

Bonesupport Holdings AB

Building momentum

Q119 results provide evidence that the strategic initiatives put in place during 2018 are beginning to deliver results. Bonesupport posted a second successive quarter of CERAMENT sales growth and, with various growth drivers gaining traction, this momentum is set to continue during 2019 and beyond. Management are targeting 40%+ revenue growth from 2020 onwards. Key drivers include the expanded global commercial footprint becoming fully operational, leverage of key clinical and health economics data, new product launches (including potentially CERAMENT G in the US in 2021), and continued improvement in market access/reimbursement. We maintain our Bonesupport valuation of SEK39/share (or SEK 2.034bn).

Year-end: December 31	2017	2018	2019E	2020E
Sales (SEKm)	129.3	96.6	228.0	350.4
Adj. PBT (SEKm)	(127.9)	(175.2)	(123.9)	(64.9)
Net Income (SEKm)	(128.9)	(176.7)	(124.3)	(65.2)
EPS (SEK)	(3.2)	(3.4)	(2.4)	(1.2)
Cash (SEKm)	533.4	261.5	124.2	39.4
EBITDA (SEKm)	(98.1)	(172.8)	(125.1)	(65.4)

Source: Trinity Delta

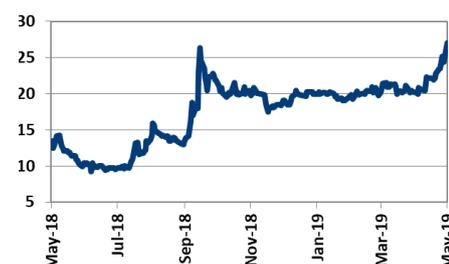
- Strong CERAMENT G/V performance in Europe/ROW** Broader and more frequent CERAMENT G/V use by existing customers boosted its sales (+54% to SEK18.1m) and overall Europe/ROW Q119 net revenue (SEK 21.3m, +41% on Q118). Greater sales focus on Germany and UK, as well as encouraging momentum in trauma due to CERTiFY data (showing equivalence to autograft) is starting to generate results, and while Q1 sales were mainly to existing customers, growth in contribution from new customers is expected later this year.
- Increasing access to the US market** US Q119 sales of SEK 11.5m (vs SEK 4.2m in Q418) marks the first full quarter of CERAMENT BVF direct distribution (40 distributors, >500 sales reps). Exclusive distribution starts on May 20th. Ascension (with c150 hospitals) adds a second significant GPO contract; further improvement in market access is anticipated. Completion of initial training, improved market access, and launch of BONIFY (100% DBM) the first product from MTF Biologics collaboration, should provide a boost to US sales from mid-year onwards.
- Industry-leading clinical data supports unique value proposition** First human radiological and histological evidence of CERAMENT's bone remodelling has been [published](#). Full CERTiFY data (non-inferiority of CERAMENT BVF to gold standard autograft in fracture defects) is anticipated in Q319. Enrolment into [FORTIFY](#) (CERAMENT G in open fractures) is on track for H219 completion, with data read out and US PMA filing in 2020. [SOLARIO](#) a new 500-pt study, is investigating whether CERAMENT G/V use would allow shorter courses of systemic antibiotics.
- We maintain our SEK39/share valuation** Our three-phase DCF model employs conservative assumptions and generates a SEK39/share (SEK 2.034bn) valuation. Near-term upside potential comes from greater visibility of strategic execution and US sales acceleration; longer-term, data from the pivotal FORTIFY study remains, in our view, the key growth driver.

Update

7 May 2019

Price	SEK27.0
Market Cap	SEK1,397m
Enterprise Value	SEK1,178m
Shares in issue	51.8m
12-month range	SEK9.04-27
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.

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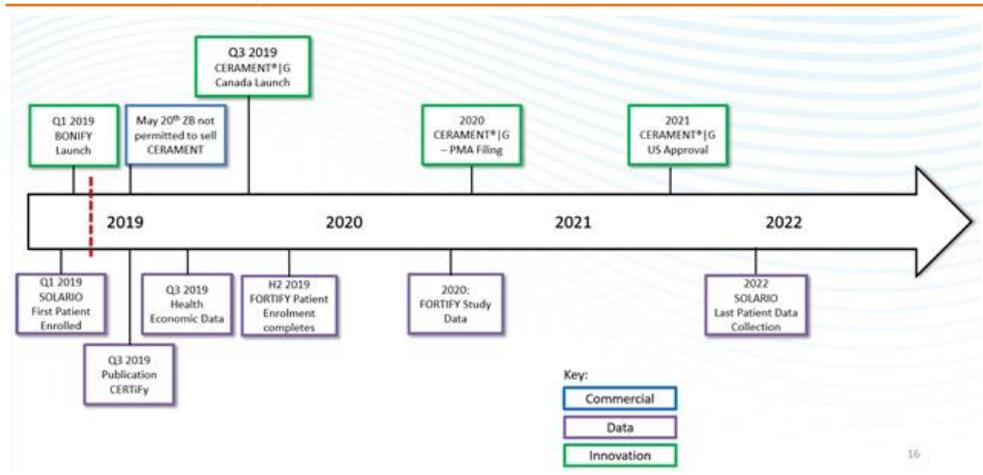
Bonesupport: on the right track

