

# OssDsign

Sector: Medtech

## While adding potential, acquisition prompts questions on financing

Redeye raises its long-term estimates and valuation somewhat following OssDsign's broadening towards synthetic bone grafts for spinal fusion through the acquisition of Sirakoss. We have a relatively conservative stance on the new product's sales potential at present, though increased clinical validation and demonstrated commercial interest could prompt a reassessment further out.

### Broadening its market potential

Adding a product for spinal fusion surgery opens a market worth some USD 2.4bn, fivefoldings OssDsign's market potential. However, limited pre-clinical data and no historic sales do not speak in favour of a rapid sales ramp-up – we expect extensive commercial activity in the coming years to capitalize on this acquisition. However, we identify several synergies between the existing commercial platform and the new product offering, which could ease the introduction of the new product.

### A slight increase in long-term sales estimates

We do not forecast any particular increase in sales in the coming years. However, we estimate that the new product will make up some 10% of total sales towards the second half of our 2020-2035 forecast period. We still expect a positive EBIT and cash flow in 2025 with sales of SEK 274m.

### Equity issue in play, share momentum on halt

We estimated a financing need of SEK 150m until reaching positive cash flow in our initial report. With the acquisition, the capital need grows larger, especially in the short-term given the cash instalments for next year of some SEK 50m. Though we expect the company to continue its success with its cranial implants in the short-term, stock market sentiment is likely to be hesitant until the financing has been successfully addressed.

### New Base Case of SEK 26

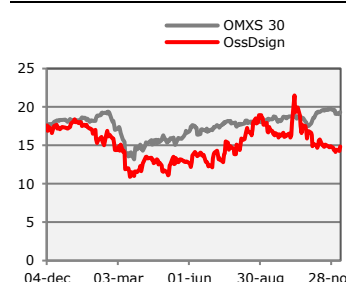
Our fundamental analysis presents an updated Base Case value of SEK 26 per share. The coming quarters' sales growth continues to be the most critical catalysts. Still, we argue that the share will likely not regain its momentum sustainably until OssDsign has a stronger financial position. Indeed, we expect equity issuance during 1H'21.

| KEY FINANCIALS (SEKm) | 2018 | 2019 | 2020E | 2021E | 2022E | 2023E |
|-----------------------|------|------|-------|-------|-------|-------|
| Net sales             | 13   | 17   | 25    | 46    | 92    | 146   |
| EBIT                  | -50  | -84  | -81   | -74   | -70   | -45   |
| EPS                   | n/a  | -4.8 | -3.7  | -3.4  | -3.2  | -2.1  |
| EV/Sales              | n/a  | 12   | 12    | 6.2   | 3,1   | 2     |

### FAIR VALUE RANGE

| BEAR | BASE | BULL |
|------|------|------|
| 10   | 26   | 37   |

### VERSUS OMXS30



### REDEYE RATING



### KEY STATS

|                          |             |
|--------------------------|-------------|
| Ticker                   | OSSD        |
| Market                   | First North |
| Share Price (SEK)        | 14.2        |
| Market Cap (MSEK)        | 251         |
| Net Debt 20E (MSEK)      | -38         |
| Free Float               | 57%         |
| Avg. daily volume ('000) | 127         |

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## Broadening its market potential

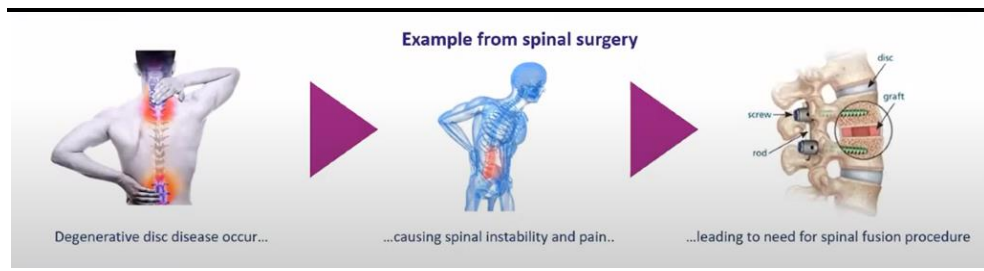
The acquisition of Sirakoss increases OssDsign's market potential upwards of USD 3bn from previously USD 0.6bn; however, we judge that its potential to capitalize on this is speculative and difficult to predict at this stage.

