Zacks Small-Cap Research

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Amedica Corp. (AMDA-NASDAQ)

AMDA: Second Quarter 2016 Financial Results; CEO Focused On Driving Revenue

Based on our 10-year DCF model that uses a 16% discount rate and a 1.5% terminal growth rate, the target price comes out to roughly $2.50/share. Our assumptions and financial model will be updated based on relevant news.

Current Price (08/16/16)	$0.65
Valuation	**$2.50**

OUTLOOK

Amedica Corp., headquartered in Salt Lake City, UT is a medical device manufacturing firm that provides a broad range of products specific to spine and orthopedic applications using medical grade silicon nitride. Amedica's spinal implants are unique in their design and construction and therefore offer a distinct differentiation from the existing implants. Amedica distributes its products through independent distributors in the U.S., Europe and South America. Additionally, the products are also marketed through private label and OEM partnerships.

We think AMDA offers an attractive investment opportunity considering the large orthopedic and spinal fusion markets that the company is addressing.

SUMMARY DATA

52-Week High	**$8.40**
52-Week Low	**$0.67**
One-Year Return (%)	**-91.22**
Beta	**-2.40**
Average Daily Volume (sh)	**837,593**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-9.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**-0.6**
P/E using 2017 Estimate	**-0.9**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$4.7 A	$4.8 A	$4.8 A	$5.1 A	$19.5 A
2016	$4.2 A	$4.0 A	$4.5 E	$6.0 E	$18.8 E
2017					$33.7 E
2018					$46.7 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.02 A	-0.11 A	-$0.15 A	-$0.4 A	-$5.5 A
2016	-$0.30 A	-$0.4 A	-$0.2 E	-$0.4 E	-$1.3 E
2017					-$0.6 E
2018					-$0.3 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

AMDA: Second Quarter 2016 Financial Results; CEO Focused On Driving Revenue

Financial Update

On August 12, 2016 Amedica Corp. (NASDAQ:AMDA), reported second quarter 2016 financial results.

Revenue came in at $4 million, very similar to first quarter results. The firm is implementing a sales strategy in key geographic regions that have yet to materialize. Management expects that their effort will pay off beginning fourth quarter of this year.

Total operating expenses came in at $5.5 million. Research and development expense ($1.6 million) and general and administrative expense ($1.3 million) largely remained unchanged as compared to the first quarter 2016. Sales and marketing expense came in ~20% lower than estimated primarily due to decrease in sales. Operating cash burn was $2.5 million and management expects to decrease this number by an additional ~30-40% year-over-year.

Net loss for the second quarter of 2016 was $5.1 million, a loss of $0.04/share.

The firm exited second quarter 2016 with cash and cash equivalents of $5.2 million. In the past, Amedica raised capital using debt which while helped increase cash flow also increased its debt load. Shortly after the close of the second quarter, the firm completed a $12.7 million public offering which provided relief as the company was grappling with debt from Magna, Riverside and Hercules. The debt obligation has now been reduced to ~$9.5 million solely with Hercules.

Business Update

FDA Approval Still Pending: On the conference call held on August 12, 2016 Amedica provided update on the ongoing FDA review of the 24-month clinical data pertaining to the Valeo C Interbody device with CsC osteo-conductive scaffold. As a reminder, Amedica responded to the FDA 510(k) filing back in June 2016. We expected response sometime during the end of July/ beginning of August 2016. However, it is difficult to speculate on FDA timelines on approval as the path forward remains an ongoing dialogue between the FDA and management. However, we remain optimistic about the potential approval, pending which we believe AMDA will commence manufacturing, marketing and sales of the product in the U.S. The recent financing should help the company in its product launch, which is expected sometime in 2H 2016. This could be a big driver of interbody fusion device sales.

Revived New Sales Strategy: Due to the rapid consolidation of customers, Amedica's revenues are primarily from a handful of physicians from two geographic locations. Customer concentration has put its traditional marketing model under stress. Two years ago, AMDA's silicon nitride products did not have sufficient clinical data to back up their marketing strategy. However, with the availability of the 24-month clinical data, Amedica is making the necessary moves to revise its marketing strategy, which includes bringing in new sales management with extensive experience in selling spine products.

Since April 2016, the firm has added three additional regional sales directors, and has 18 distributors to-date, 12 of whom were hired in the past 45 days. Amedica is already realizing the effectiveness of its revised sales team who have increased the number of customers and potential sales agreements. Improvements in operational efficiencies and top line growth are expected in the fourth quarter of 2016. Management is continuously exploring the alternatives that will enable them to best capture a wide customer base.

Silicon Nitride for Teeth: In an article published in April 2016 in Langmuir,[1] scientists at Amedica believe that Silicon Nitride holds promise as a therapeutic aid for treating severe gum disease (Porphyromonas gingivalis). Severe gum disease, also known as periodontitis can lead to tooth loss, and treating it remains a challenge. Gum disease puts nearly half of Americans at risk of bone loss as well as heart attack, stroke, and other systemic diseases.

During the study, after only 6 days of exposure, the microscopy technique revealed the formation of peroxynitrite within the bacterial cells. Peroxynitrite is an unstable compound that degraded the nucleic acids in the bacterial cells, which in turn, dramatically reduced their ability to produce essential proteins and fats making it impossible for the cells to replicate. Changing the surface chemistry of Silicon Nitride could potentially influence peroxynitrite formation and affect bacterial metabolism in different ways. Although further studies are required, current research demonstrates that the bioceramic offers a new and promising way to treat gum disease.

Valuation

We have modified our financial model to reflect Q2 2016 results and forecasts as per guidance received from management. Our fundamentals on AMDA remain intact.

[1] Silicon Nitride Bioceramics Induce Chemically Driven Lysis in Porphyromonas gingivalis, Giuseppe Pezzotti, Ryan M. Bock, Bryan J. McEntire, Erin Jones, Marco Boffelli, Wenliang Zhu, Greta Baggio, Francesco Boschetto, Leonardo Puppulin, Tetsuya Adachi, Toshiro Yamamoto, Narisato Kanamura, Yoshinori Marunaka, and B. Sonny Bal, Langmuir 2016 32 (12), 3024-3035

SNAPSHOT



- Amedica Corp. (NASDAQ:AMDA), headquartered in Salt Lake City, UT is a firm that produces medical grade silicon nitride for debilitating diseases specific to spine and orthopedic applications.
- In 2008, Amedica received FDA 510(k) clearance for Valeo Interbody Fusion Devices, Cervical Plating System and Pedicle Screw System.
- The company's manufacturing facility is FDA and CE cleared for prototyping and developing silicon nitride medical device.
- Thus far, roughly 25,000 silicon nitride interbody fusion implants have been used in spinal procedures performed globally.
- In March 2016, the firm announced a collaboration agreement with Celling Biosciences, a leader in autologous cellular therapy technologies, to research and develop biologically enhanced implants.
- On April 18, 2016 Amedica inked a ten year exclusive distribution agreement with Shandong Weigao Orthopedic Device Company Limited, China's largest manufacturer of implants and related surgical instruments for trauma and spine surgery.
- The spinal fusion and orthopedic implant market in the developed regions is mature with the U.S. being the biggest player in the spinal implant sector having big players such as Johnson and Johnson (NYSE:JNJ), Stryker (NYSE:SYK), Smith & Nephew (NYSE:SNN), Zimmer BioMet Holdings (ZMH), Medtronic (NYSE:MDT), to name a few but the emerging economies offer a high potential for growth. The company's unique biomaterial platform provides a compelling value proposition in this highly competitive market.
- Amedica is backed by a strong and experienced management team with significant knowledge and expertise in the ceramic and orthopedic segment. The Chairman and CEO, Dr. Sonny Bal is a member of the American Academy of Orthopedic Surgeons, The Association of Hip and Knee Surgeons and the International Society of Technology in Arthroplasty. He has extensive research experience on silicon nitride over the past decade. Dr. Bal received his MD from Cornell University, an MBA from Kellogg-Northwestern and a JD from the University of Missouri.
- We think AMDA offers an investment opportunity considering the large orthopedic and spinal fusion market that the company is addressing.

INVESTMENT THESIS

Amedica Corp., headquartered in Salt Lake City, UT is a medical device manufacturing firm that provides a broad range of products specific to spine and orthopedic applications. In order to minimize the risk of implant-induced failures, Amedica has designed its implants using non-oxide ceramic, a silicon nitride technology, which is known to offer positive mechanical and tribological properties. Silicon nitride is a unique material with tunable surface properties and has demonstrated osteointegration, resistance to biofilm formation, and stability in the host environment without compromising its desirable mechanical properties. Several studies employing silicon nitride in implants such as bone void fillers, intervertebral body spacers and osteofixers have found the material to be biocompatible with stable responses in local and systemic biological environment.

Amedica offers a range of Valeo interbody spinal fusion implants for Anterior Lumbar (AL), Posterior Lumbar (PL), Oblique Lumbar (OL), Transforaminal Lumbar (TL), Lateral Lumbar (LL) and Cervical (C) regions of the spine. Additionally, Amedica designs and markets a line of non-silicon nitride spinal fusion products for the treatment of deformity and degenerative spinal procedures that are complementary to its spinal fusion products. Amedica's spinal implants are unique in their design and construction and therefore offer a distinct differentiation from the existing implants made of polyether ether ketone (PEEK), titanium, trabecular metal, or cadaveric bone. The firm's implant has the potential for long life and high performance due to characteristics such as low wear, high osteo-integration and reduced incidence of infection as compared to other commercially available biomaterials. Currently the firm is developing several silicon nitride components for patients who require joint replacement and/or spinal surgeries due to osteoarthritis, osteoporosis, injury, as well as trauma. These implants are designed to offer the robustness of an active joint.

