REDEYE

Update

Equity Research

September 4

OssDsign

Sector: Medtech

Growth set to accelerate

Redeye initiates coverage of OssDsign, a medtech company offering patient-specific bioceramic cranial implants with significantly lower risk of implant removal due to infection compared to established treatment. With US market presence since 2017, strong clinical validation, and reimbursements in place, we see significant sales growth potential ahead. At current share price levels, we see an attractive entry to this momentum story and include it in Redeye's Conviction Buy List.

New US sales model

Shifting away from its sole distributor to a network of independent distributors should increase the company's reach in the key US market. The improving sales outlook is founded on a base of 70 hospitals where it has achieved VAC approval.

France, Japan to follow

Following its recent Japanese partnership, the coming signing of a French distributor will underscore OssDsign's expansion strategy. Though commercialization in Japan still has far to go, we view this Asian push positively. Moreover, we are confident that France will contribute significantly to future European growth.

Paving the way for fast growth

As the cranial implant has already obtained regulatory approval and full reimbursement in its key markets, OssDsign has neutralized pre-commercialization risk and can focus on ramping up its revenue generation. We forecast sales of SEK 20m this year rising to SEK 46m and SEK 90m in 2021 and 2022, respectively.

60 percent upside

Our fundamental analysis presents a Base Case value of **SEK 28 per share**. As the case hinges on commercializing the cranial implant, the coming quarters' sales growth is the most critical catalyst – with the potential to close the valuation gap in six to 12 months.

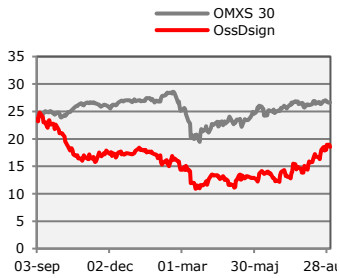
We caution, however, that OssDsign may need further equity infusions to finance its continued growth journey. While this could weigh on the shares, a strong financial position, particularly if accompanied by further fundamental progress, should also bolster investors' confidence in the case.

KEY FINANCIALS (SEKm)	2018	2019	2020E	2021E	2022E	2023E
Net sales	13	17	20	46	90	139
EBITDA	-46	-80	-80	-69	-53	-30
EBIT	-50	-84	-85	-71	-55	-32
EPS (adj.)	0.0	0.0	-4.8	-4.1	-3.2	-2.0
EV/Sales	0.8	-5.7	16.0	8.3	5.0	3.5
EV/EBITDA	-0.2	1.2	-3.9	-5.5	-8.4	-16.4
EV/EBIT	-0.2	1.1	-3.7	-5.3	-8.2	-15.4
P/E	0.0	0.0	-3.8	-4.6	-5.8	-9.5

FAIR VALUE RANGE

BEAR	BASE	BULL
10	28	40

VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	OSSD
Market	First North
Share Price (SEK)	17,7
Market Cap (MSEK)	314
Net Debt 20E (MSEK)	-45
Free Float	57%
Avg. daily volume ('000)	111

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Investment thesis

OssDsign's bioceramic patient-specific cranial implants significantly reduce the risk of implant removal due to infection compared to conventional implants and autologous bone (2 percent vs. 7-15 percent). Though its significant growth was halted in Q2 due to COVID, we see underlying momentum in its sales from:

- New sales model in the US with 70 Value Analysis Committee (VAC)-approved hospitals and an increasing number of activated hospitals
- Geographical expansion in both Asia and Europe
- Regulatory approvals and full cost coverage already achieved in all of its key markets, allowing it to concentrate resources on building sales

Moreover, addressing the elective surgery backlog should provide a further boost to sales in the short to medium term.

USA – new sales model to capitalize on the traction

After launching in 2017, OssDsign, according to its agreement, phased out its distributor in Q4 2019. Since then, it has strengthened its local presence and signed a set of independent distributors to reach additional hospitals and increase implementation rates. Considering its 70 VAC (value analysis committee) approved hospitals, we judge that this smorgasbord shortens the time for processes required for clinical implementation. We argue that this was demonstrated in 2019, with a doubling of activated hospitals compared to 2018 (45 from 21).

Further successful geographical expansion

We view OssDsign as well-positioned for a successful geographical expansion. Recently it both recorded its first sales in France before signing with a distributor and signed a Japanese partner shortly after its reimbursement approval. Although European sales are likely to exceed sales in Japan, we see long-term value creation from this expansion into Asia.

Regulatory approvals and reimbursement in place

OssDsign's cranial implant faces no regulatory or cost coverage obstacles. This allows it to focus on the main task of commercialization. Together with its momentum drivers, this puts OssDsign among the coming years' high growth potential medtech companies, we judge. We forecast sales of SEK 20m this year, followed by SEK 46m and SEK 90m in 2021 and 2022, respectively, i.e. we predict a doubling of sales for several years to come.

Though we see additional long-term value in its facial implant and burr-hole plug, these have not yet gone through the essential regulatory and cost coverage processes and lack extensive clinical data. Accordingly, we judge the cranial implant as the most appealing lens through which to consider the case currently.

Sales growth to close the valuation gap

Our fundamental analysis suggests a Base Case value per share of SEK 28 - some 60 percent above the current price.

In our view, the main drivers that should close this valuation gap relate to sales growth. With historical revenues still relatively small, though with an impressive underlying momentum, quarterly figures and positive updates on its commercialization progress should close the gap in the coming six to 12 months.

For now, sales performance will be depending heavily on COVID's impact on elective surgeries.

Additional financing required

The current cash position of SEK 72m is insufficient to support operations until positive cash flow is reached, which we forecast to be 2025. In other words, a financing solution of some sort is called for to bridge the gap, and further equity issuance thus seems likely. Depending on the company's fundamental progress and the structure of such transaction(s), the funding strongly represents both a risk and an opportunity to the investment case.

We estimate that roughly SEK 150m is required until positive cash flow, and that at least a portion of this is likely to be raised in the coming six months.

Key Catalysts

- **Quarterly sales.** We have high expectations for the coming quarters, which should demonstrate the company's ability to **1)** take charge of its US operations, **2)** increase its implementation rate at current hospitals and **3)** expand to new hospitals and markets. Sales growth meeting or exceeding forecasts should lift the share price.
  Time frame: 2-18 months
  Impact: Moderate to major

- **First sales in Japan.** While we expect only minor sales in Japan in the short term, the start should increase the confidence in OssDsign being able to expand to new markets. Its impact may depend on which hospital it generates from.
  Time frame: 0-6 months
  Impact: Minor to moderate

- **Distributor agreement in France**. To fully capitalize on opportunities in the French market, OssDsign requires a distributor. Signing one should enable broader reach and greater sales potential.
  Time frame: 0-6 months
  Impact: Minor to moderate

Key Risks

- **Disappointing sales.** As noted, each quarterly report will be a test of our expectations. Sales growth falling short could alter our view of the case and its value creation potential, particularly in the short to medium term.
  Time frame: 2 – 18 months
  Impact: minor to major

- **Additional product delay.** Though we argue that the majority of sales in the coming years will stem from its cranial implant, we see additional long-term value in its facial implant and, to a lesser degree, its standardized burr-hole plug. However, OssDsign will also have to take these products through regulatory approvals and cost coverage inclusions before they can be fully commercialized. Delays would impact its full sales potential.
  Time frame: 9-18 months
  Impact: minor to moderate

- **Further surgery backlog.** A continued negative trend in elective surgery would hurt nearer-term sales. Moreover, stressed and conservative neurosurgeons may be less prone to try out new technology.
  Time frame: 0-12 months
  Impact: Moderate to major

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Company Description

Founded in 2011, OssDsign offers patient-specific bioceramic implants for cranial and facial reconstructive surgery, as well as standardized burr hole plugs. Its cranial implants offer substantially lower rates of implant removal due to infection than the established treatments. This leads to better patient outcome, fewer repeat operations for surgeons, and lower costs for hospitals. Although OssDsign's focus has been on its cranial implant, we see long-term value creation from its additional products.

The company's head office is in Uppsala, Sweden, and it employs some 40 staff. OssDsign also has a local presence in the US, Germany, and the UK. In recent years, the company has accelerated its commercialization, laying the foundations for significant sales growth ahead. It has achieved this through geographical expansion and product launches, supported by reimbursement, regulatory approvals obtained, and strong clinical validation.

Indeed, this relatively young company has already propelled itself through the many stages required ahead of its current phase – commercialization. However, the stock performance since its IPO on First North in mid-2019 has been disappointing. After listing at SEK 27.50 per share and raising some SEK 151m, the stock is down 30 percent, and currently trades at roughly SEK 18 per share.

OssDsign: Historical highlights

2010	- The first cranial implant is operated on a patient at Karolinska University Hospital
2011	- The positive outcomes from the surgery lead Thomas Engstrand and Håkan Engqvist to found the company under the name of Oss-Q AB
2012	- The second generation of implants is produced and clinically utilized
2013	- Oss-Q AB changes name to OssDsign AB
2014	- A case report on OssDsign's implant is published in Journal of Neurosurgery
2015	- The current generation of implants is introduced. Karolinska Development, SEB Venture, and Fourietransform invest SEK 93m
2016	- The cranial implant receives commercial validation on selected European markets (Sweden, Germany, and the UK). The commercial organizational structure is established, and the 100th implant is delivered
2017	- OssDsign Cranial receives FDA clearance, broadens its commercial efforts in Europe, and delivers its 200th implant
2018	- A subsidiary is formed in the US to enable a broader launch in that market (together with Matador Medical, initially) - An additional study based on 50 patients is published in World of Neurosurgery - The 500th implant is delivered
2019	- Japanese surgeons begin to evaluate OssDsign's implant, and the regulatory process for that market is initiated - The company raises SEK 64m in a pre-IPO, followed by an additional SEK 151m in its IPO - As part of its IPO, the company communicates a rolling 12-month sales target of SEK 200m for the beginning of 2023 - OssDsign Cranial receives reimbursement in France - OssDsign takes full control of all US operations following the launch together with Matador Medical
2020	- The company receives regulatory approval in Japan for OssDsign Cranial - OssDsign Cranial is granted full reimbursement in Japan - OssDsign Cranial reports its first sales in France - Signs agreement with Muranaka Medical Instruments for launch in Japan - New CEO Morten Henneveld starts in September

People and Ownership

Given management and the Board's global backgrounds and decades-long experience in the life science and finance sectors, we are confident in their ability to continue the company's journey, now with more focus than ever on increasing sales. We provide a more detailed description of the management and Board of directors in the appendices.

While Thomas Engstrand (co-founder) resigned from his position as CMO around a year and a half ago, Håkan Engqvist (co-founder) remains as a consultant and board member. The two hold 1.13 and 1.26 percent of the shares, respectively. Moreover, the chairman of the Board, Simon Cartmell, also sits on the Board of orthobiologics company BONESUPPORT and has several decades of experience in the medtech industry.

New CEO as commercialization intensifies

Former CEO Anders Lundqvist announced his retirement plans during the summer. Anders was with the company for five years and helped aligning it for its current phase. A new CEO has since been appointed – Morten Henneveld. Morten has an extensive and international background from the medtech industry, most recently from GN Hearing as a member of the Executive Leadership Team. He has also held executive positions at orthopaedics giant Zimmer Biomet, with particular experience in turnaround strategies and executions, as well as Coloplast in the US.

Given his experience at orthopaedic giant Zimmer Biomet, amongst others, we have a positive outlook on this recruitment and are confident that he is well-suited for the phase OssDsign is now transitioning into.

Insider ownership and warrants

We view the insider holdings of management and the Board as quite poor – except for Håkan Engqvist and Viktor Drvota (through Karolinska Development). In total, management and the Board hold 0.1 and 1.7 percent of the shares only (excluding Karolinska Development's holding of 14.7 percent).

OssDsign: Management and Board of directors

Management			Board of directors		
Name	Shares	Warrants	Name	Shares	Warrants
Morten Henneveld	-	-	Simon Cartmell	27 500	122 332
Claes Lindblad	500	61 166	Anders Qvarnström	11 000	30 583
Henrik Hjort	500	24 466	Håkan Enqvist	224 000	122 332
Kajsa Björklund	3 000	24 466	Newton Aguiar	41 600	30 583
Malin Kylberg	4 000	24 466	Viktor Drvota*	2 614 096	-
Rick Thomas	2 500	85 632			
Urik Birgersson	1 600	24 466			
			Represents Karolinska Development		

Source: Redeye Research, OssDsign

The low insider ownership may be offset by the company's option programmes; however, these could potentially grant management and the Board roughly one million shares. Furthermore, the strike price of SEK 31.88 per share in the exercise period of H2 2022 suggests that today's price levels could provide an attractive additional return, should it materialize, we argue. Insider stock purchases at these levels, particularly from the newly appointed CEO, would suggest further confidence in the company's potential, and should, we believe, increase interest amongst external investors.

Top ten owners

The three largest owners, who invested in OssDsign prior to its IPO, currently hold roughly 43 percent of the shares. In the year after its listing, Karolinska Development sold 13 percent of its original stake (to settle a debt with a German venture capital firm), while SEB Venture Capital increased its holding by seven percent. We are somewhat sceptical about Karolinska Development's ownership, given its financial struggles, and we do not expect it to take part in any further financing round. If anything, we expect Karolinska Development to possibly decrease its holding, presenting a potential overhang risk.

OssDsign: Top ten owners

Owner	Number of shares	Percentage
SEB Venture Capital	2 746 368	15,49%
Karolinska Development	2 614 096	14,74%
Fouriertransform AB	2 181 632	12,30%
Eiffel Investment Group SAS	591 000	3,33%
Nordic Cross Asset Management	433 200	2,44%
Avanza Pension	424 983	2,40%
ALMI	333 020	1,88%
Theodor Jeansson	296 288	1,67%
Christian Kinch	236 992	1,34%
Håkan Engqvist	224 000	1,26%

Source: Redeye Research, Modular Finance

Changes in the top ten list

Nordic Cross Management has halved its holdings as per June 30. Before its sell-off in the second quarter, they held some 800,000 shares. We also note that Consensus Asset Management has sold their entire position of some 357,000 shares (updated on July 31). Though these institutional investors have shifted their positions, we anticipate a stronger institutional interest going forward, as OssDsign resurfaces from COVID uncertainties and continues to capitalize on its momentum. An equity issue should provide the opportunity for OssDsign to strengthen its ownership base even further.