We emphasize that its limited pre-clinical validation and no historic sales put the product (Osteo3 ZP Putty) at the bottom of a steep hill guarded by fierce competition. However, we identify several synergies for OssDsign with its US customer base and sales organization, which could help in the commercial roll-out. In addition to this, OssDsign's board of directors and management have significant experience in the field of spinal orthopedics, making the acquisition interesting in a long-term perspective.

### Sirakoss' Osteo3 ZP Putty target great unmet medical need

Patients who suffer from degenerative disc disease (a medical condition where the cartilage between two vertebrae wears out) are subject to mechanical pain and spinal instability. The surgical procedure known as spinal fusion aims to decompress and stabilize the patient's spine by fusing vertebrae back together.

#### Degenerative disc disease and spinal fusion



Source: Redeye Research, company data

The procedure may be conducted using bone from either the patient (autograft) or a deceased donor (allograft) or synthetic materials. The first step is to decompress the spine by removing a portion of the vertebrae/spinal ligaments before packing the bone graft or synthetic material between the vertebrae. Once packed, the goal is to make them heal together. However, roughly 35% of these surgeries have unsuccessful outcomes, indicating a substantial unmet medical need for more effective spinal fusion surgeries – especially considering its volume of 1.5 million annual surgeries in the US alone.

### Osteo3 ZP Putty



Source: Redeye Research, Spinalnews International

Osteo3 ZP Putty is a synthetic bone graft substitute based on a calcium phosphate material, which has shown osteoinductive capacity in pre-clinical data. While allograft and autograft have osteoinductive traits (undifferentiated cells developing into bone producing cells), synthetic materials struggle with this. Though the clinical data is limited for Osteo3 ZP Putty, we argue that such a trait certainly is exciting.

*Walsh et al. 2020*

The study aimed to evaluate the in-vivo response of Osteo3 ZP Putty combined with autograft, compared to autograft and a collagen-biphasic calcium sulphate in combination with autograft, in a rabbit spinal fusion model.

Three groups were constructed with a total of 70 rabbits by;

1. Autograft alone
2. Osteo3 ZP Putty + autograft
3. Collagen-biphasic calcium phosphate putty + autograft

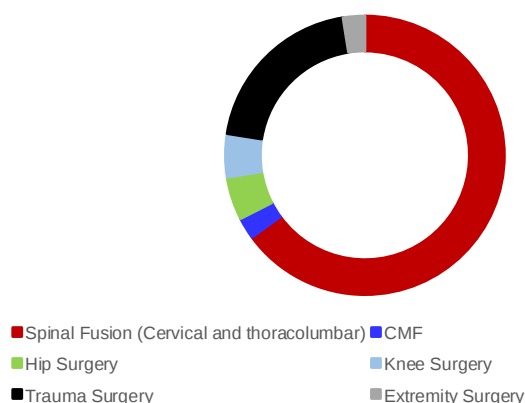
Based on 26 weeks with fusion assessment at week 6, 9, 12 and 26, histology showed normal healing and an increase in bone remodelling with the use of Osteo3 ZP Putty in combination with autograft at all timepoints. New bone formation on the material surface was also observed, while this was not seen on the collagen-biphasic calcium phosphate putty. At the last time point (week 26), histology showed a consistent bridging of bone between the transverse processes in Osteo3 ZP Putty and autograft – this was not the case for the collagen-biphasic calcium phosphate putty group.

The authors argue that such a solution, such as Osteo3 ZP Putty, could eliminate the need for excessive autograft harvest in spinal fusion surgery. While positive, we do not expect orthopaedic surgeons to adapt this product to a particularly great extension without further clinical data on humans.

