scalp cooling over time. Based on extensive analysis, 3 179 patients (1 959 in the scalp cooling arm) concluded that scalp cooling is highly unlikely to increase the incidence of scalp metastases. The clinical

evidence favors scalp cooling; however, the study was limited in the follow-up period, and the long-term effects have not been thoroughly investigated. We do not believe, however, that the risk is high, albeit that it exists.

Rugo et al., 2017 - Scalp metastasis incidence

Study	Scalp Cooling		No Scalp cooling		Length of follow up (months) scalp cooling median	Length of follow up (months) no - scalp cooling median
	Scalp mets	Tot pts	Scalp mets	Tot pts		
Lemieux et al	6	553	1		69	64
Parker	0	6			12	
Protiere et al.	0	77	0		44	
Ridderheim	0	3			15	
Ron et al.	0	19	0		14	14
Rugo	0	101			29,5	
Spaëth et al.	3	770	0		36	36
Tollenaar et al.	0	35			46	
van der Sande	0		4	885		110
Van den Hurk et al.	3	395			26	
Totals	**12**	**1959**	**5**	**1238**		
Averages					32,4	56

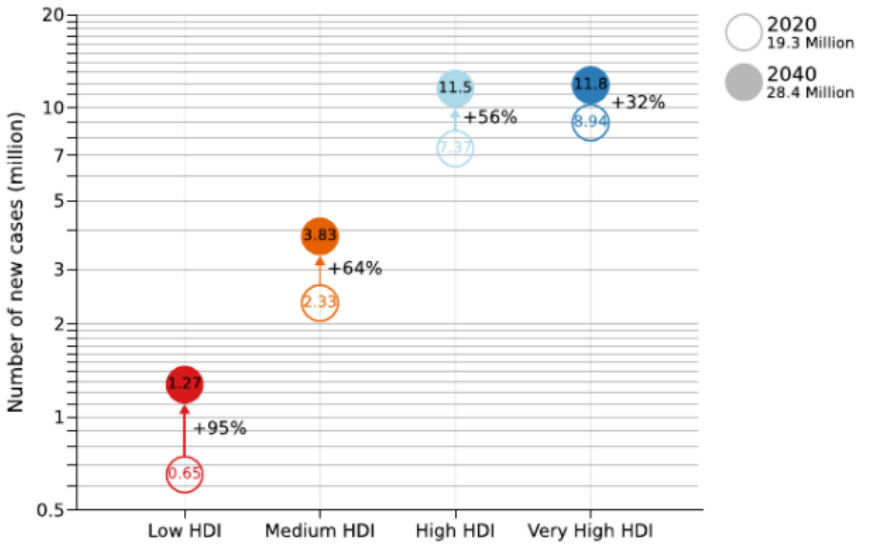
Source: Rugo et al., 2017 & Redeye Research

Market Opportunity

We estimate Paxman's total addressable market (TAM) using a patient-based market model. To keep our estimates conservative, we base this model primarily on the markets in the company's primary focus in the short to medium term and offer the highest potential. This is obvious: the USA, the five major European markets (5EU), and Japan. We acknowledge that there are more than those markets available, which Paxman already has proved by the installed base in other countries, such as Russia and Australia. However, the data on these markets are not of the same quality and are not readily available in all instances.

It is important to realize the market's potential before entering into the specific TAM for Paxman, which is conservative since it only covers particular markets. The pricing is indicative since it is difficult to assess the actual prices the company charges. Worldwide an estimated 19,3 million new cancer cases occurred in 2020. Female breast cancer and Lung cancer represent more than 23% of all new cases. The mortality rate is high, and there were almost 10 million deaths by cancer worldwide in 2020. According to GLOBOCAN estimates, there will be over 28 million new cases in 2040, increasing 47% since 2020.

World wide new cancer cases 2020 - 2040E



Source: GLOBOCAN 2020 & Redeye Research

The total addressable market for Paxman

Our market model is based on Paxman's aggregate average patient income and system revenues. At the end of our forecast period, we estimate a TAM of more than USD 0,9bn from the USA, 5EU, and Japan. We do recognize that the addressable market is much higher if we include the rest of the world. As discussed above, the actual number of new cancer cases is higher than in our estimates for TAM.

TAM for average income per patient

We primarily base our forecasts on data from the National Cancer Institute (NCI) and Datamonitor. We forecast that about 4,1 million diagnosed incident cases and 34,1 million prevalent (people living with cancer) solid tumour cancer cases in 2021. We assume that 24 % of the prevalent cases receive drug treatment.