Amedica distributes its products through independent distributors in the U.S. and abroad (Europe and South America). Additionally, the products are also marketed through private label and OEM partnerships. Currently, the bulk of Amedica's revenue is from the spinal implant market in the U.S.

Despite being a recent innovative technology, Amedica's products face some challenges in gaining widespread acceptance. The three important factors challenging the adoption are detailed below.

- Although ceramic implants are known to cause squeaking and/or cracking/fracture in a few cases, they do show lower wear rate, lower dislocation rate and a subsequent lower revision rate than metal or polyether ether ketone (PEEK) articulations. However, silicon nitride in biological implants is a recent technology and the lack of sufficient published evidence from long term follow-up studies has made it difficult to justify its benefits. Although in the short term (two years) follow-up period no/minimal occurrence of infection, subsidence, migration or even revision procedures was observed[2,3,4], a long-term follow-up study may help in highlighting the advantages of silicon nitride implants. We think it is reasonable to assume that there is a high chance that the long term effects of silicon nitride implants will not be adverse considering the short term effects of the implants have been positive.

[2] International Journal of Nanomedicine 2012:7 4829–4840
[3] Arts, Mark P., Jasper FC Wolfs, and Terry P. Corbin. "The CASCADE trial: effectiveness of ceramic versus PEEK cages for anterior cervical discectomy with interbody fusion; protocol of a blinded randomized controlled trial." BMC musculoskeletal disorders 14.1 (2013): 244.
[4] www.amedica.com

- The spinal fusion and orthopedic market in the U.S. is crowded with well-established players who offer a broad portfolio of products made of thermoplastics, metal alloys and other ceramics.

- Consequently, building product awareness by increasing the amount of published clinical evidence in peer-reviewed journals and presenting at conferences may provide further insight and support for the widespread acceptance from the clinical community and help drive adoption, increase sales and potentially support higher reimbursement rates.

Several customer and physician reviews have been documented and are continuing to be done so in journals. Management hopes to establish their products as the preferred implant for orthopedic and spinal procedures. However, this strategy may take time to pan out. For now, we see the growth in sales owing to OEM partnerships.

We think AMDA offers an attractive investment opportunity considering the large orthopedic and spinal fusion markets that the company is addressing. With a current cash balance of $12 million and cash burn rate of roughly $3 million per quarter, we believe Amedica will require additional capital prior to reaching a point of positive operating cash flow. Additionally, AMDA was close to being served a notice of default and is likely to breach its current debt covenant unless they can refinance their current loan. This is high risk to the company in the short term that investors need to keep in mind. However, given their strong product line and high revenue potential we are hopeful that they will be able to secure alternate funding. With a fully diluted share count of 12.5 million, based on our 10-year DCF financial model, we arrive at a fair value of $2.50/share. Our model and assumptions are subject to change as risks abate.

PRODUCTS

Historically, metals, plastics and ceramics have been used as interbody implants. Post-surgical failures that usually occur within one year (<10% of cases) are dislocation, infection and implant failure while those that usually occur after five years include wear of the bearing surface, osteolysis, implant loosening, and/or peri-prosthetic fracture. Patient-related factors also contribute to revision surgery; for instance, obese or younger persons leading active lifestyles (involved in impact sports such as running, playing tennis, soccer and football) have implant wear/loosening. In general, if an adverse biological response occurs in the host or if the implant breaks, it warrants a revision surgery that involves risks associated with complex interventions.

Titanium has been the most commonly used metal in standard implants including trauma plates and screws, total joint implants, pedicle screws, among others. It is biocompatible and MRI compatible. The dual acid etching processes performed on the surface of titanium has been shown to stimulate local, physiologic bone protein and growth factors that promote a natural osteogenic environment that facilitates bone integration with the implant surface[5]. Additionally, titanium that has been acid-etched causes minimal artifact, minimal subsidence and can be easily visualized using CT scans. Although other metals such as cobalt–chrome, tantalum, and stainless steels have high strength and fracture toughness, they suffer from limitations of complete radio-opacity under X-ray and create image artifacts under CT and MR imaging.

Plastics such as polyethylene, polyurethane, and others lack the strength and toughness that metal implants provide but are completely radiolucent and do not create artifacts in CT and MRI. Invibio developed PEEK, an organic polymer thermoplastic which is currently being used as an option for interbody fusions due to its strength, durability, lubricity, and X-ray translucency as well as its biocompatibility and biostability. PEEK has been used for spinal implants, femoral stems, bearing materials for hip and knee replacement, and hip resurfacing. PEEK's mechanical properties can be altered to meet specific requirements. By adding carbon fibers to the polymer matrix, PEEK's strength and stiffness can be increased. Invibio's carbon fiber-reinforced (CFR) technology is currently used in EnduRo knee revision surgeries for patients suffering from a failed total knee arthroplasty.

PEEK's imaging properties can be altered by adding barium sulphate which helps create radiological images without the generation of scatter or imaging artifacts. PEEK can be processed by injection molding, extrusion, compression molding, machining from plates/rods and/or powder coating. PEEK, however, has its limitations. Since PEEK has shown inertness and limited or completely absent intrinsic capacity to integrate with bone, a strong chemical catalyst such as bone morphogenetic protein (BMP) is used to fuse PEEK with bone. However, many hospitals and insurance carriers are restricting the use of BMP as it has been associated with complications such as ectopic bone growth and nerve inflammation.

***Amedica's Silicon Nitride platform (Non-oxide Ceramic)*:** Silicon nitride as a structural ceramic has commercial as well as industrial applications in spacecraft, turbo-machinery and electronics due to properties such as low density, low wear and tear as well as high corrosion and fracture resistance, high strength and reliable performance particularly under extreme operating conditions. Additionally, silicon nitride is biocompatible and shows superior imaging characteristics under X-ray, CT and MRI thus making it an appealing candidate material for orthopedic implants for spine, prosthetic knee and hip joints[6,7,8].

[5] Journal of The Spinal Research Foundation SPRING 2014 VOL. 9(1):35-41
[6] Anderson MC, Olsen R. Bone ingrowth into porous silicon nitride. J Biomed, Mater Res 2010;92(4):1598–605.
[7] Webster TJ, Patel AA, Rahaman MN, Sonny BB. Anti infective and osteointegration properties of silicon nitride, poly(ether ether ketone) and titanium implants. Acta Biomater 2012;8(12):4447–54.
[8] Olofsson J, Grehk TM, Berlind T, Persson C, Jacobson S, Engqvist H. Evaluation of silicon nitride as a wear resistant and resorbable alternative for total hip joint replacement. Biomatter 2012;2(2):1–9.

Further, silicon nitride exhibited high wear resistance in its polished form and the ability to support bone growth and metabolism in porous form. Coating silicon nitride with selected additives helps decrease surface oxidation, improve osteo-integration and improve antimicrobial property and therefore can be used as bearings in hip and knee surgeries. Silicon nitride implants seem to cause less detrimental biological effects, which may in turn reduce the number of revision surgeries, consequently reducing healthcare costs.

Advantages of silicon nitride implants:

- *Anti-Bacterial Properties*: Treating implant-related infections is expensive and often requires intervention. Silicon nitride's surface exhibits hydrophilic properties that hinders bacterial growth, potentially reducing the risk of infection[11,9].

- *Osteoconductive*: Even though the bulk of silicon nitride material is a non-oxide ceramic, its surface has a protective transitional layer. This layer can be chemically altered to modify its morphological characteristics (composition, thickness and structure), which results in inhibiting biofilm formation, improved bone reformation and bacteriostasis. Due to this reason, in comparison to titanium or PEEK, silicon nitride demonstrates better biocompatible and osteoconductive qualities. Therefore there exists an opportunity for better fusion with bone with decreased post-op complication rates[10,11,12].

- *Diagnostic imaging capabilities*: Silicon nitride is partially radiolucent and therefore, is MRI and CT compatible and does not produce imaging artifacts.

- *Improved Tribology*: It is known that silicon nitride bearing surfaces are prone to oxidative degradation in the presence of moisture. Silicon nitride is coated by a thin oxide surface and when this coating degrades due to wear/erosion, the surface re-oxidizes and limits degradation[13].

- The surface of silicon nitride exhibits hydrophilic properties that help promote bone on-growth and osteogenerative proteins[7].

- *Superior hardness, toughness, strength*: The compression strength and fracture toughness of silicon nitride exceeds that of the metals, plastics and ceramics such as aluminum that have been popularly used as implants in joint replacements. As compared to aluminum oxide, silicon nitride demonstrated improved toughness and strength when tested for mechanical fractures. When silicon nitride is thermally treated at a high temperature, it transforms into a rod-shaped, elongated structure that increases the difficulty of crack propogation, thereby minimizing fracture propogation. Silicon nitride demonstrated similar wear rates as cobalt-chromium and aluminium oxide bearings in hip arthroplasty. In February 2011, the first silicon nitride implant was used in hip surgery[8,14].