Stock Performance

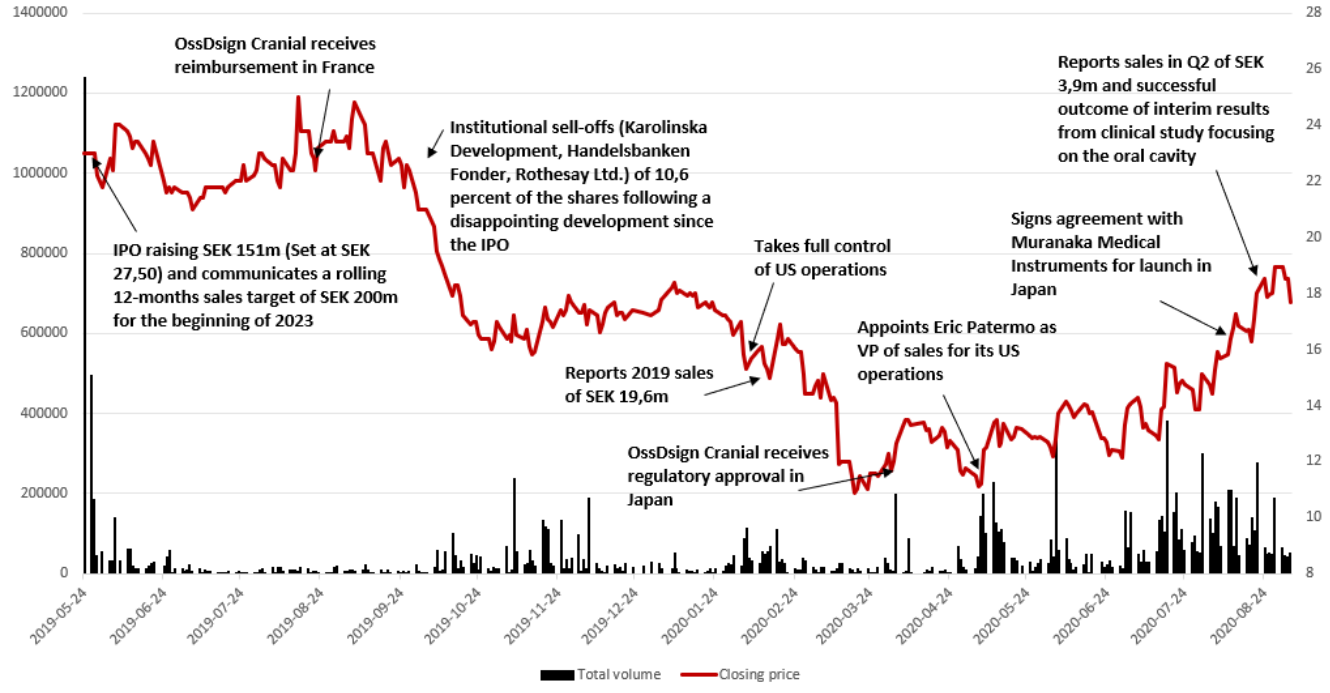
Since its IPO some 15 months ago, the share has consistently traded below its listing price (SEK 27.5) and is currently down some 30 percent. While the company has made progress since the IPO, we attribute its disappointing first year of trading to market scepticism as a result of:

- A significant off-loading of shares by one of the major shareholders (ALMI) on its first day of trading, fuelled by uncertainty over Karolinska Development's financial stability and its likely impact on the share (overhang)
- A continuing lack of insider share purchases (despite more attractive eventual entry points) along with an unchanged rolling 12-month sales target for 2023 of SEK 200m
- Institutional sell-offs in the months after a stressful performance since the IPO

After hitting its lows of SEK 11 some five months ago, the share has gained momentum and rallied 70 percent. This reflects both the general market rebound after March and the communication of several milestones, organizational strengthening and rather satisfactory Q2 sales despite COVID's impact on elective surgeries.

Going forward, we expect this momentum to continue. Cranial reconstructive surgeries should resume, driving sales growth for OssDsign and reinforcing the share's further key catalysts. Less restrictions should also allow for increased selling activities.

OssDsign: Share price performance since IPO

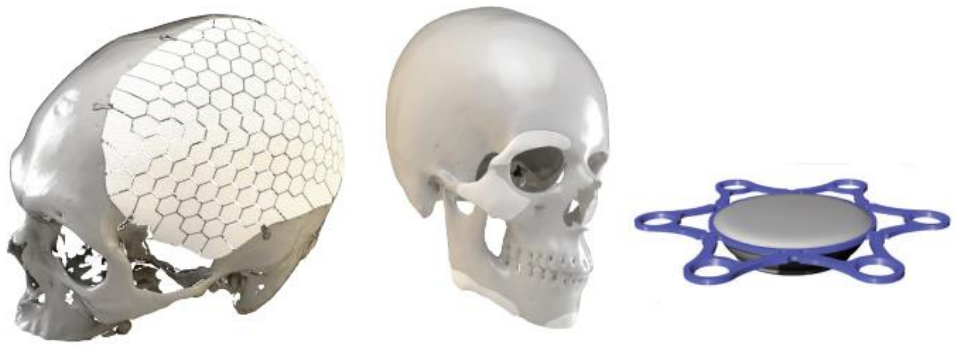


Source: Redeye Research, Nasdaq OMX

Medical Need and Product Portfolio

The company offers bioceramic custom-made implants for both cranial and facial reconstruction; OssDsign Cranial and OssDsign Facial. Recently the company also launched its first standardized off-the-shelf product; OssDsign CranioPlug for filling of burr holes and bone flap fixation.

Product portfolio – Cranial (left), Facial (centre), CranioPlug (right)



Source: Redeye Research, OssDsign

Cranial and facial reconstructive surgery typically relies on alloplastic- and metal-based implants (conventional implants) or the patient's own bone (autograft/autologous).

Complications with conventional implants and autografts are common though, with 7-15 percent requiring implant removal due to postoperative infection. OssDsign's bioceramic implants have demonstrated a rate of implant removal due to infection of 1.9-2.4 percent and also overcome the problem of a lack of mechanical support that is typical for ceramic implants. This allows the company to capitalize on a type of implant that provides better clinical outcomes, but that has previously been limited to use with smaller defects.

Currently, the products mainly compete with conventional implants, rather than the gold standard treatment of using the patient's bone. We regard this focus on taking market shares in a narrower segment as a sound strategy in a conservative business. However, there are markets where OssDsign competes with autologous bone as well.

Current bioceramic implants have faults

Generally, bioceramic implants bring a 2-15 percent risk of infection. Conventional implants, based on either alloplastics, metals, or a mixture thereof, have an infection risk of 6-13 percent. While there might be a smaller risk of infection using a bioceramic implant, they break in up to 21 percent of the cases due to their lack of mechanical support (Stefini R. et al., 2015; Moles, A. et al., 2017; Lindner D. et al., 2017). Conventional implants, on the other hand, provide a strong structure and do not run the risk of resorption, owing to their inert nature. Because of this downside, bioceramic implants have typically been used for smaller defects, since the problem of resorption and structural support correlates with the size of the defect.

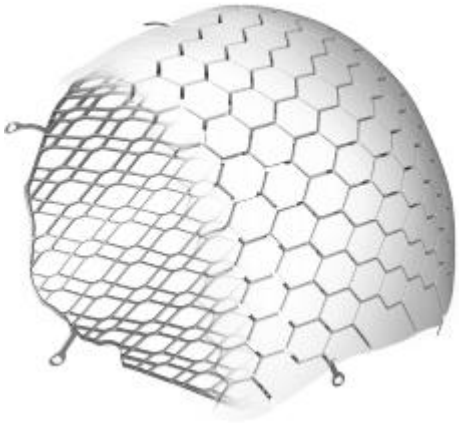
OssDsign's bioceramic implants overcome the problems

Although virtually all clinical validation is based on the company's flagship product (OssDsign Cranial), the underlying material composition and design are the same for both implants. The material composition of calcium phosphate comprises 85 percent monetite, nine percent tricalcium phosphate, and six percent calcium pyrophosphate (with a 43

percent porosity) (Engstrand, 2014). These calcium phosphates are found in human bone, which enables the bioceramic implant to transform to endogenous bone over time.

Thanks to this and a titanium skeleton, the implant has mechanical stability and enables vascularisation and tissue ingrowth. The specific and patented concentration of calcium pyrophosphate is crucial for the resorption. These factors mean OssDsign's implants overcome the shortcomings of other bioceramic implants: mechanical support, and too fast resorption, leading to insufficient healing, which in turn increases the risk of infection.

Titanium skeleton of Cranial



Source: Redeye Research, OssDsign

Decrease infection, increase profit

The reduced risk of infection results in fewer implant removals and repeat operations, which benefits the surgeon, the patient, and the hospital. The hospital, which is the customer for the implant, sees clear economic incentives by lowering the infection and implant failure rate since these pose an economic burden (an infection often costs as much as USD 100,000 per patient to treat). If infection occurs during the first three months post-surgery, the reimbursement system (in the US) does not cover the costs, and these have to be paid by the hospital.

Health economic studies required for conservative business

Like most medtech products, the implants' initial sales derive from early adopters, who typically have a great interest in innovation within their field. To gain greater market penetration and increase sales, a broader user base is required though. A broader user base may be reached by presenting a clear health economic case based on a large set of data and demonstrating the economic benefits of a product that does not require specialized extra training for the surgeons (no change to processes/behaviours). In OssDsign's case, the implants follow the same surgical procedure as conventional implants. However, we argue that the company needs a health economic study to support wider implementation of its cranial implant.

The Bone-Healing Process

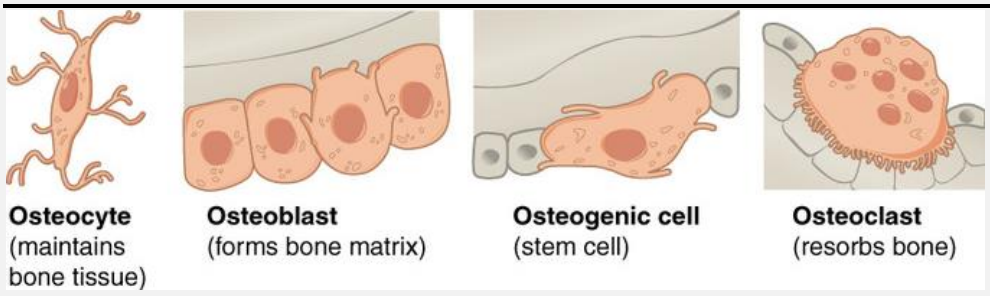
To fully comprehend how OssDsign's products work, it is essential to understand the different processes taking place as bone regenerates.

The four types of bone cells

Each one of the bone cells has a crucial role to play in bone reconstruction and healing:

1) **Osteogenic cells** – undifferentiated cells that develop into osteoblasts
2) **Osteoblasts** – help form new bone
3) **Osteocytes** – the mature form of a bone cell, transformed from an osteoblast
4) **Osteoclasts** – the cells that break down the bone. Bones have a dynamic nature, meaning that new tissue develops continuously, and old, injured, or unnecessary bone tissue dissolves. The balance between **osteoblasts** and **osteoclasts** is the never-ending story of the build-up and break-down of bone tissue

The four types of bone cells



Source: Redeye Research, LibreTexts

The four stages of bone healing

After bone has been damaged, the body begins its reconstruction of the tissue. This can be divided into four stages:

1) **Haematoma formation** – as blood vessels tear and clotted blood is accumulated at the fracture site. The clotted blood seals the broken ends of the blood vessels, depriving the bone cells of any nutrients. This causes cell death
2) **Bone regeneration** – some days after the fracture, capillaries begin to grow into the haematoma, and phagocytic cells start to devour the dead bone cells. Osteoblasts and fibroblasts arrive at the fracture site and begin to reform new bone. The fibroblast produces collagen fibres to connect the broken bone. The osteoblast forms a spongy bone
3) **Bony callus formation** – the fibrocartilaginous callus transforms into a bony callus of spongy bone. After some time, depending on the type of skull fracture, the broken bone re-joins
4) **Bone remodelling** – the bone's osteoclasts and osteoblast work in harmony on the bony callus, breaking down old bone and forming new bone

The three mechanisms of bone-healing

The process above is based on three mechanisms:

1) **Osteoconduction** – bone growing on a surface, typically on a scaffolding structure where osteoblasts and osteoclasts can build and replace bone
2) **Osteoinduction** – undifferentiated cells undergo stimulation and develop into the bone-producing osteoblasts
3) **Osteogenesis** – osteoclasts break down bone and osteoblasts produce new bone

Some or all of these mechanisms occur with autografts and bioceramics as they are biodegradable. Conventional implants do not have these mechanisms as they are non-biodegradable. However, they are biocompatible, which means the endogenous bone may encapsulate them over time.

Cranial Bone Defects

Cranial defects are often caused by hemicraniectomy – removing a piece of the skull to access the brain following a stroke or a traumatic brain injury. Tumour removal, radiotherapy, trauma, or congenital disabilities are other causes for cranial (and facial) defects.

Depending on the cause, the size of defects can vary significantly. Typically, defects of less than three centimetres in diameter do not require an implant and are treated by gluing the bone back together with bone cement (Kwarciniski J. et al. 2017).

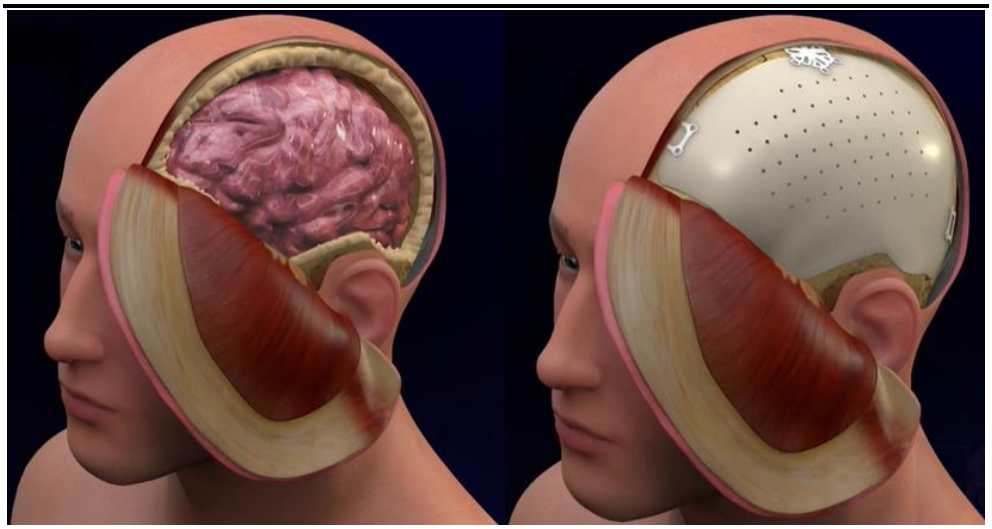
Removing a piece of the skull – craniotomy, craniectomy and cranioplasty

Stroke patients or those with a traumatic brain injury can suffer intracranial bleeding and raised intracranial pressure, which often requires a *craniotomy*. During this surgical procedure, a piece of the skull is removed, enabling the surgeon to let the brain swell and to drain blood and cerebrospinal fluids. In this procedure, a section of the skull, known as a bone flap, is removed to allow access to the brain. The bone flap is re-inserted during the same procedure

In other surgeries, known as *craniectomies*, the bone is not inserted once the procedure is completed. There are cases where the patient goes on for days or several weeks without the bone flap back in place.

Eventually, the missing piece of the skull is either replaced with an implant or re-settled with the patient's bone. However, there is a risk of complications, such as infection, skin extrusion, wound dehiscence, and general discomfort. These complications may require reconstruction of the cranial defect through a surgical procedure known as *cranioplasty*. In most cranioplasties, the autograft is replaced with an implant. There are, of course, cases where the surgeon decides to use an implant as the first line of treatment, skipping the autograft altogether.

Cranioplasty procedure – incision and exposure (left), implant placement (right)



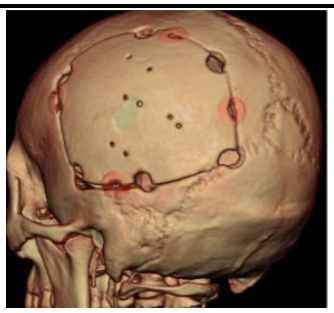
Source: Redeye Research, Highimpact.com

Traditional Treatment and Implants

Autologous treatment

The main advantage of using the patient's bone is that it allows for all three of the bone-healing mechanisms – osteoinduction, osteoconduction and osteogenesis – enabling full healing without the need to design a costly patient-specific implant. This allows for a shorter pre-operative process than with a custom-designed implant. In craniectomies, however, the freeze-preservation of the skull piece brings the risk of cell death, damaging the bone and increasing the risk of infection and rejection. The average risk of infection for autologous bone reconstruction is around eleven percent, according to Kwarciniski J. et al. 2010 and Corliss et al. 2016.

Cranial reconstructive surgery – autologous treatment



Source: Redeye Research, Fan et al. 2017

Another downside with autologous bone is that it is not optimal for large cranial defects. Studies have shown that roughly 60 percent of procedures fail if the defect is greater than 75cm² (Goiato et al., 2009). This leaves no other alternative than the use of conventional implants, as bioceramic implants are, typically, not suitable for larger defects either – until relatively recently with OssDsign Cranial.

