

# Bonesupport Holdings AB

## Swings and roundabouts

Update

29 June 2020

**SEK 378m in (gross) proceeds from Bonesupport's directed share issue will help it scale up and maintain necessary investment to drive CERAMENT's growth trajectory. Bonesupport's commercially driven strategy is delivering, with investment in new US sales territories converting into enhanced sales and new distributors now in place in key European countries. However, with the impact of the COVID-19 pandemic starting to be felt in Q120, guidance of 40+% annual revenue growth from 2020 will be off a lower base. H120 sales will be negatively impacted by postponed elective surgeries due to reprioritisation of healthcare resources; H220 is currently difficult to assess. Around 70% of proceeds will be directed into commercial activities, principally supporting CERAMENT G US launch (first approval could now occur in late 2020 following the De Novo FDA filing for chronic osteomyelitis in April) and in optimising infrastructure in Europe. We update our valuation to SEK41.5/share, or SEK2.62bn.**

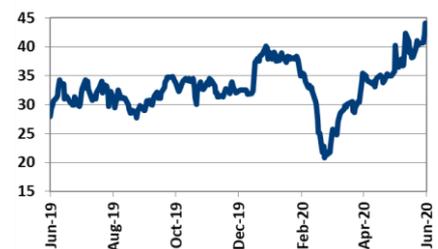
Year-end: December 31	2018	2019	2020E	2021E
Sales (SEKm)	96.6	155.5	170.4	307.2
Adj. PBT (SEKm)	(174.9)	(158.3)	(128.7)	(44.1)
Net Income (SEKm)	(176.4)	(161.1)	(127.2)	(44.2)
EPS (SEK)	(3.4)	(3.1)	(2.2)	(0.7)
Cash (SEKm)	261.7	92.1	348.9	273.7
EBITDA (SEKm)	(172.9)	(156.4)	(123.3)	(37.6)

Source: Trinity Delta

- Lower Q1 procedure rates and COVID-19 related cost cutting** Orthopaedic surgery rates dropped with deferral of non-critical/elective procedures and lower incidence of trauma during lockdown. Acute surgeries were influenced to a lesser extent. Various cost saving initiatives have been implemented (eg work time reductions, temporary salary reductions). Travel restrictions may delay recruitment of new customers but use of KOL webinars and training seeks to mitigate this.
- Possible 2020 CERAMENT G US approval** Investment in commercial infrastructure and in new US sales territories is showing traction. US Q120 sales were SEK21.2m (-9% on Q419; +84% on Q119). CERAMENT BVF is the only CERAMENT product sold in the US; however, FDA de novo filing of antibiotic eluting CERAMENT G in chronic osteomyelitis following Breakthrough Device Designation brings forward potential US approval into late-2020. Its PMA filing in trauma (likely Q421) remains contingent on data from the FORTIFY study (fully enrolled with 198 patients).
- Revitalising indirect EU/RoW markets** European commercial activity included the appointment of new distribution partners in France and Italy during Q120 (and in the Netherlands in June) as Bonesupport seeks to lift sales in potentially large markets with currently low sales. Q120 net sales of SEK22.2m were down 4% on Q419 (+4% on Q119); with CERAMENT G/V sales a casualty of deferred osteomyelitis procedures with a 6% decrease on Q419.
- Valuation reflects short-term uncertainty** Duration and severity of the COVID-19 pandemic will influence 2020 revenues. However, with fresh funds and intact long-term growth prospects, a potential US CERAMENT G launch in late 2020 would unlock upside. Our new SEK2.62bn or SEK41.5/share valuation (vs SEK2.27bn, SEK43/share) incorporates lower H120 sales expectations and dilution impact.

Price	SEK44.5
Market Cap	SEK2,810m
Enterprise Value	SEK2,430m
Shares in issue	63.15m
12-month range	SEK19.05-45.4
Free float	54.5%
Primary exchange	OMX Stockholm
Other exchanges	N/A
Sector	Healthcare
Company Code	BONEX

Corporate client Yes



### Company description

Bonesupport is a Swedish orthobiologics 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

#### Franc Gregori

fgregori@trinitydelta.org  
+44 (0) 20 3637 5041

## Bonesupport: Funds secured for investment

Bonesupport's SEK378m (gross) proceeds from its directed share issue allow management to plan and execute a more ambitious US launch programme for CERAMENT G. Following the de novo filing with the FDA in April, first approval of CERAMENT G in chronic osteomyelitis could occur in late 2020, with a potential launch in early 2021. FDA approval in trauma remains contingent on data from the FORTIFY study, which is now fully enrolled following FDA acceptance of a protocol amendment to reduce the trial size to 198 patients. New funds will also be used to optimise commercial infrastructure in Europe and allow investment into manufacturing and the R&D pipeline, without being constrained by the negative impact of the COVID-19 pandemic on sales. H120 sales will be lower as elective surgeries are postponed due to reprioritisation of healthcare resources; H220 is currently difficult to assess. Guidance of 40+% annual revenue growth from 2020 is maintained but will be off a lower base.