[9] Gorth, Deborah J. "Decreased bacteria activity on Si." International journal of nanomedicine 7 (2012): 4829-4840.
[10] Kersten et al. BMC Musculoskeletal Disorders 2014, 15:57
[11] Webster, Thomas J., et al. "Anti-infective and osteointegration properties of silicon nitride, poly (ether ether ketone), and titanium implants." Acta biomaterialia 8.12 (2012): 4447-4454.
[12] McEntire, Bryan J., et al. "In Vivo Bone Formation and Bacterial Infection Between Silicon Nitride Ceramic, PEEK, and Titanium." Bone & Joint Journal Orthopaedic Proceedings Supplement 95.SUPP 15 (2013): 129-129.
[13] Bal BS, Rahaman MN, Acta Biomater, 2012(8): 2889-98
[14] Liu, Haiyan, and Stephen M. Hsu. "Fracture behavior of multilayer silicon nitride/boron nitride ceramics." Journal of the American Ceramic Society 79.9 (1996): 2452-2457.

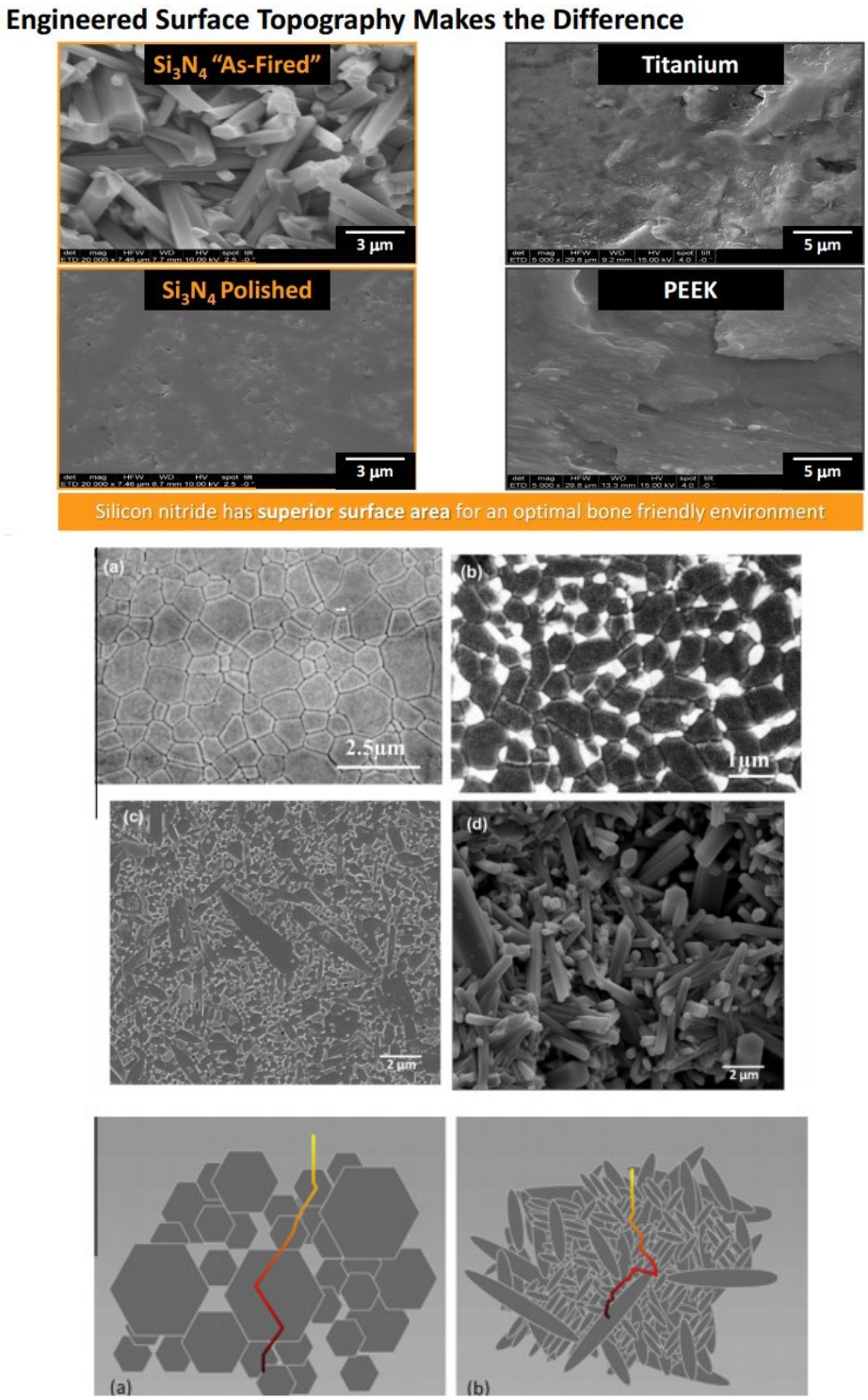
- *Non-corrosive and biocompatible:* While the primary risk associated with metal alloy implants is the release of metal ions during corrosion and wear, the silicon nitride wear particles are known to dissolve and therefore could potentially be resorbed in the body thereby reducing the risk of aseptic loosening[15,16].

Silicon Nitride: The Ideal Biomaterial

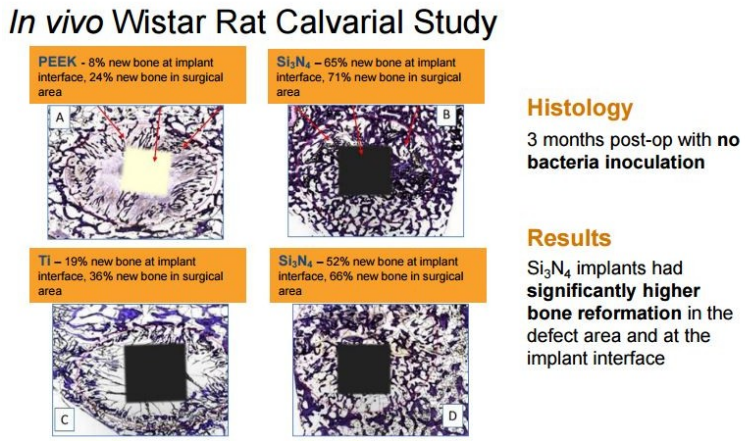
	Silicone Nitride	Plastic	Allograft	Metals
Anti-Infective	✓	✗	✗	✗
Bone Growth	✓	✗	✓	✗
Imaging Capability	✓	~	✓	✗
Strength, Hardness, Fracture Resistance	✓	✗	✗	✓
Bio Compatible	✓	✗	✓	~

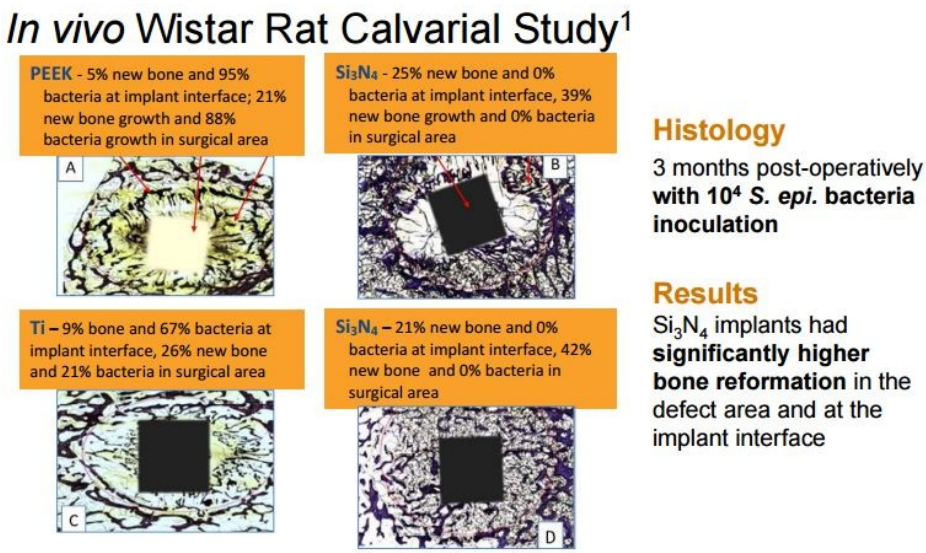
(Source: http://www.amedica.com)

[15] Olofsson, Johanna, et al. "Evaluation of silicon nitride as a wear resistant and resorbable alternative for total hip joint replacement." Biomatter 2.2 (2012): 94-102.
[16] L. Wang et al. /Wear 246 (2000) 159–173



(Source: http://www.amedica.com)





(Source: http://www.amedica.com)

- *Case Study- In vivo Wistar rat calvarial study:* A study was conducted to compare the anti-infective and osteointegrative properties of silicon nitride, PEEK and titanium implants in Wistar rats. Dense implants made of silicon nitride, PEEK, or titanium were surgically implanted in the rats which had artificially created defects in the skull. Bacterial infection was induced by injecting Staphylococcus epidermidis. The rats were killed, and the skull area was checked for new bone formation as well as for the presence or absence of bacteria on days 3, 7, and 14 and 3 months post-surgery. Quantitative evaluation of osteointegration of the three biomaterials with bone was performed. Three months post-surgical evaluation in the absence of bacterial injection revealed new bone formation around silicon nitride (□69%) that was much higher as compared with 24% and 36% for PEEK and titanium, respectively. In the presence of bacteria, new bone formation for silicon nitride, titanium, and PEEK was 41%, 26%, and 21%, respectively. Live bacteria were identified around PEEK (88%) and titanium (21%) implants, whereas none were present adjacent to silicon nitride. A push out study is used to test the mechanical integration of an implant with the existing bone. It is defined as the strength required to push an implant along the direction of new bone growth. Push-out strength testing demonstrated statistically superior bone growth onto silicon nitride as compared with titanium and PEEK. Silicon nitride bioceramic implants

demonstrated superior new bone formation and resistance to bacterial infection compared with titanium and PEEK[17].

