

Dignitana

Sector: Medtech

Growth Not About to Cool Off

Addressing a high unmet medical need

Dignitana is a Swedish medical technology company that develops, produces, and markets the DigniCap: a scalp-cooling system that reduces the hair loss typically associated with chemotherapy. DigniCap addresses a high unmet medical need – chemotherapy induced hair loss has an estimated incidence of up to 65% and is ranked as one of the most severe side effects of chemotherapy treatment among patients.

Strong growth drivers in place

Although its DigniCap system has been available in Europe since 2001 and received FDA clearance in 2015, Dignitana has now reached a strong growth phase, in our view. Boosted by the launch of the new Delta version and its revised business model, the company is set to grow revenues faster than investors expect. We see the new single-patient-use as key, allowing the company generate recurring revenue from consumables kits. The single-patient use also reduces the need for cleaning and, together with new interface, will make it less burdensome for clinics to integrate DigniCap into their workflows.

Addressing a USD 700m-plus market

We estimate DigniCap's total addressable market using a patient-based market model. To keep our estimates conservative, we base our market model on the we markets believe will be on the company's radar in the short to medium-term and offer highest potential: USA, the five major European markets (5EU), and Japan. At the end of our forecast period, we estimate a TAM of more than USD 700m.

DCF model and multiple-based valuation indicate upside

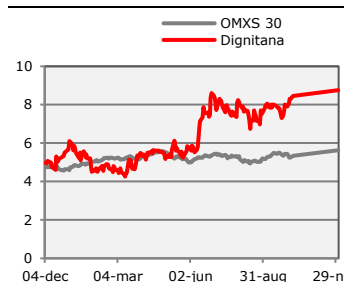
Using our cautious assumptions on pricing and market share, our 12-year DCF model indicates a Base Case fair value of SEK 11.5 per share, giving potential upside of some 30% from current levels. This values Dignitana at 8.7x our 2021 revenue forecast discounted back to present value at 13%. The multiple represents a slight discount to its peer group of high-growth medtech companies trading at a median multiple of 15.5x 2019 estimates.

KEY FINANCIALS (SEKm)	2017	2018	2019E	2020E	2021E	2022E
Net sales	23	34	43	59	99	151
EBITDA	-34	-16	-28	-25	-5	9
EBIT	-41	-24	-31	-34	-22	-7
EPS (adj.)	-2.1	-0.6	-0.6	-0.6	-0.4	-0.2
EV/Sales	0.6	-0.4	11.2	9.1	5.8	3.9
EV/EBITDA	-0.4	0.7	-17.6	-21.7	-115.6	62.2
EV/EBIT	-0.4	0.5	-15.8	-16.0	-25.7	-82.6
P/E	0.0	0.0	-14.6	-13.4	-19.9	-54.7

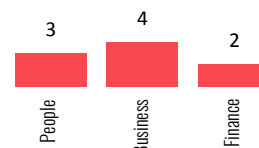
FAIR VALUE RANGE

BEAR	BASE	BULL
4.0	11.0	16.0

DIGN.ST VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	DIGN.ST
Market	First North
Share Price (SEK)	8.5
Market Cap (MSEK)	470
Net Debt 20E (MSEK)	14
Free Float	81 %
Avg. daily volume ('000)	50

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Investment Thesis

Growth case at inflection point

Although its DigniCap system has been available in Europe since 2001 and received FDA clearance in 2015, Dignitana has now reached a growth inflection point, in our view. Boosted by the launch of the new Delta version and its revised business model, the company is set to grow revenues faster than investors expect.

Set for leadership in USD 700m-plus market

As hair loss is consistently ranked as one of the most severe side effects of chemotherapy, Dignitana offers patients a powerful value proposition. Accordingly, while we factor in increased competition, we see it becoming one of the market's leading players and achieving net sales of SEK 215m in 2023. At the end of our forecast period in 2030, we assume a relatively modest market share of 15%, corresponding to sales just short of SEK 1000m.

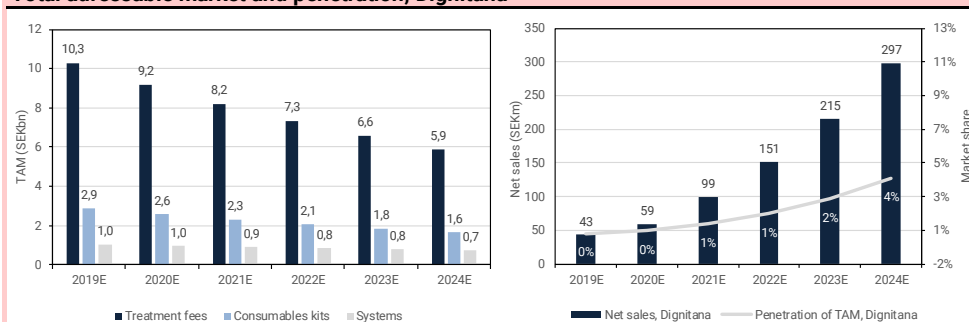
Margin expansion despite price pressure

While we expect gross margins to fall to about 50% by the end of our forecast period, the company will enjoy a relatively high degree of operating leverage on its sales. We forecast 2024 EBIT of SEK 28m on a margin of 15% and EPS of SEK 0.38.

Supporting analysis

Based on data from the National Cancer Institute and Datamonitor, we estimate that there are about 8 million drug-treated cases of solid tumour cancer per year (USA, EU5 and Japan). Assuming that 50% of patients are treated with chemotherapy, of whom 50% receive chemotherapy by infusion (with an average of five cycles), we estimate that 10 million infusions take place in Dignitana's primary markets. Even with price erosion of 33% for consumables kits and treatment fees across our forecast period, we estimate the total addressable market value at north of USD 700m in 2028.

Total addressable market and penetration, Dignitana



Source: Redeye Research

In support of the strong growth we forecast, we consider the success of the competitor Paxman's pay-per-patient business model, now implemented by Dignitana. The model allows the company generate recurring revenue from consumables kits. Further, we believe that the more user-friendly design of the delta version of DigniCap, estimated to reduce nursing time by 80%, will be a key growth driver. While we expect to see increased market activities, we argue that major investments in the commercial infrastructure and product development have been taken, enabling the company to drive strong growth in the short-term.

Reimbursement could result in upside to our estimates

Currently scalp cooling is only reimbursed on a patient-by-patient/claim-by-claim basis. Dignitana is working to change this, but in view of the process's low visibility and the often lengthy road to inclusion in the DRG system we assume status quo for now.

Reimbursement is possible in the future – in particular if positive socio-economic impact could be documented in large-scale trials (e.g. by showing a higher follow-through rate during chemotherapy, resulting in better treatment outcomes). If this comes about, we see significant upside in our sales forecasts.

Initiating coverage with a base case of SEK 11 per share

Using our cautious assumptions on pricing and market share, our 12-year DCF model indicates a Base Case fair value of SEK 11.5 per share, giving potential upside of some 30% from current levels. This values Dignitana at 8.7x our 2021 revenue forecast discounted back to present value at 13%. The multiple represents a slight discount to its peer group of high-growth medtech companies trading at a median multiple of 15.5x 2019 estimates.

Counter thesis - key risks

Lack of share catalysts

While we see significant upside in the share, we also note that upcoming quarterly reports are the only known potential catalysts for the share. Furthermore, Dignitana does not break down the different revenue streams in its financial reporting, making it difficult for investors to see what drives sales growth. As a result, it may take some time for the market to appreciate Dignitana's growth trajectory. Since sales are growing from low levels, booking of larger orders will have a significant impact - causing growth to vary significantly from quarter to quarter. Even so, we expect the trend will become visible over the next 12 months, giving potential for the share to rally.

Low entry barriers and intensifying competition

Although the installed base should be protected by some switching costs, mainly from investments in training and inclusion in workflows, Dignitana lacks sustainable competitive advantages. This could result in intensified competition and price pressure, lowering sales potential and putting pressure on margins. However, we have factored in price erosion throughout our forecast period and see a fair margin of safety here.

Fear of scalp metastasis among physicians

We view the clinical evidence rejecting a connection between scalp cooling and scalp metastases as acceptable and judge that any increased risk of scalp metastasis is very low. It should be noted, however, that the studies have mainly focused on breast cancer patients and that correlations have not been explored in other cancers to the same extent. Scalp metastases have also been reported in breast cancer, non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer and bladder cancer. Further studies may therefore be required to convince some physicians.

Advances in cancer treatment paradigm

Chemotherapy is still the backbone of the treatment paradigm in most cancers, but biologics and targeted therapies have seen significant take-up in some indications. Further, treatment approaches make up more than 90% of the oncology assets currently in late stage development. This makes it possible that the number of chemotherapy infusions will fall during our forecast period, hurting Dignitana's sales potential. However, most patients treated with non-systemic therapy eventually relapse and move on to chemotherapy. Moreover, cancer is a highly heterogeneous disease and most therapies in development target a subset of patients with a specific genetic expression (trials with biomarkers made up one-third of oncology trials in 2017). This suggests that advances will be gradual going forward.

Company Description

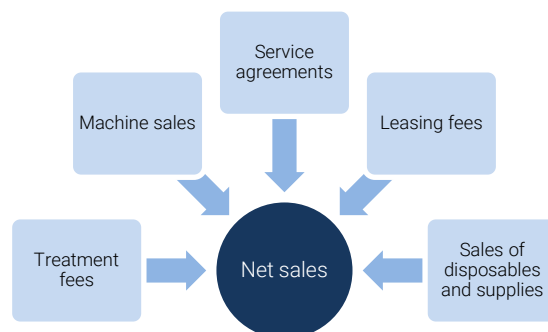
Dignitana is a Swedish medical technology company that develops, produces, and markets the DigniCap: a scalp-cooling system that reduces the hair loss typically associated with chemotherapy. The company was founded in 2007 and has its headquarters in Lund, Sweden. It is based in Dallas, USA, where it operates under the subsidiary Dignitana Inc. Currently, the company employs 29 staff and generates revenues of about SEK 40m (last 12 months). Dignitana has been stock market listed since 2009 and has traded on Nasdaq First North since 2011.

See appendix 1-2 for an overview of Dignitana's management and board of directors.

Business Model

Dignitana has five different revenue streams: treatment fees to patients (pay-per-treatment using leased machines), machine sales, service agreements, leasing fees, and product disposables and supplies. In the USA and Europe, it sells via its own sales organisation and is focusing on establishing a pay-per-treatment business model. Revenue in other markets (DigniCap is available in the Middle East, Oceania, North America and South America) is generated from unit sales, lease agreements, service and maintenance fees, and sales of product disposables and supplies. In these markets, Dignitana relies mainly on an indirect sales model (see appendix 3 for an overview of Dignitana's distributors).

Revenue streams, Dignitana



Source: Dignitana & Redeye Research

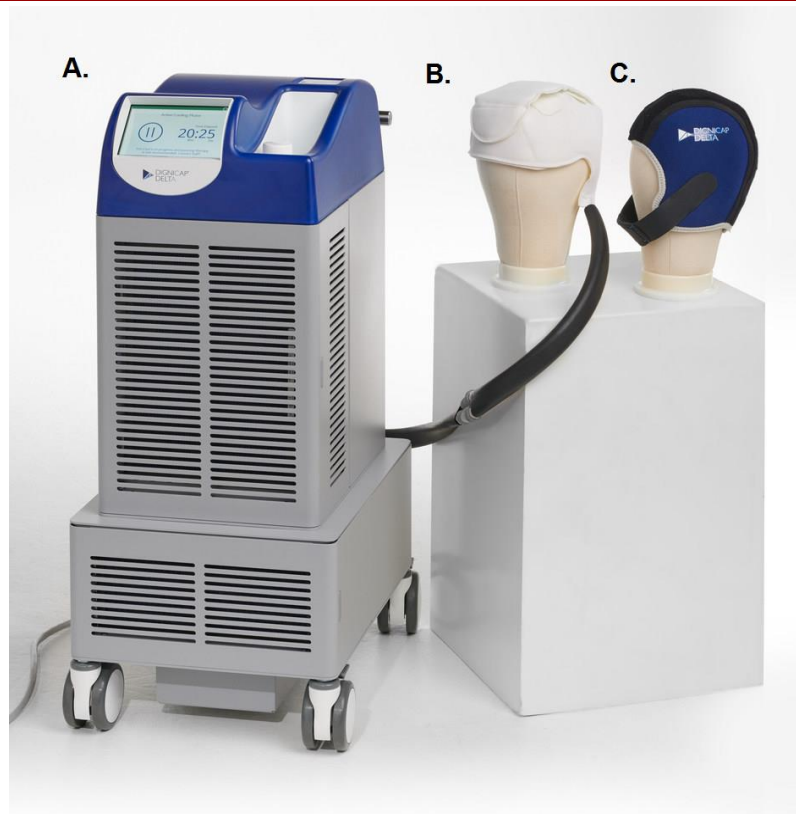
Product Overview

The DigniCap system was originally developed in 1999 by oncology nurse Yvonne Olofsson and engineer John Kern. Building on the methods used since the 1970s by some cancer patients of placing bags of frozen vegetables or ice packs on their heads, the system was developed to provide efficacious and comfortable cooling of the scalp.

