Trinity Delta

Bonesupport Holding AB

Update

Gearing up for growth

1 March 2019

Bonesupport has emerged from its transition year with FY18 results highlighting the progress, and investment, in implementing commercial initiatives to accelerate global CERAMENT penetration. The switch to direct sales from October 23 and prior supply issues at the exclusive distributor impacted US sales (SEK34.1m vs SEK 78.1m in FY17). Europe/ROW delivered strong sales growth (+22% to SEK62.5m) as the high margin antibiotic eluting products continue to gain traction. We anticipate increased sales in 2019 as the expanded global commercial footprint beds down, key clinical data (eg CERTiFy) are leveraged, and new US GPO contracts are secured. This provides a solid foundation for the company to achieve its target of 40%+ revenue growth from 2020 onwards. We value Bonesupport at SEK39/share (SEK 2.042bn).

Year-end: December 31	2017	2018	2019E	2020E
Sales (SEKm)	129.3	96.6	227.7	349.6
Adj. PBT (SEKm)	(127.9)	(175.2)	(128.8)	(68.5)
Net Income (SEKm)	(128.9)	(176.7)	(129.3)	(68.8)
EPS (SEK)	(3.2)	(3.4)	(2.5)	(1.3)
Cash (SEKm)	533.4	261.5	113.3	24.1
EBITDA (SEKm)	(98.1)	(172.8)	(125.1)	(65.4)

Source: Trinity Delta

- **European salesforce expansion to bear fruit in 2019** Bonesupport has a 25-strong sales team in Europe, following H218 recruitment of 11 of the planned 13 new hires. Broader and increased use of CERAMENT G/V has been an important sales driver. Market share is continuing to build in osteomyelitis, and traction starting to be gained in trauma. The impact of new reps is expected to be felt from Q119 which, coupled to increased conference presence and leverage of CERTiFy trauma data, should improve sales in key European markets such as Germany.
- **US commercial infrastructure set to deliver** SEK 4.2m of US sales were generated in Q418, the first 10 weeks of direct marketing of CERAMENT BVF via a network of 38 independent US distributors (c500 sales reps). GPO contracts are critical to market access; ahead of management expectations, the first contract with HCA is secured. Completion of rep training by mid-2019, further improvements in market access, and launches of complementary Collagen Matrix/MTF Biologics products in H119 should significantly boost US sales for FY19 and beyond, forming a strong commercial base for the potential launch of CERAMENT G in 2021.
- **Building the body of evidence** Two key papers in major scientific journals are expected in 2019. Firstly, detailed CERTiFy data demonstrating CERAMENT BVF's non-inferiority to gold standard autograft in treating fracture defects, and secondly data from the five-year Nuffield health economics study. Such data is important for marketing and reimbursement, and also positions Bonesupport favourably ahead of the May 2020 implementation of the new EU Medical Devices Regulation.
- **SEK39/share (SEK 2.042bn) valuation** We have updated our three-phase DCF model on the back of FY18 results. Our valuation, which employs conservative assumptions, is now SEK39/share (up from SEK37/share) or SEK 2.042bn. Near-term upside potential comes from greater visibility of strategic execution and US sales acceleration; longer-term, data from the pivotal FORTIFY study is, in our view, the key growth driver.

Price	SEK20.5
Market Cap	SEK1,061m
Enterprise Value	SEK800m
Shares in issue	51.8m
12-month range	SEK9.04-26.5
Free float	87.2%
Primary exchange	OMX Stockholm
Other exchanges	N/A
Sector	Healthcare
Company Code	BONEX
Corporate client	Yes

Company description

Bonesupport is a Swedish ortho-biologics company focused on developing and commercialising a pipeline of unique injectable drug eluting bioceramic bone graft substitutes based on its proprietary CERAMENT technology.

Analysts

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Mick Cooper PhD
mcooper@trinitydelta.org
+44 (0) 20 3637 5042

Bonesupport: emerging from a year of transition

2019 is anticipated to be an important year for Bonesupport, in which its strategic transformation comes to fruition, laying the foundation to achieve management's target of year-on-year sales growth of 40%+ from 2020 onwards. During 2018, various commercial initiatives were implemented (detailed in our October Capital Markets Day Update note) with the goal of accelerating market penetration of CERAMENT in various geographies. FY18 results evidence this strategic evolution, with a new US commercial structure, and increased, albeit focused, investment in sales and marketing. As the company continues to execute on it plans, we expect 2019 to represent a sales inflection point. We value Bonesupport at SEK39/share (SEK2.042bn).