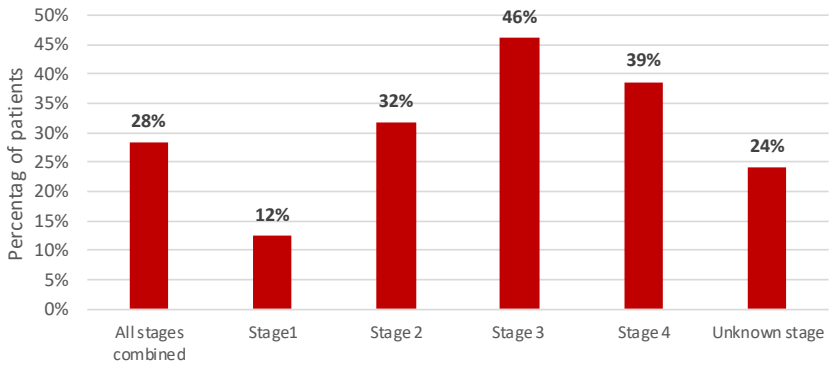
The research into investigating the share of patients that receive chemotherapy gives us a wide range of estimates. Research aiming to examine cancer patients who receive chemotherapy has resulted in highly different forecasts. At the upper end of the spectrum, we find estimates from Lacouture et al. (2018) that 65% of US cancer patients receive systemic therapy. Research by Fitch et al. (2016) also indicates that chemotherapy cases constitute the most treated cancer cases in the market. Based on the Medicare 5% sample claim database and the Truven MarketScan commercial claim database (1,614,417 patients included), the authors estimate that the share of cancer patients who are treated with chemotherapy has increased from 67% in 2004 to 75% in 2014.

Data indicates that patients who receive chemotherapy could be similar or higher in the most developed countries in Europe.

Based on the National Cancer Registration and Analysis Service data, from which diagnosis codes for cancer patients were extracted, Cancer Research UK estimates that 24.8% of diagnosed cancer patients receive chemotherapy as part of their primary treatment in the UK. Based on our assumption that about 24% are treated with drugs, the data suggests that the vast majority of patients are

treated with chemotherapy.

Cancer patients receiving chemotherapy treatment (%UK)



Source: National Cancer Research & Redeye Research

Considering the wide spread in these estimates, we choose to take a conservative stance and assume that 50% of drug-treated cancer patients receive chemotherapy in 2021 (including all stages and lines of treatment). To account for the increased use of targeted therapies and biologics, we assume that the number will decrease to 40% at the end of our forecast period.

According to Fitch et al. (2016), 64% of chemotherapy-treated patients in 2014 received infused chemotherapy (a decrease from 78% in 2004). Unfortunately, reliable data from Europe is scarce, but overall, we believe that the proportions align with the USA.

In line with being conservative in our stance, we assume that about 50% of chemotherapy-treated patients receive infused therapy. However, accounting for the increasing use of oral chemotherapy, we presume a decreasing number and will end up at around 40% at the end of our forecast period.

We estimate USD 380 as an average income per patient per cycle in our market model in the base case scenario. We do see a risk of price erosion going forward. However, the reimbursement process may prove otherwise, and we expect that Paxman will hold up the gross margin well over the following years. We assume a very slight price erosion to USD 360 in 2025. We do not expect further deterioration from that level and assume that prices will stabilize.

In total, we expect a TAM of USD just below 0,9bn for Paxman at the end of our forecast period (2034).

TAM, Paxman average income per patient

	2021E	2022E	2023E	2024E	2025E	2026E
Total incident cases of solid tumours	**4 134 468**	**4 174 610**	**4 214 996**	**4 255 333**	**4 296 877**	**4 333 934**
USA	1 540 442	1 559 247	1 578 395	1 597 987	1 618 692	1 637 302
5EU	1 822 075	1 839 232	1 856 726	1 874 641	1 892 989	1 909 782
Japan	771 951	776 131	779 875	782 705	785 196	786 850
Total prevalent cases	**34 154 784**	**34 268 986**	**34 378 049**	**34 482 060**	**34 590 547**	**34 708 764**
USA	13 579 378	13 662 707	13 745 851	13 829 567	13 914 911	14 000 820
5EU	15 494 474	15 523 185	15 555 125	15 596 547	15 642 703	15 696 635
JAP	5 080 932	5 083 094	5 077 073	5 055 946	5 032 933	5 011 309
USA						
Drug treated cases	**3 073 300**	**3 103 229**	**3 133 087**	**3 162 994**	**3 193 647**	**3 224 115**
Breast & gynecological cancer	1 051 439	1 061 746	1 071 994	1 082 133	1 092 436	1 102 538
Urological cancer	673 752	682 501	691 087	699 451	707 693	715 611
Gastrointestinal cancer	362 659	366 103	369 667	373 780	378 794	384 261
Lung cancer	296 675	298 433	300 179	301 911	303 630	305 335
Brain and nervous system cancer	88 315	88 838	89 358	89 873	90 385	90 893
Skin cancer	74 136	75 758	77 432	78 981	80 386	81 762
Head and neck cancer	42 186	42 843	43 514	44 182	44 835	45 444
Bone and joint cancer	29 376	29 550	29 723	29 895	30 065	30 234
Other	454 762	457 457	460 133	462 788	465 423	468 037
5EU						
Drug treated cases	**3 666 529**	**3 693 705**	**3 720 530**	**3 747 287**	**3 773 417**	**3 799 287**
Breast & gynecological cancer	1 166 572	1 172 594	1 178 288	1 183 771	1 188 178	1 192 394
Urological cancer	979 102	990 686	1 002 195	1 013 936	1 026 144	1 038 296
Gastrointestinal cancer	537 232	543 304	549 463	555 583	561 888	568 305
Lung cancer	290 260	290 966	291 664	292 354	293 037	293 712
Brain and nervous system cancer	117 819	117 916	117 944	117 982	117 991	118 070
Skin cancer	69 810	70 663	71 529	72 319	73 030	73 668
Head and neck cancer	62 168	62 930	63 736	64 576	65 340	66 001
Bone and joint cancer	28 741	28 811	28 880	28 948	29 016	29 083
Other	414 825	415 835	416 831	417 818	418 793	419 758
Total drug treated cases of solid tumours (incl. Japan)	**8 319 576**	**8 383 901**	**8 446 134**	**8 506 569**	**8 565 342**	**8 622 669**
Share of patients treated with chemotherapy	49%	48%	47%	46%	45%	44%
Share of patients receiving infused chemotherapy	48%	47%	46%	45%	44%	43%
Average number of chemotherapy cycles	5	5	5	5	5	5
Total chemotherapy infusions	**9 785 459**	**9 469 044**	**9 160 052**	**8 858 791**	**8 565 343**	**8 279 836**
USA	3 614 806	3 504 885	3 397 914	3 293 960	3 193 647	3 095 926
5EU	4 312 559	4 171 788	4 035 011	3 902 447	3 773 417	3 648 229
Japan	1 858 094	1 792 371	1 727 127	1 662 384	1 598 279	1 535 681
ASP per patient, WW (USD)	380	370	370	360	360	360
TAM, WW (USDm)	**1162**	**1117**	**1083**	**1017**	**986**	**956**

