

Medicrea (ALMED.PA)

Medicrea Announces Lifetime Warranty of UNiD Patient-Specific Products

Medicrea (Euronext Paris: ALMED.PA) is a medical device company marketing a range of patient-specific implants for use in spinal fusion procedures. The Company's UNiD platform provides spinal surgeons with patient-specific osteosynthesis rods and comprehensive preoperative planning solutions intended to improve postoperative spinal alignment and patient outcomes. Medicrea recently announced a lifetime warranty on their UNiD products, reflecting the Company's confidence in the stability of their spinal implants and their potential to reduce the frequency of revision surgical procedures. The Company also reported sales through the third quarter, reflecting continuing sales growth.

- Medicrea Announces Lifetime Warranty for Their UNiD Patient-Specific Products.** Medicrea's creation of a lifetime warranty for the UNiD product line is the first instance of a warranty covering spinal implants used in spinal fusion procedures. The warranty will cover the full cost of replacement implants for a revision surgery as well as the necessary UNiD Lab services. This warranty program reflects the Company's confidence in the long-term stability of their products and their potential to reduce the rate of revision surgery, which currently affects more than 1 in 3 patients. This warranty may encourage further adoption of UNiD products.
- Patient-Specific Rods May Improve Spinal Surgery Outcomes.** Osteosynthesis rods are used in most spinal fusion surgeries to fix and promote fusion of vertebrae into a proper alignment. Medicrea has developed a process for the design and manufacture of patient-specific rods, known as UNiD rods, which provides a more natural spinal curvature than current methods. At present, the rods are bent manually in the operating room resulting in 62% of patients experiencing postoperative sagittal malalignment and 37% of patients requiring revision surgery over the long-term.[\[ref, ref\]](#) These revision procedures carry a high additional cost and have higher complication rates than the original surgery. In addition, sagittal alignment is recognized as an important predictor of patient outcomes and quality of life. The personalized UNiD rods have the potential to reduce the number of patients remaining malaligned after the procedure and subsequently the number revision surgeries that are required. This could result in substantial savings for the healthcare system.

Expected Upcoming Milestones

- H2 2016 – CE marking and 510(k) clearance of Medicrea's UNiD pedicle screw.
- YE 2016 – 1,000th UNiD surgery.
- Mid-2017 – Completion of PASS LP adult deformity outcomes study.
- 2017 – FDA clearance of 3D-printed UNiD interbody cages.
- 2017 – FDA clearance of 3D-printed UNiD vertebral replacement.

Analysts

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Market Data

Price	\$6.05
Market Cap (M)	\$61
EV (M)	\$51
Shares Outstanding (M)	10.0
Avg Daily Vol	7,222
52-week Range:	\$4.76 - \$8.22
Cash (M)	\$23.2
Net Cash/Share	\$0.99
Annualized Cash Burn (M)	
Years of Cash Left	~
Debt (M)	\$13.3

All relevant values converted at 1 EUR to 1.10 USD

Financials

FY Dec		2014A	2015A	2016A
EPS	H1	(0.01)A	(0.12)A	(0.33)A
	H2	NA	NA	NA
	FY	(0.16)A	(0.19)A	NA

- **Manual Bending of Osteosynthesis Rods is a Recognized Source of Rod Failure.** [Manual bending in the OR](#) reduces the strength and lifespan of titanium spinal constructs, compromising the integrity of the implant over the long-term. Use of a French bender often leaves notches in the rod, which are an acknowledged source of rod failure.[\[ref\]](#) Fatigue of the rod is typically undetectable to the patient until complete and catastrophic failure occurs. Roughly 9% of manually bent rods break within 1 year of implantation. [\[ref\]](#) The UNiD rod is manufactured via a specialized industrial contouring which avoids creating any notches in the rod, reducing the risk of rod breakage.
- **Medicrea Continues to Grow Sales of UNiD Products.** Medicrea has achieved sales of €21.6 million (\$24.1 million) through the 9 months ending September 30th and is on pace to reach €28.8 million (\$32.1 million) for the full year. This would reflect a 3.6% growth rate in year-over-year sales. In addition, Medicrea is nearing the significant milestone of 1,000 UNiD surgeries. To date this year, greater than 60% of sales were derived from the US market and gross margins on sales were roughly 80%. Medicrea is the first company to adapt the patient-specific treatment model to the spine. Increased adoption of these products may allow Medicrea to capture an increasing share of the \$10 billion spine market.
- **Aging Population to Reshape the Spinal Fusion Market.** By 2020, the Centers for Disease Control and Prevention(CDC) estimate that the population of people 65 years or older will reach nearly 55 million in the US, representing a 16% annual growth rate. As life expectancy increases and morbidity and disability rates decrease in the overall population, people are remaining active into later years of their lives and may remain eligible for and more likely to utilize surgical options than in previous decades.[\[ref\]](#) This also reflects improvements in surgical procedures and postoperative care that make these invasive surgeries more feasible in an aging population. New spine products and advanced surgical techniques have been developed for elderly patients with osteoporosis, which may broaden the pool of eligible patients.
- **Financial Results for the First Half of 2016.** On September 22, 2016, Medicrea announced financial results for the first half of 2016. The Company reported revenue of €14.8 million (\$16.4 million) for the half-year, compared to €13.8 million (\$15.3 million) in the first half of 2015. Medicrea reported a net loss of €2.7 million (\$3.0 million) in the first half of 2016, compared to a €1.0 million (\$1.1 million) net loss in the same period in 2015. In August, Medicrea raised €20 million (\$22.6 million) through the sale of 2,400,000 convertible bonds each with a par value of €6.25 (\$7.05) and the private placement of 1,028,803 common shares at a price of €4.86 (\$5.48) per share. Medicrea plans to use net proceeds to expand the Company's commercial presence in the US.

Risk to Investment

We consider an investment in Medicrea to be a high-risk investment. Medicrea operates in a highly competitive market with many established medical device companies and the competitive advantages of Medicrea's products are not guaranteed. Furthermore, early indications of clinical advantage do not necessarily translate into strong sales. Regulatory approval for its spinal products does not guarantee wide market adoption and sales may not meet investor expectations.

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