

BONESUPPORT

Company update

US sales rebound and new clinical study

Pharma & biotech

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Recent updates indicate Bonesupport has been making progress in all key strategic directions. Sales have started to rebound in the US since the company started commercialising its CERAMENT bone void filler in Q418. The top-line results from the clinical CERTiFy study released in Q418 are also helping to increase awareness. CERAMENT G/V will be included in a new, large investigator-led SOLARIS study, which could potentially change the standard of care in osteomyelitis treatment. Our valuation is largely unchanged at SEK1.73bn or SEK33.1/share (vs SEK33.5/share).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	129.3	(127.1)	(3.22)	0.0	N/A	N/A
12/18	96.6	(174.1)	(3.45)	0.0	N/A	N/A
12/19e	199.9	(142.9)	(2.75)	0.0	N/A	N/A
12/20e	298.9	(81.2)	(1.53)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Gathering clinical evidence

A retrospective case study supporting the use of CERAMENT G was published by surgeons at the Oxford Bone Infection Unit in March 2019. The study demonstrated bone remodelling with CERAMENT G for the first time through radiology and histology in patients with chronic osteomyelitis (level IV evidence). This is one of many case studies published by various key opinion leaders (KOLs) indicating interest in Bonesupport's products.

Large investigator-led trial to include CERAMENT

A new, large investigator-led study SOLARIO has been initiated (n=500) in Europe. The study aims to show that the use of local antibiotics plus a short course of systemic antibiotics (<1 week) is as good as the current standard of care, which is local antibiotics plus >4 weeks of systemic antibiotics. Although the results are not expected until 2022, if successful this study could lead to a treatment paradigm shift and show that local antibiotics play more of a role in managing bone infections than previously thought.

US sales rebound

Q119 US sales through Bonesupport's distributor network grew by 174% q-o-q to SEK11.5m, through a mixture of new and old accounts. The network includes 40 distributors totalling over 500 sales reps and a new group purchasing organisation (GPO) contract has been secured with Ascension (150 hospitals) in Q119, which should lead to sales in Q319. We leave our medium- to long-term projections unchanged because we see the initial US sales rebound as a good start.

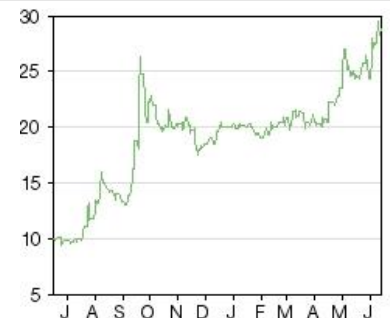
Valuation: SEK1.73bn or SEK33.1/share

We value Bonesupport at SEK1.73bn or SEK33.1/share vs SEK1.74bn or SEK33.5/share previously, due to lower net cash partially offset by rolling our model forward. Key near-term catalysts include updated US sales figures in the Q219 financial results, publication of the full CERTiFy results and health economics data in Q319.

Price SEK28.8
Market cap SEK1506m

Net cash (SEKm) at end-Q119	206.0
Shares in issue	52.3m
Free float	51.4%
Code	BONEX
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	15.7	37.1	175.3
Rel (local)	12.2	32.3	162.8
52-week high/low	SEK29.5	SEK9.4	

Business description

Bonesupport is an orthobiologics company that has four marketed bone graft substitutes and several other projects in R&D. The lead products CERAMENT BVF, CERAMENT G (gentamicin) and CERAMENT V (vancomycin) are intended to help orthopaedic surgeons manage bone voids and defects after injuries or diseases affecting bones.

Next events

CERTiFy study results published	H219
Q219 financial results	25 July 2019
Health economics data published	Q319
FORTIFY study data	2020

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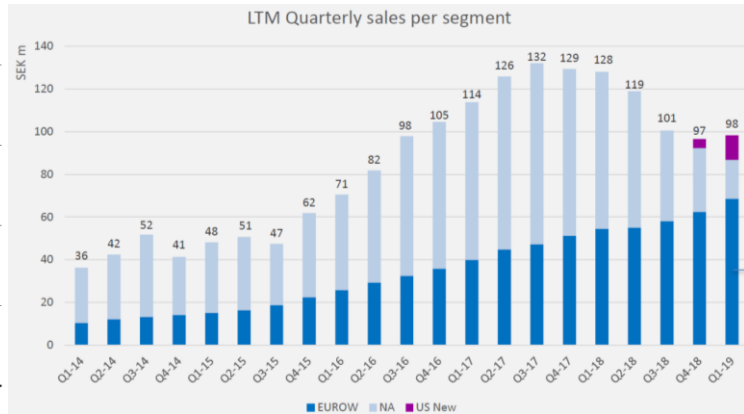
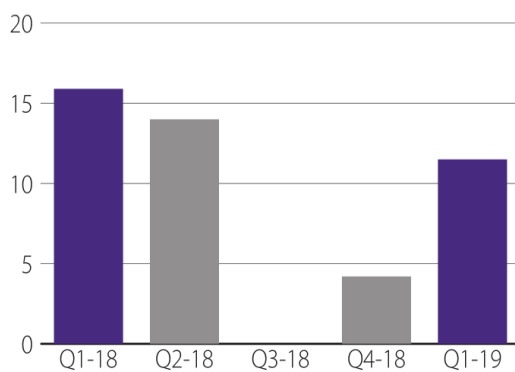
US sales rebound looks promising