### Equity raise provides additional funds to build on commercial progress

Bonesupport continues to demonstrate progress with its commercially driven strategy, with investment in new US sales territories converting into enhanced sales and new distributors in place in key European countries, such as France, Italy, and the Netherlands. The equity raise enables the company to embark on plans to scale up and maintain the necessary investment to drive CERAMENT's growth trajectory. The over-subscribed share issue in May 2020 raised SEK378m (gross), through the issue of 10.5m shares at SEK36 (a 2.7% discount to the 10-day weighted average). Exhibit 1 outlines the intended use of funds.

### Exhibit 1: Use of proceeds

Focus area	Growth acceleration lever	Amount
Commercialisation	US market introduction and penetration of CERAMENT G	c 70%
	Continued market investment in Europe	
	Regulatory approval in new markets	
	Manufacturing improvements (automation and increased capacity)	
Operational and R&D	R&D pipeline progression and supporting clinical studies	c 10%
Other	General corporate and financial purposes	c 20%
<b>Total gross proceeds</b>		<b>SEK 378m</b>

Source: Bonesupport

### Planned investment in US launch of CERAMENT G, and Europe sales and manufacturing improvements

Around 70% of proceeds will be directed into commercial activities, in particular supporting planned US launch of CERAMENT G for chronic osteomyelitis, as well as further optimisation of the European sales and marketing organisation, pursuit of regulatory approvals in new markets, and various manufacturing initiatives to better position the company in anticipation of increased future sales.

### CERAMENT G US filing in second indication on track for late-2021

The antibiotic-eluting products, CERAMENT G and V, have gained traction in the markets where they are available, having become the option of choice for many influential surgeons. A similar clinical uptake in the US would be transformative for Bonesupport. Timelines for the potential label expansion of CERAMENT G into trauma remain on track despite a COVID-19 related slow-down in recruitment into the FORTIFY study. An FDA Premarket Approval (PMA) filing is expected in late 2021 following FDA approval of a sample size amendment for FORTIFY, such that enrolment is now complete with 198 patients (vs the original plan of 230).

## Financials and valuation

### Q120 net sales up on Q119, but down on prior quarter...

Bonesupport's Q120 net sales of SEK43.4m were +32.8% on Q119 (SEK32.8m), but slightly down on the prior record quarter (Q419: SEK46.1m), with gross profit for the period of SEK38.5m (vs Q119: SEK28.2m and Q419: SEK41.1m). Both US and Europe/RoW showed sales growth vs the prior year period, but this was muted as healthcare resources were reprioritised due to COVID-19 influencing sales from mid-February in Europe, and early-March in the US.

### ...as impact of COVID-19 starting to be felt in all geographies

The sequential increase in US quarterly net sales since Q418 was broken in Q120, with a 2.8% fall in US net sales vs Q419 to SEK21.2m. However, this was up 84% on Q119. US gross margin was 93% for Q120. Europe/RoW Q120 sales of SEK22.2m grew 4% on Q119 (SEK21.3m) but were 4% lower than Q419. CERAMENT G and V posted Q120 sales of SEK18.5m (83% of Europe/RoW revenues) +2% on Q119, but down 6% on Q419. Direct markets continued to represent 86% of Europe/RoW sales. Sales in Italy and France experienced some short-term disruption as new distributors were put in place, although this was partially offset by a large Australian order. Europe/RoW gross margin was 85%.

### Temporary cost saving measures implemented in response to COVID-19

Prior periods have coupled disciplined cost control with directed investment into accelerating CERAMENT sales growth. In Q120, the 14.6% drop in selling costs (SEK35m + SEK7.1m in commissions) on Q419 reflected the early impact of COVID-19. G&A was also lower as a result, while R&D spend was subject to quarterly fluctuations in the timing of projects and clinical studies. SG&A is likely to reduce further in Q220 as work time reductions and temporary company-wide salary cuts take effect, coupled with lower travel costs and marketing spend due to travel restrictions and a shift to virtual events.