Transition completed in 2018, with commercial platform now set to deliver

Bonesupport's presence in the US and Europe/ROW synthetic bone graft markets differs, as do the market dynamics. Historic quarterly sales are shown in Exhibit 1 for each region, and we summarise key achievements in Q418 later in this note. However, the focus for 2019 is firmly on driving market penetration of CERAMENT and revenue growth.

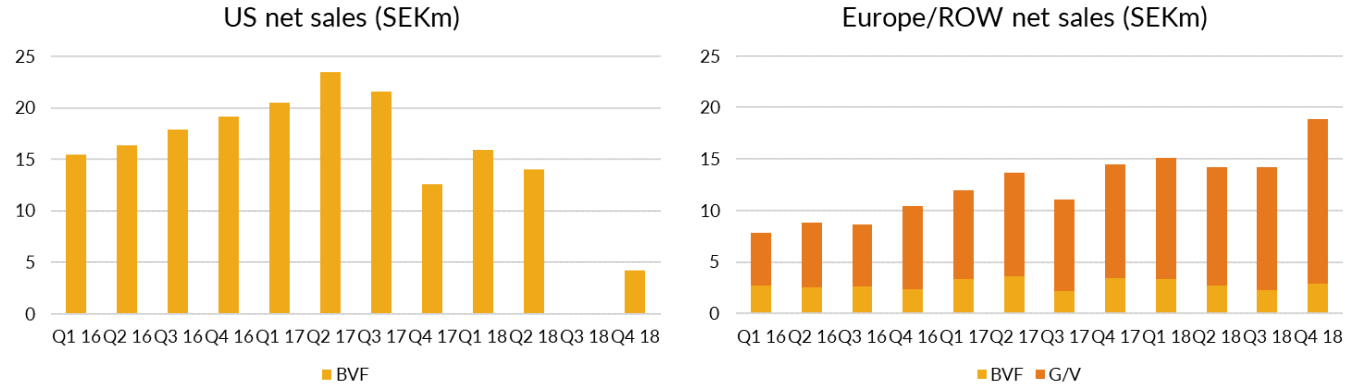
CERAMENT is well placed, with clear differentiation and robust clinical evidence

CERAMENT is positioned as a synthetic bone graft substitute with industry leading clinical data that highlights its ability to remodel to the patient's own bone, and in the case of CERAMENT G and V, to elute antibiotics directly into the bone void to protect the healing process. Data is critical to communicating the value proposition of this novel product platform to surgeons, patients, and payors. The availability of full data from the CERTiFy trauma study, expected to be published in a leading journal during 2019, should provide strong impetus on this front.

Both the important US market and the key markets in Europe are now addressed by sizeable sales teams

US sales should benefit from the direct distribution network becoming fully effective as sales reps complete their initial training (60% have done so to date), market access is improved as new GPO contracts are secured, and complementary osteobiologic products from the Collagen Matrix and MTF Biologics collaborations are launched in H119. In Europe, the larger and more commercially focused sales team should also start to make more significant inroads into geographic areas where there are large orthopaedic centres but a previously limited sales presence, and in the priority trauma and osteomyelitis indications.

Exhibit 1: Quarterly sales progression in US and Europe/ROW



Source: Bonesupport

US: notable achievements in 2018

Shift from the underperforming exclusive distributor to multiple independents now executed

CERAMENT BVF is currently the only available Bonesupport product in the US, and net sales for FY18 were SEK 34.1m (FY17: SEK78.1m). H118 sales were muted as the previous exclusive distributor, Zimmer Biomet, experienced significant hardware supply issues. Termination of this distribution agreement and the switch to a direct sales model from 23rd October 2018 meant Bonesupport booked no sales in Q318, although revenue of SEK4.2m was generated in Q418.

