YEAR IN REVIEW

Funding and Start-up Activity in Orthopaedics and Spine: 2012

Start-ups and spin-outs identified during 2012 include:

- **Accel Spine**
  Dallas, Texas  USA
  www.accelspine.com
  - Received 8 orthopaedic-related 510(k) clearances in 2012, first was Matisse Anterior Cervical Interbody Fusion Cage

- **Apto Orthopaedics**
  Akron, Ohio  USA
  - Formed by Austen BioInnovation Institute
  - 1st device will address pediatric spinal deformities; magnet-based technology platform could lead to additional less-invasive treatments for fractures

- **AtPac Medical**
  Las Vegas, Nevada  USA
  - First orthopaedic 510(k): OsteoLaso Bone Void Filler, available in granule and strip

- **Aurora Spine**
  Carlsbad, California  USA
  www.auroraspine.us
  - Established January 2012, focusing on minimally invasive devices, regenerative technologies, aging patients
  - Planning launch of disruptive MIS technology in 1Q13

- **Back 2 Basics Spine**
  Baulkham Hills, New South Wales  Australia
  www.back2basicsspine.com
  - Received 1st FDA 510(k) clearance, for Dymaxeon Spine System
  - Formed to address a departure from lumbar fusion + interbody devices to treat degenerative disorders
  - Seeks to allow hospitals to access lower cost, high quality spinal instrumentation without unnecessary expense

- **Bioventus**
  Durham, North Carolina  USA
  www.bioventusglobal.com
  - Grew from Smith & Nephew’s Biologics and Clinical Therapies division
  - Products include EXOGEN, SUPARTZ, DUROLANE

- **CellRight Technologies**
  Universal City, Texas  USA
  www.cellrighttechnologies.com
  - Developing regenerative matrices to deliver platelet-derived growth factors, bone marrow aspirate, platelet-rich plasma and antimicrobial agents following treatment of bone defects
  - Products include conventional and sports medicine grafts, etc.

- **DiscGenics**
  Salt Lake City, Utah  USA
  www.discgenics.com
  - Founded in 2008, developing human nucleus pulposus tissue technology as a source for adult disc stem cells that can be translated into Discosphere therapeutic cell populations
  - Products in development include percutaneous injectable for treatment of non-herniated degenerative discs and minimally invasive implantable for herniated discs

- **Force Medical**
  San Diego, California  USA
  - First orthopaedic 510(k): IM Nail System for tibiotalocalcaneal arthrodesis and stabilization of hindfoot and ankle, including transverse tarsal joints

- **Garventis**
  Washington, D.C.  USA
  - First 510(k) in 2012: 2GC Hip and Knee Modular Spacers
  - Both devices made from fully formed polymethylmethacrylate, radiopaque, contain gentamicin

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Wishing you Happy Holidays and a Prosperous 2013

From all of us at ORTHOWORLD
Year in Review...

**Impact Medical**
Portland, Oregon USA
www.impactmedicalco.com
- Focusing on commodity pricing + products that require low sales rep support
- Sports medicine products: graft fixation system, instrumentation for shoulder/knee, suture anchors, etc., trauma products: plates, screws, K-wires, etc.

**Ingen Orthopedics**
Cranbury, New Jersey USA
www.ingenortho.com
- Formed in 2006, 1st 510(k) clearance received in 2012: Seviin Reverse Shoulder
- Fully integrated, all-inclusive system includes primary hemi, primary keeled, primary pegged, primary reverse, fracture hemi, fracture reverse, resurfacing head
- Principals include experience from Osteotech, Zimmer

**Mainstay Medical**
Dublin, Ireland
- Founded in 2008 by entrepreneur behind KSpine, originated in Minneapolis, MN
- Raised $20MM in Series B funding (see Fundings section to follow), including support from Medtronic
- Developing an implantable electrical stimulation device to treat chronic lower back pain

**Metric Medical Devices**
Helotes, Texas USA
www.metricmd.com
- Raised $0.66MM in equity funding (see Fundings section)
- Will focus on foot, ankle and hand fracture repair
- Management includes experience at BioMedical Enterprises, Innovative Spinal Technologies

**Neurovention**
Daytona Beach, Florida USA
- First 510(k) in 2012: Lamifix Laminoplasty Plating System
- Filed trademarks include CraniClam, CraniSlide, FlexPlate, SpringClamp

**Nexus Spinal Technologies**
Salt Lake City, Utah USA
- Developing “radically disruptive” system that allows fusion to be a flexible matrix, conforming to patient’s spinal anatomy, as opposed to a rigid rod construction; sized ~40% smaller than standard fusion products
- Affiliated with Crocker Spinal Technologies (www.crockerspinaltechnologies.com)