### SEK378m equity raise provides financial flexibility

Bonesupport's Q120 operational loss was SEK29.2m (Q119: SEK39.0m, Q419: SEK38.6m), with a net loss of SEK29.4m. End-March 2020 net cash was SEK68m. An SEK60m working capital facility with Skandinaviska Enskilda Banken (SEB) and the SEK387m (gross) equity raise in May 2020 provide Bonesupport with the flexibility and financial headroom to continue to invest accordingly in pursuing its growth strategy and provides a cushion for COVID-19 repercussions.

### COVID-19 repercussions being felt across the orthopaedic industry

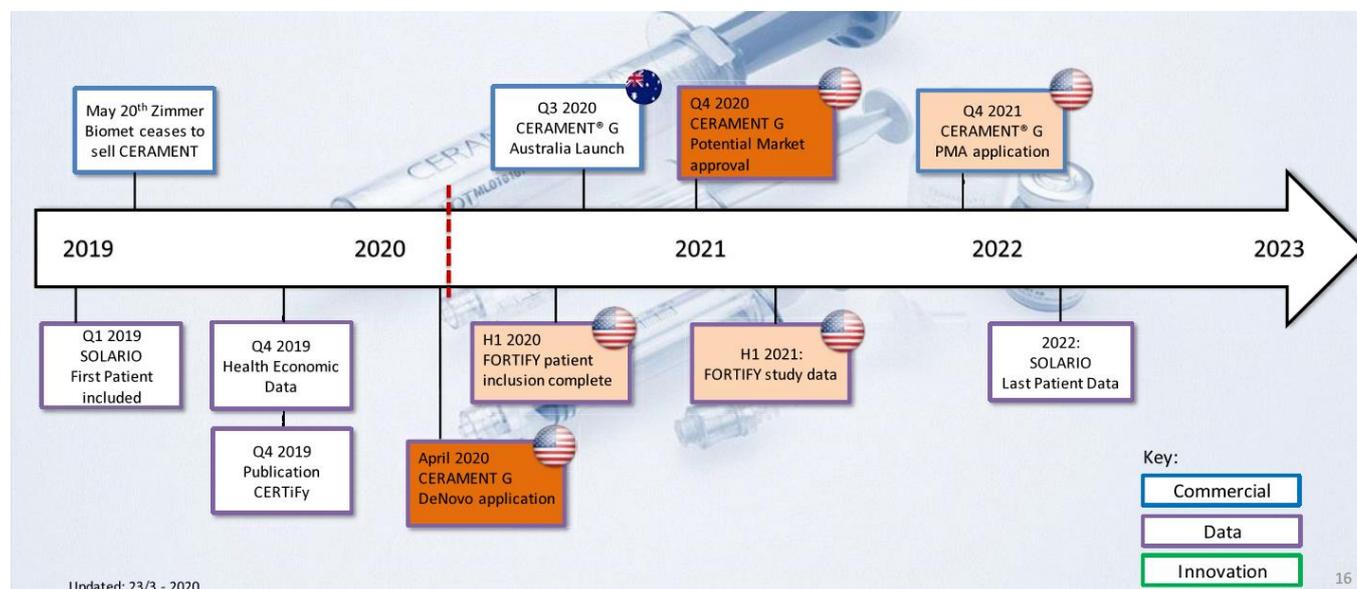
Bonesupport has made major inroads in implementing its commercially driven growth strategy for CERAMENT as it seeks to affect a paradigm shift in the way that bone voids are treated. However, in the short-term, as is being seen across the orthopaedic industry, the operational challenges and the impact of COVID-19 on the healthcare resource prioritisation will inhibit growth. The pandemic is associated with many uncertainties, some connected to its epidemiology, others to its potential scope and duration, and to governmental responses that attempt to moderate its effects on society. These factors, as well as the potential for a second peak as lockdowns are exited will influence how rapidly non-critical procedures will be rescheduled and new customers can be secured. The timing is unclear, but necessity of these operations (particularly with chronic osteomyelitis) suggest that they will ultimately have to take place, and so commercial activity levels and sales will rebound.

### Long-term prospects remain sound, and built on solid commercial foundation

In our view, Bonesupport's long term prospects remain attractive; the foundations that have been put into place mean it is well positioned to resume growth in 2021, potentially earlier. Exhibit 2 highlights the multiple value generating milestones

expected over the next two years. Management have reiterated their expectation of 40+% annual revenue growth from 2020 onwards, although we now expect this to be from a lower base. Exhibit 3 summarises the changes to our estimates.

