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.

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.

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.

Analysts

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