Re-using the patient's own bone is generally considered a cheaper and quicker alternative to implants. However, costs are high when infection occurs, and one could argue for the use of conventional implants as the first line of treatment. We do not expect this to happen in the near future, as it would require extensive health economic data and considerable behavioural change amongst surgeons in the very conservative segment of orthopaedics.

Implants – alloplastics and metals

The majority of cranial and facial implants are based on either alloplastic or metal materials. While autologous bone and bioceramics are biodegradable, being resorbed and transformed into host bone, these conventional implants only have biocompatible traits and are encapsulated by human bone over time.

Cranial reconstructive surgery – conventional implants

Source: Redeye Research, Stryker, Imaginarium

Alloplastic implants are often based on PEEK (polyaryletheretherketone), a crystalline thermoplastic material with good mechanical traits, or porous PE (polyethylene) and PMMA (poly methyl methacrylate). On average, PEEK and PMMA implants have a 6-11 percent risk of infection (Kwarciniski J. et al., 2017; Punchak M. et al., 2017).

Metal implants are typically titanium and can come in the form of plates or a mesh. The plates have no porosity and do not enable osseointegration, whereas a mesh allows for tissue ingrowth, thanks to its web-like design. Moreover, titanium implants carry an infection risk of about eight percent (Mikaemi et al., 2017).

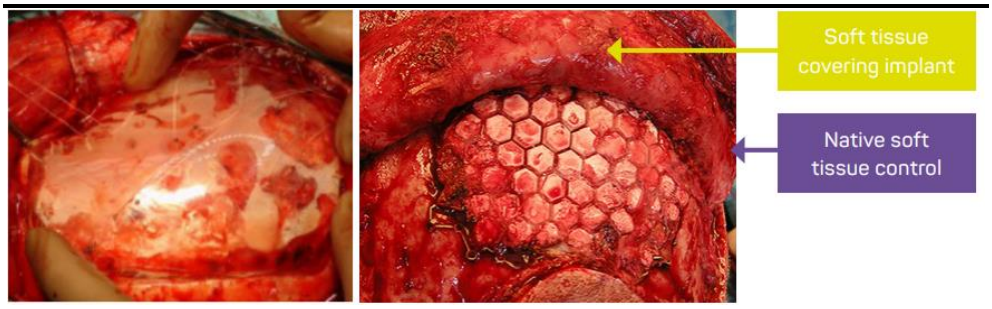
In many cases, the implants used are a mixture of both alloplastics and titanium, with the titanium acting as a frame and the alloplastic part forming the implant surface. According to Engstrand et al. 2015, surgical intervention due to complications is as high as 20-30 percent, with infection occurring with six to 13 percent of the implants, and some 80 percent of the infections prompt implant removal.

Furthermore, these combined material implants have been shown to have poor tissue integration, resulting in a weakening of nearby tissue. Over time, this may result in implant exposure as the implant penetrates the tissue, becomes visible, and increases the risk of infection.

Bioceramic implants

Bioceramic implants are based on minerals also found in human bone, such as calcium phosphate (typically hydroxyapatite). These overcome the shortcomings of alloplastic- and metal-based implants thanks to a generally lower risk of infection, which may be attributed to their ability to absorb liquids and stimulate the production of new blood vessels in the implant (hydrophilic ability). This enables better tissue regeneration, improving the healing process and decreasing the risk of postoperative infection.

Vascularisation - Alloplastic implant (left) vs. OssDsign Cranial (right)



Source: Redeye Research, OssDsign

These implants have typically been used in smaller defects because the too fast resorption in larger ones results in suboptimal healing and requires repeat surgery; the implants break in up to 21 percent of the cases. The mechanical instability is likely a significant contributor to the high variance in the risk of infection, which extends from two percent to 15 percent on average. With greater mechanical support, the risk for complications is decreased – signifying the clinical advantages of OssDsign Cranial.

The ideal cranial implant

Although conventional implants possess some of the ideal traits for a cranial implant, none have them all. Trade-offs are required throughout. We conclude that the ideal implant should:

- be replaced by endogenous bone over time
- allow for an optimal anatomical fit thanks to its design
- have good mechanical support, hindering it from breaking
- have osteoinductive and osteoconductive traits to produce new bone cells and promote bone growth
- be biocompatible or biodegradable to decrease the risk of rejection
- allow for tissue integration and bone healing, reducing the risk of infection

OssDsign Cranial has all of these traits and can also be used for larger defects. In short, OssDsign's implants alone can combine bone regeneration with mechanical support, which we view as a key reason why bioceramic implants have not seen wider implementation in cranial reconstruction, to date.

OssDsign's Product Offerings

As mentioned earlier, OssDsign offers three products: OssDsign Cranial; OssDsign Facial; and OssDsign CranioPlug. The two customer segments for these products are neurosurgeons and plastic/reconstructive surgeons. The cranial implant has been the company's main focus, and it has delivered more than 1,000 of these implants compared with roughly 50 its facial implants. OssDsign CranioPlug has just been launched while OssDsign Facial has been subject to redesign with an anticipated broader relaunch in the near future.

Material composition and structure

The material in all products constitutes calcium phosphate in different states:

- Tricalcium phosphate
- Monetite
- Calcium pyrophosphate

The specific and patented concentration of calcium pyrophosphate is crucial to resorption. With the titanium skeleton, it provides mechanical support, overcoming the fragility issue typical with bioceramic implants. Eliminating the problem of fragility could allow for wider clinical implementation of bioceramic implants (specifically OssDsign's implants), with a great opportunity to capitalize on the demand for decreased infection in healthcare.

Designing and manufacturing the implants

Using CT data and 3D-printing, the patient-specific bioceramic implants are developed in close collaboration between OssDsign's CAD engineers and the ordering surgeon. The implants have a titanium structure and a mosaic-like shell of bioceramic tiles with one-millimetre spacings. The implants are fixated with standard neuro micro screws through fixation arms that are integrated with the titanium skeleton.

OssDsign Cranial

Figure 1. (**A**, **B**) Titanium-reinforced calcium phosphate implant illustrated with 3-dimensional laser additive manufactured titanium mesh designed by computer-assisted design and computer-aided manufacturing. (**C**) Perioperative view showing inlay implant covering the defect.

Source: Redeye Research, Kihlström et al. 2018

The tiles are made up of the bioceramic material, and their design enhances the tissue fluid circulation, enabling vascularisation and optimizing tissue integration. Overall, this improves the healing process and decreases the risk of postoperative infection. As previously mentioned, bioceramic implants have primarily been used in smaller rather than larger defects. OssDsign's patented calcium pyrophosphate concentration, and titanium structure have been shown to resolve this issue. In one particular case, more than 70 percent of a patient's skull had to be removed and replaced, and the surgeon decided to use OssDsign Cranial. No postoperative infection or implant break occurred, suggesting its reliability even with larger defects.

Cranioplasty following removal of an intraosseous meningioma

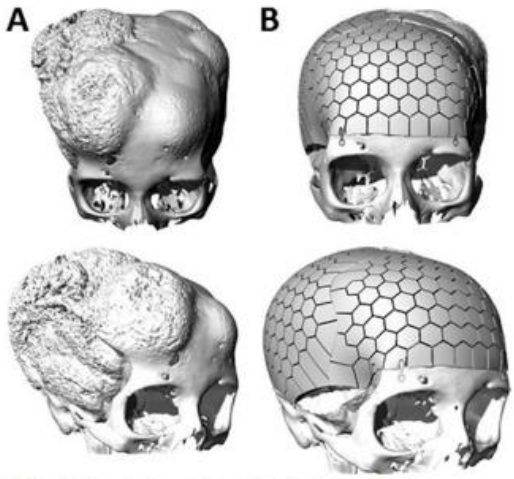


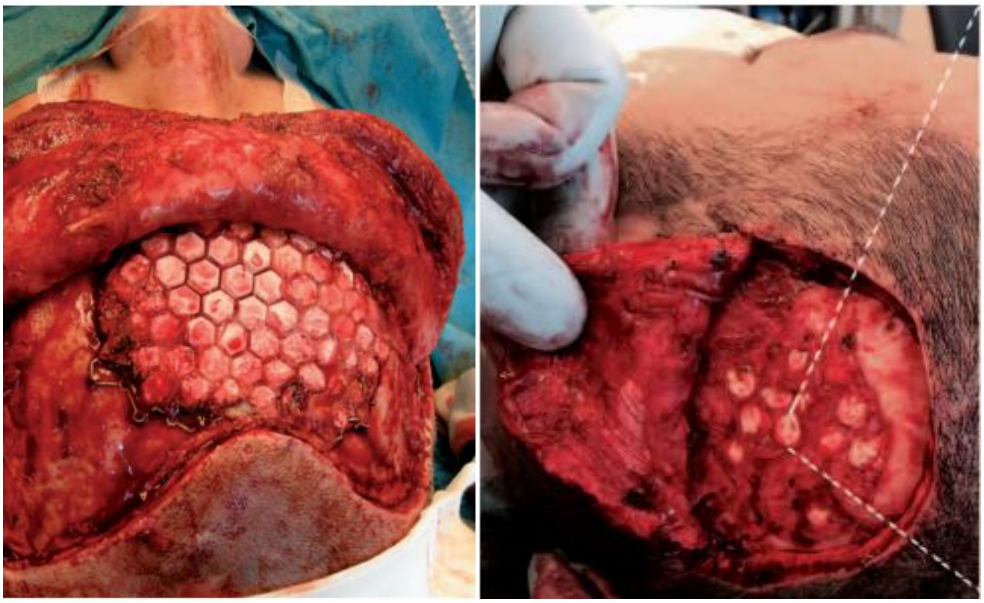
FIG. 3. A: 3D renderings of the patient's skull at presentation. **B:** Planned cranioplasty design.

Source: Redeye Research, Sundblom et al. 2018

Signs of osteoconductive and osteoinductive traits

Macroscopic and histologic examinations of removed OssDsign Cranial implants have indicated both osteoconduction and osteoinduction. While the osteoconductive traits of such an implant is not a particular surprise, osteoinduction suggests that new bone may be formed that is not adjacent to host bone. We argue that osteoinductive evidence would indicate a high degree of innovation and clinical reliability from the company's implants. For the patient, this would provide a resilient mechanical strength in other parts of the implant not connected to host bone. This could suggest more evenly distributed bone regeneration, providing good mechanical support.

Nine months after surgery in patient 1 (left), 50 months after surgery in patient 2 (right)



Source: Redeye Research, Engstrand et al. 2015

We emphasize that these findings are based on a limited sample size where CT scans were able to provide additional data. However, such examinations are costly, and we do not believe that strengthening these claims should be a priority at this time, as the implants have already demonstrated a reduced risk of implant removal due to infection through the robust clinical evidence. However, we argue that further strengthening these findings could provide a competitive advantage in the longer term. We do not expect that surgeons who have used OssDsign Cranial made their decisions based on these findings, but instead the low rate of infection should be the main selling point. Moreover, we assume that the early adopters closely follow the research and development in their fields and have their own perception of the claims of osteoconduction and osteoinduction.

Currently, OssDsign cannot freely claim osteoconductive and osteoinductive traits in all markets and for all products. However, in the case of CranioPlug, claims of osteoconduction properties are granted to be marketed by the FDA and is the only burr-hole filler product on the US market that can do so. We expect OssDsign is working on expanding claims in all markets.

OssDsign Cranial and Facial

The most common indications leading to the need for an OssDsign Cranial implant are hemicraniectomy after a stroke or a traumatic brain injury, followed by removal of brain tumours, and reconstructive surgery due to cranial traumas. A hemicraniectomy is performed by removing a large flap of the skull and opening the dura, a thick membrane of tissue covering the brain.

Surgery-wise, the procedure is no different from other patient-specific implants and does not require any extensive training. Collaborations between surgeons and CAD engineers could become a great behavioural competitive advantage for OssDsign, but currently, the company is challenging existing relationships by aiming to replace implants at hospitals. At this stage, this is a barrier to entry for OssDsign, as its competitors can offer a wide selection of other products for surgeons compared with what we judge to be OssDsign's somewhat limited selection. The largest players on this market are orthopaedic giant companies such as Zimmer Biomet and Depuy Synthes with established connections and wider product offerings throughout neurosurgery as a whole.

Tumour surgery and trauma are common indications for OssDsign Facial, although congenital disabilities have been the most common so far. However, the company has only delivered 50 of these implants so far, compared with more than 1,000 cranial implants which have more extensive clinical data as well.

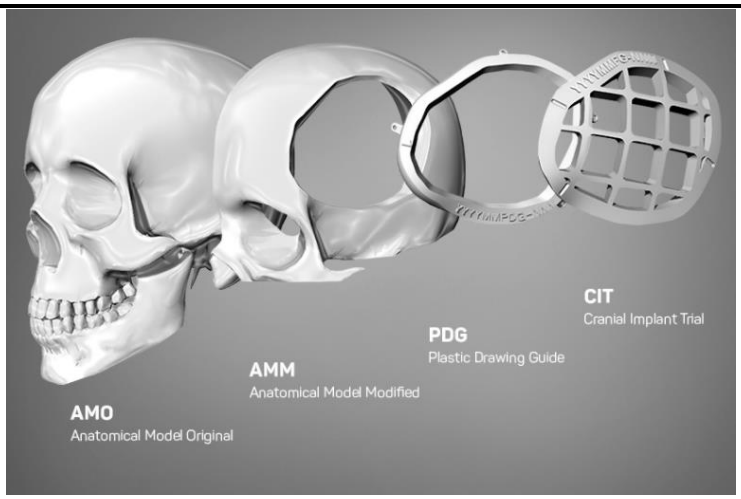
OssDsign Facial has also undergone design improvements, and the updated version was developed during H2 2019. Thanks to the improved facial implant and a soft launch this year on selected markets, we anticipate increased efforts by the company in commercializing the product from next year.

OssDsign Cranial Accessories

The company has developed a range of products to support the use of OssDsign Cranial and to ease the implanting procedure further. These are implant replicas, surgical guides and anatomical models aimed to facilitate an optimal placement and fitting of OssDsign Cranial. Each available accessory is a custom-made device specifically designed for the patient's unique anatomy, using patient-specific CT data and 3D printing.

These products are called OssDsign Cranial Accessories and constitute 3D-printed replicas of the implant (in plastic). They allow for more precise implant insertion by aiding measurement and eliminating the need to handle the actual implant until surgery. This could also help to decrease the risk of infection further.

Cranial Accessories



Source: Redeye Research, OssDsign

Moreover, OssDsign Cranial PSI Accessories obtained FDA clearance in 2019 and regulatory market approval in Europe in line with the MDD.

OssDsign Cranioplug

In addition to its patient-specific products, OssDsign has developed Cranioplug, an off-the-shelf standardized product intended for burr hole coverage or bone flap fixation.

In some neurosurgeries, a small standardized size hole is made in the patient's skull to enable brain abscess drainage, for example. This is common in the treatment of strokes, or other brain bleeds to decrease intracranial pressure and prevent haematomas. In other cases, these holes are part of the procedure of removing a bone flap. CranioPlug is designed to fill and cover burr holes and enable fixation of bone flaps.

The regenerative calcium phosphate material that encapsulates the titanium structure gradually transforms into bone in the healing process. In the US, OssDsign has labelled its claim that "the ceramic material resorbs and is replaced with bone in the healing process". According to our research, Cranioplug is the only product to make this claim, providing a unique advantage in a highly competitive and consolidated market. Cranioplug comes in four versions, all measuring either 11 or 14 millimetres with either two or six fixation arms.

Price estimates for the products

We estimate that the highest prices for the products will be in the US and Japan, followed by the EU.