From a corporate perspective, Q418 was highly successful with achievement of numerous objectives, and more meaningful sales data is expected for Q119:

- **Distribution network in place**: a 38-strong network of independent distributors (up from 25 at end-Q318) with over 500 sales reps.
- **Rep training and education underway**: training is an ongoing process; however, c300 reps have completed initial sales training, with the remainder expected to be have done so by mid-2019.
- **Initial sales are meeting management expectations**: the 23rd October 2018 marked the first sale to an existing customer, with no supply chain issues happening. Subsequent customers have been both established and new CERAMENT users. Sales in Q418, and Q119 so far, are in line with management expectations. The focus is on customer conversions, including in areas where Zimmer Biomet had limited rep coverage. Bonesupport now has access to 100% of the bone graft substitute market, vs c30% under Zimmer Biomet.
- **Own GPO contracting**: GPO contracts are essential to accessing the US market. The first major win is with HCA (Hospital Corporation of Americas) which covers 1,800+ care sites, where there was previously limited access, and was secured ahead of schedule. Sales are expected to come through in 2-3 months. Management is optimistic about further contracts in 2019.

Europe/ROW: a more focused approach

Europe starting to benefit from investment in stronger sales teams in key direct markets

Europe/ROW continued to show revenue growth with net sales of SEK62.5m, a 22% increase on FY17 (SEK 51.2). Specifically, Europe (27%) and the strong momentum in CERAMENT G and V sales (up 33% for FY18, and 45% in Q4) are major contributors to this growth. 84% of Q418 sales were generated in the five direct European markets (UK, Germany, Switzerland, Sweden, and Denmark). Bonesupport does not provide a geographic breakdown, but has disclosed that the US, Germany and the UK were the only markets to each represent over 10% of net sales during Q418.

During 2018, Bonesupport had an increased presence at medical conferences, and expanded its European sales and marketing organisation to 25 from 14; 11 of the planned 13 new hires are in place (up from 7 at end-Q318). Finding and training the right individuals are the rate limiting steps that define how quickly commercial impact is felt. Hiring, training, focused deployment, and initial customer contact of new reps has been the priority in 2018; the sales impact is expected to come through in Q119. Investment in the European sales infrastructure should reap rewards in a relatively short timeframe as new hires are experienced and are deployed in key regions with important orthopaedic centres but where

Bonesupport has historically had limited presence. As a guide, management have suggested that during his or her first 12 months, a new rep is expected to generate sales in the middle of a €70-120k range.

Bonesupport is also directing more resources towards underpenetrated markets: Germany and trauma are clear priorities.

- Germany, the largest market for bone graft substitutes in Europe, has an eight-person sales team, tasked with increasing penetration in metropolitan areas and university hospitals.
- CERAMENT G/V accounts for 75% of European sales and has an established foothold in chronic osteomyelitis. However, complex trauma is an underpenetrated and 10x larger market opportunity.

CERTiFy trauma data in Germany could address two commercial priorities

The ground-breaking level 1 clinical data from the CERTiFy study (CERAMENT Treatment of Fracture Defects) study could catalyse increasing sales in Germany and in trauma. Germany is a conservative market with strict requirements for clinical data, hence the CERTiFy results could have a disproportionate impact. The study confirmed non-inferiority of CERAMENT BVF to autograft, and the fact it was run at 20 German trauma centres provides familiarity with the CERAMENT product suite. CERAMENT BVF could be the entry point to increasing use of CERAMENT G/V which has the added clinical and health economics benefit of lowering the risk of infection and hospital readmissions in high risk injuries.

Building a body of compelling clinical evidence

Convincing clinical outcomes from the robust CERTiFy study

Top line data from CERTiFy was released in November 2018, showing that CERAMENT BVF is non-inferior to autograft in treating fracture defects. CERTiFy was a prospective, randomised controlled study which evaluated 137 patients across 20 German trauma centres, comparing outcomes with CERAMENT BVF and autograft (patient derived bone) in treating tibial plateau fractures.