In essence, the principle is similar to a standard refrigerator. The system consists of a cooling wrap and snug-fitting thermal cap made of neoprene. This connects to a cooling unit equipped with a thermoelectric chiller. Using the digital control panel on the cooling unit, the user can easily set the desired temperature and duration of treatment.

Fluid pumps transport the coolant through the system, allowing it to flow through channels in the cap. The system monitors both the fluid supply and return channels to ensure that the temperature is maintained at the specified target range.

The DigniCap Delta system



A. Cooling unit B. Cooling wrap. C. Thermal cap.

Source: Dignitana

DigniCap has been available in Europe since 2001 and received FDA clearance for the USA in 2015. Initially, the system was indicated for use in the USA by breast cancer patients. In July 2017, the indication was expanded to all patients with solid tumours. The currently marketed, fourth generation of the system (DigniCap Delta) was CE-marked in March 2019 and received FDA clearance in June 2019. The TGA cleared the device for use in Australia in October 2019. In mid-August 2019, Dignitana delivered the first DigniCap Delta in the USA.

Company timeline, Dignitana

1970s	First known use of manual gel caps for scalp cooling.
1999	DigniCap invented in Sweden by nurse Yvonne Olofsson.
2001	DigniCap available in Europe.
2009	Dignitana publicly traded in Sweden.
2010	DigniCap registered in Mexico, Russia and South Korea.
2011	DigniCap registered in Canada and Colombia.
2012	DigniCap registered in Australia and Singapore.
2014	US multi-centre trial with DigniCap completed.
2016	DigniCap study presented at ASCO.
2017	DigniCap study published in JAMA. DigniCap received expanded FDA clearance for men and women with solid tumour cancers. DigniCap available in Middle East.
2018	The latest, fourth generation of DigniCap (DigniCap Delta) receives FDA clearance.

Source: Dignitana

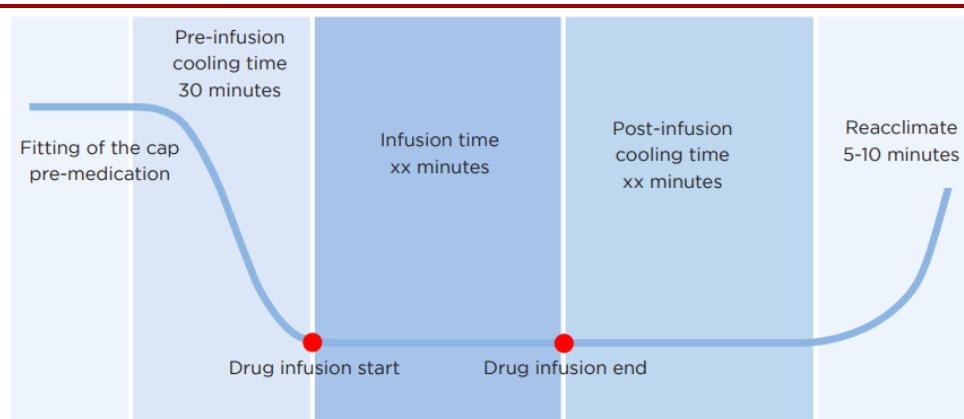
DigniCap Delta - a significant step forward

DigniCap Delta is a substantial improvement on past generations of the product. The new version was developed in response to feedback from users and is a smaller, single-patient unit – factors that increase its user-friendliness significantly. The main improvements over previous versions are:

- **Single-patient-use** providing each patient with a flexible cooling wrap and an adjustable thermal cap. By doing so, the system optimises the treatment outcome and minimises clinics' storage needs.
- **Smaller in size** and requiring less space in the clinic. DigniCap Delta is 54% smaller than the third-generation product.
- **Reduced nursing time** thanks to an intuitive interface. Dignitana estimates that nursing time per patient infusion is reduced by 80% (with interaction time shortened from 70 to 12 minutes).
- **More stable temperatures** and by using thermo-electric cooling. Previous versions were compressor-systems, which resulted in a less stable and consistent coolant flow. The company believes this will result in better treatment results.

Based on these improvements, we believe that Dignitana has improved its value proposition significantly. We see the single-patient-use as key, allowing the company target patients directly and generate revenue from consumables kits. The single patient use also reduces the need for cleaning and, together with new interface, will make it less burdensome for clinics to integrate DigniCap into their workflows. Our belief is, therefore, that new product offering will be an important growth driver for the company going forward.

DigniCap treatment cycle



Source: Dignitana

A high medical need for scalp cooling

Hair loss (alopecia) is a common and distressing side effect of chemotherapy treatment (referred to as chemotherapy-induced alopecia, or CIA) with an estimated incidence of up to 65% (Trüeb RM, 2010). Several studies have recognised that CIA is associated with severely impaired quality of life. When surveyed about chemotherapy side effects, patients consistently ranked hair loss as one of the most severe side effects of chemotherapy treatment.

Patient ranking

Rank	Coates et al. (1983)	Griffin et al. (1993)	Carelle et al. (2002)	Ataseven et al. (2017)
1	Vomiting	Nausea	Affects my family or partner	Difficulty sleeping
2	Nausea	Constantly tired	Loss of hair	Affects my family or partner
3	Loss of hair	Loss of hair	Constantly tired	Loss of hair
4	Thought of coming treatment	Thought of coming for treatment	Affects my work, home duties	Numbness in limbs
5	Length of time treatment takes at clinic	Vomiting	Affects my social activities	Shortness of breath

Source: Redeye Research

CIA occurs because of the systemic effects of chemotherapy. Chemotherapeutic agents exert their anticancer effect by targeting rapidly growing cancer cells. Unfortunately, these drugs also affect other rapidly growing cells in the body, including in hair cells. By lowering the temperature of the scalp when administering chemotherapy, blood flow to hair follicles is reduced and metabolic processes slow down, preventing or minimising hair loss.

Some chemotherapy treatments are more likely than others to cause alopecia, and the extent can vary depending on dosage and duration of treatment. A patient's hair may fall out entirely, slowly, or in sections. Generally, this alopecia is reversible, although the hair sometimes grows back thinner. While rare, cases of permanent alopecia have been reported as associated with high-dose regimens of some chemotherapeutic agents (such as taxanes). This is likely due to a loss of hair follicle stem cells.

Commonly used chemotherapeutic agents that can cause hair loss

Drug class	Drug	Incidence of hair loss
Antimicrotubules	Cabazitaxel	10%
	Docetaxel	56-76%
	Erbulin	45%
	Ixabepilone	48%
	Paclitaxel	87%
Anthracyclines	Daunorubicin	>10%
	Doxorubicin	N/A
	Epirubicin	70-96%
	Idarubicin	25-30%
Alkylating agents	Bendamustine	<1%
	Busulfan	17%
	Carboplatin	2-3%
	Cisplatin	1%
	Cyclophosphamide	N/A
	Dacarbazine	N/A
	Lomustine	N/A
	Melphalan	N/A
	Methchlorethamine	N/A
	Oxaliplatin	3%
	Procarbazine	N/A
	Temozolomide	55%
Antimetabolites	Capecitabine	6%
	Gemcitabine	15-16%
	Floxuridine	1-10%
	Fluorouracil	Depends on rate/duration of therapy

Source: Trüeb RM, 2009; Lacy C, 2009; cancer.net, 2015; patientresource.com, 2015

Clinical experience with DigniCap

Dignitana has conducted two clinical trials, one of which was a large-scale trial that formed the basis of its US regulatory clearance. The clinical evidence has been further strengthened by a number of trials by other research groups, confirming a high efficacy and beneficial safety profile for the system.

US pivotal trial in breast cancer

DigniCap was cleared by the FDA in December 2015 via the de novo process. Given the rigorous trial design and the successful treatment outcome in the majority of patients, the results demonstrated a significant clinical benefit and positive impact on patients' quality of life.

As this was the first large-scale clinical trial investigating scalp cooling during chemotherapy in the US, the results received considerable attention within the medical community. They were published ([link](#)) in the Journal of the American Medical Association (JAMA) and presented in a poster discussion at the annual meeting of the American Society of Clinical Oncology (ASCO) in 2015.

We view the design of Dignitana's pivotal trial as rigorous and recognise that it was initially conceived to meet the requirements of the FDA's more complex Premarket Approval (PMA) pathway. Following a brief review of Dignitana's PMA application in 2015, the agency converted the PMA to the de novo regulatory pathway (since the DigniCap system was not classified as a high-risk device). While this enabled a shorter time to market, we also acknowledge that this route potentially reduced the entry barriers for new competitors.

The pivotal trial ([link to trial](#)) with DigniCap was a non-randomised multi-centre (5 sites), concurrent controlled study. The overall objective was to evaluate the clinical performance, efficacy, and safety of DigniCap in early-stage breast cancer patients receiving alopecia-inducing chemotherapy regimens.

Efficacy was measured by patient self-assessment of CIA up to 4 weeks (3-6-week window) after the completion of the last chemotherapy cycle. To grade the efficacy, the study relied on the Dean scale – a method where standardised photographs are used as a reference. A score of 0 signifies no hair loss, while a score of 4 represents hair loss in excess of 75%.

The primary endpoint was defined as a maximum Dean score of grade ≤ 2 alopecia in at least 50% of patients enrolled in the treatment group, with a lower bound of the 95% CI greater than 40%, and statistical superiority over a concurrent control group that received no scalp cooling.

Secondary endpoints included measurements of safety, tolerability, and quality of life. Safety was determined by spontaneous reporting of adverse events and negative scalp changes determined by physical examination. Tolerability was defined as the percentage of patients who completed all planned cycles of chemotherapy using the DigniCap system. Quality of life was measured using the EORTC-QLQ-BR23 (a questionnaire designed for patients with breast cancer) and a Body Image Scale.

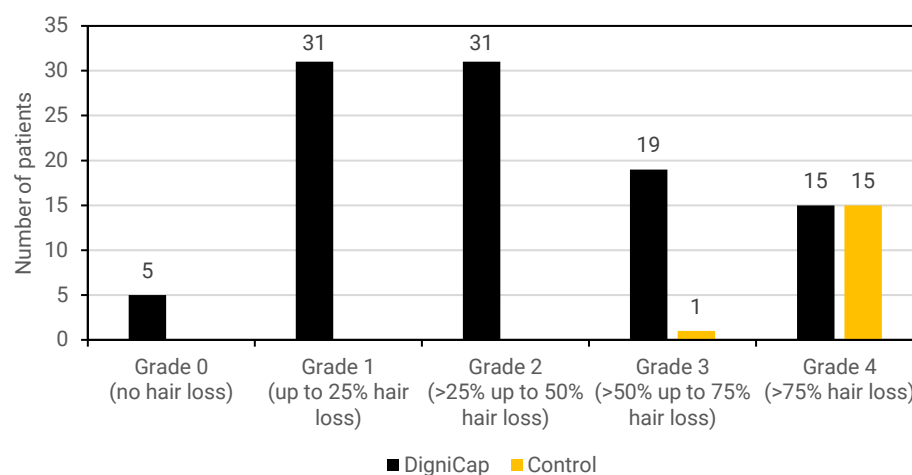
The study recruited female patients aged 18 or older with documented diagnosis of stage I or II breast cancer and planned course of chemotherapy in the neoadjuvant setting. Patients with female pattern baldness and/or autoimmune disease affecting their hair were excluded. Studied chemotherapy regimens included anthracyclines, alkylating agents, and taxane-based regimens known to have a particular impact on hair growth. Regimens included in the trial were:

- Doxorubicin (60 mg/m²) and cyclophosphamide (600 mg/m²) x 4-6 cycles IV every 2-3 weeks.
- Docetaxel (75 mg/m²) and cyclophosphamide (600 mg/m²) x 4-6 cycles IV every 3 weeks
- Paclitaxel (80 mg/m²) weekly IV x at least 12 weeks with or without IV trastuzumab
- Paclitaxel (175 mg/m²) IV every 2 weeks x 4–6 cycles (without an anthracycline) \
- Paclitaxel weekly and carboplatin AUC 2 weekly or AUC 6 every 3 weeks IV x 4-6 cycles with or without trastuzumab IV weekly or every 3 weeks
- Docetaxel (75 mg/m²) and carboplatin AUC 6 IV every 3 weeks x 4 - 6 cycles with or without trastuzumab IV weekly or every 3 weeks
- Regimens including targeted agents such as trastuzumab or lapatinib

In total, 122 patients were recruited (106 in the DigniCap treatment group), of whom 117 were evaluable (101 for efficacy in the DigniCap treatment group). Overall, 67 (66%) patients demonstrated treatment success (grade ≤ 2), compared to 0 (0%) in the control group. An independent panel review of the photographs confirmed a high level of efficacy, rating 73 patients (72%) as treatment successes.