**NovoSource**
Dayton, Ohio USA
www.novosource.net
- Raised ~$4MM in a round of funding, proceeding with a second offering
- Expects 1Q13 launch of total knee replacement, with hip implant to follow
- Cofounder experience includes Leis Medical, Innovative Medical Device Solutions
- Seeks to offer proven orthopaedic devices at low prices by paring down development and sales processes

**Qualgenix**
Woodbury, Connecticut USA
www.qualgenix.com
- (See Fundings section, to follow)
- First 510(k) in 2012, Twin Peaks Lumbar Cage (4 products cleared in year)
- “Generic” device company: cages, screws, plates; developing MRI contrast agents and streamlined orthopedic implants and instruments for standard-of-care surgical treatments, at significantly reduced prices
- Management includes founder of Doctors Research Group

**R&D Innovations**
Eldorado Hills, California USA
www.randd-innovations.com
- Universal Crosslink features small housing size, may be used in virtually any surgical situation
- Wide angulations between rod and crosslink made possible by the ball joint connector allow for connection between two adjacent spinal segment levels on opposing sides
- Markets products through independent distributors, licensing agreements with spinal implant manufacturers

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Year in Review...

**Savannah Technologies**  
Avondale, Arizona USA  
www.savannahtechnologies.com  
- First 510(k) in 2012: Spinal System, adaptable titanium alloy fixation system designed to allow dorsal stabilization of the spine

**Skeletal Design Partnership**  
Hambrook, Bristol UK  
www.skelov8.com  
- First 510(k) in 2012: Foundation Spinal System

**SkelRegen**  
West Chester, Pennsylvania USA  
www.skelregen.com  
- Formed in 2012 to investigate small molecules that target skeletal tissue formation, may aid in musculoskeletal tissue regeneration  
- Working with specific intracellular/extracellular BMP inhibitors, molecules that may activate the BMP pathway directly, etc.  
- Expects to serve segments such as spine, trauma, bone void filler, soft tissue repair, etc.  
- Management experience includes Premier, Medtronic Japan

**SurgLine**  
Newport Beach, California USA  
www.surgline.com  
- Distributes FDA cleared products at discount prices; currently offering trauma, spine, endoscopes  
- Offers volume discounts, volume rebate programs for qualifying clients  
- In late 3Q, named in an Order of Suspension of Trading due to lack of current/accurate information, questions regarding adequacy and accuracy of press releases and public filings concerning company’s operations

**Vertical Spine**  
Wayne, New Jersey USA  
www.verticalspine.com  
- Commercial stage company, developing system to enable intra-procedural collection and preparation of autologous Platelet Rich Plasma and Fibrin for placement in lumbar spine to guide and accelerate new bone formation during fusion  
- Management experience includes AirCast, Core Essence Orthopedics, Globus Medical, Laxx, Osteotech, Pioneer Surgical, Small Bone Innovations, etc.

Funding transactions completed in 2012 are presented alphabetically by name of company, and represent funding secured or planned for.

**Accelerated Orthopedic Technologies** raised $150,000 in debt financing from $400,000 offering  
- Developing tools to shape and implant cartilage grafts for articular cartilage defect repair

**Active Implants** raised $10MM in convertible debt from current investors  
- Supporting 2-year prospective, controlled clinical trial of NUsurface Meniscus Implant

**Amedica** completed $30MM financing  
- Supporting development and distribution of novel ceramic materials for orthopedics, spine, dental

**Ascendx Spine** raised $0.55MM in a funding round  
- Developing technologies to treat vertebral compression fractures

**Aursos** raised $0.09MM of planned $0.5MM Series A round of funding  
- Developing AUR-84, bear-derived parathyroid hormone peptide, for spinal fusion, bone filling and bone defect applications

**AxioMed Spine** closed Series D financing, raising $5MM in 2 tranches  
- Augments previously-announced $15MM Series D  
- Pursuing completion of U.S. Investigational Device Exemption pivotal study of Freedom Lumbar Disc

**Bacterin** closed $25MM financing for net proceeds of ~$10MM  
- Develops bone grafts, antimicrobial coatings for spinal fusion, foot/ankle surgery, etc.

**Benvenue Medical** completed $25MM Series D financing  
- Will support global commercialization of minimally invasive products to treat degenerative disc disease, bringing fusion and vertebral compression fracture treatments to the U.S.