Source: Redeye Research

TAM for systems

When we estimate the TAM for the scalp-cooling systems, we assume that they will be used on average once per day when the markets have matured. We base our estimated number of systems of 46000 on the number of chemotherapy infusions forecasted to meet the demand in the primary markets for Paxman; of course, with the worldwide presence, this number could be considerably higher, but we chose a conservative stance since the is ample room to grow within the current TAM.

In our model, we estimate an annual price of USD 2500 per leasing contract. However, we know that leasing does not present a high number within Paxman. We estimate USD 8000 for direct capital sales, which probably is conservative. The price erosion will be around 2% per year until 2025 when we assume a stabilizing price. This results in a TAM of systems of USD 40m yearly at the end of our forecast period. (2034)

TAM, Paxman systems

	2021E	2022E	2023E	2024E	2025E	2026E
Total chemotherapy infusions	**11 797 425**	**11 486 348**	**11 179 154**	**10 876 097**	**10 577 357**	**10 284 137**
USA	3 614 806	3 504 885	3 397 914	3 293 960	3 193 647	3 095 926
5EU	4 312 559	4 171 788	4 035 011	3 902 447	3 773 417	3 648 229
Japan	3 870 060	3 809 675	3 746 229	3 679 690	3 610 293	3 539 982
Usage per system						
(average treatments per day)	1	1	1	1	1	1
Infusion days per year	252	252	252	252	252	252
Systems needed to meet demand	**46 814**	**45 581**	**44 362**	**43 159**	**41 974**	**40 810**
USA	14 344	13 908	13 484	13 071	12 673	12 285
5EU	17 113	16 555	16 012	15 486	14 974	14 477
Japan	15 357	15 118	14 866	14 602	14 327	14 048
Leasing agreements USA, share of placements	20%	20%	20%	20%	20%	20%
Leasing agreements 5EU, share of placements	30%	30%	30%	30%	30%	30%
Leasing agreements Japan, share of placements	0%	0%	0%	0%	0%	0%
ASP per year, leasing (USD)	2 500	2 437	2 375	2 200	2 200	2 200
ASP per system, capital sales (USD)	9 000	8 790	8 586	8 000	8 000	8 000
Average lifelength, systems (years)	10	10	10	10	10	10
TAM, leasing agreements	**20**	**19**	**18**	**16**	**15**	**15**
USA (USDm)	7	7	6	6	6	5
5EU (USDm)	13	12	11	10	10	10
Japan (USDm)*	0	0	0	0	0	0
TAM, capital sales	**35**	**33**	**32**	**29**	**28**	**27**
USA (USDm)	10	10	9	8	8	8
5EU (USDm)	11	10	10	9	8	8
Japan (USDm)*	14	13	13	12	11	11
TAM, WW (USDm)	**55**	**52**	**49**	**45**	**43**	**42**

Source: Redeye Research

Competitive landscape

We do not see the cold cap companies as direct competitors even though they have some attractive attributes. With an increasing focus on the side effects of chemotherapy and the potential reimbursement in the US, we expect that there is a high possibility of additional competitors in a few years. There is enough space for several players, and the companies that have come the furthest have a clear advantage in an installed base and clinical data that takes time to accumulate.