The focus for 2019 is firmly on driving CERAMENT market penetration and revenue growth globally. Q119 results indicate that through its 2018 strategic transformation (detailed in our October Capital Markets Day [Update note](#)) Bonesupport has laid solid foundations for growth and has also emerged from the shadow of Zimmer Biomet-related issues in the US. Targeted 40%+ year-on-year sales growth from 2020 onwards is achievable. The commercial platform is well positioned to capture market share in the key US and European territories, especially in the trauma indication supported by compelling clinical evidence from CERTiFy. 2018 was a year of transition for the company; 2019 will be a year of delivery. We value Bonesupport at SEK39/share (SEK2.034bn).

Commercial platform well positioned to exploit key developments in 2019

Bonesupport's commercially focused strategy is starting to reap benefits, with both the important US market and the key markets in Europe now addressed by sizeable sales teams. Rich news flow during the rest of 2019 and into 2020 should further improve on the growth seen in Q119. Exhibit 1 highlights key catalysts.

Exhibit 1: Upcoming value generating milestones



Source: Bonesupport

Exclusive distribution from May 20th coincides with completion of training, GPO contracts and new product sales

In the US, the shift from the underperforming exclusive distributor to a network of multiple independent distributors has been executed; Bonesupport will become the exclusive marketer of CERAMENT BVF in the US from May 20th. This should broadly coincide with the completion of initial rep training, the improved market access position coming onstream (including in areas where Zimmer Biomet has limited or no coverage) in Q2/Q3, and first physical sales of BONIFY, a 100% DBM osteoconductive product from the MTB Biologics collaboration.

Two major GPO contracts help expand access into the whole US bone graft substitute market

Coverage of the whole bone graft substitute market in the US is one of Bonesupport's goals. Further complementary osteobiologic products from collaborations and the in-house innovation pipeline will help in achieving this, but it is strategic sales force deployment and additional GPO contracts that are central to driving growth. In addition to smaller contracts, two major GPO contracts have so far been secured: HCA (Hospital Corporation of Americas) which covers 1,200 affiliated healthcare facilities, and Ascension, covering 151 hospitals in 21 states. The latter has strong compliance and protocols which should benefit CERAMENT BVF sales.

Achieving commercial inroads in Germany and trauma... through a focused sales effort and CERTiFy data

In Europe, the commercial focus is on underpenetrated markets and indications via a larger 25-strong sales team, targeting regions with large orthopaedic centres that previously had limited sales presence. Clear priorities are Germany, Europe's largest bone graft substitute market where the sales team has doubled to eight, and trauma, a 10x larger opportunity than the historically strong osteomyelitis indication. Growth in Q119 has mainly come from existing customers who are increasingly comfortable with the CERAMENT platform, particularly CERAMENT G/V which is being used more broadly and frequently both to eradicate infections and prophylactically. As in the US, Bonesupport is seeking to convert new customers using CERTiFy non-inferiority data to take market share from autograft in trauma indications. Full data from this study should be published in Q319.

Clinical data could lead to a paradigm shift towards CERAMENT in the treatment of bone voids

CERTiFy is one example of robust clinical evidence supporting CERAMENT's clearly differentiated value proposition. Bonesupport continues to invest in studies to validate the clinical and health economic benefit of CERAMENT to patients and payors. Potentially paradigm shifting trials are shown in Exhibit 2. CERTiFy has shown non-inferiority of CERAMENT BVF to gold standard autograph in a complex trauma indication; FORTIFY is the US registration trial for CERAMENT G; and SOLARIO is a new study investigating whether use of CERAMENT G can lead to a shorter course of systemic antibiotic treatment, reducing antibiotic resistance, side-effects and cost.