At least as good as autograft, the current "gold standard", but without the risks or the costs

Autograft is considered the gold standard, with high efficacy and safety; however, the need for two surgical procedures (harvest and the transplant itself) increases its cost vs the alternatives, is painful, and is associated with infection risk. The fact that CERAMENT BVF has been shown to be clinically non-inferior, while only requiring a single procedure (reducing both surgery time and risk of infection), could increase the addressable market opportunity, with potential, longer-term, for a paradigm shift in the standard of care in trauma. According to the company, autograft currently accounts for c160k annual procedures (c31% of bone grafts in EU5, 19% in the US). Even modest capture of market share would be significant for Bonesupport, and as no competing synthetic bone graft substitute has level 1 randomised clinical data, CERAMENT would also have a first-mover advantage.

More clinical evidence is being generated…

CERTiFy results will add to the growing body of evidence supporting CERAMENT. Bonesupport and its key opinion leader (KOL) network continue to bolster this with case studies, presentations, and peer reviewed publications; most recently, a large animal model pilot study, and a long-term PK study of CERAMENT V vancomycin release in hip surgery.

The depth and breadth of supportive clinical data and documentation for CERAMENT means Bonesupport is well-prepared for the end of the transition

period and full implementation of the EU Medical Devices Regulation from May 2020. This regulation puts more stringent obligations on manufacturers to ensure the quality, performance and safety of their medical devices, including having clinical evidence to support product claims. Full implementation may also trigger shifts in competitive dynamics in some European markets, should smaller producers run into difficulties with meeting these requirements.

...including long-term health economics outcomes data

Another important facet being addressed is health economics outcomes research, which will help drive reimbursement. Data from the 5-year study led by the Nuffield Orthopaedic Centre (Oxford University Hospitals) is also expected to be published in 2019. Initial data has been positive, indicating that use of CERAMENT G in osteomyelitis reduces surgical time and the procedure rate, compared with the full range of alternative treatments available in England.

Financials and valuation

Bonesupport reported FY18 net sales of SEK96.6m, a decrease of 25% on FY17 (SEK129.3m). This decrease was primarily attributable to the disruption in the US market caused by supply issues at Zimmer Biomet during H118, followed by the switch to a direct distribution model from 23 October 2018. US net sales were SEK34.1m for FY18 (FY17: SEK78.1m), with an 87% gross margin. In Europe/ROW, sales grew 22% to SEK62.5m (FY17: SEK51.2m), with an overall 83% gross margin, and particularly strong growth in CERAMENT G/V sales (SEK51.5m vs SEK38.5m). Due to reduced US revenue, gross profit of SEK81.5m was 27% lower.

Expenditure increased in FY18 reflecting Bonesupport's focused investment in initiatives to accelerate sales of CERAMENT products. Higher selling expenses of SEK133.3m (+44% on FY17: SEK92.9m) were incurred with the switch to a direct sales model in the US, the European sales force expansion, and increased marketing activities globally. R&D spend of SEK66.1m increased more modestly (+9%), while admin expenses of SEK 58.3m (+1.5%) were broadly flat.

The wider operating loss of SEK 174.4m (FY17: SEK 99.3m), and net loss of SEK176.4m (FY17: SEK 128.9m) resulted from the combination of lower overall revenues coupled with increased, albeit more focused, investment in the commercial organisation.

Bonesupport ended December 2018 with cash and equivalents of SEK261.5m, which, according to management, is sufficient runway to profitability and positive cash flow (achieved in 2021 and 2022 respectively according to our model).

Post FY18 results, we have updated our forecasts (Exhibit 2) and valuation model. At this stage, given the near-term uncertainty around the US CERAMENT BVF sales ramp, we have only made minor tweaks to our expectations, and expect to revise our revenue forecasts later in 2019 once the sales trajectory becomes better established, all sales reps have received their training, and more information is available on the progress with GPO contracting. We highlight that Bonesupport will begin exclusive promotion of CERAMENT BVF in the US in April 2019, after which point, the levels of inventory still held by Zimmer Biomet will become irrelevant. In line with Bonesupport's focus on disciplined cost control, balanced with appropriate investment, we have reallocated some admin expenses to sales.