**Binder Biomedical** raised $0.68MM of planned $2MM in funding  
- Spinal products include NEWTON Intervertebral Body Fusion System and X-GRAFT interspinous allograft
Biomimedica closed Series B funding, raising $11.9MM of planned $14.2MM
• Developing GRADION Total Cartilage Replacement, synthetic polymer technology

BONESUPPORT received SEK 70MM (~$9.9MM) in 2nd, final tranche of funding
• Will support R&D, commercial expansion of antibiotic CERAMENT bone substitute in the U.S., Europe and Asia, etc.

Carticept Medical completed a $10MM financing round
• Supporting commercial launch of Navigator DS computer-controlled drug delivery system

Cayenne Medical closed a $10MM equity financing
• Funds supporting sales, distribution, expansion of sports medicine product offerings, e.g. Quattro Shoulder System for rotator cuff/labral repair

Cerapedics raised $3MM in funding
• Developing i-FACTOR bone graft for spinal fusion

DiFusion received $5.2MM of planned $16MM financing
• Developing CleanFUZE antimicrobial technology for use in orthopaedic implants

Globus Medical raised $104MM in its initial public offering

Histogenics completed a $49MM Series A round of financing
• Will support ongoing Phase 3 clinical trial of NeoCart autologous neocartilage tissue, EU regulatory clearance of VeriCart collagen scaffold

IlluminOss Medical secured a $28MM Series C round of financing
• Will support clinical research, European commercialization of the Photodynamic Bone Stabilization fracture treatment

Interventional Spine raised $1.6MM of a planned $4MM in funding
• Developing percutaneous systems to treat back pain, such as the PerX360° Percutaneous Lumbar Fusion and the Opticage Expandable Intervertebral Body Fusion

Invuity raised a $25MM Series D round of financing
• Developing products based on Eigr technology to enhance visualization during minimally invasive procedures, including spine and orthopaedic surgeries

Mainstay Medical raised $20MM in a Series B funding
• Will support product development, quality, clinical, regulatory, etc. activities to commercialize neurostimulation device for treatment of lower back pain

MAKO Surgical closed a public offering of ~3.5MM shares of common stock for net proceeds of ~$43MM

MedShape closed on a $3MM loan facility
• Developing shape-memory technologies for sports medicine, joint fusion, trauma applications

Metric Medical Devices raised $0.66MM of planned $1.8MM round of equity funding
• Developing internal bone fixation systems for extremities

Nextremity Solutions closed 2nd round of funding, bringing total capital raised to $6.6M, and opened 1st preferred round of $10MM
• Will support commercialization of Nextra Hammertoe Correction System, new foot/ankle implants

NLT Spine secured $5.7MM in funding in 2 Senior Term Loans
• Will support development/marketing of PROW LIF lumbar fusion device
• Plans full launch of product line in 2013

OrthoCor Medical closed a $2.4MM angel financing round
• Commenced U.S. launch of Active Knee brace

OrthoSensor closed on additional $15MM in Series B Preferred Stock financing, bringing total Series B investment to $36MM
• Funds will support commercialization of the OrthoSensor Knee Balancer, launch of company’s intelligent orthopaedic devices

Oss-Q received SEK 9MM (~$1.3MM) in financing
• Supporting development/launch of novel implant technology and related bioceramic innovations

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Year in Review...

**Paradigm Spine** raised $8.2MM of targeted $14.6MM funding

**Qualgenix** raised $2.8MM in venture capital from 27 investors
- Seeking to raise up to $10MM

**Quantum OPS** closed $1.05MM Series A financing
- Will support sales of shoulder positioning system, launch of new products, such as surgical positioners for the arm, knee, etc.

**Ranier Technology** closed a $5MM funding round
- Will support product commercialization, expansion of Precision Polyurethane Manufacturing technology beyond spinal discs, etc.

**Regentis Biomaterials** raised $10MM in a Series C financing
- Will support presence in Europe, clinical study of GelrinC biodegradable treatment for articular cartilage repair

**Regenerative Sciences** secured a $2MM investment
- Will support research of stem cell-based treatments for musculoskeletal injuries

**Relievant Medsystems** secured $30MM in Series D equity financing
- Will support global clinical development
- Sponsoring 200-patient Surgical Multi-center Assessment of RF Ablation for the Treatment of Vertebrogenic Back Pain (SMART) Trial to assess Intracept procedure

**Spinal Restoration** closed a $5MM financing
- Will support Biologic License Application submission and early commercialization for Biostat resorbable biologic disc for the treatment of discogenic pain

**Spine360** closed a $27MM financing
- Will support general growth and expansion
- Products include Talon Spinal Fixation System, lumbar cages, etc.