Of the patients who were treated with the DigniCap system, 5 (5%) had a grade of 0 (no hair loss). Patients with a grade of 1 (up to 25% hair loss) and grade 2 (>25% up to 50% hair loss) were evenly distributed, with 31 patients (31%) in each group. Among the remaining patients, 19 (19%) had a grade of 3 and 15 (15%) had a grade of 4. In the control group, one patient (6%) had a grade of 3 and 15 patients (94%) had grade of 4.

Number of patients with a maximum Dean score at any cycle



Source: Dignitana

We argue that the results are further strengthened by a subgroup analysis of the efficacy per chemotherapy regimen. This analysis showed a success rate of 61-83% in the three regimens that were most common in the study, underscoring the strong impact the technology could have in a real-life setting. When analysing the effectiveness by hair quality, patients with thick hair (n=32) had a success rate of 75%. Patients with medium-thick and thin hair (n=50) had respective success rates of 64% and 82%.

Effectiveness by chemotherapy regimen, DigniCap

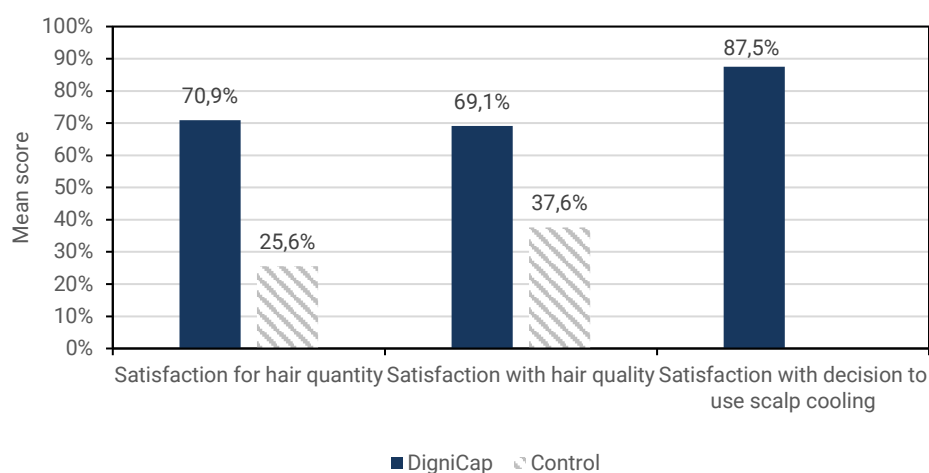
Chemotherapeutic regimen	n	Success rate	95% CI (%)	p-value
Docetaxel and carboplatin	12	83,3%	51.6, 97.9	0.022
Docetaxal and cyclophosphamide	76	60,5%	48.6, 71.6	<0.001
Paclitaxel	12	83,3%	51.6, 97.9	0.066

Source: Dignitana

Patient assessment of satisfaction with their appearance indicated a clear impact on quality of life among the DigniCap treatment group. Results from the self-reports showed a mean score of 70.9 (out of 100) for hair quantity in the DigniCap treatment group, compared to 26% in the control group. The mean score for satisfaction with hair quality was 69.1 in the DigniCap treatment group, versus 37.6 in the control group. Satisfaction with the decision to use scalp cooling had a mean score of 87.5.

More than 90% of patients in the DigniCap treatment group agreed strongly or somewhat that hair is important in itself and as part of appearance. The corresponding result was 90% in the control group at the end of the study period. It is worth noting that the perception in the control group changed during the trial, as 75% had felt strongly at baseline (when the trial was initiated).

Patient assessment of satisfaction with their hair by self-reports at each chemotherapy



Source: Dignitana

In total, 84 (83%) patients completed all the planned chemotherapy cycles using the DigniCap system. Reported adverse events (AEs) associated with the use of DigniCap were mainly headaches (4 women). No patients experienced serious adverse events (SAEs) related to treatment with DigniCap.

Patient symptom survey results showed that 74 patients (73%) experienced headaches. Among these patients, 31% had 1-2 headaches, 27% had 3-4 headaches, 22% had 5-6 headaches, and 20% had >6 headaches. Headaches disappeared when the device was no longer used.

A total of 43 (43%) patients reported that headaches were triggered or exacerbated by scalp cooling treatment (over 100 instances were reported). The average level of pain experienced by these patients was 39.3 on a scale of 0 to 100 (with 100 being the worst pain). On average, this occurred for one cycle but ranged up to 10 cycles. Scalp pain associated with cooling was reported by 75 (74%) patients (across 250 instances). The average level of any scalp pain experienced by these patients was 24.2 out of 100 (ranging from 1.7 to 85.0).

European feasibility trial

Prior to the US pivotal trial, Dignitana conducted a feasibility trial at two European centres. While the sample size was limited, results were in line with those of the US pivotal trial, indicating high efficacy and a beneficial safety profile.

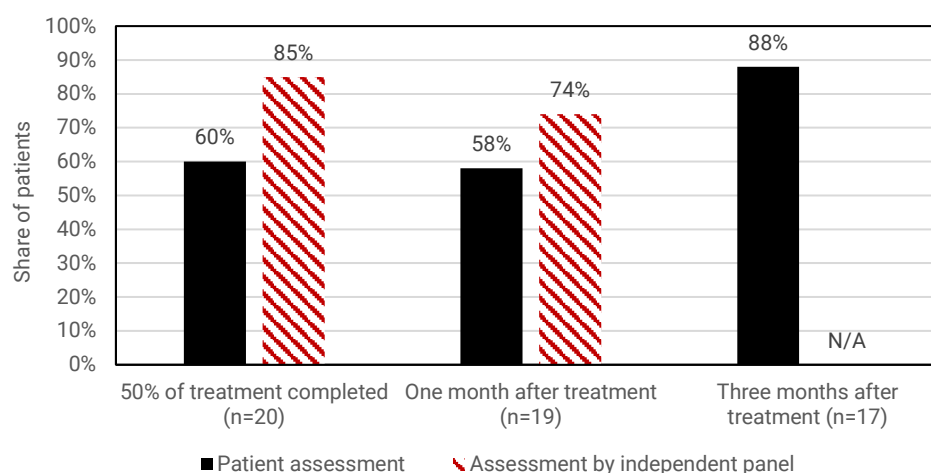
In total, the study recruited 20 patients aged 18 years or older with stage I breast cancer. To assess the extent of CIA, photographic documentation was performed before initiation of the first cycle of chemotherapy, before each subsequent cycle, and at a visit 3-4 weeks after the last cycle of chemotherapy.

CIA was measured using the Dean scale and was graded by patient self-assessment and an independent panel consisting of a hairdresser, a patient advocate, and a dermatologist specialising in hair. The trial used the same criteria as the US pivotal trial to determine successful treatment (grade ≤ 2 alopecia). To assess the safety profile, a patient symptom survey was completed at each chemotherapy cycle.

In total, 19 patients completed scalp cooling with DigniCap. Halfway through treatment (n=20), patient assessment demonstrated a success rate of 60%. Follow-up one month after treatment (n=19) showed a success rate of 58%. Three months after completion of chemotherapy, 88% of patients (n=17) reported grade <2 alopecia.

Results from the independent panel indicated a higher success rate than patient self-assessment. Halfway through treatment (n=20), the panel reported a success rate of 85%. Analysis one month after completion of chemotherapy (n=19) showed a success rate of 74%.

Patients reporting lower than grade 2 alopecia ($\leq 25\%$ hair loss)



Source: Dignitana

Considering the relatively small sample size, we will not draw any conclusions about the seemingly higher success rate reported by the expert panel, but instead we recognise that the US pivotal trial and the European feasibility trials demonstrate success rates within the range seen in other studies (see table below).

We argue that the European feasibility trial reiterates DigniCap's high impact on patients' quality of life. At the follow-up one month after completed treatment, 11% of patients reported their use of wigs as "always", 16% as "sometimes", and 74% as "never". Overall, 80% of patients strongly had agreed that their hair was important to them at baseline. At the one-month follow-up, this had risen to 81%.

One patient discontinued therapy due to cap-associated toxicity, patient-assessed hair loss, and severe anxiety (resulting in a low dropout ratio of 5%). Overall, 13 (65%) of patients reported head pain, 18 (80%) experienced chill during treatment, and 19 (95%) patients reported scalp pain while undergoing treatment.

Summary of clinical evidence with DigniCap in breast cancer

Authors	Type of study	Chemotherapeutic agents used in trial	Follow-up schedule for alopecia	DigniCap arm sample size (control arm)	DigniCap pts completed cooling (%)	DigniCap pts with <50% hair loss (%)
Henriksen et al., 2003	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, epirubicin	Patient self- assessment and clinical photographs using VAS scale	26	N/A	(88)
Kato et al., 2011	Prospective, non-randomised	5-fluorouracil, camptosar, camptothecin-11, carboplatin, cyclophosphamide, epirubicin, gemcitabine, irinotekan, paclitaxel	Modified WHO scale (Grade 1-5)	359	N/A	344 (96)
Abramov et al., 2011	Prospective, non-randomised	Unspecified anthracyclines and taxanes	CTCAE v3.0 Grade 1: (thinning or patchy)	20	N/A	100%
Meunier et al., 2013	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, docetaxel, epirubicin	Patient self- assessment with VAS scale	106	N/A Neo adjuvant treatment: 65%	N/A Neo adjuvant treatment: 65% Palliative: 83%
Friedrich & Carstensen, 2014	Prospective, non-randomised	5-fluorouracil, carboplatin, cisplatin, cyclophosphamide, docetaxel, epirubicin, eribulin, gemcitabine, paclitaxel	Patient and expert rating of photographs with VAS and Dean scale	83	64 (77)	31 (53)
Andrews et al., 2014	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, docetaxel, doxorubicin, epirubicin	Consultant evaluation with Dean scale	123 (130)	99 (80)	61 (50)
Schaffrin-Nabe et al., 2015	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, docetaxel, epirubicin, paclitaxel	Scale for alopecia.	136	N/A	88 (65)
Campenni et al., 2016	Prospective, non-randomised	Cyclophosphamide, epirubicin, unspecified taxanes	Patient self-assessment & assessment by treating physician with Dean scale	109	86 (79)	84 (77)
Traub et al., 2016	Prospective, non-randomised	Cyclophosphamide, doxorubicin, epirubicin, paclitaxel	Evaluation of photographs	12	9 (75)	9 (75)
Schaffrin-Nabe et al., 2016	Prospective, non-randomised	Cyclophosphamide, epirubicin, paclitaxel	Hair-mass- index (trichometer)	40 (8)	32 (100)	20 (63)
Drinkut et al., 2016	Prospective, non-randomised	Cyclophosphamide, epirubicin	Quantification by patients and nursing staff	34	19 (56)	34 (100)
Hernández et al., 2016	Retrospective	Unspecified taxanes and anthracyclines	Evaluation of photographs with Dean scale	120	98 (72)	28 (56)
Rugo et al., 2017	Prospective, non-randomised	Carboplatin, cyclophosphamide, docetaxel, paclitaxel	Patient self-assessment with Dean scale	106 (16)	88 (83)	67 (66)
Monzone et al., 2019	Prospective, non-randomised	cyclophosphamide, docetaxel, doxorubicin, epirubicin, paclitaxel	Patient self-assessment and physician evaluation with Dean scale	139	75 (68)	56 (43)
Mean				101	78%	74%
Median				106	79%	75%

Source: Redeye research

DigniCap in patients with solid tumours

A number of studies have evaluated the DigniCap system in cancer patients with solid tumours. Results have shown that the system is safe and effective in reducing the incidence of CIA in these patients as well.

In the largest trial conducted to date in patients with solid tumours (link to [publication](#)), scalp cooling was successful (specified as no or not visible hair loss and/or moderate or higher grade toxicities) in 65% of patients. In total, the non-randomised trial recruited 226 patients.

In breast cancer cases, treatment with DigniCap was successful in 88 of 136 patients, corresponding to a success rate of 65%. During the study, 11 different chemotherapy regimens were used, including taxanes and anthracyclines, which are highly likely to cause CIA. 76 patients received the particularly tough epirubicine + cyclophosphamide (4x3w) regimen followed by paclitaxel (12xw). In this subgroup, treatment with DigniCap was successful in 52 (68%) patients.