Exhibit 2: Summary of changes to estimates

	Sales (SEKm)			EBITDA (SEKm)			Adj. EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2019E	228.0	227.7	N/A	(130.1)	(125.1)	N/A	(2.4)	(2.5)	N/A
2020E	350.0	349.6	N/A	(74.1)	(65.4)	N/A	(1.3)	(1.3)	N/A

Source: Trinity Delta

Changes to our forecasts flow through to our valuation model. We have updated our valuation to reflect the strengthening of the SEK/US$ (9.3 vs 8.7 previously), the number of shares outstanding, last reported cash, as well as rolling forward our model to reflect the passage of time. Our three-stage DCF methodology now values Bonesupport at SEK 2.042bn or SEK39/share (vs SEK37/share previously).

Our valuation is based on explicit cash flows to 2022, followed by a ten-year trending period, and a 2.5% terminal growth rate. We forecast sales for all currently marketed CERAMENT products in Europe/RoW and the US, also including CERAMENT G in the US. For the latter we assume launch in 2021 and apply a 75% risk adjustment to recognise clinical and regulatory risk. Individual product rNPVs are summed and netted against the costs of running the business. Exhibit 3 provides a detailed breakdown of the components of our valuation.

Exhibit 3: DCF-based valuation of Bonesupport

Product	Likelihood of success	NPV ($m)	NPV (SEKm)	rNPV ($m)	rNPV (SEKm)	rNPV/share (SEK)
CERAMENT BVF (Europe/RoW)	100.0%	11.4	106	11.4	106.3	2.1
CERAMENT G/V (Europe/RoW)	100.0%	66.5	619	66.5	618.9	11.9
CERAMENT BVF (US)	100.0%	52.4	488	52.4	487.5	9.4
CERAMENT G (US)	75.0%	89.7	834	67.3	625.7	12.1
Operating costs	100%	(6.2)	(58)	(6.2)	(57.6)	(1.1)
Net cash at FY18	100%	28.1	261	28.1	261.5	5.0
Total		**242.0**	**2250.8**	**219.6**	**2042.3**	**39.4**

Source: Trinity Delta Note: Assumes USD/SEK exchange rate of 9.3.

Continued successful execution (eg commercial traction and/or success of additional products) would unlock further upside potential. The impact of CERTiFy on the trajectory of BVF sales in trauma, and US approval of CERAMENT G are two key inflection points. For the latter, removal of the risk adjustment on CERAMENT G (US) would lift our valuation to SEK2.251bn (SEK 43.5/share).

Additionally, we continue to apply a 12.5% discount rate to reflect the fact that Bonesupport is a small company operating in a highly competitive market; using a less conservative 10% discount rate results in a SEK 3.29bn (SEK 63.5/share) valuation