Dignitana

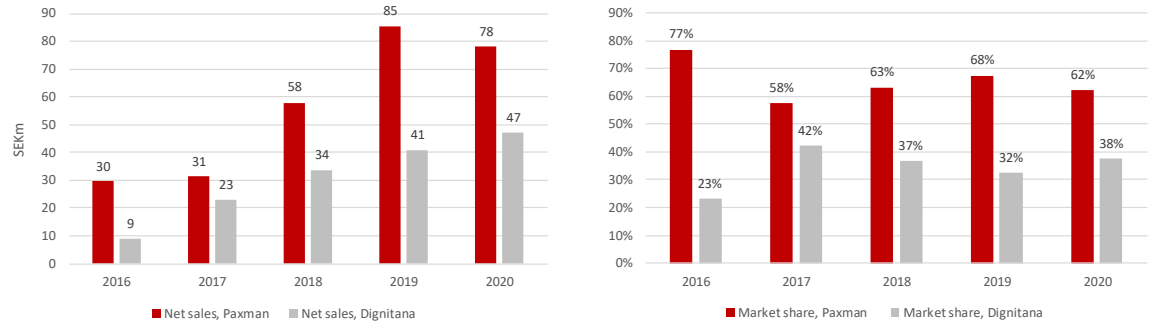
Founded in 2007, a Swedish medical technology company develops, produces, and markets its scalp cooling system, DigniCap. The company has its headquarter in Lund, Sweden, and is also based in Dallas, USA, where the CEO is based. They currently employ 27 staff and generate revenues of about 48m (last 12 months). Dignitana has been on the stock market since 2009 and has been trading on the Nasdaq First North since 2011.

The Dignitana system, just like Paxman's cooling system, is designed to prevent CIA in patients with solid tumors. The designs of the systems are similar in many aspects, with the refrigeration unit as the center with different designs of the caps.

We see some key differences between the systems; however, we believe that they are still relatively modest even though both companies continue to develop their approaches, and both systems, as we understand it meets customer needs.

Dignitana is replacing its old systems with the new DigniCap Delta, which has improved functions compared to the previous ones. Paxman's significant difference in taking a larger market share is choosing a single or dual treatment method.

Net sales and market share by value, Paxman vs. Dignitana*



* Total market value is based on the companies' net sales. (cold cap market excluded)

Source: Paxman, Dignitana & Redeye Research

Dignitana's scalp-cooling system has been available since 2001 in Europe and was cleared by FDA in 2015 for use by breast cancer patients. In mid-2017, the indication was expanded to all patients with solid tumors. The DigniCap Delta was CE-marked in March of 2019 and received FDA clearance later that year in June. The company delivered its first Delta system in August of 2019.

The FDA cleared DigniCap in 2015 via the de novo process. The trial results demonstrated a significant clinical benefit and positive impact on patients' quality of life. The trial was the first large-scale clinical trial investigating scalp cooling in the US. We view the design of Dignitana's pivotal trial as rigorous and designed to meet the FDA's more complex Premarket Approval (PMA) pathway. The FDA review converted the application to the de novo regulatory pathway, enabling a shorter time to market.

The pivotal trial was a non-randomized multi-center (5 sites) concurrent controlled study. The overall objective was to evaluate three things, clinical performance, safety, and efficacy. Efficacy was measured as patient self-assessment of CIA by using the Dean scale. (Use of standardized photos as a reference)

Results showed that scalp cooling was successful; 66% of patients in the scalp cooling arm showed treatment success, compared to 0% in the control arm.

Many other clinical trials have investigated the Dignitana scalp cooling system during the years for both breast cancer and solid tumors. In the largest trial conducted in 2015 (Schaffrin-Nabe et al.,2016) with solid tumors, scalp cooling was successful in 65% of patients. In all, the clinical documentation is regarded as solid. Results show that Dignitanas is efficacious in inhibiting CIA for the majority of patients.

The other manufacturers – Cold Caps

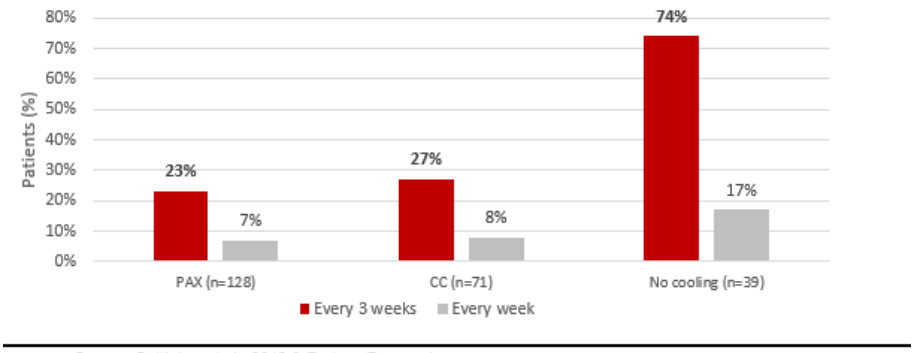
A significant number of patients still use manual gel caps for scalp cooling. Unfortunately, since the FDA does not clear manual caps, they generally cannot be stored by hospitals, requiring patients to rent or purchase the caps and take them to the clinics themselves. Some supportive chemo centers do, however, have biomedical freezers, allowing patients to freeze several dry ice caps, which are changed during a treatment session.

We have identified six large manufacturers of cold caps: Penguin Cold Caps, Chemo Cold Caps, Arctic Cold Caps, Wishcaps, Warrior Caps, and Polar Cold Caps. The prices range between USD 300 and USD 500 per month; however, there are differences between the services included, but it typically excludes shipping. In addition, some manufacturers require a deposit when patients subscribe to the service.

A more cost-effective alternative, we believe they are likely less efficacious due to the inability to maintain the correct temperature on the scalp.

In Betticher et al., 2013, Paxman went head to head with a CC (manufacturer undisclosed), and they both showed a reduced risk of alopecia of 78 % by using the protection. (See further discussion on page 17)

Paxman: Incidence of combined end point (alopecia), by docetaxel treat.sched.