OssDsign Cranial

For OssDsign Cranial we estimate a price around SEK 100,000 in the US and SEK 75,000 in Japan. For the European market, we estimate SEK 50,000, where we estimate a gross margin in the region of 60-70 percent. Given its higher price levels in the US and Japan, we expect it could be closer to 80 percent on these markets.

OssDsign CranioPlug

CranioPlug is a much cheaper product to manufacture, and so we estimate price levels of roughly SEK 2,500 in the US and about SEK 1,700 in Japan. For Europe, we assume a price range of SEK 1,250. For the standardized CranioPlug, we estimate a gross margin of roughly 90 percent.

OssDsign Facial

For the facial implant, depending on its size and complexity, we estimate an average price of SEK 30,000 in the US and SEK 22,500 in Japan. In Europe, we estimate a price range of roughly half of the US prices. The gross margins, we assume, will be close to that of OssDsign Cranial.

Applying antibiotics to the product offerings

The use of local antibiotic treatment is increasingly common in orthopaedics but has its limitations, typically in how it is administered. The standard of care still takes a systemic approach with antibiotics, which several studies suggest may impose a greater risk of antibiotic resistance.

OssDsign has not developed a solution for local antibiotic release with its products. However, soaking the implant in Gentamicin and Vancomycin (two common antibiotics in orthopaedics) enables local treatment, as Sundblom et al. (2019), demonstrated in their study. The two competing materials, alloplastic and metals, lack the possibility to absorb the antibiotic, making local antibiotic release from implants of these materials impossible.

While we view it as an advantage over alloplastic and metallic implants that OssDsign's Cranial can be soaked in and release antibiotics, we do not expect the company to start developing an antibiotic-releasing product. We note, however, that OssDsign provides guidance for how to use antibiotics with its implants if the surgeon wants to do so.

Current regulatory situations

Two of the three products have FDA clearance (Cranial since 2017 and CranioPlug since 2018), and we expect an FDA filing of OssDsign Facial next year. Recently, OssDsign Cranial was granted regulatory approval in Japan, and we expect CranioPlug to be filed there sometime during the year. We expect the FDA filing of Facial in the US to be prioritized ahead of the Japanese market, given the company's US focus. Moreover, OssDsign Cranial PSI Accessories obtained FDA clearance in 2019 and regulatory market approval in Europe in line with the MDD.

In the EU, only OssDsign CranioPlug requires a CE mark (granted in 2018), as patient-specific implants do not require this. They do need to gain regulatory market approval in line with the MDD, and OssDsign Cranial and Facial gained this in 2015.

The current regulatory status of the product portfolio

Product	Regulatory status		
	US	EU	Japan
OssDsign Cranial	FDA approved	MDD approved	PMDA approved
OssDsign CranioPlug	FDA approved	CE mark	-
OssDsign Facial	-	MDD approved	-
OssDsign Cranial Accessories	FDA approved	MDD approved	-

Source: Redeye Research

Clinical Validation

The clinical data surrounding OssDsign's technology, specifically its cranial implant, has attracted the attention of influential neurosurgery KOLs. They are crucial for market launch and initial sales, although we argue that more health economic data is essential for the implant to be used on a larger scale.

Current clinical validation is heavily tilted towards the company's cranial implant, with documentation of roughly 800 patients in total. As we expect a higher degree of commercial efforts for its facial implant and burr hole plug in the coming years, we expect increased clinical validation of these products, too. We note that while the material of the facial implant is identical to the cranial implant, it targets a different patient and surgeon segment. These surgeons are also bound to need strong clinical evidence, as well as health economic studies eventually, we judge. Moreover, considering the implant's updated design, we believe its clinical validation will be given more focus from this year.

Follow-up study of 670 patients brings strong clinical evidence

Of the many published studies and case reports we have taken part of, the most substantial clinical evidence comes from its follow-up study published in July 2019.

The study was based on a total of 670 patients (cranial implants) at more than 120 hospitals in the US, Europe, and Asia. The median follow-up time was 17 months, with a primary endpoint of implant failure due to postoperative infection. Of the 670 implants, 32 were removed (4.8 percent), although only 16 due to postoperative infection (2.4 percent). There were several other causes of the 16 other implant removals, ranging from 0.1 to 1 percent of the patient population, and none demonstrated any particular downside from using the implant. Indeed, the risk of infection is the number one problem amongst implants.

Given that only 2.4 percent of this large population group had implants removed due to infection, we argue that these findings position OssDsign's implants strongly against competing conventional implants. Furthermore, we note that the study was published in July 2019 and that interest for OssDsign Cranial had already been well-demonstrated, opting for even greater awareness, interest and clinical implementation.

More than 700 implants have been delivered since 2014 when the current generation of OssDsign Cranial was launched. In total, more than 1,000 implants have been delivered since 2010, and the value proposition has attracted a number of influential KOLs, which will help increase awareness and subsequent sales of OssDsign Cranial.

Publications based on OssDsign's technology

OssDsign's implants have been used in a clinical setting since 2012. The clinical validation suggests that:

1) OssDsign Cranial has demonstrated a significantly lower implant failure rate due to postoperative infection than conventional implants
2) The novel calcium phosphate composition of the implants leads to bone integration and bone regeneration
3) OssDsign Cranial can be used in larger defects, circumventing a problem with bioceramic implants in general

Below, we present a cohort of studies that emphasize the traits of OssDsign's product offering. In the majority of these publications, the company's implants have been used after another implant has failed. This evidence could serve as a tool for surgeons needing to decide whether to use an OssDsign implant following a failed conventional implant and could be a first step towards using OssDsign as the first-line choice.

OssDsign: Selected publications

Kihlström et al. 2018

This retrospective study of 50 patients at Karolinska University Hospital in Stockholm, Sweden, was initiated to identify the potential improved clinical outcome for patients using OssDsign Cranial. The primary objective was to assess the number of implants explantations due to infection or persistent wound dehiscence. Its secondary objective was to evaluate bone regeneration based on the examination of any retrieved specimen. Naturally, the secondary objective would only be possible to investigate given failures of the implant, which would mean, if things went well, only a small sample size.

Among the 50 patients, there was a total of 52 cranial defects, and 32 of the 50 patients had experienced a previous failure with autologous bone, alloplastic implants, metal implants, or a mixture of both. This corresponds to a 64 percent previous failure rate for this complex patient cohort. Among the 50 patients, a total of 53 cranioplasties were performed. At 25-month follow-up, the explantation rate due to post-operative infection or lasting wound dehiscence was 1.9 percent (one implant) and four percent (two implants), respectively.

The patient that required implant removal due to post-operative infection underwent a secondary cranioplasty using a new OssDsign Cranial implant and no further complications were recorded at the 6-month follow-up examination. For the two patients suffering from persistent wound dehiscence, implant removal was avoided, although one had persistent wound dehiscence 16 months after surgery.

Furthermore, one patient had a brain tumour recurrence, requiring implant removal after 31 months. This provided the opportunity to conduct a histologic examination of the implant, which indicated that the implant had partly but evenly transformed into vascularised compact bone.

The conclusion of the study was that OssDsign Cranial appeared to provide a better clinical outcome in a complex and diverse patient cohort with a high previous implant failure rate. In addition to this, proof of concept was further strengthened with the clinical retrieval of the implant from the patient with the tumour recurrence, which suggested bone regeneration and osseointegration.

Oliver Bloom et al. 2020

This case presents the successful use of OssDsign's Cranial for a 37-year-old female patient who had suffered from a recurrent epithelioid sarcoma over the posterior scalp (a rare slow-growing type of tissue cancer, located in this case on the lower backside of the skull). As a part of treatment, she underwent excision in 2010, with a subsequent reconstruction using a local rotational flap (tissue freed and rotated from another area to cover the defect). After the cancer recurred in 2013, the patient developed osteomyelitis (bone infection), which lasted from 2015 to 2016. In early 2017, following CT and MRI scans and multidisciplinary team discussion, it was decided that the patient should undergo reconstructive surgery of the affected area using a combination of a PEEK or hydroxyapatite-coated titanium implant.

After the medical team contacted OssDsign, several meetings were held to produce the patient-specific implant. 23 days after accepting the design proposal from OssDsign, the implant was delivered to the team. In this particular case, the implant was soaked in the well-used antibiotic Vancomycin, which can be used in orthopaedic surgery where there is a risk of, or active, infection. No post-operative complications were recorded, and there were no wound healing issues in the immediate post-operative period.

In addition to preventing further surgeries thanks to its single operative reconstruction, the implant was confirmed in PET and CT scans after surgery to have a formation of bone in the middle of the implant. Given a bone formation at a distal location from the patient's own bone, it could further suggest that the bioceramic tiles have osteoinductive traits. Although these additional findings are intriguing, we emphasise that additional studies based on a much larger patient cohort are required. This finding is nonetheless interesting and should raise interest amongst orthopaedic surgeons. Moreover, other studies also suggest that OssDsign Cranial may have osteoinductive traits.

Engstrand et al. 2014

In this study, a 53-year-old male had been subject to a violent trauma several years earlier in an attack involving a hammer. The attack caused a large temporoparietal cranial bone defect at 80x90 millimetre (upper left side on the front of the skull). The defect had dire consequences for the patient, having been subject to 24 surgical procedures since. Autologous bone graft, PMMA cement and a titanium implant were used, but with no success due to either infections, resorption or protrusion through the skin.

The polymer and metallic implants the patient had used earlier are inert, lacking bioactive characteristics. Though there are other bioactive solutions which possess bone growth stimulation (bioceramics), they are typically used for healing smaller defects and fractures, as we have previously mentioned. Bone regeneration of larger defects is more challenging and typically requires several surgical interferences, often in combination with autologous bone or cell transplantation to initiate bone healing.

With the objective to stimulate bone healing, the surgery team decided on using OssDsign cranial on this therapy-resistant patient. The implant by OssDsign provided scaffolding for this large cranial defect, constructed of ceramic tiles interconnected with titanium wires. After surgery, the patient recovered without complications and was able to leave the hospital three days later. Follow-up examinations every third month over 30 months showed no signs of infection, inflammation or thinning of the soft tissue covering the implant. CT and PET scans 30 months after surgery demonstrated signs of bone ingrowth, which serves as further evidence of bone regeneration.

Engstrand et al. 2015

In this study, two patients' cranial implants from OssDsign were subject to investigation after having been removed due to aesthetical concerns and fixation of titanium plates. These removals provided the opportunity for inspection of the implants and surrounding areas through biopsies, gene expression analyses, and histological examinations. The removals and subsequent investigations took place nine and 50 months after surgery, respectively.

The first patient was a 41-year-old male who underwent neurosurgery for the treatment of frontal sinus chronic infection. After surgery, the patient suffered an infected bone flap and a failed PMMA implant, resulting in a bone defect measuring roughly 60 cm^2. A patient-specific calcium phosphate implant (OssDsign Cranial) was manufactured and implanted at the site, although it was surgically removed after nine months owing to aesthetical concerns regarding the forehead.

Upon inspection, this first patient's implant appeared to lack macroscopic and histological evidence of any bone formation in the central part of the ceramic tiles. However, further histological examination showed both blood vessels and collagen fibres. Between the calvaria (top of the skull) defect and the pre-existing parietal bone (side and roof of the cranium), newly formed bone appeared to be in contact with the ceramic tiles. This showed that the ceramic tiles at the border zone to the host bone appeared to be integrated. Analysis with gene expression indicated higher expression of the proteins osteopontin, osteocalcin, and collagen type 1 in both the central defect and its border sites compared to the parietal bone and the surrounding soft tissue. These proteins play an essential role in the formation of new bone.

The second patient was a 33-year-old male suffering from a parietal defect measuring roughly 35 cm^2 after trauma. This patient did not have any other implant before undergoing reconstruction with OssDsign's implant but complained of discomfort stemming from the fixating titanium plates after some time. This required removal of the implant, allowing for inspection 50 months after surgery.

Unlike the inspection of the first patient's implant, this implant appeared to have bleeding bone covering the entire ceramic tile surface. Tiles at the border of the implant seemed to be integrated with host bone, while bone growth was also found in the middle of the implant. Macroscopically, the ceramic tiles showed transformation into bone.

Although based on a very limited population group, this study provides important information about the products' ability to regenerate bone in cranial defects. Its conclusion is in accordance with the other studies in respect to indicating osteoinductive traits and that the implants are osteoconductive.

Sundblom et al. 2018

This case report is based on a 39-year-old female with severe swelling of the right temporal bone, growing over numerous years due to a tumour. This condition required the patient to undergo a radical surgical removal and subsequent cranioplasty involving more than 70 percent of the calvarial surface area. No prior implants had been used on this patient, as she had recently migrated from a part of Africa where her medical need could not be sufficiently met.

After tumour removal, OssDsign's patient-specific, titanium-reinforced bioceramic implant was put in place, significantly improving the aesthetics of the patient's skull.

The patient recovered swiftly after the surgery, and an examination conducted 14 days after the operation indicated normal neurological results. A follow-up examination six weeks after the operation showed no complications in wound healing, and the cosmetic outcome was good. MRI check-up five months after the surgery showed no indication of infection and at the six-month follow-up, the patient was still well and showed no signs of infection.

The fact that more than 70 percent of the calvarial surface area required cranioplasty and was followed up with an implant from OssDsign further strengthens the claim that the company's implants can be used for large defects. As mentioned earlier, bioceramic implants have typically been used for smaller defects, due to their lack of mechanical stability over larger areas. This is a strong case for these implants' ability to serve an unmet medical need, we argue.

Market Opportunity

The Market for Cranial and Facial Implants

According to Evaluate, the orthopaedic market is set to generate sales in excess of USD 40bn this year, with an expected CAGR of 3.7 percent in the coming years. The global markets for cranial and facial implants are estimated to experience a CAGR of some six and seven percent, respectively. For 2020, these markets were expected to generate sales of roughly USD 2.7bn. However, this year will see a significant setback owing to the coronavirus, although we anticipate growth returning next year, fuelled by a return-to-normal scenario and elective surgeries resuming.

The main growth factors are:

- An expanding and ageing population
- A rise in tumour prevalence and traumas
- A rise in the incidence of stroke among young adults
- Increased innovation in both developed and developing economies

In the coming years, the US is expected to account for slightly under half the market value, while Asia-Pacific should see the fastest growth, at around eight percent annually. The US and the EU are estimated to experience slightly slower growth of five to seven percent.

Furthermore, the markets for cranial and facial implants, particularly in developed economies, are expected to see increased collaboration between manufacturers and surgeons. This should further strengthen the positions of the three leading orthopaedic companies – Zimmer Biomet, Depuy Synthes, and Stryker – which currently represent roughly 65 percent of the market.

Hospitals are the main customer group – consolidation in key market

The end-user of implants is a surgeon either at a hospital or a neurosurgery/facial reconstructive speciality centre. The majority of the procedures (some 70 percent) are expected to be carried out in hospitals, owing to an increase in medical professionals, new hospitals, and increased surgery volumes.

The hospital market in the US is less fragmented than in Europe, as a result of its geography and effect on logistics distribution networks, but also owing to general consolidation in the hospital market over the past three decades. Operating on a consolidated market could ease the complexities surrounding increasing volume and market penetration, we argue and is a trend that plays in OssDsign's favour.

The Market for OssDsign

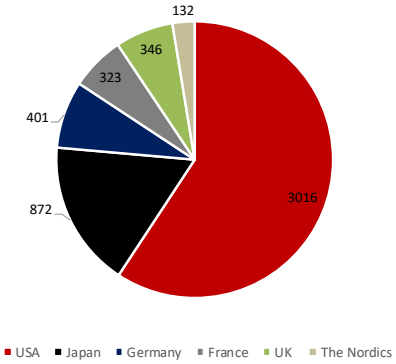
We estimate the total OECD market value of its product portfolio at SEK +7bn. This corresponds well to OssDsign's own estimates for 2016, adjusted for a CAGR of roughly seven percent since.