Q119 sales of CERAMENT BVF in the US were SEK11.5m. This represents growth from SEK4.2m in Q418, which was the first quarter that Bonesupport's own distributor network started promoting CERAMENT in the US. US sales were down 28% y-o-y, but in Q118 US distribution was managed solely by Zimmer Biomet. After Bonesupport terminated the agreement it booked no sales in Q318 because Zimmer had exclusivity until 23 October 2018. Over the last two quarters Bonesupport's sales have been via its newly established network of independent distributors, including 40 distributors totalling over 500 sales reps. In its Q119 call, Bonesupport explained there was a 'good mix of new and legacy accounts' and the top-line CERTIFY study results are helping increase awareness of CERAMENT.

Bonesupport has secured a new GPO contract with [Ascension](#) (150 hospitals) and management expects to start generating sales from end of Q219/start of Q319. This is in line with Bonesupport's previous guidance for all GPO contracts (see our [previous note](#)). We expect additional GPO contracts to be added gradually.

Exhibit 1: Bonesupport's US quarterly sales (LHS) and 12-month rolling sales per segment (RHS)

Net Sales per quarter, SEKm



Source: Bonesupport

Sales of CERAMENT products in Europe grew 41% to SEK21.3m y-o-y. The main contributors to this were the antibiotic-eluting CERAMENT G/V, which saw sales increase by 54% y-o-y. This increased traction is due to the expansion of the sales team in 2018 starting to have an impact and due to the CERTIFY top-line results being promoted.

The total operating loss for Q119 was SEK39.0m (vs SEK33.1m in Q118) largely due to higher selling expenses. Bonesupport is implementing cost-control measures to ensure it remains funded to profitability (2021) with existing resources, as previously guided. Administrative costs will reduce, whereas investments in the commercial side will continue to increase following the change in the distribution model. We reflected the shift in our model previously. Given that Bonesupport's investment case is still in a turnaround phase, our estimates are subject to revision once more performance data points are announced. For now, we leave our medium- to long-term projections unchanged since we see initial US sales rebound as a good start.

KOL relationships underpin CERAMENT G/V acceptance

In the field of orthopaedics, we believe building and maintaining relationships with surgeons is essential for commercial success. The continued growth in CERAMENT G/V sales is underpinned

by strong KOL engagement and multiple case studies now [published](#) by surgeons using the antibiotic-eluting CERAMENT G/V in Europe help increase awareness of the product.

We attended the Oxford Bone Infection Conference in March 2019. Bonesupport has a strong relationship with the Oxford Bone Infection Unit, one of the most important centres for treating bone infection in Europe. KOL Martin McNally is head of this unit and has influence across Europe in this field, especially because he is the president of the [European Bone and Joint Infection Society \(EBJIS\)](#). McNally and colleagues presented several patient case studies at the conference, where CERAMENT G was showcased. In addition, they have published several articles about CERAMENT G, including patient case studies.

Bone remodelling shown for the first time with CERAMENT G

The most recent case study was [published](#) in March 2019 by the Oxford Bone Infection Unit supporting the use of CERAMENT G. This was a retrospective study in patients with chronic osteomyelitis having a single-stage procedure. The study found that using CERAMENT G resulted in an infection recurrence of just 4.3% and mean void filling was 73.8% at final follow-up. For the first time in humans, bone remodelling with CERAMENT G was demonstrated by radiology and histology.

Case studies are a type of observational study providing level IV evidence (whereas the [FORTIFY study](#) will provide level I clinical evidence in bone infection). They are not randomised or controlled, so results should be interpreted with care. However, they are peer reviewed and published in journals so they are still an important way for orthopaedics companies to build evidence and promote their products to surgeons. Several case studies have now been conducted with CERAMENT G across Europe, which we believe is evidence that Bonesupport is successfully establishing relationships with European KOLs.