Summary of clinical evidence with DigniCap in solid tumours

Authors	Type of study	Chemotherapeutic agents used in trial	Follow-up schedule for alopecia	DigniCap arm sample size (control arm)	DigniCap pts completed cooling (%)	DigniCap pts with <50% hair loss (%)
Lundgren et al., 1999	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, docetaxel, epirubicin, methotrexate, paclitaxel	Independent observers' assessment with VAS scale	9 (2)	9 (100)	9 (100)
Ridderheim et al., 2003	Prospective, randomised	5-fluorouracil, bleomycin, carboplatin, cisplatin,	Evaluation of photographs with VAS scale	74	72 (97)	N/A
Byahov et al., 2006	Prospective, non-randomised	Unspecified (majority anthracyclines)	CTCAE v 3.0	77	N/A	N/A Anthracyclines: 79% Non-anthracyclines: 94%
Ekwall et al., 2013	Prospective, randomised	Carboplatin, paclitaxel	Investigator rating of photographs with VAS scale	47	43 (91)	22 (51)
Udrea et al., 2014	Prospective, non-randomised	Capecitabine, carboplatin, cisplatin, docetaxel, epirubicin, etoposide, irinotecan, paclitaxel, other unspecified	US NCI (CTCAE) v4.0	108	104 (96)	62 (57)
Schaffrin-Nabe et al., 2015	Prospective, non-randomised	5-fluorouracil, cyclophosphamide, docetaxel, epirubicin, paclitaxel	Scale for alopecia	226	223 (99)	146 (65)
Fehr et al., 2016	Prospective, non-randomised	5-fluorouracil, carboplatin, cyclophosphamide, docetaxel, doxorubicin, epirubicin, paclitaxel	Evaluation of photographs	55	43 (78)	28 (56)
Mean				85	93%	66%
Median				74	96%	57%

Source: Redeye research

The success of scalp cooling was shown to be dependent on the chemotherapy dose. While a success rate of 50-75% was seen with an epirubicin dose of <100 mg/m², an epirubicin dose of 150 mg/m² was associated with no scalp cooling success.

Certain types of medications are known to amplify CIA (antihypertensives, cardiovascular drugs, antidiabetics, and analgesics). Results indicated that this might be the case when patients using these are treated with scalp cooling as well. Only 17 (49%) patients with regular co-medication demonstrated good hair preservation, compared to 35 (85%) out of 41 patients without co-medication (p < 0.001).

Weaker treatment results were also seen in older patients and in patients with thinning hair. Pre-menopausal patients had a 5.9 times higher chance of no or not visible hair loss (OR = 5.9, 95% CI = 1.1–29.7) than menopausal patients. Scalp cooling was successful in 18 (55%) patients with scarce hair growth. Of 43 patients with normal hair density, 34 (79%) showed no visible CIA.

Results showed that scalp cooling had a high impact on patients' quality of life – only 63 (28%) of the 226 recruited patients opted for a wig after treatment. Moreover, treatment with DigniCap was generally well tolerated and reported side effects mainly consisting of slight sensations of cold and mild cranial pressure (reported by 60% of patients with breast cancer and 64% of patients with other solid tumours). These effects were shown to be temporary and disappeared after a couple of minutes. In total, seven patients dropped out of the study due to cold intolerance or aversion, resulting in a low dropout rate of 3%.

Summarising DigniCap's clinical documentation

In summary, we view the DigniCap system's clinical documentation as solid. Results show that DigniCap is efficacious in inhibiting CIA for the majority of patients. We also recognise that the clinical documentation is strengthened by similar findings from other research groups.

While the range of success rates is broad (43-100%), we argue that this is likely a result of the often small sample sizes and differences in follow-up methods. Recognising that the majority of trials (employing either patient- or expert-assessed follow-up methods) reported a success rate of about 60% or higher, we see a clear trend in favour of DigniCap. Moreover, we recognise that the trials were conducted with previous generations of the DigniCap system and that the latest generation might yield better results.

Lastly, we acknowledge that scalp cooling has had a significant positive impact on patients' quality of life and that side effects were mainly mild in severity. We therefore consider this a convincing offering to patients undergoing treatment with chemotherapy.

Scalp metastases – likely an unwarranted fear

Concerns about the risk of scalp metastasis have contributed to the slow acceptance of scalp cooling technology in the USA. However, research shows that the concerns have been exaggerated; incidence of scalp metastasis is low and is not likely increased by scalp cooling.

No scalp metastases have been observed in either of Dignitana's clinical trials. Further support is given by Rugo et al. (2017), which reviewed 10 studies analysing the incidence of scalp metastasis with scalp cooling over time. Based on an extensive meta-analysis, including data from 3,197 patients (1,959 in the scalp-cooling arm), the authors concluded that scalp cooling is highly unlikely to increase the incidence of scalp metastases in patients with early-stage breast cancer receiving adjuvant chemotherapy.

Results showed a low incidence rate of scalp metastasis, regardless of scalp cooling. The incidence rate in the scalp-cooling arm amounted to 0.61% versus 0.41% in the control arm. This represents $p=0.43$ (no statistical significance).

We view the clinical evidence in favour of scalp cooling as acceptable and believe that increased risk of scalp metastasis, if even a factor, is likely very low. We do note, however, that the analysis focused on adjuvant treatment of early-stage breast cancer patients and that correlations have not been explored as much in other cancers. Scalp metastases have also been reported in non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer.

In addition, the study was limited in its follow-up period. The estimated weighted mean follow-up was 42.1 months in the scalp-cooling arm, compared to 87.4 months in the control arm. Since the long-term effects of scalp cooling and scalp metastasis have not been thoroughly investigated, there is a risk, albeit low, of a different outcome with a longer follow-up period.

Market Opportunity

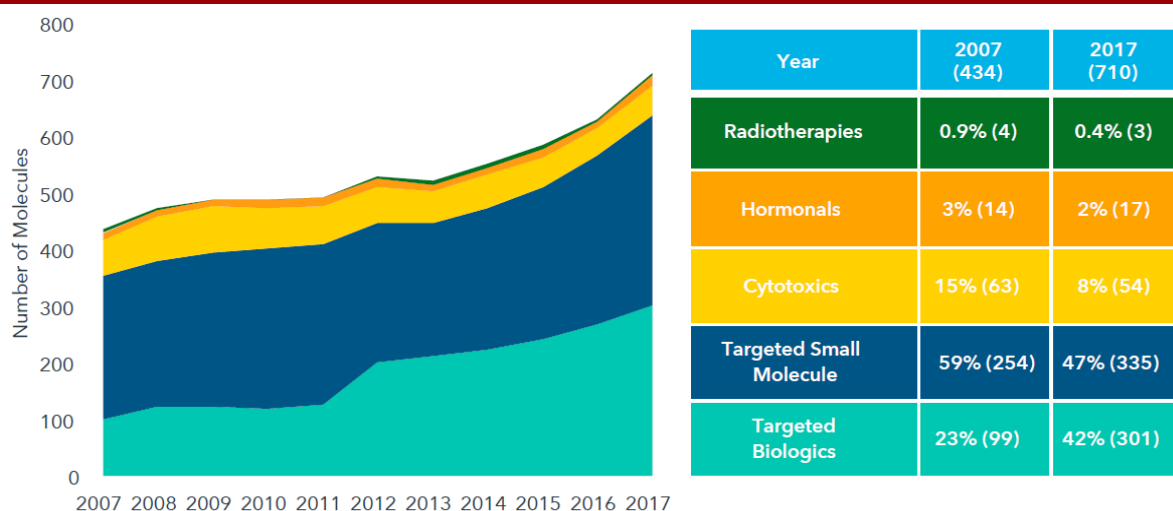
We estimate DigniCap's total addressable market (TAM) using a patient-based market model. To keep our estimates conservative, we base our market model on the we markets believe will be on the company's radar in the short to medium-term and offer highest potential: USA, the five major European markets (5EU), and Japan. In support of our method, we also consider that data of acceptable quality is lacking in other markets.

Increased use of targeted therapies and biologics

Significant advances have been seen with targeted therapies and biologics in some cancers, but infused chemotherapy remains the backbone of the treatment paradigm in most indications. Moreover, most patients who receive non-systemic treatment eventually relapse and progress on to chemotherapy.

Recognising that more than 90% of late-stage oncology assets are targeted therapies and biologics, however, and that the use of oral chemotherapy is increasing, it is possible that the number of chemotherapy infusions will decrease during our forecast period (2019-2030). While it is challenging to estimate the impact of drug candidates that could potentially achieve market approval, we acknowledge that most therapies are targeting a subset of patients with a specific genetic expression (trials with biomarkers accounted for 34% of oncology trials in 2017), which likely means that advances will be gradual.

Oncology drug candidates in late-stage development



Source: Iqvia Institute, 2018

Total addressable market for DigniCap

Our market model is based on DigniCap treatment fees, consumables kits and system revenues. At the end of our forecast period, we estimate a TAM of more than USD 700m.

TAM for treatment fees and consumables kits

Based on data from Datamonitor and the National Cancer Institute (NCI), we forecast that there will be about 4.0 million diagnosed incident cases and 32.6 million prevalent cases of solid tumour cancer in 2019. Of the prevalent cases, 24% are assumed to receive drug treatment.

Research aiming to investigate the share of cancer patients who receive chemotherapy has resulted in highly different estimates. 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 majority of 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 the share of patients who receive chemotherapy could be similar or higher in the most developed countries in Europe. Based on data from the National Cancer Registration and Analysis Service, 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)

Stage at diagnosis	Percentage of patients
All stages combined	28.4%
Stage 1	12.4%
Stage 2	31.8%
Stage 3	46.1%
Stage 4	38.7%
Unknown stage	24.2%

Source: National Cancer Research, 2018

Considering the wide spreads in these estimates, we choose to take a conservative stance and assume that 50% of drug-treated cancer patients receive chemotherapy in 2019 (including all stages and lines of treatment). To account for an 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). Reliable data from Europe is scarce, but overall, we believe that the proportions are in line with the USA.

To keep our estimates conservative, we assume that about 50% of chemotherapy-treated patients receive infused therapy. Accounting for increased use of oral chemotherapy, we assume that this will decrease to 40% at the end of our forecast period. Moreover, we estimate that a patient receives an average of five chemotherapy cycles, which we consider a conservative estimate given our review of the scientific literature.

We estimate a price of USD 300 per treatment cycle and consumables kit in our market model, but we also assume price erosion to USD 200 in 2024, when the price is expected to stabilise. In total, this results in a TAM of USD 656m for DigniCap at the end of our forecast period.

TAM for DigniCap treatment fees and consumables kits

	2019E	2020E	2021E	2022E	2023E	2024E
Total incident cases of solid tumours	4 047 536	4 092 022	4 132 377	4 172 491	4 212 846	4 253 154
USA	1 494 828	1 514 550	1 532 820	1 551 582	1 570 681	1 590 230
5EU	1 792 373	1 810 085	1 827 426	1 844 597	1 862 107	1 880 037
Japan	760 335	767 387	772 131	776 312	780 058	782 887
Total prevalent cases	32 587 226	32 825 188	33 001 083	33 112 112	33 218 160	33 319 497
USA	12 890 219	12 970 840	13 051 492	13 131 848	13 212 043	13 292 834
5EU	14 838 564	14 948 377	15 019 182	15 047 535	15 079 011	15 119 723
JAP	4 858 443	4 905 971	4 930 409	4 932 729	4 927 106	4 906 940
USA						
Drug treated cases	2 891 954	2 917 931	2 945 424	2 974 591	3 003 699	3 032 861
Breast & gynecological cancer	1 017 152	1 027 615	1 037 920	1 048 146	1 058 316	1 068 375
Urological cancer	638 526	643 735	650 616	659 227	667 678	675 908
Gastrointestinal cancer	344 904	348 120	351 411	354 787	358 286	362 333
Lung cancer	274 222	275 889	277 548	279 192	280 825	282 446
Brain and nervous system cancer	83 939	84 449	84 957	85 460	85 960	86 456
Skin cancer	70 896	72 519	74 136	75 758	77 432	78 981
Head and neck cancer	40 778	41 504	42 186	42 843	43 514	44 182
Bone and joint cancer	2 625	2 641	2 657	2 673	2 688	2 704
Other	418 912	421 459	423 993	426 505	429 000	431 476
5EU						
Drug treated cases	3 537 563	3 565 999	3 593 529	3 620 565	3 647 255	3 673 882
Breast & gynecological cancer	1 157 187	1 163 644	1 170 123	1 176 167	1 181 880	1 187 383
Urological cancer	939 563	951 980	963 476	975 040	986 533	998 258
Gastrointestinal cancer	513 658	519 608	525 642	531 685	537 816	543 909
Lung cancer	270 202	270 881	271 546	272 207	272 859	273 505
Brain and nervous system cancer	113 036	113 162	113 339	113 432	113 459	113 496
Skin cancer	68 008	68 946	69 810	70 663	71 529	72 319
Head and neck cancer	60 551	61 377	62 168	62 930	63 736	64 576
Bone and joint cancer	2 587	2 593	2 600	2 606	2 612	2 618
Other	412 771	413 808	414 825	415 835	416 831	417 818
Total drug treated cases of solid tumours (incl. Japan)	7 961 783	8 029 527	8 093 785	8 157 255	8 218 653	8 278 259
Share of patients treated with chemotherapy	50%	49%	48%	47%	46%	45%
Share of patients receiving infused chemotherapy	50%	49%	48%	47%	46%	45%
Average number of chemotherapy cycles	5	5	5	5	5	5
Total chemotherapy infusions	9 952 228	9 637 846	9 328 711	9 028 052	8 734 350	8 447 905
USA	3 614 942	3 502 394	3 394 828	3 292 132	3 192 173	3 095 013
5EU	4 421 953	4 280 270	4 141 819	4 007 065	3 876 110	3 749 171
Japan	1 915 333	1 855 182	1 792 064	1 728 855	1 666 067	1 603 721
ASP per treatment, USA (USD)	300	277	255	235	217	200
ASP per consumables kit, WW (USD)	300	277	255	235	217	200
TAM, WW (USDm)	1388	1241	1109	992	887	793
Treatment fees, USA (USDm)	1084	969	866	774	692	619
Consumables kits, WW (USDm)	304	272	243	217	194	174

Source: Redeye Research

TAM for systems

To estimate the TAM for scalp-cooling systems, we assume they will be used on average once per day when the market has reached a high degree of maturity. Based on the number of chemotherapy infusions in our forecast, we estimate that about 36,700 systems would be needed to meet the demand in Dignitana's primary markets in 2019. We assume the life length of a system to be 10 years.