The company's estimates stem from a variety of sources, such as industry reports and national databases. Its estimates correspond to a prevalence we can identify from the literature that ranges between 0.02 and 0.03 per 1,000 population for cranial and facial implants and roughly 0.97 per 1,000 population for burr hole plugs.

Key markets value of SEK 5bn

Looking at the key markets of the US, Japan, Germany, France, UK, and the Nordic region, we estimate the company's total addressable market value at roughly SEK 5bn.

Geographical distribution of key markets value (SEKm)



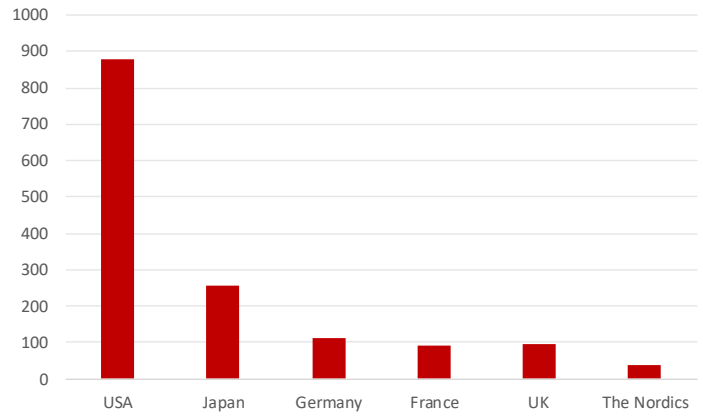
Source: Redeye Research

OssDsign Cranial

Patient-specific cranial implants make up the majority of implants and are expected to grow at a rate of just above seven percent annually in the coming years. Implants based on metal and polymer are expected to have the largest market share. Given that metal-based implants make up roughly 70 percent of the market, we view implants based on these materials to be the leading competitors to OssDsign's.

Considering the expected growth, we adjust OssDsign's estimates to be in line with 2020 figures – indicating roughly 33,000 implants. For its key markets, we estimate a potential volume of close to 19,000 implants – 58 percent of the total number of implants. Moreover, given an expected higher price level on these key markets, as opposed to the overall OECD market, we estimate a market value of roughly SEK 1,5bn.

OssDsign Cranial potential market value (SEKm)



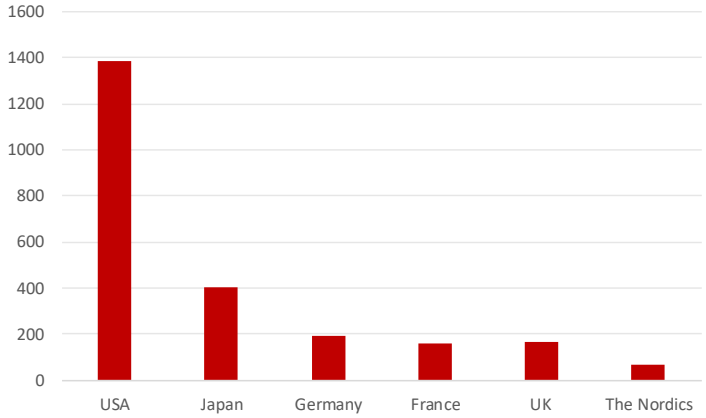
Source: Redeye Research

OssDsign CranioPlug

According to the World Stroke Organization and other industry sources, the total number of patients in the US and the EU who undergo surgery as a result of strokes, chronic subdural haematomas, or traumatic brain injuries amounts to 580,000. However, each patient is likely to have more than one burr hole (two to three is usual).

Adjusted for growth since OssDsign's CranioPlug market volume estimates (2016), we judge today's figures should be over 1,2m. For its key markets, we estimate a potential volume of 660,000 CranioPlugs – 54 percent of the total number of implants. We estimate that the addressable market for this product is close to SEK 2,4bn.

OssDsign CranioPlug potential market value (SEKm)

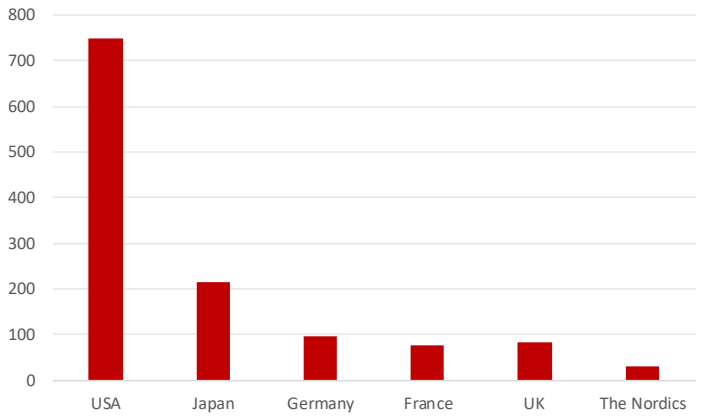


Source: Redeye Research

OssDsign Facial

The majority of facial implants are based on polymer materials, such as silicon. We estimate that the potential OECD market volume should amount to roughly 46,000 implants. For the key markets, we estimate a volume of approximately 27,000 – 58 percent of the total number of facial implants. The addressable market, we estimate to be around SEK 1,2bn.

OssDsign Facial potential market value (SEKm)



Source: Redeye Research

Coronavirus will affect 2020

We emphasize that our market value estimates do not consider the impact of the coronavirus on elective surgeries and decreased trauma cases. Actual overall market figures for 2020 should be less than we present in this report. However, given the lack of consensus on how much the outbreak will impact market values, we restrain from estimating its precise number.

Some reports and webinars have suggested an overall decrease of 30-40 percent in elective orthopaedics surgeries in Q2. In OssDsign's case, its Q2 2019 sales figures were up some eleven percent year-on-year, though down 50 percent quarter-on-quarter.

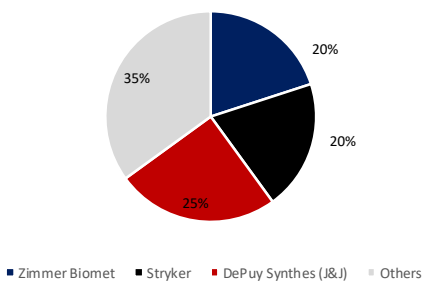
Our figures relate to pre-coronavirus estimates, and given an anticipated return-to-normal scenario, we argue that there is no particular long-term negative effect on OssDsign's potential. A decrease this year should not offset investor interest in OssDsign, particularly given the long-term horizon.

Competitive Landscape

Highly concentrated and demanding

The market for facial and cranial implants is highly concentrated, with a few orthopaedic mega-companies (DePuy Synthes, Stryker and Zimmer Biomet) making up roughly 65 percent of its revenue. Accordingly, it is a challenging environment in which to gain traction in the face of the established players' advantages – notably their financial muscle and, especially in a conservative field such as orthopaedics, long-standing market presence and customers relationships.

Market situation of cranial and facial implants



Source: Redeye Research, OssDsign

Looking for growth

The orthopaedic market is one of the largest but slowest growing medtech markets. According to Evaluate, it is set for CAGR of some 3.7 percent in the coming years. However, as growth in cranial implants is estimated at some 5-8 percent, it offers growth opportunities.

Moreover, the orthopaedics industry continues to see significant mergers and acquisitions activity. We identify the acquisition of 14 orthopaedics companies with average sales of USD 36m (range 5m-64m) between 2013 and 2019. This suggests that companies tend to acquire innovative smaller companies, once they have proved to generate sales. For this reason, we do not anticipate an eventual acquisition of OssDsign for many years to come.

SMEs acquisitions 2013-2019

Date	Company	Acquired by	Market	Sales (USD)	EV (USD)	EV/sales
2013	Biotech international	Wright	Extremities	15	80	5,3
	Trauson	Stryker	Spine, hip	60	685	11,4
2014	Small bone innovations	Stryker	Extremities	48	375	7,8
	TYRX	Medtronic	Medical devices	20	160	8,0
2015	TEI Biosciences	Integra LifeSciences	Reconstructive surgery	64	312	4,9
	Xspine	Bacterin	Spinal implant	42	90	2,1
	Medical innovations	Cantel Medical Corp.	Medical devices	24	80	3,3
	SurgiQuest	CONMED Corp.	Medical devices	48	265	5,6
	TriVascular Technologies	Endologix Inc.	Medical devices	32	211	6,6
2018	Cartiva	Wright	Synthetic cartilage implant	35	435	12,4
	Ceterix orthopaedics	Smith & Nephew	Meniscus repairs	5	105	21,0
2019	Vilex	OrthoPediatrics Corp.	Extremities	12	50	4,2
	Vertiflex	Boston Scientific	Spinal implant	60	465	7,8
	Paradigm Spine	RTI Surgical	Spinal implant	40	300	7,5
			Average	**36**	**258**	**8**
			Low	5	50	2,1
			High	64	465	21

Source: Redeye Research

If OssDsign manages to grow its number of delivered cranial implants significantly, it would be easier for the competition to sweep it up rather than putting focus and resources on developing a similar or superior implant. Though, as argued above, it is unlikely to occur in the short to medium term.

Until then, the biggest challenge for OssDsign is competing with smaller players and convincing surgeons to use its implants. These can be met through its extensive and growing clinical validation and increased sales and marketing activities.

Commercialization of the Product Portfolio

In the last couple of years, OssDsign has initiated and finalized several crucial activities for market launch and a coming sales ramp-up. Clinical validation and marketing efforts have led to impressive momentum, enabling broader clinical implementation for its cranial implants. We argue that its continued growth is supported by:

- **Regulatory approvals** – OssDsign Cranial has received regulatory approval in all of its markets.
- **Reimbursement in place** – OssDsign has checked this essential box required for broad implementation of the product (Cranial)
- **Controlling US operations** – Since Q4 2019, the company has operated in the US on its own accord after having launched with master distributor Matador Medical
- **Geographical expansion** – Sales were initiated in France earlier this year, and OssDsign is in discussions with a strategic distribution partner for the market. In August, OssDsign signed an agreement with Muranaka Medical Instruments for its launch in Japan
- **Additional value in the product portfolio** – In the coming years we expect OssDsign to accelerate its marketing efforts for the other products in its portfolio

Regulatory approval positions OssDsign for sales focus

Currently, OssDsign Cranial has regulatory approval on all of its key markets. OssDsign Cranioplug is approved for the EU and the US, and we anticipate a filing for the Japanese market sometime next year. Moreover, OssDsign Facial is currently approved for the EU market, and we expect an FDA filing next year for the US (510(k)) and potentially also the Japanese PMDA.

Regulatory approval is essential for the commercialization of any medtech company's product. We consider OssDsign's short- and medium-term potential to lie in the US and European markets, particularly for its cranial implant. As its key product has regulatory approval on its two most important markets, we argue that the company is not held back by any regulatory processes and may proceed with its sales and marketing activities.

Reimbursement, check!

In addition to regulatory approvals, cost coverage is essential for products to be clinically implemented by hospitals. In OssDsign's case, its cranial implant has access to healthcare payment systems in all of its key markets. This is an important step to clinically widening its utilization amongst practitioners.

Although reimbursement covers hospitals for the costs related to the indication or treatment of a patient, there are economic incentives for hospitals to either use less expensive products or products that reduce treatment costs (through less complications). In the US, the so-called DRG reimbursement system grants the hospital a fixed sum to cover the treatment of a specific diagnosis. This allows the hospital to make a profit if its costs are lower than the fixed amount and can be used to argue for the use of cheap products. However, if complications occur during a specific period after a patient's initial treatment, the hospital may have to carry the costs. For example, if infection occurs within the first three months of surgery, the hospital is responsible for taking that cost under the DRG system. Reducing the risk of infection could save hospitals a lot of money.

We emphasize that having reimbursement in place is no guarantee for sales and that before any device starts to generate sales, it will undergo extensive scrutiny before a potential purchase. In this case, the US hospitals' value analysis committee (VAC) will investigate

OssDsign's product offerings and determine if its implementation is of economic benefit to the hospital, amongst other criteria. These value analysis committee processes can take from one month up to nearly a year. Currently, OssDsign Cranial has 70 VAC approvals in the US, and CranioPlug has 25.

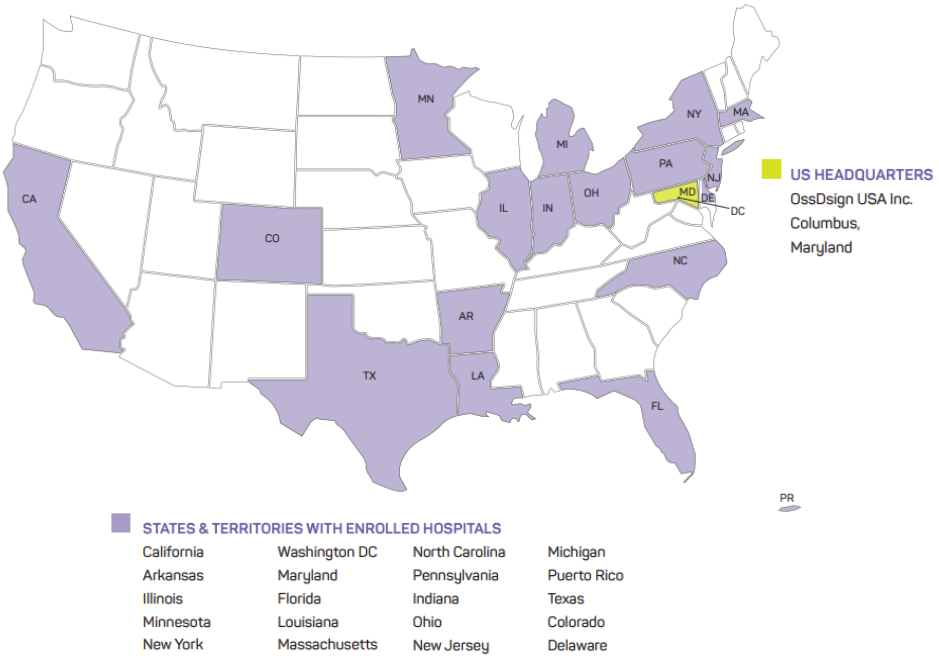
Taking control of its US operations

Roughly 50 percent of global medtech market sales come from the US. This is mainly thanks to considerably higher reimbursements there than elsewhere, a high degree of innovation, and, of course, its large population. Consequently, the US market brings opportunities, and any medtech company that aims to make it big is likely to have a US focus. This is no different for OssDsign, which signed 24 new hospitals during 2019, reaching a total of 45 hospitals. Last year, 40 percent of sales came from its US operations, and we expect this market to account for the majority of sales in our forecast period.

Distributor phased out – improved US outlook

OssDsign launched its cranial implant together with its master distributor Matador Medical in 2017. Matador Medical focuses on introducing new medtech products to the US market, and the plans and agreements between the two said that OssDsign would successively take over the US operations. The transition was completed in Q4 last year, and OssDsign has since strengthened its local presence with three technical sales managers and an operations director based at OssDsign's wholly-owned subsidiary in Columbia, Maryland. Obviously, we anticipate an expanded force in the US to fully capitalize on OssDsign Cranial, Cranioplug, and its new sales model. Establishing agreements with independent distributors to widen market potential is a sound strategy once the demand for a certain product has gained traction, we argue. We also expect this greater control over its operations to allow for a more flexible business model and the termination of the agreement to increase margins.

US market outlook



Source: Redeye Research, OssDsign annual report 2019

Currently, the focus has been on metropolitan areas such as New York, Los Angeles, and Chicago and other areas with high population density. In total, OssDsign Cranial has been implemented at hospitals across 20 states, representing roughly 68 percent of the entire US population. Currently, OssDsign has signed +45 distributors giving some 140 salespeople.