New, large investigator-led SOLARIO study

A new, large randomised trial has been initiated by the Oxford University Hospital's NHS Foundation Trust in collaboration with the EBJIS: **Systemic Or Local Antibiotic Regimes In Orthopaedics (SOLARIO)** ([NCT03806166](#)). Bonesupport is not directly sponsoring the trial (the company only donated a research grant to the EBJIS), so it will not be able to influence the design. However, the potential benefit for Bonesupport could be substantial. The study aims to show that the use of local antibiotics plus a short course of systemic antibiotics (<1 week) is as good as the current standard of care, which is local antibiotics plus >4 weeks of systemic antibiotics.

Traditional understanding in treating osteomyelitis is that long-term systemic antibiotic therapy (oral or intravenous) is the mainstay approach, while local antibiotics were perceived as more of a supportive therapy. The SOLARIO study investigates whether using local antibiotics allows shorter courses of systemic antibiotics to limit antibiotic resistance, side effects and cost. The rationale of the study is that locally delivered antibiotics can achieve much higher concentrations than those administered systemically due to poor bone tissue perfusion. Although the results are not expected to be released until 2022, if successful this study could lead to a treatment paradigm shift and show that local antibiotics play more of a role in managing bone infection than previously thought. A positive study outcome could also support the premium pricing of CERAMENT, because a shorter-duration antibiotic therapy should save costs and help combat antimicrobial resistance.

The study (n=500) is designed as non-inferiority, randomised, controlled trial comparing the two treatment regimens. Products from different manufacturers are allowed, but they must contain an antibiotic and be approved by the regulatory authorities. This limits the product selection to PMMA beads, Collagen fleeces plus antibiotics, CERAMENT G/V, Herafil G (Heraeus) and Osteoset T

(Wright Medical). We discussed how these products differ in our previous reports (most details in the [initiation report](#)), but we view CERAMENT G/V at the top in terms of innovation.

Exhibit 2: Overview of the SOLARIO study (NCT03806166)

Aim	To determine whether treatment with local antibiotics can allow for shorter courses of oral or intravenous antibiotics following surgery for bone or joint infection to limit antibiotic resistance, side effects and cost.
Summary design	SOLARIO: a randomised open-label multi-centre clinical trial
No. of patients	500
Key inclusion criteria	Orthopaedic infection, undergoing surgical treatment for the infection, locally administered antibiotics at the site of orthopaedic infection, would ordinarily be managed with a prolonged course (>=4 weeks) of systemic antibiotics
Endpoints	Primary endpoint: Definitive treatment failure (infection recurrence) Secondary endpoints: Possible or probable treatment failure, serious adverse events, antibiotic side effects, quality of life measures
Sites	UK: Wrightington Hospital, Royal National Orthopaedic Hospital, Bone Infection Unit Nuffield Orthopaedic Centre, Royal Liverpool Hospitals
Completion date	March 2022

Source: BONESUPPORT, clinicaltrials.gov

Valuation

We value Bonesupport at SEK1.73bn or SEK33.1/share versus SEK1.74bn or SEK33.5/share previously, due to lower net cash partially offset by rolling our model forward. Our DCF model uses a 10% discount rate and includes a forecast period until 2028. The terminal value assumes a long-term 2.0% growth rate.

Bonesupport has changed the way it accounts for leases under the new IFRS 16 rules. It now records remaining financial leases in the balance sheet as short- and long-term liabilities of SEK5.2m and SEK8.0m respectively. This was balanced with a corresponding increase in tangible long-term assets. The net effect on P&L was minor. Bonesupport had cash of SEK219.1m at end-Q119 and, according to our model, this is sufficient to finance the company to break even in 2021.

The main near-term catalysts for the share price include publication of the full results of the CERTiFy study expected in H219, publication of the health economics study data in Q319 and an update on sales under the independent distributor network in the US at the Q219 results in July 2019. Results of the FORTIFY trial are expected in 2020.