### Market background

The global market for bone grafts is estimated at roughly USD 4bn and is expected to grow with a CAGR of some 8%. Sirakoss' Osteo3 ZP Putty targets the bone graft market for cervical and thoracolumbar spinal fusion, valued at approximately USD 1.8bn in the US. On a global level, this number corresponds to USD 2.6bn.

### Global distribution of bone graft market value



Source: Redeye Research, company data

We view the US as the clear market to target with the new product for several reasons;

- 70% of the total value of the bone graft spinal market
- FDA approval in place
- Established and growing customer base with its cranial implants
- Less fragmented hospital market than in Europe, easing the complexities surrounding commercial activities

**While the product does have a 510(k) approval, it currently does not hold a CE-mark.**

We anticipate regulatory processes to commence sometime during next year or early 2022 and estimate sales from the EU by 2023.

The orthopaedics market is dominated by a few large players; Zimmer Biomet, Depuy Synthes, and Stryker. These giants provide comprehensive product offerings to its customers, causing hurdles for smaller companies to access hospitals with their solutions. Moreover, behavioural change amongst orthopaedic surgeons is hard to impact, signifying the importance of clinical validation and relationship building between customer and company. Though OssDsign has succeeded and continues to thrive in its construction of a customer base, the implementation of Osteo3 ZP Putty is likely to take time.

#### **Capitalizing on the acquisition**

We identify several synergies between the commercial platform for its cranial implants and Osteo3 ZP Putty, specifically;

- Surgeon overlap – 80% of OssDsign's existing customer base put 80% of its practice in spine surgery
- Sales channel overlap – 80% of OssDsign's US distributor network have 80% of current business in spine orthopaedics
- Hospitals and clinics overlap – 100% of the existing hospitals and clinics perform bone graft procedures

At the time of our [initial report](#) in Q3 this year, OssDsign had some 70 value analysis committee (VAC) approved hospitals. We expect these and the activated hospitals to serve as first customers for Osteo3 ZP Putty, though the product must go through the same, sometimes relatively lengthy, VAC process. OssDsign expects sales already in H2 2021, though, if so, we expect these to be insignificant to group sales.

Moreover, we see additional long-term benefits of this acquisition, but we emphasize the time perspective. Until further clinical validation and sales traction can be demonstrated, we view its sales contribution realistically as relatively low. The additional long-term benefits we see relate to Osteo3 ZP Putty's potential positive impact on the sales for OssDsign's cranial (and facial) implants. We argue that the general relevance and visibility of OssDsign increases as it widens its product offering, targeting surgeons that are operative in both spinal fusion surgeries and cranial reconstruction. This could positively impact sales, though it does not incline us to make any particular re-take on our sales estimates for these products at this time.

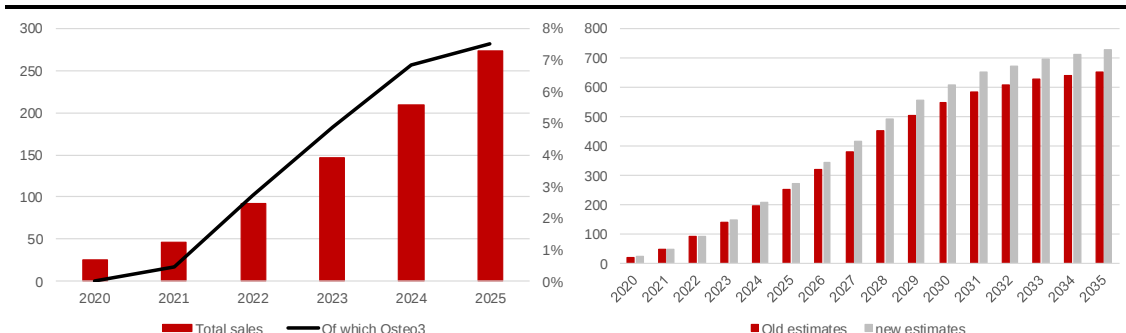
## Financial projections

### Increasing our long-term sales estimates

We adjust our sales estimates upwards, if heavily tilted to the long-term. We forecast that sales from the acquired product will make up a modest percentage of total sales in the years to come, reaching some 10% towards the second half of our forecasting period 2020-2035.

