

## Bonesupport

### Accelerated FDA pathway for CERAMENT G

23 March 2020

- Bonesupport is set to file a *de novo* application for FDA approval of its novel antibiotic eluting synthetic bone graft CERAMENT G. This follows the FDA granting CERAMENT G a “[breakthrough device](#)” designation for osteomyelitis and should result in an expedited review. This would make it the first such product to be approved, possibly as soon as end-2020.
- [Osteomyelitis](#) is a persistent and serious infection of the bone and accounts for roughly half of all non-trauma-related amputations. Around 50,000 bone graft procedures are performed annually in the US for this indication and the market is estimated at c \$100m pa.
- The PMA ([premarket approval application](#)) submission for the remaining CERAMENT G indications, including trauma, remains on track for filing by end-2021. The PMA will employ the efficacy and safety data from the comprehensive [FORTIFY](#) trial that is currently underway and scheduled to report preliminary data around mid-2021.
- The US commercial infrastructure has been materially strengthened in anticipation of CERAMENT G launches. It currently uses c 40 specialist distributors and around 500 salespeople, with an increased focus on trauma applications. Already the sales impact is apparent with growth in end-user demand, higher margins, and stronger customer relationships.
- The market for infection indications in the US and EU5 is estimated at c \$200m pa, a fraction of the \$660m global opportunity that CERAMENT G & V could address. However, the FDA breakthrough designation, coupled with earlier approval, would prime the market for CERAMENT G's wider availability in 2021/2 and could, possibly also lead to some off-label use.
- Bonesupport has been posting strong growth of the antibiotic eluting CERAMENT G & V in the markets where it is already available; they have clearly gained traction (representing 85% of EURoW sales for FY19) and have become the option of choice for many influential surgeons. A similar clinical uptake in the commercially important US market would be transformative for Bonesupport.

Price (SEK)	21.2
Market Cap (SEKm)	1,120
Primary exchange	OMX Stockholm
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.

**Trinity Delta view:** Bonesupport is continuing to make excellent progress, with the FDA's “breakthrough device” designation for CERAMENT G being the latest example. The focus on commercial execution is paying off, with global sales clearly gaining momentum. It is the restructured, and increasingly proven, US commercial platform (post-Zimmer Biomet termination) that will now launch CERAMENT G as early as 2021. Also, we believe FDA approval remains the *de facto* “gold standard” and that it could impart a “halo” effect to sales in existing European markets. Our valuation for Bonesupport is SEK2.27bn or SEK43.3/share.

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