Geographical expansion plays an important part

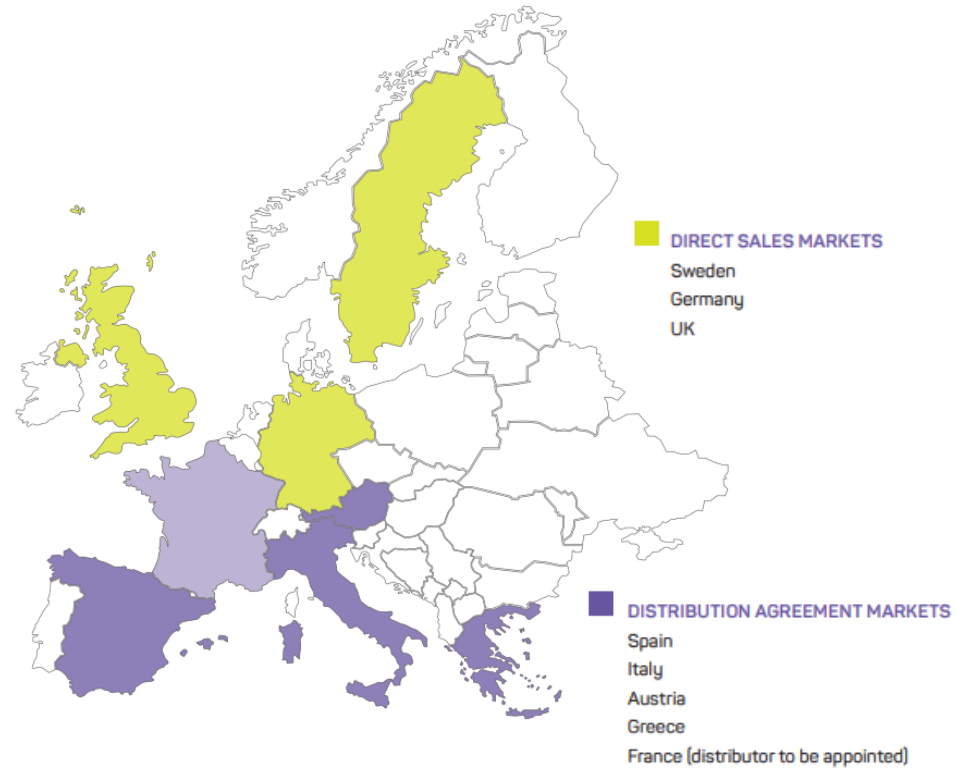
Besides its current market presence and the importance of the US for its growth potential, we regard the geographical expansion in France and Japan as of great significance.

Europe is set for growth

Earlier this year, the first sales were recorded in France as orders of OssDsign Cranial were placed even before a distributor agreement has been signed. In Europe, OssDsign had a base of some 83 hospitals as of the end of 2019. We estimate Germany accounts for roughly 18 percent of all neurosurgeries in Europe (but only 11 percent of the population), making it an important market for OssDsign, particularly as the company uses a direct sales model there – currently making up roughly 33 percent of EU sales.

In the coming years, we argue that the European market will show impressive as we anticipate a continuous clinical implementation of its implants. Considering that OssDsign has already gained market access to many European countries, activities can adhere to a sales focus.

EU market outlook



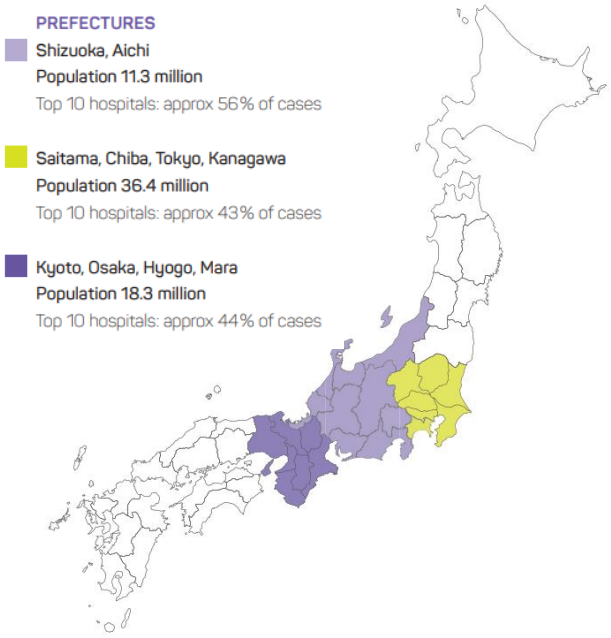
Source: Redeye Research, OssDsign annual report 2019

Becoming big in Japan

In Japan, nationwide reimbursement was achieved shortly after regulatory approval this spring. Given that Japan is the second-largest medtech market in the world, we see great long-term potential for OssDsign Cranial there, particularly as it has attracted one of the country's most profiled neurosurgeons, Professor Takuji Yamamoto, as its KOL.

As in the US, OssDsign's strategy in Japan is to focus on highly populated areas; in this case, three prefectures totalling roughly 50 percent of the Japanese population. The top ten hospitals in these regions represent approximately 43 to 56 percent of the procedures for each region or around 25 percent of the entire volume.

Japanese market outlook



Source: Redeye Research, OssDsign annual report 2019

Expanding the direct sales model in the long term

Although the geographical expansion is likely to be conducted with a distributor sales model, we argue that OssDsign will approach several of its key markets using a direct sales model in the future. Currently, direct sales have been implemented in Sweden, Germany, and the UK. It is difficult to predict which of its distributor markets would be replaced with a direct sales model, and we do not expect this in the short term. However, countries with a higher degree of implant use, focus on innovation, and high reimbursements are good candidates, such as France.

UK NHS contract eases sales activities

Since Q4 2019, OssDsign has had a contract with the UK's National Health Service (NHS). This has provided the opportunity to increase sales on the UK market significantly as this is a full nationwide agreement for the products for all 1,600 NHS hospitals. The hospitals are now able to order OssDsign's implants through the NHS network with harmonized prices across all connected hospitals. Inclusion in the NHS agreement strengthens the validation of the product and reduces administrative work.

Additional value in the product portfolio brings long-term value

Given the expected strengthened clinical validation of OssDsign Facial and further commercialization of OssDsign CranioPlug, we argue that the company's product portfolio will widen its revenue source in the medium to long term.

Between the two additional products, we see the facial implant requiring a longer runway for commercialization, given its higher level of complexity compared with the burr hole plug. In addition, the company will have to target plastic and facial reconstructive surgeons as opposed to the neurosurgeons it is more used to working with, which is an obstacle for easing in a new product.

In our forecast period of 2020-2035, we expect most commercial efforts and sales growth to stem from its cranial implant. In the medium to long term, we believe facial implants will account for a substantial chunk of the value for the company, and CranioPlug to contribute rather modestly.

Research and development

The company conducts its research and development in Uppsala. At this site, OssDsign has a unit comprising of approximately four people. Currently, we expect that most of the work goes into the facial implant while there are two products in the pipeline, though in pre-clinical stages (spinal applications and dental/jaw implants). OssDsign has a research and development collaboration with the Department of Biomaterials at Ångström Laboratory, Uppsala University, where co-founder Håkan Engqvist is a professor and head of the department.

Recently, OssDsign announced positive interim results from its clinical study of 20 patients for its dental application. The results showed that the implantation of its calcium phosphate material ensued bone formation and anchoring of dental implants. We view these results as positive, further strengthening claims of its chemical properties, though commercialization being far away, currently. Consequently, in our sales forecast, we do not yet factor this in.

Patents

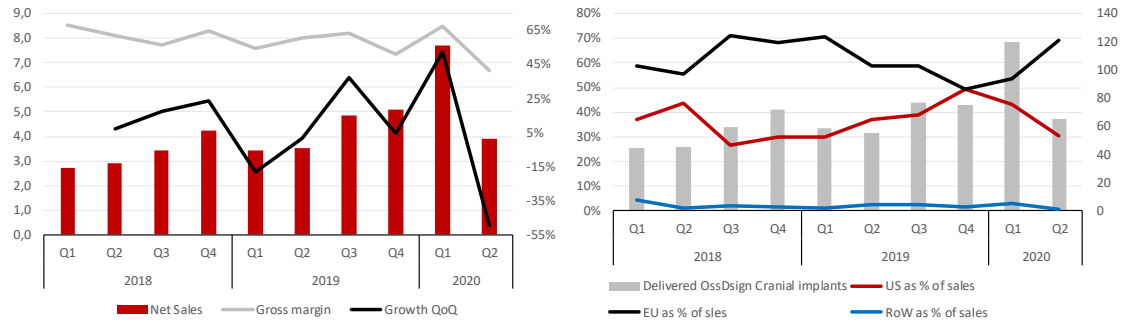
The company has several registered or pending patents in its portfolio, with expiration dates ranging from 2029 to 2036. We view its patent situation as solid for putting off any particular attack on its products as the patents stretch beyond our forecast period. After our forecast period, we expect OssDsign to have established a strong market presence, acting as a further competitive advantage once the patents begin to expire. For a list of its patents, we refer to the appendices.

2020-2035 Financial Forecast

Historical figures

In its first six months of 2020, OssDsign recorded sales of SEK 11,6m. While Q1 figures showed a 52 percent quarterly increase, COVID had a severely depressing impact on sales in Q2 – down 50 percent compared to Q1. However, Q2 still signified momentum (sales SEK 3,9m) comparing it to the same period for 2019 (SEK 3,5m). Going forward, as we have previously mentioned, we anticipate that physical restraints affecting its sales activities, and a postponement of elective surgeries will begin to ease off – opening up for OssDsign to continue on its trajectory in the short to medium term.

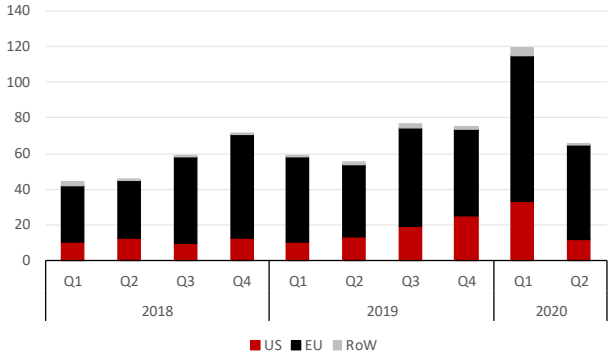
Net Sales figures FY2018-2H20 (left), geographical distribution, number of implants (right)



Source: Redeye Research

The most affected region in Q2 was the US, where we estimate that the number of OssDsign Cranial implants, compared to Q1, declined by some 65 percent. Moreover, we estimate that the number of Cranial implants in the EU dropped by only 35 percent. We argue that its traction on the EU market, with almost double the number of activated hospitals compared to the US, is the main reason for this lower decline.

Number of delivered OssDsign Cranial implants

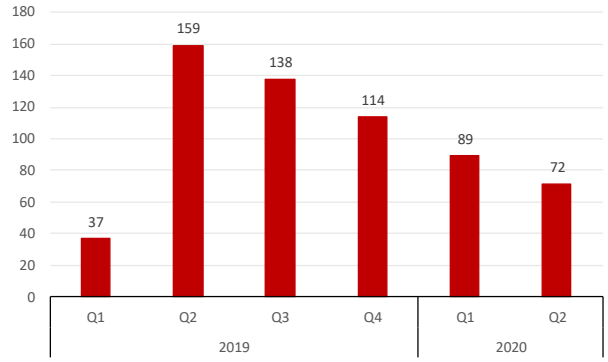


Source: Redeye Research

Financing and cash position

In 2019, OssDsign raised a total of SEK 215m (SEK 151m in the IPO and SEK 64m in a pre-IPO) and has since it went public (in Q2 of last year) had an average burn rate of SEK 22m per quarter. In line with increased selling and marketing activities required for sales growth, we expect it to increase in the coming years, though, turning around in 2023 and begin generating free cash flow by 2025. We anticipate an equity issue until so.

Historical cash position



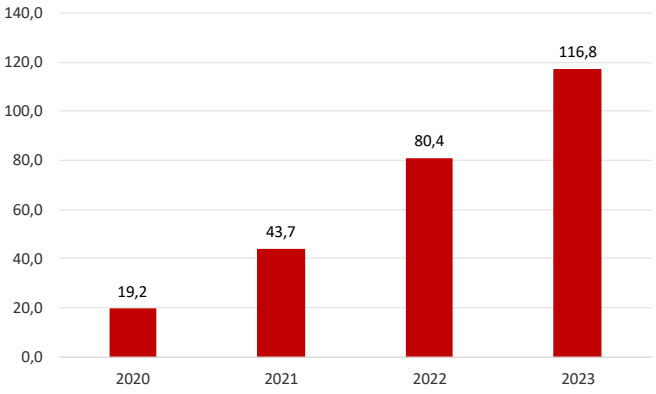
Source: Redeye Research

Cranial leads the way

We forecast that OssDsign Cranial will generate the majority of the company's sales in the 2020-2035 period for the following reasons;

- Regulatory approvals and cost coverage obtained on its key markets
- Commercial partnerships in place
- A higher anticipated price per procedure compared to the facial implant
- Extensive clinical validation

OssDsign Cranial: 2020-23 sales estimates (SEKm)



Source: Redeye Research

Regulatory approvals and cost coverage

Cranial has come the furthest of the company's products towards regulatory approval and cost coverage. Unlike the facial implant and CranioPlug, Cranial has checked all of the boxes required to enable sales and marketing. Accordingly, it will have the bulk of the company's initial commercial focus.

Partnerships

Moreover, OssDsign recently signed a partnership for the cranial implant's Japanese launch. We anticipate a distributor partnership for France closing in the coming months too and see these deals boosting sales significantly.

OssDsign's additional products are obvious candidates for the partners to take on in the future on the back of their experience of Cranial and existing relationships with the company.

Premium product

We estimate that the cranial implant will remain the highest priced product in the company's portfolio at roughly SEK 50,000 in Europe, SEK 100,000 in the US and SEK 75,000 in Japan.

Clinical validation supports sales ramp-up

Clinical validation of the product - based on some 800 cranial implants - supports its clinical use and boosts the outlook for further sales. With an increased focus on Facial in the years to come, we anticipate the facial implant's clinical validation being extended too.

Significant growth

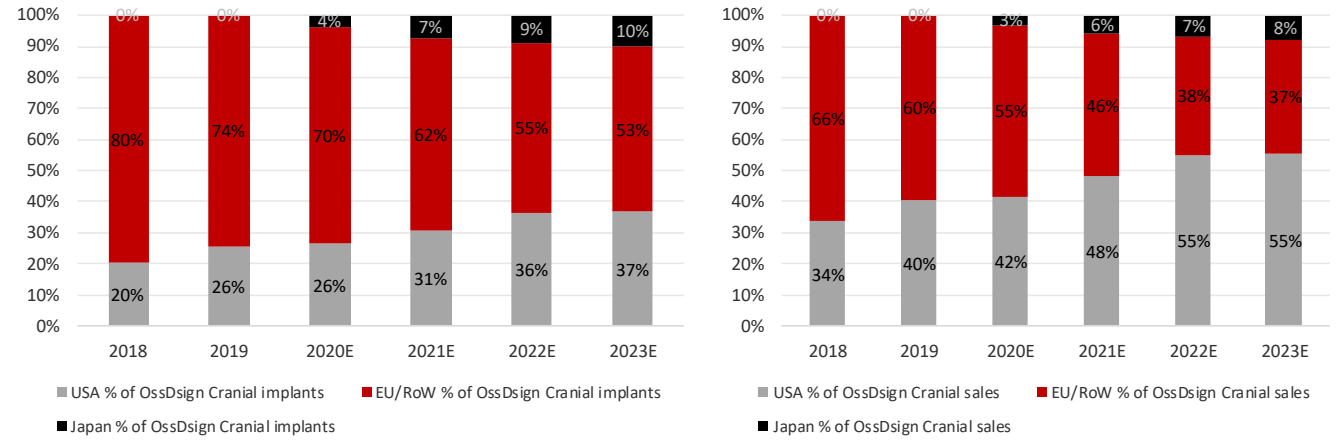
Growth in the number of procedures with the cranial implant will be fuelled by the following;

- Elective surgeries returning in the coming quarters, providing the opportunity to capitalize on a backlog of postponed cranial reconstruction surgeries
- Increasing uptake by hospitals in both the US and Europe, as well as launch in Japan
- Increased implementation rate at hospitals (rate of surgeons and rate of surgeries)

In total, Cranial has been surgically inserted in over 1,000 patients so far. We estimate that the total number of patients in 2019 undergoing a procedure using an OssDsign Cranial implant was around 260, with about three-quarters of the procedures taking place in Europe and the remainder in the US.