Case Study – TLIF Procedure

Details

- 47-year old woman
- LBP and leg weakness with spinal stenosis at L4-L5 and disc herniation

Surgery and Follow-up

- Decompression, laminectomy and posterior spinal fusion (TLIF) using local autograft harvested from lamina
- Treated with a back brace, but patient was up and walking 2 miles per day within 2 weeks
- One year follow-up showed solid posterolateral fusion through and behind the implant

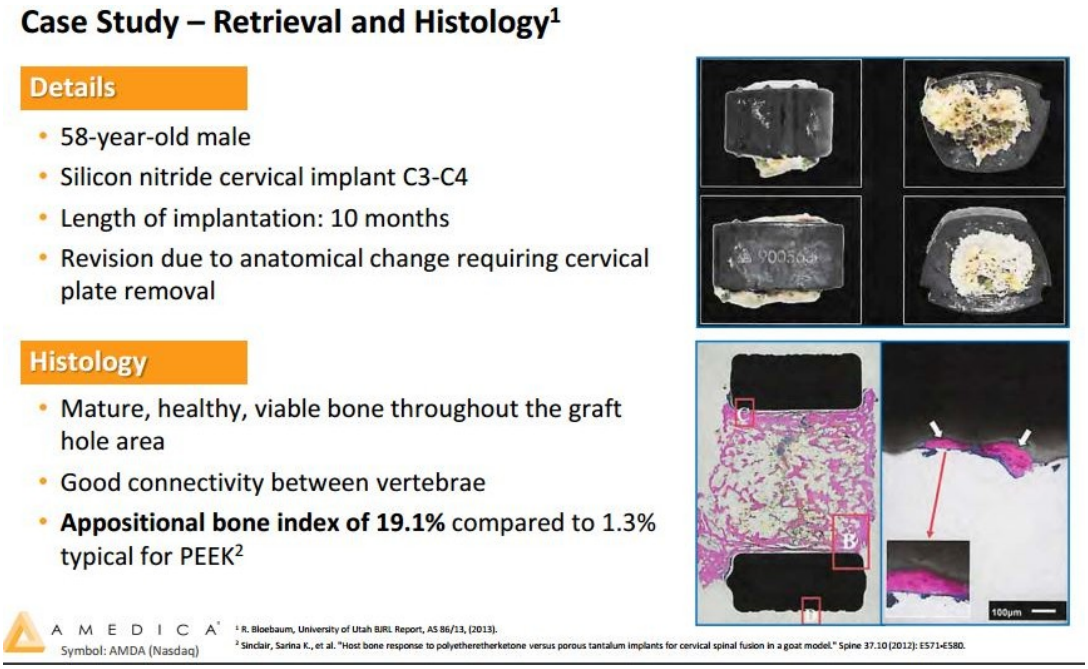


(Source: http://www.amedica.com)

- *Case Study – Transforaminal Lumbar Interbody Fusion (TLIF) procedure:* In a TLIF procedure, a structural support is placed within the middle or anterior space of the spinal disc and fixed using pedicle screws. Two patients underwent a TLIF procedure with posterior spinal fusion instrumentation and received the Valeo® TL Lumbar Interbody Fusion implant. The patients were evaluated after one year and images were obtained using CT and dynamic x-ray scans. Radiological images, undistorted by the implant, demonstrated solid interbody as well as posterolateral fusion. Bone appeared to be well formed through and behind the implant in the interbody space suggesting that Valeo TL fusion device promotes bony growth on the implant thus making it less likely to migrate.

  In general, a graft must have osteoconductive properties in order to promote fusion of PEEK and bone. In the absence of this property, the implants may still migrate, despite fixation with screws since there is no ability for the bone to grow into the existing vertebrae. Although, most grafts allow bony growth only through the implant, this clinical report is the first to demonstrate that a ceramic graft allows growth onto as well as through the implant[18].

[17] Webster, T. J., et al. "Anti-infective and osteointegration properties of silicon nitride, poly (ether ether ketone), and titanium implants." Acta Biomaterialia (2012).
[18] www.amedica.com/files/3613/7606/6505/Clinical_and_Radiographic_Outcomes_of_2_Patients.pdf



(Source: http://www.amedica.com)

- *CASCADE study:* This single center, randomized, controlled CASCADE (CAncelous Structured Ceramic Arthrodesis DEvice) trial was designed to demonstrate the effectiveness and clinical improvement of ceramic spacers manufactured with a central core of cancellous structured ceramic (CsC) as compared to the golden standard PEEK cages in patients treated with anterior cervical discectomy and fusion. CsC closely mimics the pore size of cancellous bone and is likely to allow bone to grow through the material due to its osteoconductive matrix. The investigators enrolled 104 patients and Neck Disability Index (NDI) and radiological properties were documented focusing on fusion and subsidence. This study had three month, six month, one year and two year follow-up periods.

  The silicon nitride implant with no bone or bone fillers demonstrated fusion rates that are equivalent to the more popularly used PEEK. PEEK spacers are often enhanced using expensive porous metal coatings, hydroxyapatite and related materials to overcome its limitations of fusing with bone. Amedica's composite, solid-and-porous CsC spacers are able to deliver bone fusion without the use of any bone, bone void fillers, or biologics. The CASCADE study is the first to show that a synthetic material, such as silicon nitride, has the ability to heal and fuse as good as the patient's own bone.

Table 1 Selection criteria for trial eligibility

Inclusion criteria

- Age 18-75 years
- Radicular signs and symptoms in one or both arms (i.e., pain, paresthesia or paresis in a specific nerve root distribution) or symptoms and signs of acute or chronic myelopathy
- At least 8 weeks prior conservative treatment (i.e., physical therapy, pain medication)
- Radiographic diagnosis of cervical disc herniation and/or osteophyte at 1 level (C3-C4 to C7-T1) in accordance with clinical signs and symptoms
- Ability and willingness to comply with project requirements
- Written informed consent given by the subject or the subject's legally authorised representative

Exclusion criteria

- Previous cervical surgery (either anterior or posterior)
- Increased motion on dynamic studies (> 3 mm)
- Severe segmental kyphosis of the involved disc level (> 7 degrees)
- Patient cannot be imaged with MRI
- Neck pain only (without radicular or medullary symptoms)
- Infection
- Metabolic and bone diseases (osteoporosis, severe osteopenia)
- Neoplasm or trauma of the cervical spine
- Spinal anomaly (Klippel Feil, Bechterew, OPLL)
- Severe mental or psychiatric disorder
- Inadequate Dutch language
- Planned (e)migration abroad in the year after inclusion

(Source: Arts et al. BMC Musculoskeletal Disorders 2013, 14:244)

Types of silicon nitride products offered by Amedica



(Source: http://www.amedica.com)

Solid Silicon Nitride: A dense form of silicon nitride is used in interbody spinal fusion devices, hip and knee replacement implants, and dental implants.

Porous Silicon Nitride: This composite is designed to have an interconnected pore structure (about 90-600 microns) to mimic cancellous bone (interior bone in humans). This form is used as a substitute for the orthobiologics that are currently used to fill interbody implants and help stimulate bone in-growth and attachment (bone void filler/scaffold).

Composite Silicon Nitride: In order to mimic the structure of natural bone this composite was engineered as a fully dense, load-bearing solid component on the outside and as a porous component on the inside. The intention is to promote bone in-growth on the inside. This composite can be used in interbody spinal fusion devices as well as for components for total hip and knee replacement implants.

Silicon Nitride Coating: A thin coat of silicon nitride is applied on other metallic substrates such as cobalt-chromium, titanium and steel alloys to increase the wear-resistance and create an anti-bacterial barrier between the bone and device. It is used in hip stems and screws.

APPLICATIONS

Spinal fusion implants: Patients with broken vertebrae, deformities of the spine, spinal disorders, herniated disk or chronic low back pain undergo spinal surgery to permanently connect/fuse the affected vertebrae (spinal fusion) in order to eliminate motion between them. Spinal interbody fusion implants support bone formation and remodeling by promoting bone growth and formation of blood vessels. Although the spinal fusion process eliminates motion between the degenerated vertebrae and compromises spinal flexibility, it provides immediate structural support to the vertebrae. In some cases, the surgeon implants a metal/plastic/bone spacer (cage) between the adjoining vertebrae using metal screws/plates/rods to increase the rate of fusion, stabilize the spine and maintain spine alignment.

The most commonly used spinal fusion implants were either made of PEEK, titanium or allograft bone. Threaded titanium cages (no pedicle screw fixation) lost popularity as it was challenging to image titanium. Further, the implant led to clinical failures because of the complex surgical technique.

Silicon nitride, in addition to its positive mechanical properties, is anti-infective and osteo-regenerative which makes it a unique candidate that could potentially improve clinical efficacy. Amedica provides a range of Valeo Interbody Fusion devices for cervical, thoracic and lumbar regions of the spinal column. In 2008, the FDA cleared the first generation spinal implant and in 2012 cleared the second-generation spinal implant for lumbar interbody fusion. The design was enhanced to support minimally invasive procedures as well as lumbar lateral interbody fusion approaches.

Valeo Interbody Fusion implants are used in restoration of disc height, lordosis and cervical alignment. Thus far, roughly 25,000 silicon nitride interbody fusion implants have been used in spinal procedures performed globally.