Exhibit 2: Key clinical trial summaries

Trial (identifier)	Design	Outcome measures	Status
CERTiFy (NCT01828905)	Multi-centre, prospective, randomised controlled trial comparing CERAMENT BVF with autologous iliac crest bone graft in the treatment of tibial plateau fractures (n=136)	Co-primary endpoints: (1) SF-12 Physical Component Summary at wk 26; (2) pain level assessed by visual analogue scale (VAS) 26 wks post-surgery. Key secondary endpoints: (1) SF-12 Mental Component Summary at wk 26; (2) costs of care.	December 2017: fully enrolled. November 2018: top line data (non-inferiority in terms of SF-12 Physical Component Summary at wk 26). Q319: publication of complete dataset expected in major orthopaedic journal.
FORTIFY (NCT02828363)	Multi-centre, prospective, randomised controlled trial of standard of care (intermedullary nail) ± CERAMENT G in surgical repair of open diaphyseal tibial fractures (n=230)	Primary endpoint: Composite of absence of deep infection at fracture site, absence of secondary procedures intended to promote fracture union, and improvement in the SF-36v2 Physical Component Summary at 12 mths. Safety endpoint: serious device related adverse events for the CERAMENT G arm over 12 mths.	May 2017: first patient enrolled. January 2018: FDA agreed protocol amendment (inclusion of smaller fractures). H219: completion of enrolment. 2020: follow up expected to complete; US PMA submission. 2021: potential FDA approval of CERAMENT G.
SOLARIO (NCT03806166)	Randomised, open label, multi-centre non-inferiority trial of long (4+ wks) vs short (7 days) courses of oral or IV antibiotics (n=500)	Primary endpoint: definitive treatment failure (infection recurrence) over 12 mths. Secondary endpoints: possible/probable treatment failure over 12 mths; serious adverse events over 12 mths; antibiotic side-effects (baseline, 6wks and 3 mths post surgery); Quality of Life; cost.	February 2019: first patient enrolled. March 2022: last patient data.

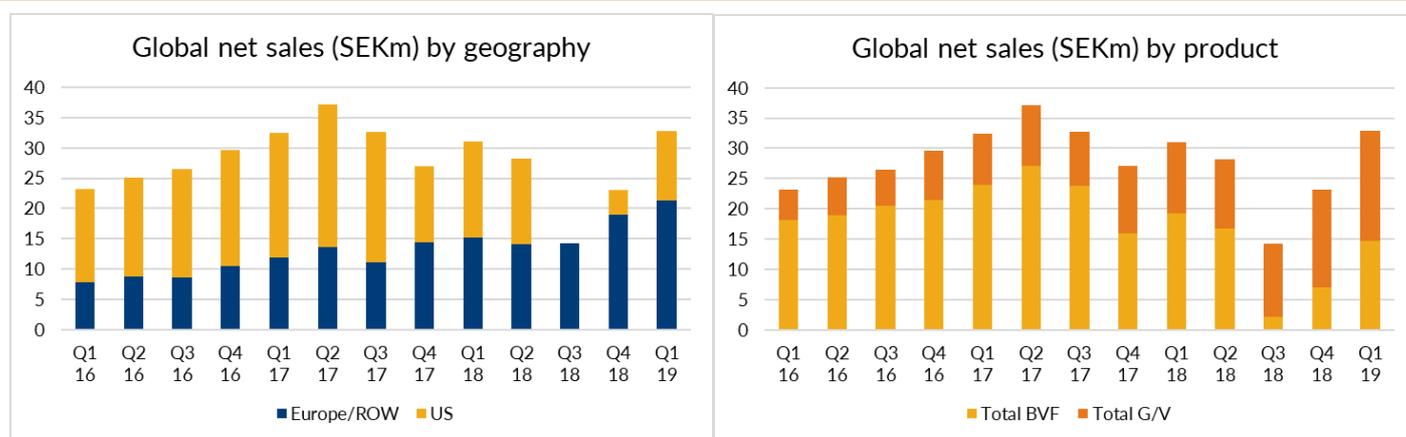
Source: Trinity Delta, Bonesupport, Clinicaltrials.gov

Financials and valuation

Net revenue continues on upward trajectory after Q318 lowpoint

Bonesupport's Q119 net sales were SEK 32.8m, a 6% increase on Q118 and 42% higher than Q418. Quarterly sales development by geography and product is shown in Exhibit 3. Europe/ROW sales of SEK 21.3m continued their upward trajectory (+41% on Q118; +13% in Q418) and achieved a gross margin of 84%. CERAMENT G/V performed particularly strongly, with 54% growth to SEK18.1m vs Q118; these antibiotic eluting products now account for 85% of Europe/ROW sales (vs 78% on Q118). Q119 was the first full quarter of US sales under Bonesupport's direct distribution model (from October 23rd), with US net sales of SEK 11.5m (-28% on Q118; +274% on Q418) and an 89% gross margin. Gross profit for the quarter was SEK 28.2 m (Q118: SEK 25.5m; Q418: SEK 19.6m).