Our model estimates an annual price of USD 3,600 per leasing contract and USD 3,000 for capital sales. We forecast annual price erosion of about 4% until 2024, when the price is expected to stabilise. This results in a TAM of USD 63 million per year at the end of our forecast period.

TAM for DigniCap systems

	2019E	2020E	2021E	2022E	2023E	2024E
Total chemotherapy infusions	11 867 561	11 569 063	11 269 180	10 973 869	10 682 070	10 394 025
USA	3 614 942	3 502 394	3 394 828	3 292 132	3 192 173	3 095 013
5EU	4 421 953	4 280 270	4 141 819	4 007 065	3 876 110	3 749 171
Japan	3 830 666	3 786 399	3 732 533	3 674 672	3 613 787	3 549 841
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	47 093	45 908	44 720	43 547	42 388	41 247
USA	14 345	13 898	13 472	13 064	12 667	12 282
5EU	17 547	16 985	16 436	15 901	15 381	14 878
Japan	15 201	15 025	14 812	14 582	14 340	14 087
Leasing agreements USA, share of placements	100%	100%	100%	100%	100%	100%
Leasing agreements 5EU, share of placements	80%	80%	80%	80%	80%	80%
Leasing agreements Japan, share of placements	0%	0%	0%	0%	0%	0%
ASP per year, leasing (USD)	3 600	3 471	3 347	3 227	3 111	3 000
ASP per system, capital sales (USD)	3 000	2 893	2 789	2 689	2 593	2 500
Average lifelength, systems (years)	10	10	10	10	10	10
TAM, leasing agreements	102	95	89	83	78	73
USA (USDm)	52	48	45	42	39	37
5EU (USDm)	51	47	44	41	38	36
Japan (USDm)*	0	0	0	0	0	0
TAM, capital sales	6	5	5	5	5	4
USA (USDm)	0	0	0	0	0	0
5EU (USDm)	1	1	1	1	1	1
Japan (USDm)*	5	4	4	4	4	4
TAM, WW (USDm)	108	101	94	88	82	77

Source: Redeye Research

Competitive landscape

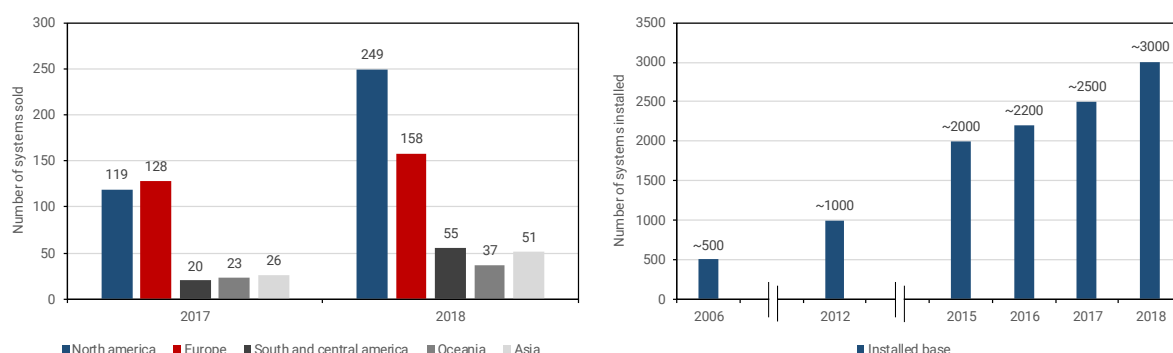
Currently, there is only one competitor with a refrigerated scalp-cooling system. While we expect to see additional competitors enter the market in the next few years, we believe there is enough space for several players. Overall, we view the current competitive landscape as beneficial to Dignitana.

Paxman

Founded in 1996, Paxman has been active in the field of scalp cooling for more than 20 years. The company's headquarters are in Huddersfield, UK, and it currently has 46 employees. Paxman generated revenues of SEK 81m (LTM). The company has been listed on Nasdaq First North since June 2017.

Like DigniCap, Paxman's scalp-cooling system is indicated to prevent CIA in patients with solid tumours. The design of the Paxman system is quite similar to DigniCap. It consists of a refrigeration unit that can be used with two single-patient-use caps consisting of a silicone cap and neoprene cover. The cap is sold to patients as a kit that includes products used for hair care during chemotherapy and to clean the cooling cap.

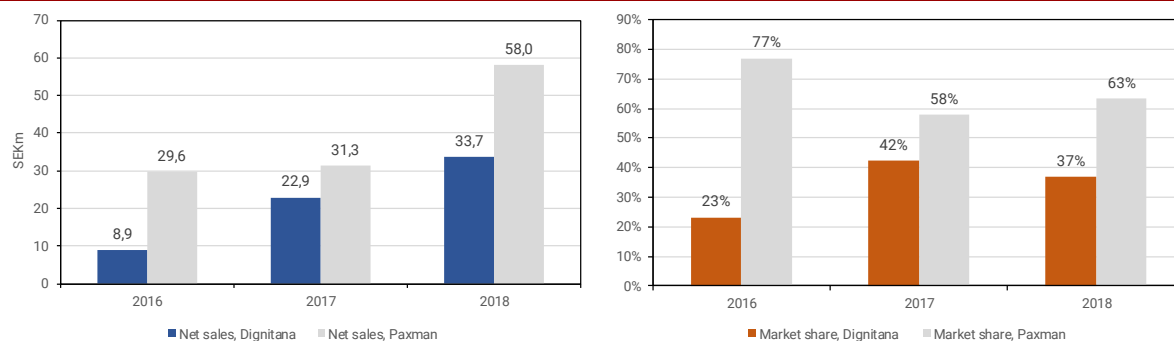
Systems sold by market and installed base



Source: Paxman

While the DigniCap and Paxman scalp-cooling systems have some key differences, we believe these are relatively modest and that both systems can meet customer needs. Paxman did, however, introduce single-patient-use caps earlier than Dignitana and we believe this explains why their scalp cooling system has been able to gain market share over DigniCap. We also see the option to choose single or dual treatment as a competitive advantage for Paxman and believe that future versions of DigniCap are likely to include this same feature.

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



*Total market value is based on the companies' net sales. Sales of manual cold caps (described in detail below) are not included.

Source: Dignitana, Paxman

Paxman's scalp-cooling system was cleared by the FDA for use in breast cancer patients via the 510(k) route in April 2017. The approval was based on an interim analysis of a clinical trial that, at the time, had enrolled 142 breast cancer patients at six clinical sites in the USA ([link to trial](#)). Patients who were recruited received either anthracycline or taxane-based chemotherapy for at least four cycles.

The study relied a slightly different method to assess efficacy but used essentially the same measure of success as Dignitana's clinical trials. To measure efficacy, the Paxman trial relied on the Common Terminology Criteria for Adverse Events (CTAE) scale for alopecia. The primary endpoint was defined as less than 50% hair loss (grade <2), which was assessed by a clinician unaware of treatment assignment.

Results showed that scalp cooling was successful in 48 (51%) patients in the scalp-cooling arm, compared to 0 patients in the control arm ($p < 0.001$). 91 (64%) of patients received taxane-based chemotherapy. In total, 54 adverse events (AEs) were reported in the scalp-cooling arm. No SAEs were reported; all AEs were grade 1 or 2.

A number of other clinical trials have investigated the Paxman scalp-cooling system since the pivotal trial. Large-scale trials have shown a success rate of 48-94%. However, different methods of measuring efficacy have been used and the success of scalp cooling has varied greatly depending on the regimen. In the largest trial to date, recruiting 1,411 patients, the success rate ranged from 8-80%, depending on the regimen.

While we caution that cross-trial comparisons should not be considered head-to-head data, we believe that clinical datasets suggest a comparable efficacy for the Paxman scalp-cooling system and DigniCap in the treatment of CIA. We will mention, however, that we base our analysis on old versions of DigniCap and that success rates might have improved significantly with the new DigniCap Delta.

Cold cap manufacturers

A significant number of patients still use manual gel caps for scalp cooling. Since manual caps are not cleared by the FDA, 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 centres do, however, have biomedical freezers, allowing patients to freeze a number of dry ice caps, which are changed during a treatment session.

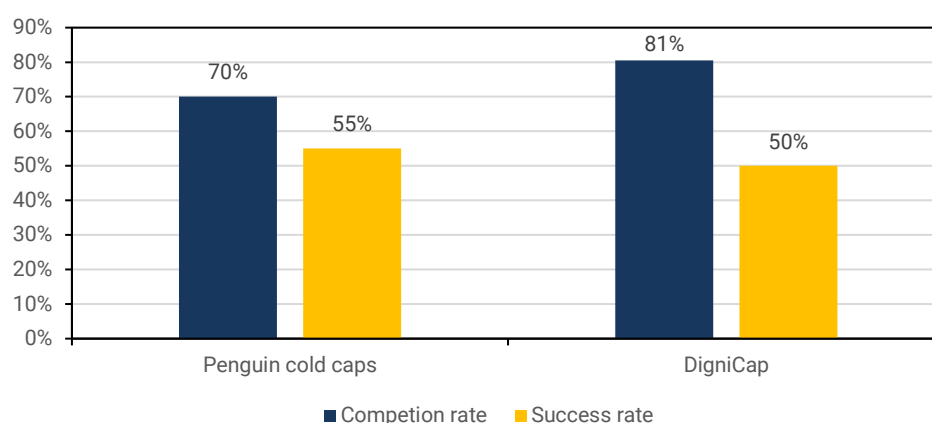
We have identified six large manufacturers of cold caps: Penguin Cold Caps, Chemo Cold Caps, Arctic Cold Caps, Wishcaps, Warrior Caps, and Polar Cold Caps. Their prices range between USD 325 and USD 449 per month, but this typically excludes shipping and some manufacturers require a deposit when patients subscribe to the service.

While manual cold caps might be a more cost-effective alternative, we believe they are likely less efficacious due to the inability to maintain the right temperature on the scalp. This is currently being investigated by Peking University, which is conducting a randomised clinical trial ([COHAIR](#)) to compare the effect of the DigniCap system with manual cold caps. According to [clinicaltrials.gov](#), the trial plans to recruit 256 patients and report the first results in 2020.

Results from a head-to-head trial with DigniCap and Penguin's cold caps was conducted by Andrews et al. (2014) at the Patricia Ritchie Centre in Australia. The study, investigating the effectiveness and feasibility of the two products, recruited 253 women with early-stage breast cancer. After analysing the results, the authors concluded that ease of use was significantly higher with DigniCap, as the manual caps needed to be changed every half an hour. Moreover, many patients experienced some discomfort because manual caps are very cold (-35°C) when placed on the patient's head. This was most likely the reason for the higher completion rate in the DigniCap treatment arm (81% vs 70%).

The success rate, graded by the Dean scale and measured by a consultant, indicated a slightly higher success with Penguin's cold caps (55% vs 50%) than DigniCap. We note, however, that the results were not statistically significant ($p=0.12$) and that most large-scale trials with DigniCap have indicated a higher success rate than seen in this trial. We also acknowledge that the trial was conducted with an older version of DigniCap.

Comparison of DigniCap and Penguin cold caps



Source: Andrews et al., 2014

As the scalp-cooling market continues to grow, we believe that a regulated, standardised method is likely to be preferred by both clinics and regulatory authorities. 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. Animal studies from more than a decade ago showed that the tumour suppressor protein p53 could play an important role in CIA and that injecting the WNT3a protein could prevent hair loss. Recent studies have also shown that inhibition of the protein kinase CDK4/6 could make hair follicles much less susceptible to the damaging effects of taxanes.

This research is at an early stage, however, and none of the approaches has attracted the attention of the pharmaceutical industry. Currently, it seems unlikely that any of these approaches will result in commercial products. In addition, we recognise the time-consuming process of drug development (usually 10-15 years from discovery phase to market), easing worries in the pharma industry about soaring competition in this field.