In general, a hollow-body PEEK spacer for cervical and lumbar spinal fusion is usually filled with an osteoconductive material such as allograft, bone autograft or synthetic biologic formulations. The CASCADE study is the first to demonstrate that a synthetic material such as silicon nitride designed as a composite interbody spacer (a solid cortical outer portion around a structured cancellous ceramic core (CsC) can heal and fuse as good as the subject's own bone. This eliminates the need to use hollow interbody spacers filled with bone/bone void fillers to achieve optimal fusion. This is a very interesting concept that gives the firm a competitive advantage via product differentiation.



Valeo® II PL/OL



Valeo® II TL



Valeo® II AL



Valeo® II C



Valeo® II LL



(Source: http://www.amedica.com)

Pedicle screws: In order to prevent motion between the segments on the vertebrae being fused, firm anchor points using screws (pedicle screws) are connected with a rod. Pedicle screws are mechanically advantageous in that they provide short, rigid segmental stabilization, which helps in stabilizing the spine in the absence of intact inherent body parts, which is otherwise not possible with non-pedicle screw systems. Amedica's screws incorporate the patented Helical Flange® technology. The helical flange technology incorporates a square thread instead of buttress or dove-tail thread for their screws. While interlocking the flanges, this design minimizes seat splay and cross threading.

Amedica features several pedicle screw systems such as the Valeo PS, triple-lead thread and unique facet technology pedicle screws. The triple-lead pedicle screw helps provide immobilization and stabilization of spinal segments in addition to helping in spinal fusion. The facet fixation locks the vertebrae together and stabilizes the spine. It is designed to be used in small incision procedures rather than traditional interbody fusion procedures which causes minimum tissue damage, decreased blood loss and shorter time for the patient to recover.



(Source: http://www.amedica.com)

Manufacturing: Amedica has the only FDA-cleared and ISO 13485 certified silicon nitride medical device manufacturing facility (30,000 square foot) in the world, and is the only provider of ceramics-based medical devices used for spinal fusion applications. The manufacturing facility is located in Salt Lake City, Utah and is vertically integrated allowing for rapid in-house prototyping and development.

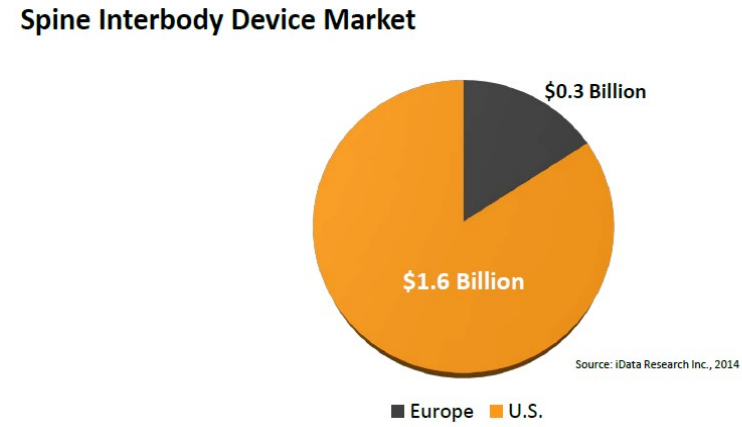
Reactive-bonding is a method of manufacturing silicon nitride where silicon powder is formed into shape and then mixed with nitrogen. This process avoids damage to the shape caused by shrinkage during the sintering step, allows for excellent dimensional control and reduces the amount of costly machining and finishing needed after firing.

INTELLECTUAL PROPERTY

Amedica has a broad patent portfolio, some issued while some others pending and are directed towards the design of pedicle screws, intervertebral fusion devices as well as hip and knee implants. As of February 1, 2016, the firm had 48 issued U.S. patents, 18 pending U.S. patent applications, 11 granted foreign patents and 12 pending foreign patent applications. The patents begin to expire in 2016, with the last of these patents expiring in 2032.

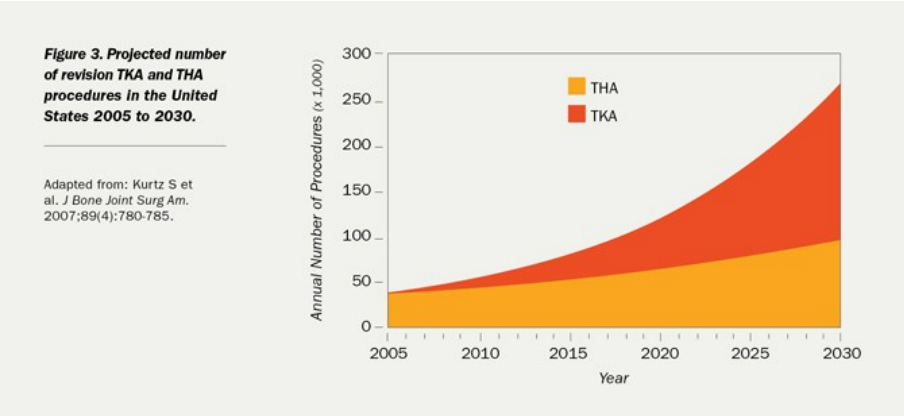
MARKET

Currently, most of Amedica's revenue comes from the U.S., although the products are also sold in Europe and South America. Despite the market being filled with big players in developed countries, the demand for spinal and orthopedic procedures in these regions is expected to grow at a CAGR of ~5-6% over the next five years[19,20,21]. Further, the rising demand by the government to reduce spending on healthcare is favorable to the future growth of this sector. The emerging economies in the Eastern hemisphere represent the next big opportunity for expansion since a double-digit growth is expected in the developing economies (Asia Pacific region)[22].



(Source: http://www.amedica.com)

[19] http://galwaydashboard.ie/publications/medical-sector.pdf
[20] http://www.marketresearch.com/product/sample-8230547.pdf
[21] http://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/21361-10-predictions-for-the-global-orthopedic-device-market.html
[22] http://www.beckersspine.com/spine/item/21206-5-observations-on-spinal-fusion-market-analysis.html

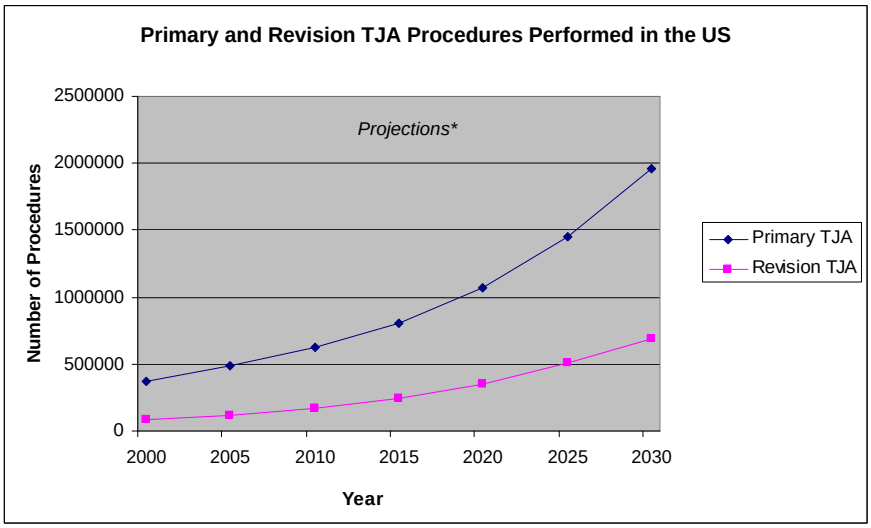


(Source: http://praxis.iuhealth.org/article/revision-knee-and-hip-replacement-surgery)

U.S. Market:

Total joint replacement market: The U.S. population continues to age. Knee replacement surgeries are associated with osteoarthritis and generally affect Americans that are older than 65 years of age. As per CDC, pain and decreased mobility from osteoarthritis are the most common reasons for patients undergoing hip and knee joint replacement surgeries in the U.S. Adding to this pool is the prevalence of obesity, which is also expected to rise in the U.S. due to lifestyle factors. Roughly 30% of Americans suffer from obesity. Obesity-related changes to joint structure and function exacerbates the need for joint replacement.

In general, a joint replacement is expected to last anywhere from ten to fifteen years. Total joint replacement procedures are the most cost-effective and successful surgeries performed in the U.S. In 2015, about one million joint (hip and knee) replacement procedures were performed and this number is expected to double by year 2030. Of the total number of surgeries performed, 10% fail due to factors related to mechanical complications from an implant or graft, external fixation device using internal screws/pins and/or internal fixation device such as a nail/plate/rod, infection and inflammatory reaction due to internal joint prosthesis.



(Source: www.cdc.gov/nchs/ppt/icd9/att_tjr_oct04.ppt)

Spine market: Globally, Germany, U.S. and China comprise the three largest markets for spinal fusion surgeries. As per Global Analysis and Market Forecasts, the global spinal fusion market is anticipated to remain strong and grow at a CAGR of roughly 5%. As per Deloitte 2014 Global healthcare outlook, health care reform implementations and economic conditions may create more pressure to contain costs in established markets which could stunt growth in these regions. While high demand and governmental efforts to expand access to care in emerging economies will drive growth in these regions, governmental regulations in these countries may put pressure on pricing. In 2015, North America commanded the largest market share of ~65% in this sector. Medtronic and DePuy Synthes accounted for more than 45% of this market share in 2014.

Dental market: Dental implants are a part of cosmetic dentistry and have become commonplace in western cultures. There is anecdotal evidence that dental implant success rates are 95% or higher. Treatment duration has considerably reduced due to advances in dental implant systems with better understanding of bone biology. As per American Academy of Implant Dentistry, the dental implant and prosthetic market in the U.S. is expected to reach $6 billion by 2018.