Going forward, we expect the European market to continue leading in the number of procedures compared to the US, given OssDsign's long-standing presence and accelerating growth into additional markets – most recently, France. However, given its higher price level, the US offers a greater financial opportunity and should comprise the majority of sales in our forecast period, followed by Europe and Japan.

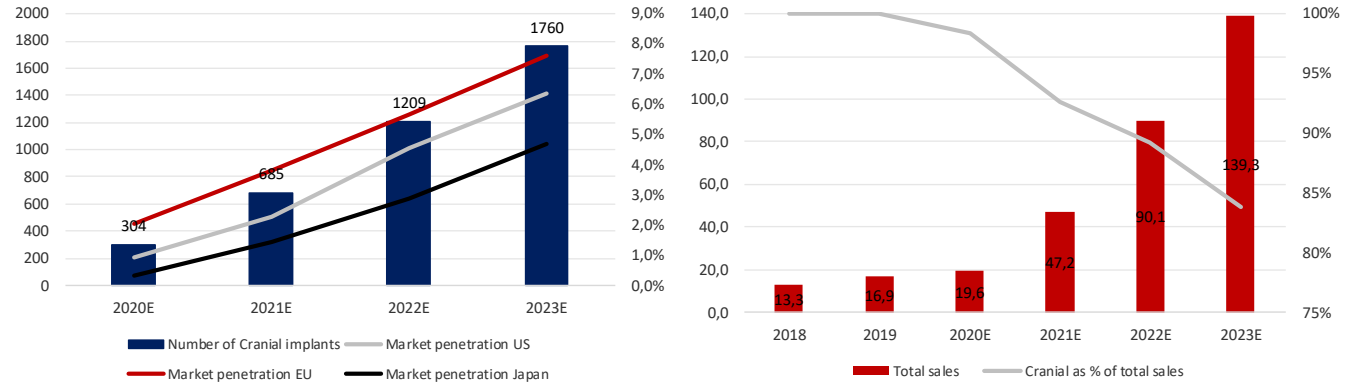
OssDsign Cranial: 2018-23 geographical distribution (SEKm)



Source: Redeye Research

We estimate that the number of cranial implants will exceed 300 this year and should pass 1,750 by 2023. This would significantly increase group sales, particularly after 2020, where we anticipate year-on-year growth of some 20 percent. Between 2020 and 2023, we expect hefty growth (CAGR) of 92 percent, which would take group sales to roughly SEK 140m by 2023.

OssDsign Cranial: 2020-23 market penetration (left) and percentage of total sales (right) (SEKm)



Source: Redeye Research

CranioPlug sales estimates

Moderate impact

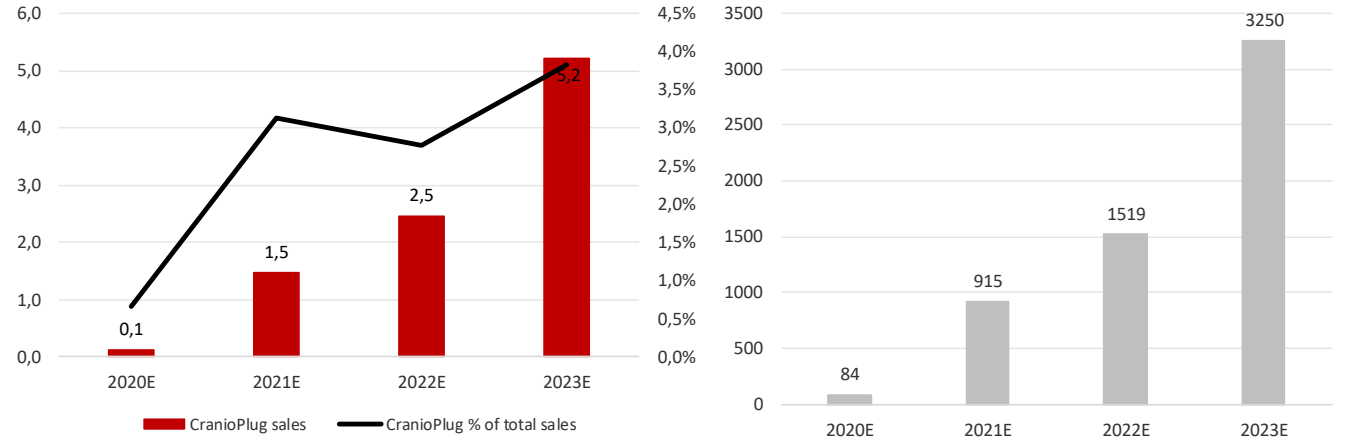
We expect OssDsign's off-the-shelf standardized burr-hole plug, CranioPlug, to only add moderately to sales. Given its current lack of extensive clinical data and existing products' relatively low rate of failure, as well as their lower implementation rate in Europe compared to the US, CranioPlug does not make up a significant part in our sales forecast.

Our rather low expectations of this product are further supported by input from an interview with an experienced neurosurgeon. In contrast, he praised Cranial – having used it in roughly 30 percent of his cranial reconstruction surgeries since 2016.

We see CranioPlug contributing roughly ten percent of total sales towards the end of the forecast period and no more than three to five percent of 2021-23 sales.

Note that as above, we estimate roughly two to three CranioPlugs per procedure. Accordingly, the number of products is greater than the number of patients estimated.

OssDsign CranioPlug: 2020-23 sales estimates (left) and number of products (right)



Source: Redeye Research

OssDsign Facial sales estimates

Long-term growth prospects

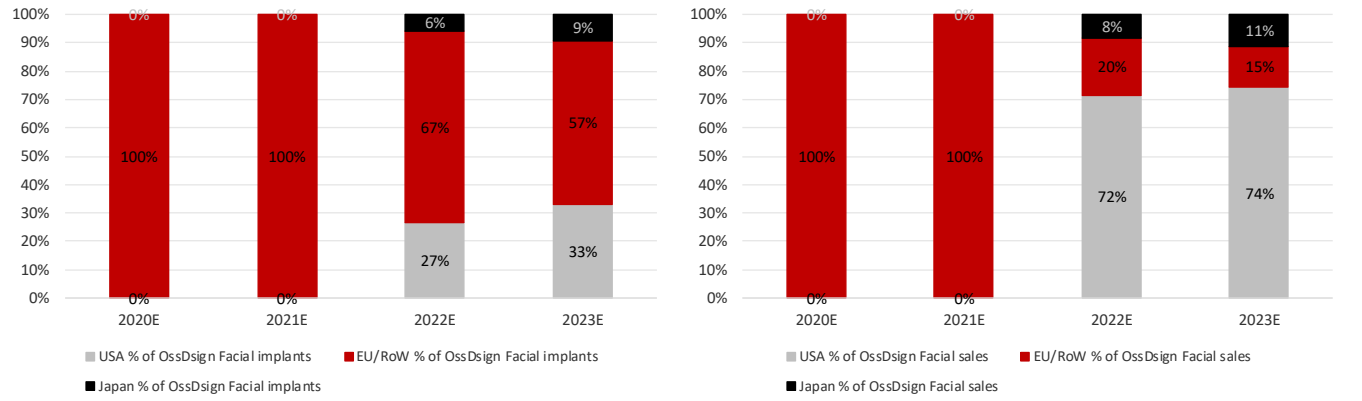
In view of its identical chemical composition to OssDsign Cranial, we expect the company's facial implant to generate significant long-term value. Once it obtains regulatory approvals and cost coverage in its key markets and is backed up by more extensive clinical data, we believe sales should start to take off.

From an initial spurt in 2022 Facial should rise to some 20 percent of sales by 2025, we forecast.

OssDsign's commercial strategy, setting up partnerships and establishing itself as an innovative company with its cranial implant, provides a template for the broader launch of its facial implant. However, we acknowledge the fact that this implant targets a different set of surgeons, mainly plastic surgeons rather than neurosurgeons. This will require OssDsign to convince a new customer group, which we judge will take some time given the industry's conservatism.

Currently, Facial only has regulatory approval in Europe, where it will be relaunched shortly after design improvements. We do not expect the implant to gain FDA 510(k) clearance or PMDA approval in Japan until 2022, following filings sometime in 2021.

OssDsign Facial: 2020-23 geographical distribution



Source: Redeye Research

We anticipate a rather quick ramp-up once Facial's broader launch has been rolled out, facilitated by regulatory approvals in the US and Japan, as well as inclusion in health care cost coverage systems in its key markets. In the period up to 2022, we expect the company to add to clinical validation for the facial implant, while the cranial implant's uptake should also increase awareness of the facial implant's properties and utility.

Note that we estimate roughly two OssDsign Facial implants per procedure. Accordingly, the number of products is greater than the number of patients estimated.

Total sales estimates

With an increasing number of hospitals using Cranial, we expect its implementation rate to increase in the years to come. As the company's other products obtain regulatory approval and cost coverage, their clinical implementation should take off too. We expect the US to contribute the majority of sales going forward, heavily tilted towards the cranial implant, which we also anticipate being the biggest seller.

OssDsign: 2020-25 total sales estimates

USA	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales	8,1	21,9	48,8	76,8	110,5	145,8
Cranial as % of sales	99,2%	95,8%	90,4%	84,3%	79,5%	74,9%
# of OssDsign Cranial	*80*	*210*	*441*	*647*	*878*	*1092*
CranioPlug as % of sales	0,8%	4,2%	3,1%	4,2%	4,6%	5,5%
# of OssDsign CranioPlug	*30*	*405*	*680*	*1429*	*2250*	*3544*
Facial as % of sales	0,0%	0,0%	6,5%	11,5%	16,0%	19,6%
# of OssDsign Facial	*0*	*0*	*105*	*295*	*588*	*953*
EU	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales	10,5	20,2	33,6	48,9	62,2	76,4
Cranial as % of sales	97,6%	93,1%	86,8%	82,7%	79,8%	76,4%
# of OssDsign Cranial	*204*	*400*	*630*	*889*	*1109*	*1317*
CranioPlug as % of sales	0,6%	2,7%	2,4%	3,2%	3,8%	4,5%
# of OssDsign CranioPlug	*54*	*510*	*773*	*1546*	*2319*	*3479*
Facial as % of sales	1,8%	4,2%	10,8%	14,1%	16,5%	19,1%
# of OssDsign Facial	*13*	*60*	*263*	*505*	*762*	*1098*
Japan	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales	0,6	3,8	6,0	11,0	18,6	26,3
Cranial as % of sales	100,0%	70,0%	92,5%	85,0%	82,9%	80,2%
# of OssDsign Cranial	*11*	*50*	*106*	*179*	*294*	*402*
CranioPlug as % of sales	0,0%	0,0%	1,3%	3,0%	3,7%	4,1%
# of OssDsign CranioPlug	*0*	*0*	*66*	*275*	*578*	*911*
Facial as % of sales	0,0%	0,0%	6,2%	12,0%	13,5%	15,7%
# of OssDsign Facial	*0*	*0*	*24*	*84*	*159*	*263*
Rest of World	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales	0,4	1,3	1,7	2,6	3,8	5,0
Cranial as % of sales	100%	97,1%	92,9%	89,3%	79,9%	75,9%
# of OssDsign Cranial	*9*	*25*	*32*	*46*	*61*	*75*
CranioPlug as % of sales	0%	2,2%	2,8%	4,0%	4,2%	5,0%
# of OssDsign CranioPlug	*0*	*26*	*43*	*91*	*144*	*223*
Facial as % of sales	0,0%	0,6%	4,2%	6,7%	15,9%	19,0%
# of OssDsign Facial	*0*	*2*	*5*	*16*	*25*	*37*
Total	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Sales	19,6	47,2	90,1	139,3	195,1	253,5
USA as % of sales	41,3%	46,4%	54,2%	55,1%	56,6%	57,5%
EU as % of sales	53,5%	42,9%	37,3%	35,1%	31,9%	30,1%
Japan as % of sales	3,1%	7,9%	6,7%	7,9%	9,5%	10,4%
RoW as % of sales	2,1%	2,8%	1,9%	1,8%	2,0%	2,0%
Cranial as % of sales	98,4%	94,9%	89,2%	83,9%	79,9%	75,9%
CranioPlug as % of sales	0,7%	3,2%	2,7%	3,8%	4,2%	5,0%
Facial as % of sales	1,0%	1,9%	8,0%	12,4%	15,9%	19,0%
# of OssDsign Cranial	*304*	*685*	*1209*	*1760*	*2342*	*2887*
# of OssDsign CranioPlug	*84*	*941*	*1562*	*3341*	*5291*	*8156*
# of OssDsign Facial	*13*	*62*	*396*	*901*	*1535*	*2350*

Source: Redeye Research

2020-35 income statement forecast

We estimate CAGR of 93 percent in the period 2020-23, 67 percent in the period 2020-25 and 26 percent in the period 2020-2035. We estimate a gross margin of some 77 percent next year, increasing each year towards a long-term level of 80 percent, mainly due to increased sales in the US.

OssDsign: 2020-35 income statement forecast

	2020E	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**	**2033E**	**2034E**	**2035E**
Net sales	20	46	90	139	195	253	319	382	452	505	550	585	607	627	641	654
Gross marign	*61%*	*77%*	*78%*	*78%*	*79%*	*79%*	*79%*	*79%*	*79%*	*79%*	*79%*	*79%*	*80%*	*80%*	*80%*	*80%*
Sales growth	*16%*	*136%*	*95%*	*55%*	*40%*	*30%*	*26%*	*20%*	*18%*	*12%*	*9%*	*6%*	*4%*	*3%*	*2%*	*2%*
EBIT	-85	-71	-55	-32	-1	21	45	71	121	156	186	207	215	223	226	230
EBIT margin	*-435%*	*-154%*	*-61%*	*-23%*	*0%*	*8%*	*14%*	*18%*	*27%*	*31%*	*34%*	*35%*	*35%*	*36%*	*35%*	*35%*
Taxes	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*-5*	*-41*	*-42*	*-44*	*-44*	*-45*
Net income	**-85**	**-72**	**-57**	**-35**	**-5**	**17**	**40**	**65**	**114**	**149**	**173**	**158**	**164**	**169**	**172**	**175**

Source: Redeye Research

Cash flow-positive in 2025

Our forecast anticipates significant growth in other external and personnel costs due to increased commercial, regulatory and clinical activity. With a growing number of implants to be designed and manufactured, the number of CAD engineers will be crucial for OssDsign to deliver and capitalize on its growth prospects.

We estimate that personnel costs will equate to around 50 percent of sales in the coming years, though trending downwards thanks to increased scalability from technical advances in production and design. Towards the second half of the period, we estimate that personnel costs will decline towards 40-36 percent of sales.

We estimate that other external costs will be at roughly 50 percent of sales during the forecast, mainly driven by geographical and product expansion through partnerships.

Against this background, OssDsign should reach a positive EBIT margin in 2025 and positive cash flow in the same year. EBIT should increase once focus shifts from the top to the bottom line as its products (primarily Cranial and Facial) establish themselves in the market more sustainably.