Source: Betticher et al., 2013 & Redeye Research

As the scalp-cooling market grows, we believe that both clinics and regulatory authorities likely prefer a regulated, standardized method, which is indicated by the processes now in motion with the CPT codes and other measures in the market. Moreover, we believe that machine scalp cooling with single-patient caps will offer clinics greater user-friendliness, reducing the logistics burden associated with dry ice caps.

Other approaches

Prevention of hair loss during chemotherapy through pharmaceutical treatment has shown some promise in early-stage research. More than a decade ago, animal studies showed that the tumor suppressor protein p53 could play an important role in CIA and that injecting the WNT3a protein could prevent hair loss. Recent studies have also demonstrated that inhibition of the protein kinase CDK4/6 could make hair follicles much less susceptible to the damaging effects of taxanes.

However, this research is still in its early stages, and none of the approaches has attracted the pharmaceutical industry's attention to any significant degree. Currently, it seems unlikely that any of these approaches will result

in commercial products. In addition, we recognize the time-consuming process of drug development (usually 10-15 years from the discovery phase to market), easing worries in the pharma industry about soaring competition in this field.

Financial Forecasts

Paxman had as many of the MedTech companies a challenging 2020 with limited access to clients worldwide as the world closed down. As a result, the sales development was negative 8,5% after a solid performance in Q1 2020. The difficult conditions have continued into 2021 with continued negative sales figures in the Q1 2021 of -14,2%.

Although a bit of uncertainty in the short-term development due to the lingering effects of the pandemic, we expect that Paxman will soon return to the growth numbers that the company saw before the pandemic. The inclusion of scalp cooling in the NCCN clinical guidelines in 2019/2020 and the AMA's introduction of the CPT codes and eventually (2023) the Texas bill for insurance legislation make for an exciting next 12 months. The transition from the system where the patients pay for their treatment to a system where healthcare providers pay for the treatment and then receive reimbursement will be facilitated by the CPT codes introduced. This is a big step forward, and Paxman is working with both insurance companies and CMS to review the reimbursement policies.

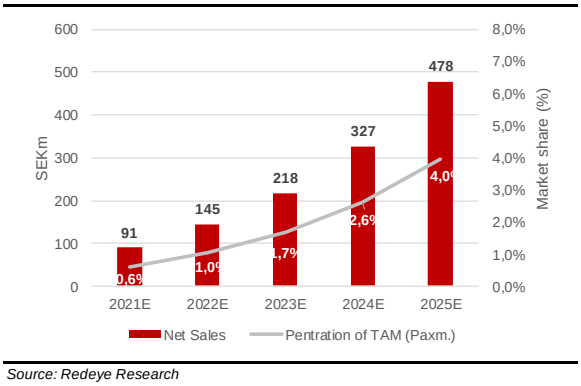
With these factors now in place and increased market activities post-Covid, we see high growth potential in the near term (end of 2021 and 2022) and long term. To be conservative in our estimates, we have not factored in the CIPN business; this could potentially generate revenue (if all goes well in clinical trials) already in 2024.

Continued robust rollout even in pandemic conditions

Paxman had at the end of the Q1 installed 101 systems so far in 2021 and with a strong order book. We see this as impressive since the possibilities to visit clients have been very limited in certain markets during the last 12 months. In addition, being a truly international company while having a regional business model may have helped them during these challenging times by being closer to their markets on a physical level and the digital presence that has been increasingly important during 2020.

We estimate that Paxman will reach a market share of 20% and sales just north of SEK 2000m at the end of our forecast period (2034). The estimated market penetration assumes that physicians may not recommend scalp cooling to patients who may see less benefit (e.g., patients with comedication and old age); however, the process towards reimbursement may mitigate that factor and drive even higher growth. We factor in slight price pressure, while we do not expect this to affect the gross margin more than marginally or at all.

Net sales and market penetration, Paxman



Source: Redeye Research

As stated above, we estimate that Paxman will reach a market share of just over 20% and sales just above SEK 2000m. The market penetration is based on our TAM model. However, this does not represent the whole potential worldwide market. We see an increasing awareness among physicians and hospitals and key opinion leaders. The process that led to the CPT codes and the Texas legislative process signifies increased awareness, even if the latter is a long process in society. Paxman is also working with a lot of different organizations to raise awareness around this issue.

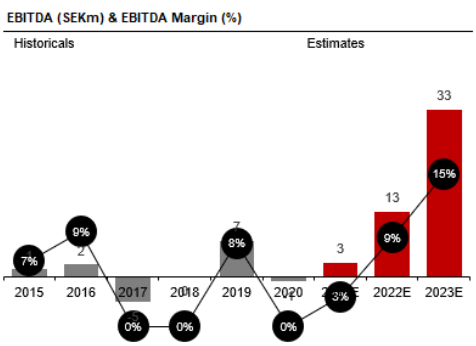
Reimbursement potential game-changer

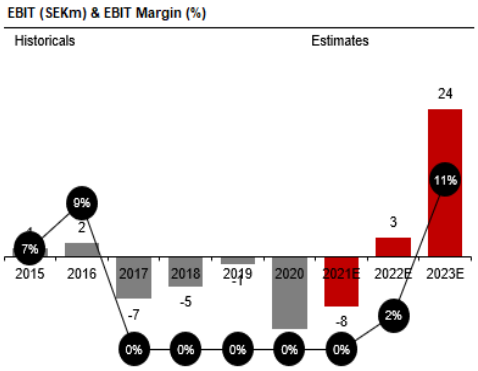
The CPT codes that will be in effect from 1 July this year can make a fundamental change for the growth opportunities for scalp-cooling with reimbursement. The potential to achieve even higher growth than we expect is

not negligible. The reimbursement process is underway, and we are looking forward to seeing at what levels they come in during the second half of 2021.