Exhibit 3: Quarterly sales progression by geography and product



Source: Trinity Delta, Bonesupport

Focused investment in accelerating CERAMENT penetration in Europe/ROW and US

Costs have stabilised at a lower level reflecting Bonesupport's focused investment in initiatives to accelerate CERAMENT sales coupled with disciplined cost control in other business areas. Selling expenses are gradually levelling with a 5% increase on Q418 (the first quarter of US direct sales). Sales costs are nearly double the Q118 figure, although this is not comparable as it predates the European sales force expansion and Zimmer Biomet was the exclusive US distributor. Q119 R&D (SEK 16.9m) and admin (SEK 10.4m) spend are also stabilising at a lower level.

Operating loss widened to SEK 39m (Q118: SEK 33.1m) due to Bonesupport's increased, albeit more focused, investment in the commercial organisation. Net loss was SEK 39.0m vs SEK 33.6m in Q118.

Post Q119 results, we have made only modest adjustments to our forecasts (Exhibit 4), principally tuning the revenue split between CERAMENT BVF and CERAMENT G/V for Europe/ROW and reducing the run-rate for admin spend.

Exhibit 4: Summary of changes to estimates

	Sales (SEKm)			EBITDA (SEKm)			Adj. EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2019E	227.7	228.0	0.1%	(125.1)	(119.6)	N/A	(2.5)	(2.4)	N/A
2020E	349.6	350.1	0.1%	(65.4)	(59.0)	N/A	(1.3)	(1.2)	N/A

Source: Trinity Delta

Current cash of SEK 219.1m provides funding through to profitability in FY21

Bonesupport ended March 2019 with cash and equivalents of SEK 219.1m, which, according to management, is sufficient runway to profitability and positive cash flow (achieved in 2021 and 2022 respectively according to our model).

Valuation remains SEK 39/share...

Our updated valuation model is shown in Exhibit 5. Changes to our forecasts flow through to this, and our model has also been updated to reflect the strengthening of the SEK/US\$ (9.5 vs 9.3 previously) and last reported cash, as well as rolling forward our model to reflect the passage of time. Our three-stage DCF methodology values Bonesupport at SEK 2.034bn or SEK39/share vs SEK 2.042bn (SEK39/share previously).

Exhibit 5: 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%	9.5	91	9.5	90.9	1.7
CERAMENT G/V (Europe/RoW)	100.0%	67.8	646	67.8	646.4	12.4
CERAMENT BVF (US)	100.0%	51.7	493	51.7	493.5	9.5
CERAMENT G (US)	75.0%	91.4	872	68.5	653.9	12.5
Operating costs	100%	(6.0)	(57)	(6.0)	(56.9)	(1.1)
Net cash at Q119	100%	21.6	206	21.6	206.0	4.0
Total		236.0	2251.7	213.2	2033.7	39.0

Source: Trinity Delta Note: Assumes USD/SEK exchange rate of 9.5 and 12.5% discount rate. The valuation is based on explicit cash flows to 2022, followed by a ten-year trending period, and a 2.5% terminal growth rate.

...albeit with room for upside from continued successful execution

We expect to revisit our forecasts and valuation later in 2019 as the commercial infrastructure in both Europe/ROW and the US becomes more established; it is expected to be fully operational by mid-2019. Currently, three sales positions are yet to be filled in Europe and initial training in the US is ongoing. In Europe/ROW, increased penetration in key geographies and indications with historically limited presence is gaining traction. While in the US, the impact of CERTiFy data and major GPO contracts on the trajectory of BVF sales in trauma from 2019, and FDA approval of CERAMENT G potentially in 2021 are two key inflection points. Continued successful execution, leverage of clinical and health economics outcomes data, and new product launches could unlock further upside potential.