Equity issue to fund growth

At the end of Q2 20, OssDsign reported a net cash position of some SEK 72m, with a cash burn of roughly SEK 17m compared to Q1. We anticipate the cash burn increasing over the remainder of the year and factor in OssDsign issuing additional equity in the next six months.

In total, we estimate that an additional SEK 150m is required until the company turns cash flow-positive in 2025.

Valuation of OssDsign

Our valuation of OssDsign is based on a discounted cash flow (DCF) model. Our fundamental long-term analysis suggests upside of some 60 percent from current levels to our base case of SEK 28 per share.

The share has seen a consecutive upward moment in recent months, which we expect to remain as confidence in its sales growth potential strengthens going forward on the back of quarterly reports and recent milestones showing progress.

Fair Value Range – scenario-based approach

At Redeye, we approach the valuation of a stock through a set of three scenarios to provide a more dynamic view of the case.

Of the three scenarios, the Base Case is the one we judge most likely. Our bull and bear cases reflect more optimistic and pessimistic scenarios (valued at +100 percent and -50 percent versus the share's current levels, respectively).

Base Case – SEK 28 per share, 60 percent upside

Our Base Case is based on the following;

- Aggressive sales growth for Cranial in the coming year, bolstered by an increased number of hospitals and implementation rate to address the elective surgery backlog
- Sales to reach some SEK 47m in 2021 and SEK 90m in 2022, with a positive EBIT margin achieved by 2025 by when sales should be some SEK 250m
- Positive cash flow in 2025, requiring a total additional capital raise of SEK 150m
- A US market share of around 12-13 percent for its cranial and facial implants in the second part of the sales forecast; similar figures for Europe and Japan too

OssDsign: Base Case

Assumptions		Fundamental value	
CAGR sales 2020 - 2023	92%	Discounting factor	13%
CAGR sales 2020 - 2035	26%	Value of equity	497
		Value per share	**28**
Terminal		Current share price	17,7
EBIT margin	35%		
Growth	2%	**Potential**	**58%**

Source: Redeye Research

- **Bear Case – SEK 10 per share, 45 percent downside**

  In our pessimistic scenario, we expect a slower implementation rate amongst neurosurgeons of both OssDsign Cranial and CranioPlug, and a prolonged regulatory and cost coverage process of its facial implant on the US and Japanese market.

  We estimate sales of SEK 22m next year and SEK 37m in 2022 and SEK 69m in 2023. We forecast a market share of six to seven percent of its cranial implant in the US, EU and Japan towards the end of the period with an EBIT margin of 25 percent.

- **Bull Case – SEK 40 per share, 125 percent upside**

  In our optimistic scenario, we expect that US operations accelerate aggressively with the new sales model and that the relaunch of OssDsign Facial in the EU succeeds. Additional clinical studies for the facial implant open up for a rapid US and Japan sales ramp up after introduction in 2022, fuelled by the success and awareness from its cranial implant.

  We estimate sales of SEK 52m next year, followed by SEK 130m in 2022 and SEK 200m in 2023. We expect a positive cash flow in 2023 and a growing EBIT margin in the years after, reaching 40 percent towards the end of the forecast period.

Sensitivity Analysis

The WACC reflects risks related to the company and the market. The WACC is used when calculating the discounted cash flow and has a great impact on the valuation. Because of its impact, we illustrate what value our models would indicate when applying changes to the WACC.

WACC and value per share

	WACC				
	11%	12%	13%	14%	15%
Market Capitalization	709	585	497	408	337
Value per share	40	33	28	23	19

Source: Redeye Research

Appendices

Appendix 1 – Management

Morten Henneveld, CEO

- Born: 1976
- At OssDsign since: September 2020
- Experience: Most recently, Senior Vice President, Business Transformation and Strategy, member of the Executive Leadership Team at GN Hearing. Vice President at Zimmer Biomet EMEA Spine division (2012-2016) and President Zimmer Biomet Spine manufacturing in France. Extensive and international medtech experience with a period in the US during his years at Coloplast (2008-2012)
- Education: MSc. International Business Administration, Copenhagen Business School, Denmark
- Holdings: 0 shares, 0 warrants

Claes Lindblad, CFO

- Born: 1967
- At OssDsign since: 2016
- Experience: 25 years of experience from leading roles within finance, sales and marketing in the life science industry
- Education: MSc. Chemical and administrative sciences from Karlstad University
- Holdings: 500 shares, 61,166 warrants

Henrik Hjort, Director Marketing & Business Development

- Born: 1977
- At OssDsign since: 2015
- Experience: Co-founder of Novus Scientific and global product manager. Over 15 years' experience in the life science field from marketing, sales, corporate governance and development. Experience from start-ups and multi-national companies
- Education: MSc. Biotechnology Engineering from Uppsala University, Sweden, as well as economy and entrepreneurship at Cornell University, New York, USA
- Holdings: 500 shares, 24,466 warrants

Kajsa Björklund, Director Technical Operations

- Born: 1973
- At OssDsign since: 2016
- Experience: Director Project Management, Global R&D at Thermo Fischer Scientific. Nearly 20 years' experience from the life science industry with a focus on medtech
- Education: MSc. Chemistry from Uppsala University. PhD. Inorganic Chemistry, Uppsala University. Executive MBA from Mgruppen Svenska Managementgruppen AB
- Holdings: 3,000 shares and 24,466 warrants

Malin Kylberg, Director Quality Assurance & Regulatory Affairs

- Born: 1969
- At OssDsign since: 2017
- Experience: Quality manager at Recipharm Uppsala AB. Has worked with quality assurance in the life science industry for over 20 years, with experience from quality work and regulatory issues
- Education: MSc. Natural sciences and mathematics from Uppsala Unviersity
- Holdings: 4,000 shares and 24,466 warrants

Rick Thomas, VP Commercial Operations

- Born: 1974
- At OssDsign since: 2016
- Experience: 20 years' experience from medtech and pharmaceuticals from both larger organizations (Medtronic) and companies in a start-up phase. Management member of Apatech (orthobiologics company) which was acquired by Baxter for around USD 330m in March 2010
- Education: BSc. Science in pharmacology from Sheffield University, UK
- Holdings: 2,500 shares and 85,632 warrants

Ulrik Birgersson, Director Clinical Engineering

- Born: 1979
- At OssDsign since: 2016
- Experience: Director of Clinical Engineering at SciBase AB. Over 15 years of life science industry experience with focus on pre-clinical and clinical studies as well as trial applications
- Education: MSc. Computer Technology Engineering at KTH as well as PhD. From Karolinska Institutet
- Holdings: 1,600 shares and 24,466 warrants

Appendix 2 – Board of Directors

Simon Cartmell, Chairman of the Board

- Born: 1960
- Chairman of the Board since: 2016
- Experience: 35 years' experience in senior executive and Board positions in listed and private companies within the life science industry, either directly or as an Operating Partner at UK based VC firms. Simon is also a board member of orthobiologics company BONESUPPORT
- Education: BSc. Medical Microbiology from the University of Manchester, as well as a MSc. Management and Economics from the University of London
- Holdings: 27,500 shares and 122,322 warrants

Anders Qvarnström, Board member

- Born: 1960
- Board member since: 2019
- Experience: 35 years' international experience from listed and private medtech companies. Global experience from running and setting up sales and marketing in the US, EU and Japan
- Education: MSc. Chemical Engineering from KTH
- Holdings: 11,000 shares and 30,583 warrants

Håkan Engqvist, co-founder of OssDsign

- Born: 1972
- Board member since: 2016
- Experience: Lengthy research experience focusing on bioceramic materials. Primary inventor of OssDsign Cranial. Experience from founding other companies and board positions in other medtech companies
- Education: Civ. Engineer in material sciences at Uppsala University
- Holdings: 224,000 shares and 122,332 warrants

Newton Aguiar

- Born: 1964
- Board member since: 2019
- Experience: Senior Healthcare Advisor in Warburg Pincus and partner and Head of Europe for Avista Capital. Currently board member of Intervacc, with considerable experience from other boards
- Education: BSc. Chermistry from McGill University, MBA from JL Kellog Graduate School of Management, Northwestern University, USA
- Holdings: 41,600 shares and 30,583 warrants

Viktor Drvota

- Born: 1965
- Board member since: 2016
- Experience: CEO of Karolinska Development, several board positions throughout the life science field with over 18 years' experience. Responsible for life science at SEB Venture Capital (2002-2016)
- Education: MD, PhD, Assoc Prof in Cardiology at Karolinska Institute
- Holdings: -

Appendix 3 - Patents

Table of patents

Patent	Description	Registered	On-going requests	Expiration
FP1336, Ceramic materials I	Ceramic composition and pre-blended cement	US	EU	2029-11-12
FP1551, Craniomasaic I	Design of OssDsign Cranial	US, EU, China, Hong Kong, Japan, Australia, South Africa, South Korea	India, Brazil	2031-03-10
FP1780, Ceramic materials II	Enhancements, longer durability and temperature resistance	US	-	2032-09-10
FP1781, Ceramic materials III	Porosity, particle size in cement	US	-	2032-09-10
FP1821, CranioPlug	First design	US, EU, China, Hong Kong, Japan, Australia	South Africa, South Korea, India, Brazil	2032-08-21
FP1973, Ceramic pyrophosphate	Composition of calcium pyrophosphate concentrations	US, EU, China, Japan, Australia	Hong Kong, South Africa, South Korea, India, Brazil	2033-12-16
FP1992, Craniomosaic II	Design of OssDsign Cranial 2D	US, China	EU, Hong Kong	2034-02-12
FP2234, Craniomosaic 3D	Design of OssDsign Cranial 3D	-	US, EU, China, Hong Kong, Japan, South Korea, South Africa, Australia, India, Brazil	2034-08-13
FP2357, Ceramic materials V	Method related to microporous ceramics	-	US, EU, China	2035-04-02
FP2431, Ceramic materials VI	Ceramic composition of calcium pyrophosphate	-	US, EU	2036-09-23
FP2448, Facial	Design of OssDsign Facial	-	US, EU	2036-11-23
FP2449, Ceramic materials VII	Cement formulation	-	US	-
FP2450, CranioPlug II	Design of CranioPlug II	-	US	-

Source: Redeye Research, OssDsign

Summary Redeye Rating

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

Rating changes in the report

People: 3

Business: 3

Financials: 1

INCOME STATEMENT	2018	2019	2020E	2021E	2022E
Net sales	13	17	20	46	90
Total operating costs	-60	-96	-99	-115	-144
EBITDA	-46	-80	-80	-69	-53
Depreciation	-4	-4	-5	-2	-2
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	-50	-84	-85	-71	-55
Share in profits	0	0	0	0	0
Net financial items	-6	0	0	-1	-2
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-56	-84	-85	-72	-57
Tax	0	0	0	0	0
Net earnings	-56	-84	-85	-72	-57

BALANCE SHEET	2018	2019	2020E	2021E	2022E
Assets					
Current assets					
Cash in banks	14	114	33	-33	-99
Receivables	23	8	9	14	23
Inventories	1	2	2	5	9
Other current assets	0	0	0	0	0
Current assets	39	123	44	-15	-68
Fixed assets					
Tangible assets	5	4	13	12	14
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
O intangible rights	29	26	27	23	25
O non-current assets	0	0	0	0	0
Total fixed assets	33	30	40	35	40
Deferred tax assets	0	0	0	0	0
Total (assets)	72	153	84	20	-28
Liabilities					
Current liabilities					
Short-term debt	19	15	15	16	17
Accounts payable	0	0	16	23	30
O current liabilities	0	0	0	0	0
Current liabilities	19	15	31	39	47
Long-term debt	5	3	3	4	4
O long-term liabilities	0	0	0	0	0
Convertibles	0	0	0	0	0
Total Liabilities	24	18	34	42	51
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	47	135	50	-22	-79
Minority interest (BS)	0	0	0	0	0
Minority & equity	47	135	50	-22	-79
Total liab & SE	72	153	84	20	-28

FREE CASH FLOW	2018	2019	2020E	2021E	2022E
Net sales	13	17	20	46	90
Total operating costs	-60	-96	-99	-115	-144
Depreciations total	-4	-4	-5	-2	-2
EBIT	-50	-84	-85	-71	-55
Taxes on EBIT	0	0	0	0	0
NOPLAT	-50	-84	-85	-71	-55
Depreciation	4	4	5	2	2
Gross cash flow	-47	-80	-80	-69	-53
Change in WC	-24	15	15	0	-6
Gross CAPEX	-37	-1	-16	4	-7
Free cash flow	-108	-66	-81	-66	-67

CAPITAL STRUCTURE	2018	2019	2020E	2021E	2022E
Equity ratio	66%	88%	59%	-111%	279%
Debt/equity ratio	51%	13%	37%	-87%	-27%
Net debt	10	-96	-15	52	120
Capital employed	58	40	35	30	41
Capital turnover rate	0.2	0.1	0.2	2.3	-3.2

GROWTH	2018	2019	2020E	2021E	2022E
Sales growth	0%	27%	16%	136%	95%
EPS growth (adj)	0%	0%	0%	-16%	-21%

DCF VALUATION		CASH FLOW, MSEK	
WACC (%)	13.0 %	NPV FCF (2020-2021)	-184
		NPV FCF (2022-2028)	102
		NPV FCF (2029-)	475
		Non-operating assets	114
		Interest-bearing debt	-18
		Fair value estimate MSEK	489
Assumptions 2020-2026 (%)			
Average sales growth	59.3 %	Fair value e. per share, SEK	27.6
EBIT margin	-93.1 %	Share price, SEK	18.5

PROFITABILITY	2018	2019	2020E	2021E	2022E
ROE	0%	-92%	-92%	0%	0%
ROCE	-140%	-74%	-77%	-218%	180%
ROIC	0%	-146%	-214%	-202%	-184%
EBITDA margin	-350%	-471%	-407%	-151%	-59%
EBIT margin	-378%	-496%	-435%	-154%	-61%
Net margin	-422%	-500%	-437%	-156%	-63%

DATA PER SHARE	2018	2019	2020E	2021E	2022E
EPS	0.00	0.00	-4.81	-4.06	-3.20
EPS adj	0.00	0.00	-4.81	-4.06	-3.20
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	0.00	0.00	-0.82	2.94	6.79
Total shares	0.00	0.00	17.73	17.73	17.73

VALUATION	2018	2019	2020E	2021E	2022E
EV	10.1	-95.5	313.4	380.2	448.5
P/E	0.0	0.0	-3.8	-4.6	-5.8
P/E diluted	0.0	0.0	-3.8	-4.6	-5.8
P/Sales	0.0	0.0	16.8	7.1	3.6
EV/Sales	0.8	-5.7	16.0	8.3	5.0
EV/EBITDA	-0.2	1.2	-3.9	-5.5	-8.4
EV/EBIT	-0.2	1.1	-3.7	-5.3	-8.2
P/BV	0.0	0.0	6.6	-14.8	-4.2

SHARE PERFORMANCE		GROWTH/YEAR	18/20E
1 month	25.4 %	Net sales	21.4 %
3 month	51.6 %	Operating profit adj	30.3 %
12 month	-21.6 %	EPS, just	0.0 %
Since start of the year	7.6 %	Equity	2.5 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES

SHARE INFORMATION	
Reuters code	
List	
Share price	18.5
Total shares, million	17.7
Market Cap, MSEK	328.1

MANAGEMENT & BOARD	
CEO	Morten Henneveld
CFO	Claes Lindblad
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Chairman	Simon Cartmell

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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 (2020-09-16)

Rating	People	Business	Financials
5p	16	12	3
3p - 4p	109	86	35
0p - 2p	4	31	91
Company N	129	129	129

Duplication and distribution

CONFLICT OF INTERESTS

Oscar Bergman owns shares in the company: No
Anders Hedlund 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.