Financial Forecasts

Building on the launch of the DigniCap Delta system, as well as increased market activities, we see a high growth potential for Dignitana in the near-term. Accounting for increased competition, we forecast a gradual gross margin contraction over our forecast period. We expect to see OPEX growth continue to increase in the near to medium-term, as the sales and support organisation is strengthened.

Intensified commercialisation ahead

At present, DigniCap is used at 16 community cancer groups with more than 340 facilities in 43 locations. While the installed base has grown over several years, we recognise that a high utilisation of new technology in hospitals usually is preceded by extensive training and support from the manufacturer. We therefore believe that many of the contracts are not yet in full effect and, furthermore, expect to see a strong contribution to growth from the launch of DigniCap Delta.

Contracted US community cancer center groups

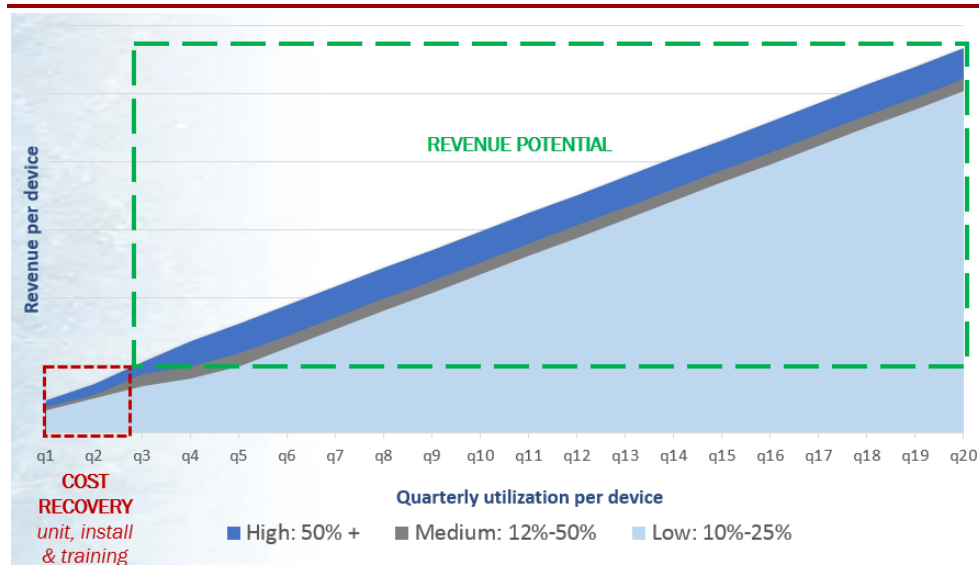


Source: Dignitana

Our belief is that Dignitana will focus on replacing the older DigniCap versions, enabling the company to generate recurring revenues from the sale of consumables kits. Therefore, the strong growth seen in our forecast in the near to medium-term (we expect sales to increase from SEK 59m in 2020 to SEK 215m in 2023) does not rely on a rapidly increasing installed base, but rather stem, to a large degree, from increased efforts in developing existing contracts.

With the launch of DigniCap Delta consumables kits, we expect to see an increasing contribution from Europe (EU countries accounted for 18% of net sales in 2018). We do, however, expect the USA to continue to offer the highest potential, and attribute more than half of the forecasted net sales to the market at the end of our forecast period (68% in 2018).

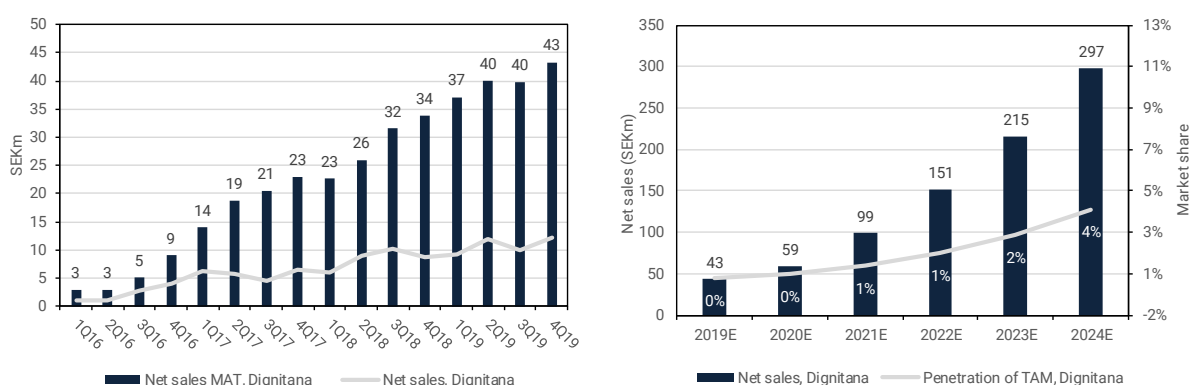
Pay-per-treatment, illustrative example of revenue potential with increased utilisation



Source: Dignitana

At the end of our forecast period, we estimate that Dignitana will reach a market share of 15% and sales just short of SEK 1000m. The estimated market penetration assumes that physicians may not recommend scalp cooling to patients who may see less benefit (e.g. patients with co-medication and patients of old age) and that use will be less frequent with chemotherapies that are particularly tough for the hair cells. Further, we factor in both the possible entry of new competitors and price pressure across the whole product portfolio.

Net sales and market penetration, Dignitana



Source: Redeye Research

Increasing awareness through clinicians and patient organisations

Aside from the collaborations with physicians and hospitals, Dignitana is working with non-profit organisation HairToStay, focused on raising awareness and financial aid for scalp cooling. While the awareness of scalp cooling still is at a relatively low level, we acknowledge the strong media coverage that Dignitana has seen by local and international TV channels, websites, magazines, and believe that it indicates an upwards trend.

Reimbursement could result in upside to our estimates

Our estimates assume that scalp cooling will continue to be reimbursed only through individual claims by patients (on a patient-by-patient/claim-by-claim basis). Dignitana is working to change this, but in view of the process's low visibility and the often lengthy road to inclusion in the DRG system, we assume status quo for now.

In March 2018, Dignitana began the action of obtaining a Current Procedural Terminology (CPT) code for FDA-cleared scalp cooling used to prevent CIA, which would enable reimbursement for health care providers. However, later the same year, the American Medical Association (AMA) announced that they had rejected the company's application. Dignitana commented that they will continue to provide necessary documentation and data needed to aid in future assessments, but the current status of the process is currently unknown.

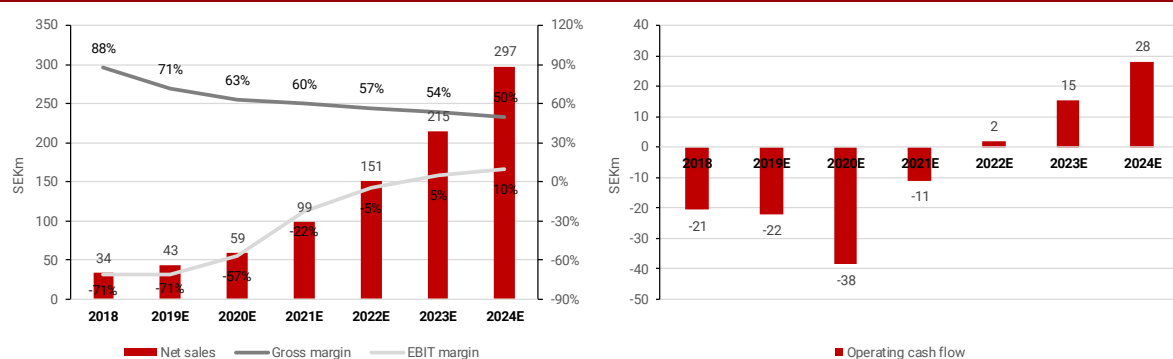
We believe that reimbursement could be possible in the future – in particular if a positive socio-economic impact could be documented in large-scale trials (e.g. by showing a higher follow-through rate during chemotherapy, resulting in better treatment outcomes). If this comes about, we see significant upside in our sales forecasts.

Growth strategy will require continued investment

Accounting for the expected price erosion, we expect that gross the margin will decrease from today's about 74% (LTM) to 50% at the end of our forecast. Further, we recognise that the DigniCap has many potential end customers (Dignitana estimates that about 20,000 clinics are offering chemotherapy worldwide today). While we expect the company, to focus more on developing existing contracts and target high-volume hospitals, we believe that the company will need to strengthen its sales and support organisation.

The aggressive growth strategy modelled in our forecast is therefore assumed to require significant investment in the near to medium-term. Sustainable profitability on an annual basis is therefore not reached until 2023. In 2025, we expect to see an EBIT margin of 20% and an EPS of SEK 0.87. At the end of our forecast, we forecast an EBIT margin of 26%.

Margin expansion/contraction and operating cash flow, Dignitana



Source: Redeye Research

Income statement, Dignitana

	1Q18	2Q18	3Q18	4Q18	1Q19	2Q19	3Q19	4Q19E
Net sales	5,9	9,0	10,2	8,7	9,2	11,9	9,9	12,2
Cost of goods sold	-0,5	-0,9	-1,2	-1,5	-2,2	-3,4	-3,2	-3,7
Gross income	5,4	8,0	9,0	7,2	7,1	8,6	6,8	8,5
Other external costs	-6,6	-5,9	-7,5	-6,3	-6,1	-8,6	-8,7	-8,8
Personnel costs	-5,6	-4,9	-5,0	-4,0	-4,7	-5,3	-5,1	-5,5
Other operating expenses	0,0	0,0	0,0	0,0	0,0	0,1	-0,3	-0,1
Other operating income	0,1	0,0	0,1	0,1	0,9	0,1	0,4	0,1
Own work capitalised	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
EBITDA	-6,8	-2,7	-3,5	-3,0	-2,8	-5,2	-6,9	-5,8
Depreciation and amortisation	-2,0	-2,0	-2,0	-2,1	-1,9	-1,9	-3,1	-3,2
EBIT	-8,8	-4,7	-5,4	-5,1	-4,7	-7,1	-9,9	-8,9
Net interest	-0,2	-0,7	-0,9	0,0	-0,6	-0,4	-0,2	-0,2
EBT	-9,0	-5,4	-6,3	-5,1	-5,3	-7,5	-10,1	-9,2
Taxes	0,0	0,0	0,0	-0,2	-0,1	0,0	0,0	0,0
Net income	-9,0	-5,4	-6,3	-5,3	-5,3	-7,5	-10,2	-9,2
Sales growth	-4%	56%	123%	34%	57%	33%	-2%	40%
Gross margin	91%	90%	88%	83%	77%	72%	68%	70%
EBITDA margin	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
EBIT margin	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
Net margin	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
EPS	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.

	2018	2019E	2020E	2021E	2022E	2023E	2024E
Net sales	33,7	43,3	59,3	98,6	151,0	215,1	297,3
Cost of goods sold	-4,1	-12,4	-21,9	-39,6	-65,1	-98,9	-148,7
Gross income	29,7	30,9	37,3	59,0	85,8	116,2	148,7
Other external costs	-26,4	-32,1	-35,3	-39,6	-44,8	-50,1	-56,0
Personnel costs	-19,6	-20,5	-24,6	-29,4	-35,0	-41,6	-49,3
Other operating expenses	0,0	-0,4	-0,4	-0,4	-0,4	-0,4	-0,4
Other operating income	0,3	1,4	0,3	0,3	0,3	0,3	0,3
Own work capitalised	0,0	0,0	0,0	0,0	0,0	0,0	0,0
EBITDA	-16,0	-20,6	-22,6	-10,0	5,9	24,4	43,3
Depreciation and amortisation	-8,1	-10,1	-11,1	-12,1	-13,0	-14,0	-15,0
EBIT	-24,0	-30,7	-33,8	-22,1	-7,1	10,4	28,3
Net interest	-1,8	-1,4	-1,4	-1,5	-1,5	-1,5	-1,5
EBT	-25,8	-32,1	-35,2	-23,6	-8,6	8,9	26,8
Taxes	-0,2	0,0	0,0	0,0	0,0	-1,9	-5,9
Net income	-26,0	-32,1	-35,2	-23,6	-8,6	6,9	20,9
Sales growth	47%	28%	37%	66%	53%	42%	38%
Gross margin	88%	71%	63%	60%	57%	54%	50%
EBITDA margin	N.M.	N.M.	N.M.	N.M.	4%	11%	15%
EBIT margin	N.M.	N.M.	N.M.	N.M.	N.M.	5%	10%
Net margin	N.M.	N.M.	N.M.	N.M.	N.M.	3%	7%
EPS	N.M.	N.M.	N.M.	N.M.	N.M.	0,13	0,38

Source: Redeye Research

Valuation

Dignitana was initially listed at Spotlight (previously aktietorget) in 2009, but decided to list its shares at First North Growth Market in 2011. Despite strong growth, the share price has fluctuated, mostly reflecting failure to meet sales expectations and the impact of several rights issues. However, the share has seen an upwards trend over the last few months and we believe that the share is still undervalued.