## Exhibit 2: CERAMENT value generating milestones



Source: Bonesupport

## Exhibit 3: Summary of changes to estimates

	Sales (SEKm)			EBITDA (SEKm)			Adj. EPS (SEK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2020E	263.1	170.4	(35.2%)	(66.7)	(123.3)	N/A	(1.4)	(2.2)	N/A
2021E	380.6	307.2	(19.3%)	(2.3)	(37.6)	N/A	(0.2)	(0.7)	N/A

Source: Trinity Delta

### New valuation of SEK41.5m/share or SEK2.62bn

Our updated forecasts (including impact of COVID-19 and potential 2021 US launch of CERAMENT for chronic osteomyelitis), coupled to rolling forward our DCF valuation and updating cash and shares outstanding for the fund raise reduces our valuation (Exhibit 4) to SEK41.5/share vs SEK43/share previously.

## Exhibit 4: 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%	5.0	47	5.0	46.9	0.7
CERAMENT G/V (Europe/RoW)	100.0%	68.2	644	68.2	643.7	10.2
CERAMENT BVF (US)	100.0%	81.5	769	81.5	769.1	12.2
CERAMENT G (US)	75.0%	169.4	1,599	127.0	1,199.0	19.0
Operating costs	100%	(44.3)	(418)	(44.3)	(418.4)	(6.6)
Net cash at Q220e	100%	40.3	381	40.3	380.9	6.0
<b>Total</b>		<b>320.0</b>	<b>3,020.9</b>	<b>277.7</b>	<b>2,621.3</b>	<b>41.5</b>

Source: Trinity Delta Note: Assumes USD/SEK exchange rate of 9.4 and 12.5% discount rate. The valuation is based on explicit cash flows to 2025, followed by a ten-year trending period, and a 2.5% terminal growth rate.