Exhibit 4: Summary of financials

Year-end: Dec 31 SEKm	2016	2017	2018	2019E	2020E
INCOME STATEMENT					
Revenues	**104.6**	**129.3**	**96.6**	**227.7**	**349.6**
Cost of goods sold	(16.3)	(16.9)	(13.9)	(26.1)	(40.0)
Gross Profit	**88.3**	**112.4**	**82.8**	**201.6**	**309.6**
R&D costs	(38.2)	(60.6)	(66.1)	(70.7)	(73.5)
Sales costs	(79.8)	(92.9)	(133.3)	(197.9)	(241.1)
Admin costs	(60.7)	(57.5)	(58.6)	(61.6)	(64.2)
Other expenses	1.6	(0.7)	1.9	2.9	3.0
Underlying operating profit	**(88.7)**	**(99.3)**	**(173.4)**	**(125.7)**	**(66.2)**
Other revenue/expenses	0.0	0.0	0.0	0.0	0.0
EBITDA	**(87.4)**	**(98.1)**	**(172.8)**	**(125.1)**	**(65.4)**
Operating Profit	**(88.7)**	**(99.3)**	**(173.4)**	**(125.7)**	**(66.2)**
Interest income	0.0	0.0	0.0	0.4	1.1
Interest expense	(11.6)	0.0	0.0	(3.4)	(3.4)
Other financing costs/income	(9.2)	(28.6)	(0.5)	0.0	0.0
Profit Before Taxes	**(109.6)**	**(127.9)**	**(173.9)**	**(128.8)**	**(68.5)**
Adj. PBT	**(109.6)**	**(127.9)**	**(173.9)**	**(128.8)**	**(68.5)**
Current tax income	(0.6)	(1.0)	(1.5)	(0.5)	(0.3)
Net Income	**(110.2)**	**(128.9)**	**(175.4)**	**(129.3)**	**(68.8)**
EPS (SEK)	**(4.3)**	**(3.2)**	**(3.4)**	**(2.5)**	**(1.3)**
Adj. EPS (SEK)	**(4.3)**	**(3.2)**	**(3.4)**	**(2.5)**	**(1.3)**
DPS (SEK)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	25.8	39.8	51.1	51.8	51.8
Gross margin	*84.4%*	*87.0%*	*85.7%*	*88.5%*	*88.6%*
EBITDA margin	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**183.7**	**588.1**	**316.4**	**191.9**	**133.6**
Cash and cash equivalents	141.5	533.4	261.5	113.3	24.1
Accounts receivable	20.2	20.7	18.7	37.4	57.5
Other current assets	7.5	12.0	12.5	12.5	12.5
Non-current assets	**5.1**	**8.6**	**9.8**	**11.7**	**13.7**
Property, plant & equipment	0.4	3.1	3.9	4.2	4.5
Intangible assets	4.5	5.2	5.5	7.1	8.9
Other non-current assets	0.2	0.2	0.4	0.4	0.4
Current liabilities	**(69.7)**	**(145.7)**	**(47.3)**	**(49.9)**	**(58.2)**
Short-term debt	(25.1)	(98.6)	0.0	0.0	0.0
Accounts payable	(11.8)	(11.6)	(12.5)	(15.8)	(24.1)
Other current liabilities	(32.8)	(35.6)	(34.8)	(34.1)	(34.1)
Non-current liabilities	**(84.8)**	**(0.2)**	**(0.3)**	**(0.3)**	**(0.3)**
Long-term debt	(84.6)	0.0	0.0	0.0	0.0
Other non-current liabilities	(0.2)	(0.2)	(0.3)	(0.3)	(0.3)
Equity	**34.3**	**450.8**	**278.5**	**153.5**	**88.9**
Share capital	687.7	1,220.4	1,220.3	1,220.3	1,220.3
Other	(653.4)	(769.7)	(941.7)	(1,066.8)	(1,131.4)
CASH FLOW STATEMENTS					
Operating cash flow	**(81.9)**	**(107.5)**	**(171.6)**	**(145.6)**	**(86.4)**
Profit before tax	(109.6)	(127.9)	(173.9)	(128.8)	(68.5)
Non-cash adjustments	28.5	45.3	4.6	7.9	7.2
Change in working capital	10.8	(12.5)	0.7	(20.4)	(22.5)
Interest paid	(11.6)	(11.7)	(0.9)	(3.0)	(2.3)
Taxes paid	(0.1)	(0.7)	(2.2)	(1.2)	(0.3)
Investing cash flow	**(1.4)**	**(4.7)**	**(2.7)**	**(2.6)**	**(2.8)**
CAPEX	(1.4)	(4.6)	(2.3)	(2.6)	(2.8)
Other investing cash flows	0.0	(0.1)	(0.4)	0.0	0.0
Financing cash flow	**155.1**	**504.8**	**(98.8)**	**0.0**	**0.0**
Proceeds from equity	103.7	532.8	0.0	0.0	0.0
Increase in loans	51.4	(27.9)	(100.1)	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	1.4	0.0	0.0
Net increase in cash	**71.8**	**392.6**	**(273.1)**	**(148.1)**	**(89.2)**
Exchange rate effects	0.8	(0.7)	1.2	0.0	0.0
Cash at start of year	68.9	141.5	533.4	261.5	113.3
Cash at end of year	**141.5**	**533.4**	**261.5**	**113.3**	**24.1**
Net cash at end of year	**31.8**	**434.7**	**261.5**	**113.3**	**24.1**

Source: Company, Trinity Delta Note: Historical adjustment of number of shares following 5:1 consolidation in 2017.

Mick Cooper PhD CFA mcooper@trinitydelta.org +44 20 3637 5042

Lala Gregorek lgregorek@trinitydelta.org +44 20 3637 5043

Franc Gregori fgregori@trinitydelta.org +44 20 3637 5041

Disclaimer

More information is available on our website: www.trinitydelta.org