Trauma market: In the U.S. the orthopedic trauma implants market consists of several segments of which the plate and screw market is anticipated to remain the dominant market segment going forward as per iDataResearch. DePuy Synthes (J&J) enjoyed a ~40% share of the U.S. orthopedic trauma device market in 2013, followed by Stryker with a share of 16% and Smith & Nephew having 10%.

Sports medicine market: The sports medicine market is comprised of prosthesis, joint implants, fracture repair and arthroscopy devices, among others. Some of the major players in this market include Biomet, Inc., Wright Medical Technology (WMGI), Stryker Corporation and Zimmer Holdings, Inc.

China Market:
The Chinese market for orthopedic implants is expected to grow at a CAGR of about 16%. Although the market size is only about a quarter of the U.S., the high growth rate in this region is fueled by improving reimbursement environment, an increasing number of patients preferring minimally invasive surgery, an aging population with degenerative disease, increasing disposable income and new technologies such as improved implant materials. Additionally, the Chinese government has opened doors for better access to healthcare in the rural areas. This market is led by Weigao Orthopaedic Device (~5% market share), followed by other top players including Trauson, DePuy Synthes, Biomet, Medtronic, NuVasive, Stryker, Zimmer, Orthofix International and B. Braun Aesculap. As per Frost and Sullivan, the Chinese orthopedic market is highly fragmented and therefore presents an opportunity for market leaders such as Weigao.

The Chinese orthopedic market is comprised of trauma, spine and joint markets. The implants are classified as a Class III device and directly regulated by the CFDA. Most of the domestic companies in China, including those acquired by Stryker and Medtronic in 2013, focus on the trauma market as it requires less expertise. Weigao, a subsidiary of Shandong Weigao (HKSE: 1066) enjoys a 4.5% market share in the trauma segment and 3% in the spine segment. If Amedica can target all three sectors then it can benefit from cross-selling opportunities.

REGULATORY APPROVAL

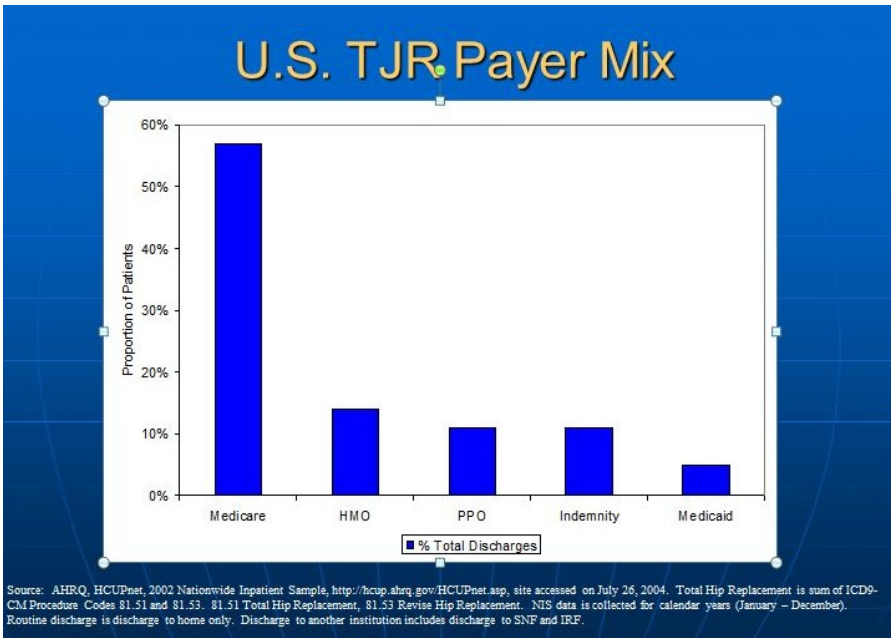
Since the beginning of 2015, Amedica has been working with the FDA towards an ultimate goal of obtaining regulatory clearance for their Valeo C Interbody device with CsC osteo-conductive scaffold. The FDA confirmed that it would review the product as a Class II medical device. The firm is pursuing FDA 510(k) clearance for this device (Class II), which was submitted in Q1 2015. At that time, Amedica presented 12-month clinical performance data from the CASCADE study. This trial was blinded and randomized and compared outcomes of cervical fusion using devices manufactured with CsC to PEEK spacers filled with bone autograft. The FDA typically responds with a decision or seeks additional information in 3-6 months' time. Subsequent to the submission, the FDA requested additional data pertaining to the CsC device. The filing of the response happened in June 2015. In July 2015, the FDA requested Amedica to provide them with 24-month clinical performance data to support the device application. The firm had to wait until the data was available and then submitted the 24-month outcome from the CASCADE study in November 2015. The FDA requested further clarification from management for which AMDA responded in June 2016. Amedica's response re-starts the clock to obtain the response from the FDA which puts the company in a position to potentially enter the market sometime in 2H 2016. If FDA approves this product for commercialization, we believe the clearance would open up the U.S. market for AMDA and that could be a big driver of interbody fusion device sales. However, the FDA may deny clearance or ask for additional information, which could push back eventual launch due to additional time needed to gather requisite data and deliverables.

The company has also designed prototypes of femoral head and femoral condyle using their solid silicon nitride composite. The femoral heads are currently being tested. If the prototypes show high performance during the biomechanical testing, Amedica plans to initiate clinical trials to support an FDA application.

REIMBURSEMENT

As per CMS, Medicare beneficiaries are expected to increase to more than 60 million by 2022. CDC estimates that more than 36% of Americans are on a high deductible insurance plan. As the demand for replacement surgeries escalates, so do the costs for Medicare and third party payers. Consequently, costs for hospitals continue to outpace reimbursements which could prove detrimental to patients.

Clinical data and cost-benefit analysis studies are often required by healthcare clinics to educate hospital administrators and justify the need for differentiated products. The recent findings on silicon nitride could potentially result in a shift of market dynamics that could increase utilization. As government reimbursement plans prefer value-based, outcome-oriented healthcare, a large number of peer-reviewed articles need to be published describing the use of silicon nitride implants, which might help increase reimbursement.



(Source: www.cdc.gov/nchs/ppt/icd9/att_tjr_oct04.ppt)

COMPETITORS

The main competing biomaterials include PEEK, predominantly manufactured by Invibio, BIOLOX® delta, a traditional oxide ceramic manufactured by CeramTec, allograft bone, metals, and coated metals. The noteworthy drawbacks of these materials are that they do not actively participate in the bone fusion process and lack anti-infective characteristics. The main competitors to Amedica are Stryker, Smith & Nephew, BioMet Zimmer Holdings, DePuy Synthes, among others. DePuy Synthes, the orthopedic division of Johnson & Johnson, commands almost one quarter of the orthopedic market followed by Stryker.

Invibio offers a range of PEEK-OPTIMA polymers suitable for interbody fusion. The PEEK-OPTIMA HA Enhanced promotes early and enhanced contact between the implant and bone. Titan Spine, LLC, (Mequon, WI) manufactures titanium interbody fusion implants with its proprietary surface technology. In vivo testing of BioMG's magnesium alloy implant demonstrated its biocompatibility, as well as its ability to serve as a catalyst for the promoting new bone structures around the implant. Proxy Bio-XT creates a new generation of stronger, resorbable implants.

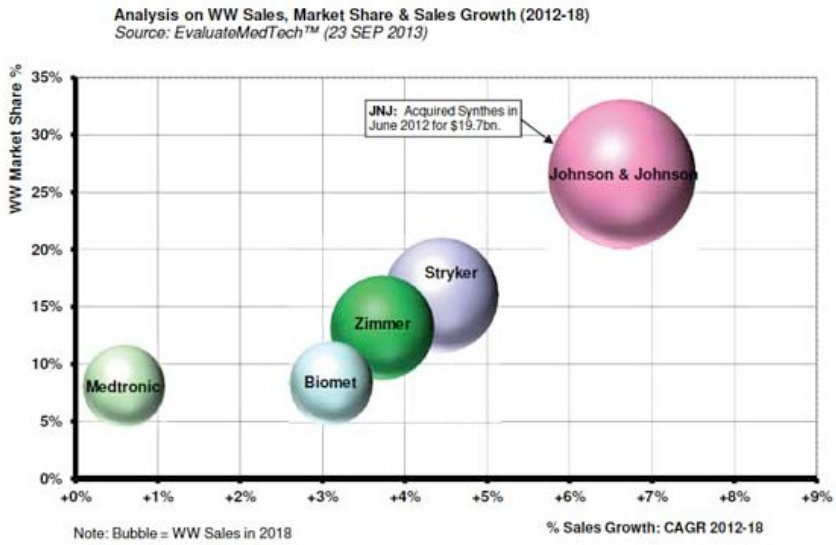
The major players buy ceramic components from manufacturers such as CeramTec, Kyocera and CoorTek, Inc., among others, which are incorporated into their OEM products.

The high cost of 3D manufacturing is offset by the cost to effectively produce complex shapes, including custom implants. Stryker announced FDA clearance of the 3D printed titanium posterior lumbar cage for use in degenerative disc disease, grade I spondylolisthesis, and degenerative scoliosis. This implant allows bone in-growth and is expected to be commercialized in Q2 2016. The lumbar cage is intended for use with autografts and/or allogenic bone grafts, as well as supplemental spinal fixation systems.