**Exhibit 5: Summary of financials**

Year-end: December 31	SEK m	2017	2018	2019	2020E	2021E
<b>INCOME STATEMENT</b>						
<b>Revenues</b>		<b>129.3</b>	<b>96.6</b>	<b>155.5</b>	<b>170.4</b>	<b>307.2</b>
Cost of goods sold		(16.9)	(15.2)	(19.6)	(19.8)	(34.7)
<b>Gross Profit</b>		<b>112.4</b>	<b>81.5</b>	<b>135.9</b>	<b>150.6</b>	<b>272.6</b>
R&D costs		(60.6)	(66.1)	(68.9)	(67.1)	(63.7)
Sales costs		(92.9)	(133.3)	(182.3)	(167.2)	(201.6)
Admin costs		(57.5)	(58.3)	(43.3)	(41.9)	(47.2)
Other expenses		(0.7)	1.9	0.5	0.5	0.6
<b>Underlying operating profit</b>		<b>(99.3)</b>	<b>(174.4)</b>	<b>(158.1)</b>	<b>(125.1)</b>	<b>(39.4)</b>
Other revenue/expenses		0.0	0.0	0.0	0.0	0.0
<b>EBITDA</b>		<b>(98.1)</b>	<b>(172.9)</b>	<b>(156.4)</b>	<b>(123.3)</b>	<b>(37.6)</b>
<b>Operating Profit</b>		<b>(99.3)</b>	<b>(174.4)</b>	<b>(158.1)</b>	<b>(125.1)</b>	<b>(39.4)</b>
Interest income		0.0	0.0	0.0	0.4	0.6
Interest expense		0.0	0.0	0.0	(4.0)	(5.3)
Other financing costs/income		(28.6)	(0.5)	(0.2)	(0.0)	0.0
<b>Profit Before Taxes</b>		<b>(127.9)</b>	<b>(174.9)</b>	<b>(157.3)</b>	<b>(126.7)</b>	<b>(44.1)</b>
<b>Adj. PBT</b>		<b>(127.9)</b>	<b>(174.9)</b>	<b>(158.3)</b>	<b>(128.7)</b>	<b>(44.1)</b>
Current tax income		(1.0)	(1.5)	(2.8)	(0.5)	(0.2)
<b>Net Income</b>		<b>(128.9)</b>	<b>(176.4)</b>	<b>(160.1)</b>	<b>(127.2)</b>	<b>(44.2)</b>
<b>EPS (SEK)</b>		<b>(3.2)</b>	<b>(3.4)</b>	<b>(3.1)</b>	<b>(2.2)</b>	<b>(0.7)</b>
<b>Adj. EPS (SEK)</b>		<b>(3.2)</b>	<b>(3.4)</b>	<b>(3.1)</b>	<b>(2.2)</b>	<b>(0.7)</b>
<b>DPS (SEK)</b>		<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
Average no. of shares (m)		39.8	51.4	51.9	63.2	63.2
<i>Gross margin</i>		<i>87.0%</i>	<i>84.3%</i>	<i>87.4%</i>	<i>88.4%</i>	<i>88.7%</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>
<b>BALANCE SHEET</b>						
<b>Current assets</b>		<b>588.1</b>	<b>316.4</b>	<b>173.1</b>	<b>406.8</b>	<b>370.4</b>
Cash and cash equivalents		533.4	261.5	92.1	348.9	273.7
Accounts receivable		20.7	18.7	29.8	28.0	50.5
Inventories		22.1	23.7	39.3	21.7	38.0
Other current assets		12.0	12.5	11.9	8.1	8.1
<b>Non-current assets</b>		<b>8.6</b>	<b>9.8</b>	<b>23.2</b>	<b>24.5</b>	<b>29.6</b>
Property, plant & equipment		3.1	3.9	14.6	11.1	10.4
Intangible assets		5.2	5.5	7.7	12.4	18.2
Other non-current assets		0.2	0.4	1.0	1.1	1.1
<b>Current liabilities</b>		<b>(145.7)</b>	<b>(47.3)</b>	<b>(66.0)</b>	<b>(61.5)</b>	<b>(70.8)</b>
Short-term debt		(98.6)	0.0	(4.7)	(3.7)	(3.7)
Accounts payable		(11.6)	(12.5)	(13.6)	(12.8)	(22.3)
Other current liabilities		(35.6)	(34.8)	(47.7)	(45.0)	(44.8)
<b>Non-current liabilities</b>		<b>(0.2)</b>	<b>(0.3)</b>	<b>(6.0)</b>	<b>(4.6)</b>	<b>(4.6)</b>
Long-term debt		0.0	0.0	(5.7)	(4.3)	(4.3)
Other non-current liabilities		(0.2)	(0.3)	(0.3)	(0.3)	(0.3)
<b>Equity</b>		<b>450.8</b>	<b>278.5</b>	<b>124.3</b>	<b>365.2</b>	<b>324.6</b>
Share capital		1,220.4	1,220.3	1,224.7	1,591.0	1,591.0
Other		(769.7)	(941.7)	(1,100.4)	(1,225.8)	(1,266.4)
<b>CASH FLOW STATEMENTS</b>						
<b>Operating cash flow</b>		<b>(107.5)</b>	<b>(171.6)</b>	<b>(164.3)</b>	<b>(101.9)</b>	<b>(69.0)</b>
Profit before tax		(99.3)	(174.4)	(158.1)	(125.1)	(39.4)
Non-cash adjustments		16.7	3.8	17.4	5.0	4.7
Change in working capital		(12.5)	2.0	(18.1)	21.6	(29.2)
Interest paid		(11.7)	(0.8)	(0.2)	(3.5)	(4.7)
Taxes paid		(0.7)	(2.2)	(5.2)	0.2	(0.4)
<b>Investing cash flow</b>		<b>(4.7)</b>	<b>(2.7)</b>	<b>(4.2)</b>	<b>(5.2)</b>	<b>(6.2)</b>
CAPEX		(4.6)	(2.6)	(4.2)	(5.2)	(6.2)
Other investing cash flows		(0.1)	(0.1)	0.0	0.0	0.0
<b>Financing cash flow</b>		<b>504.8</b>	<b>(98.8)</b>	<b>(1.6)</b>	<b>363.4</b>	<b>0.0</b>
Proceeds from equity		532.8	(0.2)	4.1	365.9	0.0
Increase in loans		(27.9)	(98.6)	(5.7)	(2.5)	0.0
Other financing cash flow		0.0	0.0	0.0	0.0	0.0
<b>Net increase in cash</b>		<b>392.6</b>	<b>(273.1)</b>	<b>(170.1)</b>	<b>256.3</b>	<b>(75.2)</b>
Exchange rate effects		(0.7)	1.2	0.7	0.5	0.0
Cash at start of year		141.5	533.4	261.5	92.1	348.9
<b>Cash at end of year</b>		<b>533.4</b>	<b>261.5</b>	<b>92.1</b>	<b>348.9</b>	<b>273.7</b>
<b>Net cash at end of year</b>		<b>434.7</b>	<b>261.5</b>	<b>81.7</b>	<b>340.9</b>	<b>265.7</b>

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

**Lala Gregorek**

[lgregorek@trinitydelta.org](mailto:lgregorek@trinitydelta.org)

+44 (0) 20 3637 5043

**Franc Gregori**

[fgregori@trinitydelta.org](mailto:fgregori@trinitydelta.org)

+44 (0) 20 3637 5041

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