Exhibit 6: Summary of financials

Year-end: Dec 31	SEKm	2016	2017	2018	2019E	2020E
INCOME STATEMENT						
Revenues		104.6	129.3	96.6	228.0	350.4
Cost of goods sold		(16.3)	(16.9)	(13.9)	(26.7)	(40.1)
Gross Profit		88.3	112.4	82.8	201.3	310.3
R&D costs		(38.2)	(60.6)	(66.1)	(71.9)	(74.7)
Sales costs		(79.8)	(92.9)	(133.3)	(198.8)	(242.3)
Admin costs		(60.7)	(57.5)	(58.6)	(54.4)	(58.0)
Other expenses		1.6	(0.7)	1.9	3.5	3.6
Underlying operating profit		(88.7)	(99.3)	(173.4)	(120.3)	(61.1)
Other revenue/expenses		0.0	0.0	0.0	0.0	0.0
EBITDA		(87.4)	(98.1)	(172.8)	(119.6)	(59.0)
Operating Profit		(88.7)	(99.3)	(173.4)	(120.3)	(61.1)
Interest income		0.0	0.0	0.0	0.3	1.2
Interest expense		(11.6)	0.0	0.0	(3.8)	(5.1)
Other financing costs/income		(9.2)	(28.6)	(0.5)	(0.0)	0.0
Profit Before Taxes		(109.6)	(127.9)	(173.9)	(123.9)	(64.9)
Adj. PBT		(109.6)	(127.9)	(173.9)	(123.9)	(64.9)
Current tax income		(0.6)	(1.0)	(1.5)	(0.4)	(0.3)
Net Income		(110.2)	(128.9)	(175.4)	(124.3)	(65.2)
EPS (SEK)		(4.3)	(3.2)	(3.4)	(2.4)	(1.2)
Adj. EPS (SEK)		(4.3)	(3.2)	(3.4)	(2.4)	(1.2)
DPS (SEK)		0.0	0.0	0.0	0.0	0.0
Average no. of shares (m)		25.8	39.8	51.1	52.1	52.3
<i>Gross margin</i>		<i>84.4%</i>	<i>87.0%</i>	<i>85.7%</i>	<i>88.3%</i>	<i>88.6%</i>
<i>EBITDA margin</i>		<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
BALANCE SHEET						
Current assets		183.7	588.1	316.6	200.9	146.5
Cash and cash equivalents		141.5	533.4	261.7	124.2	39.4
Accounts receivable		20.2	20.7	18.7	37.5	57.6
Other current assets		7.5	12.0	12.5	10.0	10.0
Non-current assets		5.1	8.6	9.8	25.2	25.9
Property, plant & equipment		0.4	3.1	3.9	17.5	16.5
Intangible assets		4.5	5.2	5.5	7.3	9.0
Other non-current assets		0.2	0.2	0.4	0.3	0.3
Current liabilities		(69.7)	(145.7)	(47.3)	(59.0)	(67.1)
Short-term debt		(25.1)	(98.6)	0.0	(5.2)	(5.2)
Accounts payable		(11.8)	(11.6)	(12.5)	(16.1)	(24.2)
Other current liabilities		(32.8)	(35.6)	(34.8)	(37.8)	(37.8)
Non-current liabilities		(84.8)	(0.2)	(0.3)	(8.2)	(8.2)
Long-term debt		(84.6)	0.0	0.0	(8.0)	(8.0)
Other non-current liabilities		(0.2)	(0.2)	(0.3)	(0.3)	(0.3)
Equity		34.3	450.8	278.7	158.8	97.1
Share capital		687.7	1,220.4	1,220.3	1,220.3	1,220.3
Other		(653.4)	(769.7)	(941.6)	(1,061.5)	(1,123.2)
CASH FLOW STATEMENTS						
Operating cash flow		(81.9)	(107.5)	(171.6)	(134.9)	(82.0)
Profit before tax		(109.6)	(127.9)	(173.9)	(123.9)	(64.9)
Non-cash adjustments		28.5	45.3	4.7	7.0	9.4
Change in working capital		10.8	(12.5)	0.7	(14.0)	(22.4)
Interest paid		(11.6)	(11.7)	(0.9)	(3.6)	(3.9)
Taxes paid		(0.1)	(0.7)	(2.2)	(0.4)	(0.3)
Investing cash flow		(1.4)	(4.7)	(2.6)	(2.5)	(2.8)
CAPEX		(1.4)	(4.6)	(2.3)	(2.6)	(2.8)
Other investing cash flows		0.0	(0.1)	(0.2)	0.0	0.0
Financing cash flow		155.1	504.8	(98.8)	(1.3)	0.0
Proceeds from equity		103.7	532.8	(1.5)	0.0	0.0
Increase in loans		51.4	(27.9)	(98.6)	(1.3)	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	(272.9)	(138.8)	(84.8)
Exchange rate effects		0.8	(0.7)	1.2	1.3	0.0
Cash at start of year		68.9	141.5	533.4	261.7	124.2
Cash at end of year		141.5	533.4	261.7	124.2	39.4
Net cash at end of year		31.8	434.7	261.7	111.1	26.3

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

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