Expected strong growth will require investments

The number of clinics that are offering chemotherapy worldwide is estimated to exceed at least 20000. To continue to drive growth, a continued strengthening of the organization is necessary, albeit not to a high degree in the short to medium term. We have accounted for a certain growth in OPEX over the coming years to generate the growth numbers that we account for. The aggressive growth strategy will also require investments in the near to medium term. We see sustainable profitability on an annual basis will be reached by 2023. In 2026 we expect to see EBIT margins of 18%. At the end of our forecast, we estimate an EBIT margin of 20%. (2034)





Financial position

Paxman's cash balance (and equivalents) amounted to SEK 39,6m at the end of Q1. There is long-term and short-term interest-bearing debt at SEK 36,7m at the end of Q1, yielding a net cash position of SEK 3m.

The financing that was done in February was a necessary cash infusion to continue to drive growth. The entrance of the two institutional investors also gives added stability going forward if new financing is needed. In the short term, the funding is adequate, we believe, but it depends on the company's plans to accelerate further when reimbursement kicks in.

Income Statement	2019	2020	2021E	2022E	2023E
Revenues	**85**	**78**	**91**	**145**	**218**
Y/Y Growth (%)	47,0%	(8,5%)	16,3%	60,0%	50,0%
Cost of Revenues	32	32	36	58	87
Gross Profit	**54**	**46**	**55**	**87**	**131**
Gross Profit Margin (%)	62,9%	58,4%	60,2%	60,0%	60,0%
Other Operating Expenses	33	30	31	45	57
Personnel Costs	24	22	28	37	47
R & D Expenses	-	-	-	-	-
Other Op. Expense / (Income)	(10)	(5)	(7)	(7)	(7)
Exchange Rate Differences	-	-	-	-	-
EBITDA	**7**	**(1)**	**3**	**13**	**33**
EBITDA Margin (%)	8,3%	(1,3%)	3,0%	8,9%	15,3%
Depreciation	8	11	11	10	9
EBIT	**(1)**	**(12)**	**(8)**	**3**	**24**
EBIT Margin (%)	(1,5%)	(15,0%)	(8,8%)	2,2%	11,0%
Associated Income / (loss)	-	-	-	-	-
Interest Income	-	-	-	-	-
Interest Expenses	1	8	4	2	2
EBT	**(3)**	**(20)**	**(12)**	**2**	**22**
Income Tax Expenses	(5)	(1)	-	0	5
Effective Tax Rate (%)	0,0%	0,0%	0,0%	20,6%	20,6%
Non-Controlling Interests	-	-	-	-	-
Net Income	**3**	**(19)**	**(12)**	**1**	**18**

Source: Paxman & Redeye Research

Valuation

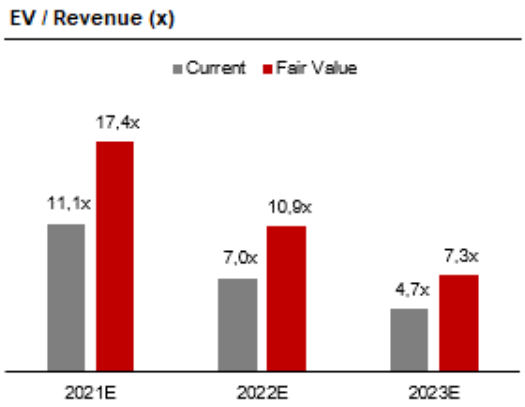
To value Paxman, we apply a discounted cash flow (DCF) model. Our model uses a WACC of 11% (reflecting both current market rates of return and risk specific to the company) across our Base, Bull, and Bear cases to discount the forecasted cash flows. This WACC is derived from our proprietary Redeye rating model with a risk-free interest rate of 1%.

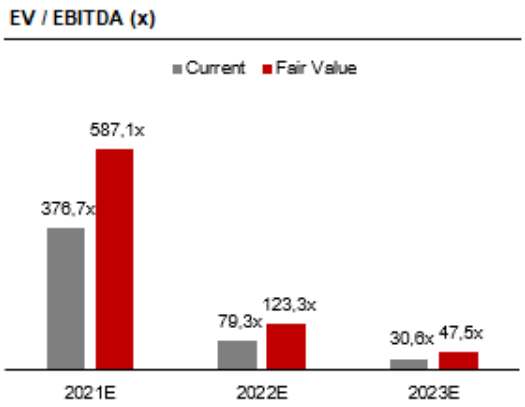
Paxman's share had a strong performance since a significant dip at the beginning of 2020 when the pandemic entered the stage. The current levels are in the region of the levels that could be seen in 2019, with a share traded between SEK 50-60 per share. A general rebound can explain the strong performance in the market since the dip in 2020 and that there has been some positive news with the potential to drive growth going into 2022. The latest rebound coincided with the capital raise when Alcur and Creades entered as owners, which shows the importance of investor sentiment when reputable owners enter the stage.