Exhibit 3: Assumptions, projected cash flow and DCF valuation, SEKm

	2019e	2020e	2021e	2022e	2023e	2024e	2025e	2026e	2027e	2028e
EBIT* (risk adjusted)	(143.9)	(82.1)	30.7	165.7	223.9	258.7	267.8	273.2	276.0	277.4
Tax**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
D&A	1.8	5.7	5.0	4.5	4.1	3.9	3.7	3.6	3.5	3.4
Change in WC	(17.9)	(9.4)	(12.8)	(33.3)	(14.4)	(10.2)	(2.8)	(1.8)	(1.3)	(0.9)
Capex	(2.3)	(2.0)	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)	(2.0)
Operating FCF	(162.3)	(87.8)	20.7	134.8	211.5	250.4	266.6	272.8	276.2	277.9
										NPV (SEKm)
Free cash flows FY19-28e										677.7
Terminal value (2.0% growth rate assumed)										848.1
Total NPV										1,525.8
Net cash (last reported)										206.0
Valuation										1,732
Valuation/share (SEK)										33.1
Discount rate										10.0%
Tax rate (long term)										22%

Source: Edison Investment Research. *EBIT here includes risk-adjusted cash flows associated with CERAMENT G launch in the US in 2021. **Tax loss carry forwards (SEK604m as end-2017) offset taxes during our forecast period.

Exhibit 4: Financial summary

	SEK'000s	2016	2017	2018	2019e	2020e
December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		104,599	129,301	96,623	199,935	298,891
Cost of Sales		(16,312)	(16,871)	(15,157)	(29,990)	(44,834)
Gross Profit		88,287	112,430	81,466	169,945	254,057
Research and development		(38,233)	(60,636)	(66,064)	(66,064)	(66,064)
EBITDA		(87,399)	(98,116)	(172,847)	(142,088)	(76,454)
Operating Profit (before amort. and except.)		(87,601)	(98,486)	(173,664)	(143,112)	(81,284)
Intangible Amortisation		(1,144)	(799)	(740)	(778)	(849)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(88,745)	(99,285)	(174,404)	(143,890)	(82,133)
Net Interest		(20,821)	(28,600)	(465)	196	56
Profit Before Tax (norm)		(108,422)	(127,086)	(174,129)	(142,917)	(81,228)
Profit Before Tax (reported)		(109,566)	(127,885)	(174,869)	(143,694)	(82,077)
Tax		(625)	(1,007)	(1,536)	(1,536)	(1,536)
Profit After Tax (norm)		(109,047)	(128,093)	(175,665)	(144,453)	(82,764)
Profit After Tax (reported)		(110,191)	(128,892)	(176,405)	(145,230)	(83,613)
Average Number of Shares Outstanding (m)		25.8	39.8	51.0	52.6	54.1
EPS - normalised (SEK)		(4.22)	(3.22)	(3.45)	(2.75)	(1.53)
EPS - normalised and fully diluted (SEK)		(4.22)	(3.22)	(3.45)	(2.75)	(1.53)
EPS - reported (SEK)		(4.26)	(3.24)	(3.46)	(2.76)	(1.55)
Dividend per share (SEK)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		84.4	87.0	84.3	85.0	85.0
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		5,091	8,591	9,771	24,716	22,143
Intangible Assets		4,469	5,244	5,511	6,019	6,311
Tangible Assets		442	3,099	3,885	18,322	15,458
Investments		180	248	375	375	375
Current Assets		183,718	588,093	316,370	173,525	96,677
Stocks		14,489	22,079	23,681	32,866	36,850
Debtors		20,242	20,678	18,683	27,388	32,755
Cash		141,501	533,367	261,468	100,733	14,534
Other		7,486	11,969	12,538	12,538	12,538
Current Liabilities		(69,742)	(145,725)	(47,321)	(52,499)	(52,499)
Creditors		(44,639)	(47,105)	(47,321)	(47,321)	(47,321)
Short term borrowings		(25,103)	(98,620)	0	(5,178)	(5,178)
Long Term Liabilities		(84,763)	(173)	(289)	(8,249)	(8,249)
Long term borrowings		(84,599)	0	0	(7,960)	(7,960)
Other long term liabilities		(164)	(173)	(289)	(289)	(289)
Net Assets		34,304	450,786	278,531	137,493	58,072
CASH FLOW						
Operating Cash Flow		(70,184)	(95,060)	(168,652)	(155,786)	(81,612)
Net Interest		(11,640)	(11,737)	(822)	196	56
Tax		(109)	(737)	(2,151)	(1,536)	(1,536)
Capex		(67)	(3,037)	(1,609)	(2,323)	(1,966)
Acquisitions/disposals		0	0	0	0	0
Financing		103,714	504,833	0	0	0
Other		4,091	8,686	(45)	(1,286)	(1,141)
Dividends		0	0	0	0	0
Net Cash Flow		25,805	402,948	(173,279)	(160,735)	(86,199)
Opening net debt/(cash)		(5,994)	(31,799)	(434,747)	(261,468)	(87,595)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	(13,138)	0
Closing net debt/(cash)		(31,799)	(434,747)	(261,468)	(87,595)	(1,396)

Source: Bonesupport, Edison Investment Research

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