ConforMIS, Inc., a privately held medical device company based in Bedford, MA, designs implants and instruments based on the patient's CT scan. An automated process uses

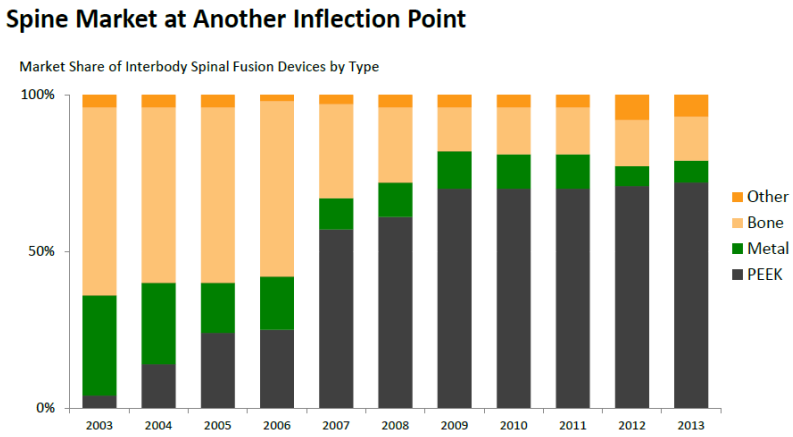
proprietary iFit Image-to-Implant® software to map the surface of the joint in three dimensions and then uses that information to design the implants.

EIT Emerging Implant Technologies has used additive manufacturing to fabricate nanostructural features of the trabecular bone structure using titanium and 3D printing. The biomechanical properties of the implant allow for in-growth into the existing vertebrae, thereby promoting the healing and fusion of bones without needing additional bone graft.



EvaluateMedTech predicted which companies would lead the orthopedic sector five years from now.

(Source: http://www.qmed.com/news/top-ten-players-global-orthopedics-market)



(Source: http://www.amedica.com)

Amedica versus its competitors:

- While PEEK can be modeled accurately and has mechanical characteristics that mimic bone, the thermoplastic cannot carry load like metal implants and will require the bone and muscles to support functionality. Much like PEEK, titanium alloys have gained popularity as implants. In comparison the non-oxide ceramic, silicon nitride, is a matrix of elongated structures that, in addition to offering comparable mechanical properties like other biomaterials, also offers fracture toughness.

- Silicon nitride exhibits fracture toughness of almost double that of other ceramics and mechanical testing has shown decreased hydrothermal degradation as compared to Zirconia and Alumina[23].

- Further silicon nitride promotes bone in-growth and prevents infection as compared to other biomaterials currently used as implants.

- In March 2016, the firm announced a collaboration with Celling Biosciences, a leader in autologous cellular therapy technologies, to research and develop biologically enhanced implants. Celling Biosciences conducted an in vivo study to test the attachment characteristics of mesenchymal stem cells with silicon nitride and PEEK. Amedica's silicon nitride has a natural nano-surface topography and chemistry that play an active role in implant integration and therefore helps in better cell adhesion and compatibility. The result from the study showed five times greater cell adhesion as compared to the PEEK. The current trends in surface modification efforts have not been successful in replicating this.

- While metal-on-metal femoral heads result in cobalt poisoning along with side effects such as fatigue, sensory impairment, cognitive dysfunction, etc. silicon nitride is known to be non-toxic. Several competitors offer surface-coating of PEEK with titanium or cobalt-chromium to help with integration with bone. However, addition of new materials increases cost and does not overcome the drawback of needing to fill the spacer with expensive biologics to facilitate fusion.

- Amedica hopes to sign more OEM/private label partnerships to use their 3D printing technology which would allow them to custom fabricate scaffolds and implants. This would make them the only player capable of custom fabricating silicon nitride implants.

- AMDA anticipates significant opportunities stemming from its ongoing and potential OEM and private label partnerships that may help drive meaningful operating leverage and cost savings while enhancing the firm's global footprint.

The firm hopes to publish results from the CASCADE study in peer-reviewed journals in an effort to increase product awareness.

FINANCIAL ANALYSIS

Sales strategy:

- *Direct Sales:* Independent sales distributors who are managed by Amedica's in-house sales and marketing team, sell Amedica's products to surgeons and hospitals in the U.S. and in select markets in Europe and South America.

- *OEM and private label partnerships:* The company has been constantly on the lookout to expand their geographical presence. The firm inked a partnership deal with Kyocera

[23] Kumar, Narinder, N. C. Arora, and Barun Datta. "Bearing surfaces in hip replacement–Evolution and likely future." medical journal armed forces india 70.4 (2014): 371-376.

Industrial Ceramics Corporation in 2013 who agreed to manufacture medical devices using silicon nitride in Vancouver, Washington. Japan-based Kyocera is the world's number one producer of advanced ceramics. This move enhances AMDA's position in the orthopedic implant industry, while significantly expanding their reach in Japan and other markets where this sector is on the upswing. Management is also of the opinion that the Kyocera partnership will help reduce manufacturing costs (by ~25%) and result in improving margins as well as rapid global expansion of silicon nitride implants..

More recently, in December 2015 the firm signed a private label supply agreement with BoTEC Medical, a subsidiary of WinnTi Medical Group, one of the fastest growing orthopedic companies in China. BoTEC is focused on selling extremity and spine solutions. Amedica has agreed to supply their spinal interbody fusion devices to BoTEC for distribution and sale in worldwide markets.

On April 18, 2016 Amedica inked a ten year exclusive distribution agreement with Shandong Weigao Orthopedic Device Company Limited, China's largest manufacturer of implants and related surgical instruments for trauma and spine surgery. Weigao being the leader in the orthopedic segment in China with expertise in acquiring CFDA clearance of medical devices, will be a key partner and ally for Amedica towards selling in the Chinese market. In general, Class III devices that have received marketing approval by the regulatory authority in the country of origin (in Amedica's case the U.S.) are not required to undergo clinical trials in China. However, the Chinese regulatory agency determines if a clinical trial is required based on a review by a panel of experts for implantable devices. At this time we are not sure whether Amedica will be required to conduct additional clinical trials in China as support for obtaining CFDA clearance.

Management believes that these partnerships can help fully realize silicon nitride's opportunity in the long term.

Revenue: Majority of the revenue is generated from sales in the U.S. Management's guidance is that revenue from sales of silicon nitride products will continue to increase through their distributor network and growing OEM/private label partnerships while revenue from non-silicon nitride products will remain flat. A small number of hospitals and surgeons account for a substantial portion of Amedica's revenues. The firm's largest customer accounted for 12% of the revenues in 2014 and 2015.

Operating margin: The firm expects to incur additional research and development costs as they continue to develop new spinal fusion products, joint replacement products and silicon nitride-coated metals. Management also expects that sales and marketing expenses will remain flat or decline slightly due to the recently implemented cost saving measures in 2015. The products sold through private labels have a lower selling price (low gross margin) but a higher EBITDA margin as commissions are not paid to support these sales and there are no sales and marketing costs associated with this product. In an effort to help improve the firm's financial performance and increase operational efficiency, management's financial objective for the current year and beyond is to reduce OpEx. Thus far, Amedica has reduced staff by 28%, OpEx by 35% and manufacturing costs by 25% through partnership with Kyocera.

Debt balance: In June 2014, Amedica obtained a secured loan from Hercules Technology Growth Capital Inc. in the amount of $20 million which matures on January 1, 2018 and accrues interest at a rate of 12.7% annually. Despite the debt obligation having maturity greater than one year, the loan is classified as a current liability as management believes they might be unable to honor the financial liquidity covenant[24]. The loan is secured by all of Amedica's assets including their IP.

[24] https://www.sec.gov/Archives/edgar/data/1269026/000149315216008221/form10-k.htm

The Hercules loan has an end of term fee whereby Amedica will be required to pay $1.7 million upon prepayment or at maturity. Amedica is required to maintain a cash and cash equivalents balance of at least $9 million if the loan balance exceeds $19 million. For every $1 million paid towards the term loan, the minimum cash balance requirement is reduced by $500,000 and was $8 million at December 31, 2015.

In the beginning of May 2016, Amedica and Riverside agreed to exchange $2.0 million of the principal amount of the Hercules term loan (held by Riverside) for a convertible promissory note for $2.0 million. Subsequent to this transaction approximately $2 million of convertible bonds were exchanged for common stock of the company thereby reducing their convertible bond balance by the same amount. The principal amount of the Hercules term loan is now $11 million and the liquidity covenant is reduced to $5 million. This is a positive for the company and the short-term threat of default has been successfully averted.

On July 8, 2016 Amedica Corp. obtained gross proceeds of close to $12.7 million from a secondary offering. Amedica issued a total of 3.608 million class A units at $1 per unit with each unit comprising of one share of common stock and one warrant and 7.392 million class B units at $1,000 per unit with each comprising of one share of preferred stock convertible into 1,000 shares of common stock and warrants to purchase 1,000 shares of common stock. The offering immediately added 3.6 million common shares and if preferred stock are converted that will represent another 7.4 million shares, a total of 11 million shares at that time. Additionally, an optional overallotment of 1.65 million additional shares of common stock and an equal number of warrants were exercised by the underwriters . As of June 6, 2016, the firm had 13.3 million shares outstanding. With this secondary offering, the basic share count comes out to 18.6 million and if preferred stocks are converted then the outstanding share count comes out to 26 million. Although priced at a discount to the ~$1.30 quoted market price the day prior to the offering, the cash raised should help strengthen the firm's balance sheet. The firm paid off its term loan in the amount of $0.88 million to Magna and $0.84 million to Riverside.

Q2 2016 Financial Results:

On August 12, 2016 Amedica Corp. (NASDAQ:AMDA), reported second quarter 2016 financial results.