DCF

Base case – SEK 90

Our Base case of SEK 90 represents an upside of almost 70% from current trading levels and corresponds to a 2022E EV/S multiple of 10,9x. Given the transformation, the EV/S multiple is the most relevant, and the other EV multiples will come down rapidly as the results improve in the coming years. We expect that the reimbursement process will push the sales in the coming years, potentially already towards the end of 2021E. There is no doubt that the market potential is there; with the strong growth in new cancer cases, we believe that the healthcare providers are getting more and more convinced by the benefits of scalp cooling. With the eventual coverage by insurance, one of the deterring factors of the cost will at least be less important for the patients. Our key assumptions are stated below:





Key assumptions

- Sales CAGR 2021E-2025E: 51%
- Sales CAGR 2025E-2034E 18%
- Terminal growth: 2%
- Average EBIT margin 2021E-2025E: 9%
- Average EBIT margin 2025E-2034E: 20%
- Terminal EBIT margin: 16%

DCF assumptions in Base				
Assumptions:	**2021E-2025E**	**25E-2034E**		**DCF-value**
CAGR Revenue	51%	18%	WACC	11%
Average EBIT-margin	9%	20%	NPV of FCF	917
			NPV of Terminal Value	668
Terminal				
Sales growth	2,0%		Sum of NPV	1 584
EBIT-margin	16%		Net Debt	-3
			DCF-value	**1 587**
			Fair value per share	**90**
			Current share price	58

Source: Redeye Research

Bear case – SEK 45

Key assumptions

- Sales CAGR 2021E-2025E: 39%
- Sales CAGR 2025E-2034E 16%
- Terminal growth: 1,5%
- Average EBIT margin 2021E-2025E: 6%
- Average EBIT margin 2025E-2034E: 18%
- Terminal EBIT margin: 14%

In the Bear case, we expect increasing competition within the focus areas. We also see lower organic growth and lower operating margins based on rising price pressure. We also expect that the new opportunities are slower to make a difference on the top line.

Bull case – SEK 130

Key assumptions

- Sales CAGR 2021E-2025E: 54%
- Sales CAGR 2025E-2034E 20%
- Terminal growth: 2,5%
- Average EBIT margin 2021E-2025E: 10%
- Average EBIT margin 2025E-2034E: 22%
- Terminal EBIT margin: 18%

In the Bull case, we expect that the reimbursement will boost sales even faster and that a higher acceptance among physicians adds to the growth both in the short and long term.

Multiple-based valuation

To further evaluate the value of Paxman, we analyze the share against other companies in the same industry. This approach relies on the assumption that similar companies will sell at similar valuation multiples. However, it should be noted that MedTech companies are a relatively rare commodity in Sweden. Even if the number has improved in the last years, the consensus estimates are often derived from a few analysts or only one, making it a bit of an uncertain metric.

As a reference, we have compiled a table with Swedish high-growth companies active in medical technology and supplies. In general, these companies are forecasted to achieve high growth and experience margin expansion, where some have come further than others. They do, however, indicate market expectations and performance. The most relevant measure at this point is to use EV/Sales; however, unsurprisingly, the peer group companies trade in a wide range of EV/S of 2,2-24,7 on 2022 estimates. As seen below, the more mature and proven companies trade at an EV/S range of 16-22, while younger and to an extent more unproven as low a 2-5x.

Paxman is currently trading at 11x, and 7x EV/S for 2021 and 2022 and 10,9 EV/S on our Base case motivated value in 2022E. This is lower than the EV/S for the reference group as a wholes median of 14,2x. Given that Paxman right now has profitability that will turn positive, the EV/EBITDA number is not so relevant part from the fact that they will decrease rapidly with improved profits.

	EV	Revenue	EV/Revenue		EV/EBITDA		Revenue Growth		EBITDA-margin	
SEKm	USDm	2020	2021E	2022E	2021E	2022E	2021E	2022E	2021E	2022E
Vitrolife	4 283	136	23,4	20,8	56,4	51,3	35%	12%	42%	41%
Biotage	1 384	119	9,9	8,8	32,1	31,6	17%	13%	31%	28%
Cellavision	994	51	14,5	12,3	44,2	35,2	33%	18%	33%	35%
Xvivo Perfusion	1 119	20	29,8	22,6	168,6	149,5	91%	32%	18%	15%
Sedana Medical	842	15	40,6	21,9	-363,8	125,7	34%	85%	-11%	17%
Bactiguard	808	19	25,1	17,2	87,4	38,3	72%	46%	29%	45%
Surgical Science	714	11	32,3	24,7	90,5	62,0	94%	30%	36%	40%
Genovis	328	7	21,7	16,4	69,4	43,4	81%	17%	29%	32%
Boule Diagnostics	142	44	2,6	2,2	15,4	11,4	26%	17%	17%	19%
SynthticMR	204	5	20,9	15,4	58,1	33,9	83%	36%	36%	45%
Senzime	159	1	54,5	12,9	-32,7	-88,6	186%	321%	-167%	-15%
Irras	34	1	9,1	3,4	-2,3	-2,9	365%	168%	-394%	-118%
OssDsign	56	3	13,2	6,3	-5,8	-7,8	56%	110%	-229%	-80%
Dignitana	53	5	7,4	4,9	-20,5	-28,5	47%	65%	-36%	-17%
Average	1 449	53	21,8	13,6	14,1	32,5	87%	69%	-41%	6%
Median	994	20	21,3	14,2	38,1	34,5	64%	34%	23%	24%
Paxman	**123**	**9**	**11,1**	**7,0**	**376,0**	**79,0**	**16%**	**60%**	**3%**	**9%**