OssDsign aims to begin commercializing Osteo3 ZP Putty during H2 2021 and states that it is to generate "meaningful sales" by 2022. We will follow the development closely as it rolls-out, and our estimates are subject to possible changes as things progress.

### 2020-2025 Estimates (SEKm)



Source: Redeye Research

### Income statement forecast

While the contribution of sales from Osteo3 ZP Putty is expected to be relatively modest, in our view, we forecast it to have attractive gross margins as is typical for the synthetic bone graft market. We forecast gross margins between 85-90%, which positively impacts our forecasting period's total gross profit. Thus, we slightly increase our gross profit estimates for the period in addition to slightly increased sales.

### OssDsign: 2020-35 income statement forecast (SEKm)

|              | 2020  | 2021  | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 |
|--------------|-------|-------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Net sales    | 25    | 46    | 92   | 146  | 209  | 274  | 344  | 415  | 494  | 556  | 609  | 651  | 675  | 698  | 714  | 728  |
| Sales growth | 49%   | 84%   | 99%  | 59%  | 43%  | 31%  | 26%  | 21%  | 19%  | 13%  | 10%  | 7%   | 4%   | 3%   | 2%   | 2%   |
| Gross margin | 65%   | 77%   | 78%  | 78%  | 79%  | 79%  | 79%  | 79%  | 80%  | 80%  | 80%  | 80%  | 80%  | 80%  | 80%  | 80%  |
| EBIT         | -82   | -77   | -73  | -47  | -11  | 35   | 78   | 114  | 160  | 188  | 213  | 229  | 238  | 246  | 251  | 256  |
| EBIT margin  | -324% | -166% | -79% | -32% | -5%  | 13%  | 23%  | 27%  | 32%  | 34%  | 35%  | 35%  | 35%  | 35%  | 35%  | 35%  |
| Taxes        | 0     | 0     | 0    | 0    | 0    | 0    | 0    | 0    | 0    | -18  | -45  | -48  | -50  | -52  | -53  | -54  |
| Net Income   | -82   | -78   | -75  | -49  | -14  | 32   | 75   | 111  | 157  | 167  | 165  | 178  | 185  | 191  | 195  | 199  |

Source: Redeye Research

### Acquisition puts additional pressure on capital need

We estimate that roughly SEK 200m of external funding is required until the company turns cash flow positive in 2025. Now, with the acquisition and its terms for payment, the short-term capital will increase significantly as OssDsign has two cash instalments for the acquisition next year of some SEK 50m (SEK 25m on June 30, 2021 and SEK 25m on December 31, 2021).

We forecast a cash position of some SEK 42m at the end of 2020 and believe that an equity issue is most likely within the coming six months to fund both operations and the cash instalments.

In our view, investors keen on taking a position in OssDsign are likely to await an equity issue to enter on potentially more attractive levels. Once the financial risk is mitigated, we have a positive long-term view on OssDsign's potential – a stronger balance sheet will direct investors to pay attention to the significant sales growth we see ahead on the basis of its cranial and facial implants.

## Valuation of OssDsign

We raise our valuation of OssDsign slightly as an effect of the increased long-term sales projections due to the acquisition. However, we judge it rather difficult to have a strong view on the contribution of the acquisition and take a relatively conservative stance on its added value.

### Fair value range – a scenario-based approach

At Redeye, we approach the valuation of a company through a set of three scenarios to provide for a more dynamic view of the case:

- Base Case = SEK 26 (75% upside)
- Bull Case = SEK 37 (250% upside)
- Bear Case = SEK 10 (-33% downside)

**Base Case** (SEK 26): Cranial and facial implants continue to be main contributors

We anticipate an aggressive sales growth for its Cranial implant in the coming years and that it will remain the main contributor to group sales in our forecast period. We expect sales to reach some SEK 46m in 2021, SEK 92m in 2022, and SEK 136m in 2023. We forecast a positive EBIT margin by 2025 by when sales should be some SEK 274m. We anticipate Osteo3 ZP Putty to make up roughly 10% of total sales in our forecast period.