Revenue came in at $4 million, very similar to first quarter results. The firm is implementing a sales strategy in key geographic regions that have yet to materialize. Management expects that their effort will pay off beginning fourth quarter of this year.

Total operating expenses came in at $5.5 million. Research and development expense ($1.6 million) and general and administrative expense ($1.3 million) largely remained unchanged as compared to the first quarter 2016. Sales and marketing expense came in ~20% lower than estimated primarily due to decrease in sales. Operating cash burn was $2.5 million and management expects to decrease this number by an additional ~30-40% year-over-year.

Net loss for the second quarter of 2016 was $5.1 million, a loss of $0.04/share.

The firm exited second quarter 2016 with cash and cash equivalents of $5.2 million. In the past, Amedica raised capital using debt which while helped increase cash flow also increased its debt load. Shortly after the close of the second quarter, the firm completed a $12.7 million public offering which provided relief as the company was grappling with debt from Magna, Riverside and Hercules. The debt obligation has now been reduced to ~$9.5 million solely with Hercules.

Amedica exited second quarter 2016 with roughly $5.2 million in cash and cash equivalents. With approximately $3 million burn rate per quarter, Amedica's current cash balance comes out to ~$17 million with proceeds from the recent capital raise included (less the underwriting fees and commissions).

LEADERHIP TEAM

B Sonny Bal, MD, JD, MBA
Chairman of the Board, CEO & President
Bal serves as Chairman and CEO since October 2014. He is a member of the American Academy of Orthopedic Surgeons, The Association of Hip and Knee Surgeons and the International Society of Technology in Arthroplasty. He has researched and published on silicon nitride over the past decade. Serves on the editorial board of several peer reviewed orthopedic journals. Received his MD from Cornell University, an MBA from Kellogg-Northwestern and a JD from the University of Missouri.

Ty Lombardi, CPA,
CFO
Joined Amedica in March 2014 and was appointed to serve as the Vice President Finance and Principal Accounting Officer in January 2015. Prior to joining Amedica he served as a principal consultant from January to March 2014 and provided a wide range of financial and accounting services. Certified Public Accountant and a MS in Accounting from Brigham Young University.

Bryan McEntire,
Chief Technology Officer
McEntire has more than 30 years of experience in advanced ceramic product development, quality engineering and manufacturing. Prior to joining Amedica, McEntire held various senior roles in notable ceramics and materials companies. He is an author or co-author of over 30 technical papers on ceramic materials, processing and characterization, and served as an invited short-course lecturer on Forming of Ceramics at the Annual Meeting of the American Ceramic Society from 1986 to 1995. He holds BS and MBA degrees in Materials Science and Engineering, and Operations Management from the University of Utah.

Chad Lewis
VP Business Development
Lewis has over 10 years of medical device product development in a myriad of orthopedic disciplines spine, sports medicine, joint arthroplasty, trauma, extremities). Prior to joining Amedica, he served as the Engineering Manager of the Salt Lake City Co-Innovation group within IMDS (now Coorstek Medical) providing strategic consulting to orthopedic OEMs on a wide range of medical product development services and business development. Lewis was a post-doctoral fellow at University of California – San Diego, Bioengineering Department prior to entering into the medical device industry. He received his Ph.D. in Mechanical Engineering from Colorado State University and a B.S.N. from the University of Northern Colorado.

David O'Brien
VP Operations
O'Brien has over 24 years of industrial experience in the manufacturing of medical devices and ceramics. From 2005 to 2014, he fulfilled several engineering leadership roles for Covidien including Manufacturing Engineering Manager for the Norfolk, Nebraska facility. He has extensive experience with Lean and other Continuous Improvement initiatives. O'Brien holds an MS in Ceramic Engineering from the Georgia Institute of Technology, and a BS in Physics from the University of Texas at San Antonio.

Mike Houston

VP Commercialization

Houston has stewardship over the Marketing, Product Development and Communications of the company, while also playing a key role in the support of Amedica's sales efforts. Prior to joining Amedica Houston managed the investor relations, corporate communications and public relations activities relating to science and technology at Ancestry.com. Houston holds a BA in business administration from the University of Utah.

VALUATION/RECOMMENDATION

At this time, we have modeled revenue growth in our financial model from the sale of spinal fusion and orthopedic implants in the U.S. We do not incorporate revenue contribution from the sale of Amedica's products in China until there is sufficient information available to estimate the probability of regulatory approval and launch timelines. We will update our model when there is more clarity on the regulatory approval timeline. If and when Amedica obtains marketing approval in China, it could potentially result in a significant upside to our current revenue estimates and valuation, given the double digit growth of orthopedic market in this region.

We model ~$19 million revenue for fiscal 2016. We model net income of approximately $2 million ($0.10EPS) in 2020 which is up from a net loss of $24 million (-$5.50 EPS) in 2015. If Amedica continues to grow its revenue, keep gross margins relatively flat and gain some leverage in operating expenses from the OEM partnerships, we expect the company to show an improving EPS. All of the aforementioned assumptions are incorporated into our financial model. Based on our 10-year DCF model that uses a 16% discount rate to account for the risks and uncertainties outlined in the report and a 1.5% terminal growth rate, the target price comes out to roughly $2.50/share. This implies more than 50% upside to the current trading price.

Risks

Raising capital: The company defaulted on its loan obligations and in an effort to pay off its creditors underwent a number of equity issuances that resulted in dilution to shareholders and decrease in the stock price. Raising additional funds through equity in the future could further dilute shareholder value while raising capital through debt may prove difficult given their history with their creditors in the past and require Amedica to accept stiff obligations with unpleasant concessions.

Model-based assumptions are prone to large variations: Our projected revenue growth from the sales of Amedica's products from the current year and beyond is largely best-guesses based on the company's ability to grow revenues. Revenue could underperform relative to our model if the customer base does not grow at our assumed forecast or is less correlated to revenue growth than what we are assuming. Achieving our price objective includes competitive, reimbursement and financial risks.

FINANCIAL MODEL

AMEDICA CORP. (Income Statement)

AMDA	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E	2019 E
Product revenue	**$19.5**	**$4.2**	**$4.0**	**$4.5**	**$6.0**	**$18.8**	**$33.7**	**$46.7**	**$58.7**
YoY growth	*-65%*	*-11%*	*-16%*	*-7%*	*18%*	*-11%*	*80%*	*38%*	*26%*
Costs of revenue	$6.3	$0.89	$1.0	$1.4	$1.9	$5.3	$10.8	$14.9	$18.8
Gross Margin	*68%*	*79%*	*75%*	*68%*	*68%*	*72%*	*68%*	*68%*	*68%*
Gross profit	**$13.2**	**$3.3**	**$3.0**	**$3.1**	**$4.1**	**$13.5**	**$22.9**	**$31.7**	**$39.9**
Research and Development	$6.4	$1.6	$1.6	$1.8	$1.7	$6.7	$7.0	$7.4	$7.8
% R&D	*33%*	*38%*	*39%*	*40%*	*29%*	*36%*	*21%*	*16%*	*13%*
General and Administrative	$6.4	$1.6	$1.4	$1.6	$2.4	$6.9	$7.4	$7.9	$8.4
% G&A	*33%*	*37%*	*34%*	*36%*	*39%*	*37%*	*22%*	*17%*	*14%*
Sales and Marketing	$12.4	$2.6	$2.6	$2.8	$7.1	$15.1	$18.3	$22.3	$27.1
% S&M	*64%*	*62%*	*64%*	*62%*	*118%*	*80%*	*54%*	*48%*	*46%*
Total operating expenses	$25.2	$5.8	$5.5	$6.2	$11.2	$28.7	$32.7	$37.5	$43.3
Operating Income	**($12.0)**	**($2.5)**	**($2.5)**	**($3.1)**	**($7.1)**	**($15.2)**	**($9.8)**	**($5.8)**	**($3.3)**
Operating margin	*-62%*	*-58%*	*-62%*	*-70%*	*-118%*	*-81%*	*-29%*	*-12%*	*-6%*
Interest income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest expense	($4.3)	($0.9)	($2.4)	($0.6)	($0.6)	($4.5)	($2.4)	($2.4)	$0.0
Gain (loss) on extinguishment of debt	$2.2	$0.0	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Change in fair value of derivative liabilities	($7.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Loss on extinguishment of derivative liabilities	($1.3)	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Offering costs	($0.8)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total other income (expense)	($11.9)	($0.9)	($2.6)	($0.6)	($0.6)	($4.5)	($2.4)	($2.4)	$0.0
Pre-Tax Income	**($23.9)**	**($3.4)**	**($5.1)**	**($3.7)**	**($7.7)**	**($19.6)**	**($12.2)**	**($8.2)**	**($3.3)**
Tax Rate	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*
Provision for income taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net comprehensive loss	**($23.9)**	**($3.4)**	**($5.1)**	**($3.7)**	**($7.7)**	**($19.6)**	**($12.2)**	**($8.2)**	**($3.3)**
Net margin	*-123%*	*-80%*	*-126%*	*-83%*	*-128%*	*-105%*	*-36%*	*-18%*	*-6%*
EPS	**($5.5)**	**($0.3)**	**($0.4)**	**($0.2)**	**($0.4)**	**($1.3)**	**($0.6)**	**($0.3)**	**($0.1)**
Weighted average common shares O/S	4.34	11.19	12.76	18.00	20.00	15.49	20.00	25.00	28.00

Source: Zacks Investment Research *Anita Dushyanth, PhD*

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