Income statement & Balance sheet

Income Statement	2019	2020	2021E	2022E	2023E
Revenues	**85**	**78**	**91**	**145**	**218**
Y/Y Growth (%)	47,0%	(8,5%)	16,3%	60,0%	50,0%
Cost of Revenues	32	32	36	58	87
Gross Profit	**54**	**46**	**55**	**87**	**131**
Gross Profit Margin (%)	62,9%	58,4%	60,2%	60,0%	60,0%
Other Operating Expenses	33	30	31	45	57
Personnel Costs	24	22	28	37	47
R & D Expenses	-	-	-	-	-
Other Op. Expense / (Income)	(10)	(5)	(7)	(7)	(7)
Exchange Rate Differences	-	-	-	-	-
EBITDA	**7**	**(1)**	**3**	**13**	**33**
EBITDA Margin (%)	8,3%	(1,3%)	3,0%	8,9%	15,3%
Depreciation	8	11	11	10	9
EBIT	**(1)**	**(12)**	**(8)**	**3**	**24**
EBIT Margin (%)	(1,5%)	(15,0%)	(8,8%)	2,2%	11,0%
Associated Income / (loss)	-	-	-	-	-
Interest Income	-	-	-	-	-
Interest Expenses	1	8	4	2	2
EBT	**(3)**	**(20)**	**(12)**	**2**	**22**
Income Tax Expenses	(5)	(1)	-	0	5
Effective Tax Rate (%)	0,0%	0,0%	0,0%	20,6%	20,6%
Non-Controlling Interests	-	-	-	-	-
Net Income	**3**	**(19)**	**(12)**	**1**	**18**

Source: Paxman & Redeye Research

Balance Sheet	2019	2020	2021E	2022E	2023E
Current Assets					
Cash & Equivalents	2	4	26	17	21
Inventories	12	14	10	21	31
Accounts Receivable	12	6	10	16	24
Other Current Assets	7	6	-	-	-
Total Current Assets	**32**	**29**	**45**	**54**	**75**
Non-Current Assets					
Property, Plant & Equipment, Net	34	29	24	23	27
Goodwill	-	-	-	-	-
Intangible Assets	12	12	14	17	21
Right-of-Use Assets	-	-	-	-	-
Shares in Associates	-	-	-	-	-
Other Long-Term Assets	7	6	6	6	6
Total Non-Current Assets	**53**	**48**	**44**	**46**	**54**
Total Assets	**85**	**77**	**89**	**100**	**129**
Current Liabilities					
Short-Term Debt	17	32	-	-	-
Short-Term Lease Liabilities	-	-	-	-	-
Accounts Payable	20	11	7	11	17
Advances From Customers	-	-	-	-	-
Prepaid Income	-	-	-	-	-
Accrued Expenses	2	3	4	6	9
Other Current Liabilities	3	3	4	7	11
Total Current Liabilities	**43**	**50**	**15**	**24**	**36**
Non-Current Liabilities					
Long-Term Debt	14	16	16	16	16
Long-Term Lease Liabilities	-	-	-	-	-
Other Long-Term Liabilities	-	-	-	-	-
Other Long-Term Liabilities, % of Rev.	0,0%	0,0%	0,0%	0,0%	0,0%
Total Non-current Liabilities	**14**	**16**	**16**	**16**	**16**
Non-Controlling Interest	-	-	-	-	-
Shareholder's Equity	28	11	58	59	77
Total Liabilities & Equity	**85**	**77**	**89**	**100**	**129**
Net Debt	30	45	(9)	(1)	(4)
Net Gearing (%)	105,2%	410,1%	-15,9%	-1,3%	-5,4%

Source: Paxman & Redeye Research

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 4

Industry experience is found among both senior executives and board members. Long tenure in both senior executives and board have a positive impact on the rating.

Business: 4

We expect that the scalp cooling market will see price pressure and that chemotherapy will decrease over time. However, we recognize that the market is underdeveloped, and those significant growth opportunities remain, especially with increased awareness and reimbursement now in view.

Financials: 2

Paxman is not yet sustainably profitable and is in a capital-intensive phase. With a rights issue of SEK 59m (before transaction costs) in February 2021, we see no need to acquire additional capital in the short term.

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye Rating (2021-06-15)

Rating	People	Business	Financials
5p	20	15	3
3p - 4p	99	78	37
0p - 2p	6	32	85
Company N	125	125	125

Duplication and distribution

CONFLICT OF INTERESTS

Mats Hyttinge. owns shares in the Company:/No
Redeye performs/have performed services for the company and receives/have received compensation from the company in connection with this.