We also note that upcoming quarterly reports are the only known potential share catalysts. As a result, it may take some time for investors to appreciate Dignitana's sales growth trajectory and we expect that the gap to our fair value could be closed gradually over the next quarters.

DCF

To value Dignitana, we apply a discounted cash flow (DCF) model. Our model uses a WACC (reflecting both current market rates of return as well as risk specific to the company) of 13% to discount the forecasted cash flows. To keep our valuation conservative and account for the need for additional capital in our forecasts, we do not include the cash raised in Q3'19. Assuming a terminal growth rate of 2%, our model indicates a value of about SEK 11 per share.

DCF model, Dignitana

(SEKm)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	TP
EBIT	-31	-34	-22	-7	10	28	63	107	159	210	248	253	
Depreciation and amortisation	3	0	17	17	16	17	17	18	19	20	21	23	
Paid taxes	0	0	0	0	-2	-6	-14	-23	-35	-46	-54	-56	
Change in working capital	5	-5	-6	-8	-9	-11	-13	-15	-17	-18	-19	-2	
Other items	0	0	0	0	0	0	0	0	0	0	0	0	
Operating cash flow	-22	-38	-11	2	15	28	54	87	127	166	196	218	
Gross capex, tangible assets	-3	-4	-4	-5	-5	-5	-6	-6	-7	-8	-8	-6	
Gross capex, intangible assets	-11	-12	-13	-14	-15	-16	-17	-18	-20	-21	-22	-17	
Free cash flow to the firm	-37	-54	-28	-17	-4	7	31	62	100	138	165	195	1804
Discounted FCFF	-36	-47	-22	-11	-3	4	15	26	37	45	48	50	466
Sum of FCFF present value	572												
Interest-bearing debt	-10												
Cash and cash equivalents	22												
Value of equity, FCFE	584												
Value per share	11												
CAGR 2019-23	45%												
CAGR 2023-2030	32%												
EBIT margin 2030	26%												
EPS 2025	0,87												
WACC	13,0%												
Terminal growth rate	2,0%												
Number of shares FY1 (mn)	55,2												

Source: Redeye Research

Scenario analysis

To give a dynamic view of the Dignitana investment case, we also value the company by taking optimistic and pessimistic stances. The resulting bull and bear cases are presented below.

Dignitana's bull case fair value is SEK 16 per share. In this scenario we assume the following:

- Net sales reach SEK 348m in 2024, corresponding to a CAGR of 48%. This high growth could reflect improved reimbursement for scalp cooling and/or less price pressure than what we have account for in our forecast.
- An EBITDA margin of 20% in 2024. This rapid margin expansion is assumed to be driven by high sales growth and strong cost control.

Dignitana's bear case fair value is SEK 4 per share. In this scenario we assume the following:

- Sales reach SEK 214m in 2024, corresponding to a CAGR of 36%. This sluggish growth could reflect soaring competition or scepticism about using scalp cooling outside of breast cancer.
- An EBITDA margin of 8% in 2024. We assume slightly higher investment in research and development to strengthen the value proposition.

Sensitivity analysis, share price vs. WACC

	11%	12%	13%	14%	15%
Bull case	24	19	16	14	11
Base case	15	13	11	9	7
Bear case	6	5	4	3	3

Source: Redeye esearch

Multiple-based valuation

To further evaluate the value of Dignitana, we analyse the share against other companies in the same industry. This approach relies on the assumption that similar companies will sell at similar valuation multiples. It should, however, be noted that medtech companies are relatively scarce in Sweden and that consensus estimates are often derived from few analysts.

For reference, we have compiled a table with Swedish high-growth companies active in medical technology and supplies. Since many of these peers are forecast to achieve high growth and margin expansion, EV/Sales gives an indication of their future cash flows. Based on analyst consensus, the peer group companies currently trade in EV/S ranges of 2.9-91.5x 2019 year estimates.

We note that the median multiple is 16.5x and that, after excluding the outliers, most companies are trading within the range of 7.5-20.5x EV/Sales. When looking 2-3 years ahead, the median multiple is 11.4-9.0x. However, companies that are expected to grow sales by more than 20% in 2021 are trading at 2.1-21.2x 2021 year estimates (median 8.8x).

High growth companies, medical technology and supplies*

	Sales 2018 (SEKm)	EBIT margin 2018	CAGR 2019- 2021	Net sales		
				2019	2020	2021
Vitrolife	1151	34%	10%	1468	1653	1831
Biotage	911	19%	22%	1088	1199	1319
Raysearch	627	15%	7%	757	887	1032
Boule Diagnostics	424	13%	-1%	493	520	559
Cellavision	365	31%	18%	447	560	634
Bonesupport	97	-180%	-25%	169	273	394
Xvivo Perfusion	188	10%	27%	226	299	412
Bactiguard	150	-8%	2%	182	272	342
Surgical Science	66	-6%	15%	121	185	230
Sedana Medical	58	-14%	43%	71	86	137
SyntheticMR	48	39%	36%	51	70	97
Genovis	35	-3%	51%	62	75	108
OssDsign	13	-378%	73%	20	31	74
Irras	6	-2391%	-50%	6	71	219
Episurf	4	-1438%	60%	6	10	19
Senzime	3	-833%	1601%	11	42	68

	Market cap (SEKm)	Share perf. LTM	Share perf. YTD	EV/Sales		
				2019	2020	2021
Vitrolife	19 941	18%	24%	13,1x	11,7x	10,5x
Biotage	8 007	6%	13%	7,5x	6,8x	6,2x
Cellavision	7 370	37%	60%	16,1x	12,8x	11,3x
Xvivo Perfusion	4 464	14%	25%	18,6x	14,1x	10,2x
Raysearch	3 696	1%	11%	5,0x	4,2x	3,7x
Sedana Medical	3 051	64%	71%	41,0x	33,9x	21,2x
Bactiguard	2 824	117%	102%	16,5x	11,1x	8,8x
Surgical Science	2 562	271%	278%	20,5x	13,4x	10,8x
Bonesupport	1 742	73%	58%	9,2x	5,7x	4,0x
Genovis	1 710	297%	293%	27,7x	22,9x	15,9x
Boule Diagnostics	1 291	14%	27%	2,9x	2,7x	2,6x
SyntheticMR	917	-20%	-21%	17,5x	12,8x	9,2x
Senzime	834	130%	112%	72,3x	18,9x	11,7x
Irras	634	-43%	-36%	91,5x	7,8x	2,5x
OssDsign	307	-35%	-35%	7,7x	4,9x	2,1x
Episurf	124	-58%	-49%	16,5x	9,9x	5,2x
Median				16,5x	11,4x	9,0x
High				91,5x	33,9x	21,2x
Low				2,9x	2,7x	2,1x

Source: Bloomberg, Redeye Research

In our multiple-based approach, we apply a range of 8-10x EV/Sales to our 2021 estimates. The chosen range represents a slight discount compared to the selected peer group. On the one hand, we think a slight discount is warranted given the track company's short track record of strong growth. On the other hand, this target could ultimately prove conservative given what we see as the company's differentiated growth rate going forward.

To arrive at valuation ranges for the share, we discount the estimates at 13% (together with the net cash position). This multiples-based approach indicates a value per share of SEK 10-12 per share, which is in line with our DCF model.

Appendices

The information detailed in this chapter was retrieved from Dignitana's [website](#) 2019-12-04.

Appendix 1. Senior executives

William Cronin

- Chief Executive Officer since 2017 (at Dignitana since 2014)
- William Cronin holds a BA from Muhlenberg College in Pennsylvania and has a Master's in Business Administration in Finance from the University of Texas, Dallas.
- Mr. Cronin began his career in finance, starting with Shearson Lehman Brothers in New York in 1987 and then moving to Dallas in 1992 to work with Capital Institutional Services as their Head of International Sales and Trading. After leaving CIS in 1999, Mr. Cronin became President of Direct Trading Institutional, an early pioneer in high speed electronic trading, which was ultimately sold to Knight Capital Group (KCG: NYSE). Mr. Cronin became involved with scalp cooling after his wife's diagnosis with breast cancer in 2011. After her success with scalp cooling, together they founded Chemo Cold Caps, LLC, one of the largest US-based providers of manual scalp cooling solutions to patients. Mr. Cronin began working with Dignitana in 2014 as the company's clinical trial was being completed, becoming COO of the US subsidiary after FDA clearance in 2015. He was appointed CEO of Dignitana Inc. in 2016 and of AB in November 2017.
- Holdings: 4 245 739 through shareholding in C3 Device Partners as of 2019-08-29.

Mary Hatcher

- Chief Financial Officer since 2019
- Mary Hatcher has more than 20 years of broad, practical experience in diverse industries including retail and telecommunications, after key roles in finance and investor relations at Blockbuster, 7-Eleven and Excel Communications. She has a proven ability to impact business growth and manage through changing and challenging situations and has significant experience leading financial transactions, debt restructuring, strategic negotiations and cost reduction.

James McKinney

- President and Chief Operating Officer since 2018 (at Dignitana since 2016)
- James McKinney holds a BSc and an MBA from Colombia State University
- Mr. McKinney brings extensive experience and a proven track record in leadership and operations including physician relations and partnership, program design and implementation, financial performance and system integration. Jim joined Dignitana in June 2016 as a healthcare consultant. He was appointed COO in November 2016, and President in March 2018. His prior leadership roles include CEO of Clinical Partners and HB Anesthesia Groups and Division President of Iasis, President and COO of Leland Medical, and President and CEO of Brim Healthcare. He also serves as a healthcare consultant to Catholic Healthcare Systems and Catholic Relief Services.

Cameron O'Mara

- Vice President Global Sales since 2019
- Cameron O'Mara received his BA in Psychology from Harvard College.
- Mr. O'Mara brings extensive experience originating new market opportunities for innovative products and services globally. After beginning his career at Arena Capital Partners LP, a middle market private equity firm in New York City, Cameron co-founded several global clean drinking water companies. As part of his duties he spearheaded project development efforts across over twenty emerging markets; establishing partnerships and formal dialogue with local influencers and government officials throughout. Cameron was invited to discuss creative solutions to improve fresh drinking water supplies and associated health standards with Heads of State and senior government ministers across three different continents.

Melissa Bourestom

- Vice President Marketing and Investor Relations since 2016
- Melissa Bourestom holds a BA from Vanderbilt University – International Communications.
- Ms. Bourestom brings to Dignitana more than 25 years of experience in marketing, communications, event planning and sales. Her expertise is in building strong customer relationships via traditional and digital marketing strategies. Prior to joining Dignitana, she served as Executive Director of the American Advertising Federation Dallas and directed marketing and sales for myFootpath, an education technology start-up in Chicago. She previously worked in sales for Brinker International, in clinical services at Children's Medical Center Dallas, and in account management at Spier Advertising NY.

Josephine Divers

- Vice President Clinical Oncology Services since 2016
- Josephine Divers is a registered nurse and holds BSc from Ryerson University in Toronto, Ontario. She is currently enrolled in Texas Women's University Masters program in Nursing Education.
- Ms. Divers brings extensive experience in professional, collaborative patient care with the ultimate goal of facilitating patient needs with health care professional's specialization and unique talents. She has been a registered nurse for over 20 years, and holds the Oncology Nurses Society credentials of certification in Breast Cancer Nursing Care. She has international oncology experience in Canada, the United States, Vietnam and Costa Rica. This includes administrative experience in leadership roles as Operations Manager, Educator and Infusion Clinic Nurse. Prior to joining Dignitana she served as a Registered Clinical Oncology Nurse at Baylor/Sammons Cancer Center. Her research and clinical trial experience include published literature in Cancer medicine, Journal of Oncology Nursing, as well as various findings presented at the national Oncology Nursing Society Congress. She continues to be an active member of the Oncology Nursing Society, serves as a member on various advisory panels, as well as educational presentations and in-services related to breast cancer care, and scalp cooling to nurses, physicians and hospital administrators.

Darren Henderson

- Vice President Quality and Regulatory Affairs since 2017
- Darren Henderson holds a B.A. Degree Management, Texas AM University Commerce and a A.A.S. Degree, General Science, Mountain View College. He also holds a Regulatory Affairs Certification (RAC) and is a member of the Regulatory Affairs Professions Society (RAPS.)
- Mr. Henderson has over twenty-eight years' experience working with class I, II, and III medical device companies such as Johnson and Johnson, GlaxoSmithKline and Thermo Fisher Scientific. His past work includes time in research and development and managing departments including production, quality assurance and quality control, sales, regulatory affairs, purchasing and warehousing. For the past several years he has worked as a consultant helping global medical device companies meet the demanding regulations of various governmental bodies.