**Bull Case** (SEK 37): A greater uptake of Osteo3 ZP Putty

In our optimistic scenario, we estimate sales of SEK 52m next year, followed by SEK 136m in 2022 and SEK 216m in 2023 and a low but positive EBIT margin in the same year. We have a more favourable view of the success of Osteo3 ZP Putty, making up some 15% of total sales in the forecast period.

**Bear Case** (SEK 10): Lower implementation rate amongst surgeons

We estimate sales of SEK 30m next year, SEK 40m in 2022, and SEK 74m in 2023. Moreover, we do not expect a positive EBIT until 2026. We forecast that Osteo3 ZP Putty make up approximately 10% of total sales in the forecast period.

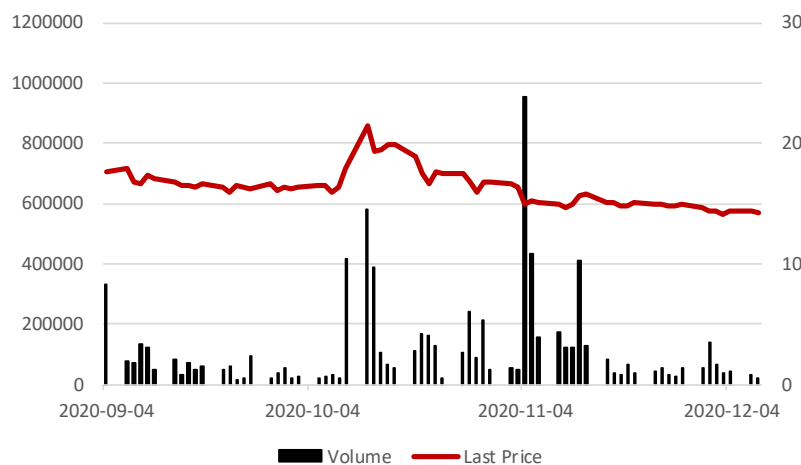
## Share performance

We raise our Base Case to SEK 26 (23), offering an upside of some 75% from today's levels – though, we once again emphasize its forthcoming equity issue and that our Base Case will have to be adjusted once completed. Moreover, we do not expect the stock to begin any sustainable climb until the financing is resolved (expected within six months). Still, quarterly results may boost the share in the short-term, but we believe it will not regain lasting momentum until the balance sheet has been strengthened.

We released our initial report on September 4<sup>th</sup> with a Base Case of SEK 28 (since adjusted to 23 following the directed share issue). In the two months since, the share has continued its negative performance, down some -16%. Since its IPO some 1.5 years ago, the share has consistently traded below its listing price (SEK 27.5). While the company has made progress since its listing and, in our view, is set to continue on its path, we argue that the share price is currently, and understandably, disconnected from the likelihood of success of the operations. We attribute this to two main factors;

- A continuous overhang from financially distressed owner Karolinska Development
- Historical institutional sell-offs since the IPO
- A forthcoming extensive equity issue, putting investors at bay until resolved

### OssDsign: Share price performance since the initial report



Source: Redeye Research, Bloomberg

## 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**

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1

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Assumptions 2020-2026 (%)FINANCIAL INFORMATION

|                                                                        |                              |
|------------------------------------------------------------------------|------------------------------|
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## Redeye Rating and Background Definitions

### Company Quality

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

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

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

### People

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

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

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

### Business

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

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

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

### Financials

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

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

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

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### Redeye Rating (2020-12-09)

| Rating    | People | Business | Financials |
|-----------|--------|----------|------------|
| 5p        | 20     | 16       | 3          |
| 3p - 4p   | 107    | 88       | 40         |
| 0p - 2p   | 5      | 28       | 89         |
| Company N | 132    | 132      | 132        |

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### CONFLICT OF INTERESTS

Oscar Bergman owns shares in the company : Yes

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.