Bill Leuchten

- Vice President Group US Sales since 2015
- Bill Leuchten holds a BA Business Administration for Saint Michaels College
- Mr. Leuchten has worked in sales and product development for over 30 years, including roles with the automotive aftermarket division with Dow Chemical in Switzerland, South Africa and Detroit, Michigan, as well as sales for Expo Marketing, Inc. and Engineered Adhesive Systems, Inc.. He has worked with scalp cooling for over five years, initially in sales for Chemo Cold Caps, a company providing manual gel caps for scalp cooling.
- Holdings: C3 Partners

Appendix 2. Board of directors

Thomas N. Kelly

- Chairman of the Board since 2018
- Thomas N. Kelly attended University of Kansas in Lawrence, and is an active alumnus serving as member of the President's Advisory Council.
- Mr. Kelly serves as Managing Director of KMK & Associates LLC, a private equity firm with a wide range of interests from agriculture to manufacturing. He is also a Director of The Leaders Bank, headquartered in Oak Brook, Illinois. With diverse leadership roles in numerous companies and civic organizations, Mr. Kelly is a trusted and experienced leader known for his ability to anticipate and navigate business challenges with accountability and transparency. He serves on the Boards of the Donald P. and Byrd M. Kelly Foundation, which primarily supports Catholic education in the Chicago area. Other appointments: Managing Member of KMK & Associates LLC, Director of Leaders Bank, Director of Grandstand Sportswear and Glassware, Managing Member of 3840 Greenway Circle LLC, Director of Harger Woods Corporate Center LLC, Managing Member of D.P. Kelly & Associates, Director Of Elarasys Worldwide LLC, Director of Continental Community Holdings, Director and Secretary of Donald P. and Byrd M. Kelly Foundation.
- Holdings: 30 327 as of 2019-08-29

William Cronin

See senior executives.

Greg Dingizian

- Board Member since 2019
- Courses in Economics at Lund University
- Mr. Dingizian is the owner and CEO of his own holding company, Adma Förvaltnings AB. Greg has extensive experience from leading positions, including the duty as CEO of GOTIC AB, Wihl Sonesson AB, Victoria Park AB and HSB Malmö EK.för and several other companies. He has extensive experience from board work within a number of companies, e.g. as Chairman of the Board of Directors in Annehem Fastigheters AB, Victoria Park AB and Board member in over fifty other companies.
- Holdings: 13,700,000 in total – 12,200,000 through shareholding by Adma Förvaltnings AB (whereof 1,240,000 has been lent out) and 1,500,000 through shareholding by Skandia as of 2019-10-16.

Inrid Atteryd Heiman

- Board Member since 2018
- Ms. Atteryd Heiman attended Lund University, where she obtained a BA in Finance and B2B marketing, and Uppsala University where she obtained an MBA in International Business. She has also completed the StyrelseAkademien board member training.
- Ms. Atteryd Heiman has worked with companies spanning the women's health, food, pharmaceutical, biotech, life science, and financial services industries. Most recently, from 2014 to 2015 she served as Acting Chief Executive Officer of Ellen AB (Publ), a biotech company offering patented probiotic products treated to improve women's health where she also has served as Chairman of the Board. Ms. Atteryd Heiman's leadership experience includes services as Chief Executive Officer for three successful companies, several board chairman positions, and board member positions, primarily with those listed on OMX First North Growth and Spotlight Stock Market which demands effective communication with the market and shareholders. She has a proven ability to successfully strategize business development and drive profit and growth. Through her years as a management consultant she has been involved in change management, efficiency optimization, strategy development, mergers, and acquisitions.
- Holdings: 10 000 as of 2019-08-29

Pontus Kristiansson

- Board Member since 2019
- Pontus Kristiansson is a strategy consultant with Altaverita AB. Pontus has more than 20 years' experience as founder, CEO and Board executive of several startup and growth businesses. He started his career with the consumer goods marketing company Procter & Gamble and thereafter as a strategy consultant with McKinsey & Co before launching his first technology company 1999. He is also a climate impact investor and Chairman of the investment firm Realinvest AB. He has extensive experience from acting in leading positions and of Board work within a number of companies, e.g. as CEO and Board member of Kollektiva Innovation Studios AB, Vice President of Marketing at Rich Relevance Inc., Board member of IKANO Försäkring AB, CEO and Board member of Avail Intelligence AB, Business Development Consultant at Maersk Data Sverige AB and CEO of Absalon Group AB.
- Holdings: 8 000 as of 2019-08-29

Mikael Wahlgren

- Board Member since 2018
- Mikael Wahlgren is Owner and Senior Legal Adviser of Linton & Wahlgren AB and has worked as General Counsel for Alfa Laval and in-house counsel supporting several multinational Swedish and foreign listed companies including Skanska, ABB, Rolls-Royce and NCC. Mr. Wahlgren's extensive legal expertise in Swedish and international commercial legal matters has earned him a reputation as one of the most respected and sought-out counsels in business today managing, organizing and supporting company leadership, Boards of Directors and other stakeholders with legal guidance, strategic thinking and risk awareness.
- Holdings: 10 000 as of 2019-08-29

Appendix 3. Distributors

MIDDLE EAST

- Armenia – Tesla Medical Solutions
- Bahrain – Tesla Medical Solutions
- Iraq – Tesla Medical Solutions
- Jordan – Tesla Medical Solutions
- Kuwait – Tesla Medical Solutions
- Lebanon – Tesla Medical Solutions
- Morocco – Tesla Medical Solutions
- Oman – Tesla Medical Solutions
- Palestine – Tesla Medical Solutions
- Qatar – Tesla Medical Solutions
- Sudan – Tesla Medical Solutions
- Syria – Tesla Medical Solutions
- Tunisia – Tesla Medical Solutions
- UAE – Tesla Medical Solutions
- Yemen – Tesla Medical Solutions

ASIA

- Coming soon with Konica Minolta Medical & Graphic Inc.

OCEANIA

- Australia – Aurora BioScience Pty Ltd
- New Zealand – Aurora BioScience Pty Ltd

NORTH AMERICA

- Canada – Sphynx Medical
- Mexico – Celeritas Trading
- United States – Dignitana, Inc.

SOUTH AMERICA

- Colombia – Massal LLC
- Venezuela – Univico A/S

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.

People: 3

Industry experience is found among both senior executives and board members. The rating is negatively impacted by a short tenure.

Business: 4

We expect that the scalp cooling market will see price pressure and that the use of chemotherapy will decrease over time. We do, however, also recognise that the market is underdeveloped and that significant growth opportunities still remain.

Financials: 2

Dignitana is not yet profitable and is currently in a capital intensive phase. With a rights issue of SEK 42m (before transaction costs) in September 2019, we see no need to acquire additional capital in the short-term.

INCOME STATEMENT	2017	2018	2019E	2020E	2021E
Net sales	23	34	43	59	99
Total operating costs	-57	-50	-71	-84	-104
EBITDA	-34	-16	-28	-25	-5
Depreciation	-4	-5	-1	0	-5
Amortization	-3	-3	-2	-9	-12
Impairment charges	0	0	0	0	0
EBIT	-41	-24	-31	-34	-22
Share in profits	0	0	0	0	0
Net financial items	-2	-2	-1	-1	-1
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-42	-26	-32	-35	-24
Tax	0	0	0	0	0
Net earnings	-43	-26	-32	-35	-24

BALANCE SHEET	2017	2018	2019E	2020E	2021E
Assets					
<i>Current assets</i>					
Cash in banks	1	22	31	22	22
Receivables	47	18	10	12	15
Inventories	3	6	9	14	19
Other current assets	0	0	0	0	0
Current assets	51	47	51	26	33
<i>Fixed assets</i>					
Tangible assets	19	15	17	21	20
Associated comp.	0	0	0	0	0
Investments	0	0	0	0	0
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	0	0	0
0 intangible rights	11	19	28	40	40
0 non-current assets	0	0	0	0	0
Total fixed assets	31	34	45	61	61
Deferred tax assets	0	0	0	0	0
Total (assets)	82	80	96	87	94
Liabilities					
<i>Current liabilities</i>					
Short-term debt	5	7	42	66	95
Accounts payable	15	15	16	17	19
0 current liabilities	0	0	0	0	0
Current liabilities	20	22	58	84	114
Long-term debt	11	3	3	3	4
0 long-term liabilities	0	0	0	0	0
Convertibles	0	0	0	0	0
Total Liabilities	31	25	61	87	118
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	51	55	35	0	-24
Minority interest (BS)	0	0	0	0	0
Minority & equity	51	55	35	0	-24
Total liab & SE	82	80	96	87	94

FREE CASH FLOW	2017	2018	2019E	2020E	2021E
Net sales	23	34	43	59	99
Total operating costs	-57	-50	-71	-84	-104
Depreciations total	-7	-8	-3	-9	-17
EBIT	-41	-24	-31	-34	-22
Taxes on EBIT	0	0	0	0	0
NOPLAT	-41	-24	-31	-34	-22
Depreciation	7	8	3	9	17
Gross cash flow	-34	-16	-28	-25	-5
Change in WC	-36	26	5	-5	-6
Gross CAPEX	-14	-11	-14	-25	-17
Free cash flow	-84	-1	-37	-54	-28

CAPITAL STRUCTURE	2017	2018	2019E	2020E	2021E
Equity ratio	62%	68%	36%	0%	-25%
Debt/equity ratio	31%	19%	129%	-	-415%
Net debt	15	-12	14	69	99
Capital employed	66	43	49	69	75
Capital turnover rate	0.3	0.4	0.5	0.7	1.0

GROWTH	2017	2018	2019E	2020E	2021E
Sales growth	156%	47%	28%	37%	66%
EPS growth (adj)	32%	-70%	-9%	9%	-33%

DCF VALUATION		CASH FLOW, MSEK	
WACC (%)	13.0 %	NPV FCF (2018-2020)	-105
		NPV FCF (2021-2027)	113
		NPV FCF (2028-)	564
		Non-operating assets	22
		Interest-bearing debt	-10
		Fair value estimate MSEK	584
Assumptions 2017-2023 (%)			
Average sales growth	44.8 %	Fair value e. per share, SEK	10.6
EBIT margin	-17.8 %	Share price, SEK	8.5

PROFITABILITY	2017	2018	2019E	2020E	2021E
ROE	-80%	-49%	-72%	0%	0%
ROCE	-66%	-36%	-42%	-45%	-31%
ROIC	-176%	-36%	-71%	-69%	-32%
EBITDA margin	-147%	-47%	-64%	-42%	-5%
EBIT margin	-177%	-71%	-71%	-57%	-22%
Net margin	-186%	-77%	-74%	-59%	-24%

DATA PER SHARE	2017	2018	2019E	2020E	2021E
EPS	-2.10	-0.64	-0.58	-0.64	-0.43
EPS adj	-2.10	-0.64	-0.58	-0.64	-0.43
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	0.73	-0.30	0.25	1.26	1.79
Total shares	20.27	40.55	55.16	55.16	55.16

VALUATION	2017	2018	2019E	2020E	2021E
EV	14.9	-12.0	483.9	539.4	568.9
P/E	0.0	0.0	-14.6	-13.4	-19.9
P/E diluted	0.0	0.0	-14.6	-13.4	-19.9
P/Sales	0.0	0.0	10.9	7.9	4.8
EV/Sales	0.6	-0.4	11.2	9.1	5.8
EV/EBITDA	-0.4	0.7	-17.6	-21.7	-115.6
EV/EBIT	-0.4	0.5	-15.8	-16.0	-25.7
P/BV	0.0	0.0	13.5	-1,985.1	-19.7

SHARE PERFORMANCE		GROWTH/YEAR	16/18E
1 month	-	Net sales	37.4 %
3 month	6.8 %	Operating profit adj	-13.0 %
12 month	71.4 %	EPS, just	-47.3 %
Since start of the year	54.9 %	Equity	-17.4 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Greg Dingizian	19.0 %	19.0 %
C3 Device Partners	8.7 %	8.7 %
Avanza Pension	8.7 %	8.7 %
Chldn-Ubs Financial Services Inc	7.7 %	7.7 %
Johan Stormby	5.8 %	5.8 %
Nordnet Pensionsförsäkring	4.0 %	4.0 %
Ibkr Financial Services AG	3.2 %	3.2 %
Livförsäkringsbolaget Skandia	3.0 %	3.0 %
Abn Amro Global Custody Services Nv	2.3 %	2.3 %
Amir Poursamad	2.3 %	2.3 %

SHARE INFORMATION	
Reuters code	DIGN.ST
List	First North
Share price	8.5
Total shares, million	55.2
Market Cap, MSEK	470.0

MANAGEMENT & BOARD	
CEO	William Cronin
CFO	Mary Hatcher
IR	
Chairman	Thomas N. Kelly

FINANCIAL INFORMATION	

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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 (2019-12-04)

Rating	People	Business	Financials
5p	11	11	2
3p - 4p	86	65	28
0p - 2p	9	30	76
Company N	106	106	106

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CONFLICT OF INTERESTS

Arvid Necander owns shares in the company : No

Oscar Bergman 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.