**Spinlab** raised CHF 4.7MM (~$4.9MM) in a Series C financing round
- Will support commercial activities in Europe, product development

**SurgaColl Technologies** secured a €2MM (~$2.5MM) investment fund
- Will support global launch of HydroxyColl bone graft substitute, preclinical trials of ChondroColl cartilage regeneration product

**Tepha** raised $11.3MM in equity financing from 38 investors
- TephaFLEX polymer is used in surgical suture and surgical meshes

**VertiFlex** raised $8MM in a round of equity funding
- Developing Superior Interspinous Spacer System

**Vertos Medical** raised $5MM in funding
- Developing products to treat lumbar spinal stenosis, such as the mild devices intended for lumbar decompressive procedures

**Zyga Technology** raised $25MM in a Series C financing
- Will support sales, marketing and clinical strategies for the SImmetry Sacroiliac Joint Fusion System and GLYDER facet resurfacing product

Sources: Company press releases, web sites, articles in the public domain, FDA 510(k) Releasable Database, filings with the U.S. Securities and Exchange Commission

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**Year in Review**

**Notable Product Launches from 2012**

The following products represent select devices launched during 2012 across a span of segments.

**ARTHROSCOPY/SOFT TISSUE**

**Covidien:** AS Meniscal Repair Device, designed to enable “all-inside” arthroscopic repair of torn knee meniscus via all-suture fixation. One-thumb slide actuation.

**COMPUTER-ASSISTED SURGERY**

**Stryker:** Stryker ADAPT for use with the Gamma3 Locking Nail to treat hip fracture. System automatically identifies the Gamma3 nail relative to a patient’s anatomy, provides guidance for implant alignment/lag screw length and positioning.
Year in Review...

**Fracture Fixation**

**MedShape:** 1st surgical use of DynaNail Ankle Arthrodesis Nail, NiTiNOL-based intramedullary nail. A new NiTiNOL material includes titanium to provide the rigidity of traditional IM nails with axial compressive properties of an external fixation frame.

**Joint Replacement**

**ConforMIS:** iTotal G2 Knee Replacement system, featured anatomic implant design with personalized fit, patient-matched anatomic shape and reportedly greater bone preservation than traditional TKR. Requires only one reusable instrument tray in the OR.

**Spine**

**Biomet Spine:** Cellentra VCBM (Viable Cell Bone Matrix), comprising viable osteogenic stem cells, verified osteoinductivity and an osteoconductive scaffold.

**Medtronic:** U.S. launch of ACD enhanced instrument set for insertion of BRYAN Cervical Disc.

**Orthopaedic Implant Company:** Low-cost pedicle screw system, to reportedly save up to $3,000 per fusion level for hospitals and surgical centers.

**Osseon Therapeutics:** U.S. commercial release of Osseoflex SB steerable balloon, Osseoflex SN+ steerable needle for treatment of vertebral compression fractures. Two cases recently completed in Florida, one in Maryland.

Though not commercially launched, we would be remiss not to mention PMA approvals for:

- **Globus Medical:** Secure-C cervical disc
- **NuVasive:** PCM cervical disc
- **Paradigm Spine:** coflex Motion Preserving Intralaminar Stabilization device

**OTHER**

- **Esaote:** G-scan Brio, Weight-Bearing MRI system optimized for musculoskeletal exams; E-MRI Brio Release 2 platform for acquisition/reconstruction of 2D sequences to speed examination with high image quality.

- **VirtaMed:** ArthroS, virtual reality training simulator for knee arthroscopy that allows surgeons to practice procedures before performing on patients.

Sources: Company press releases, web sites, articles in the public domain, filings with the U.S. Securities and Exchange Commission

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**QUARTERLY REVIEW**

**Final 3Q12 Results**

ORTHOWORLD’s estimates place 3Q12 market growth at 3% over 3Q11, as shown in Exhibit 1 on the following page. Performance highlights follow and pertain to 3Q unless otherwise noted.

**AAP Implantate**

- €8.6MM (~US $10.9MM), +25% (Trauma +46%; Biomaterials +7%; Gels/Fluids/Bone Material Contract Manufacture +>100%)
- Received FDA clearance for LOQTEQ plating systems, expecting clearance of entire product family in 4Q
- Developing 6 additional LOQTEQ systems
- Appointed new distributors in 6 geographic markets

- Received approval under the CE Mark for new bone cement

**Bacterin**

- Tissue sales $8.6MM, +19%
- Entered into 4th U.S. GPO contract, with Premier
- Instituted key opinion leader program for surgeons to witness production of Osteo-Sponge, added training sessions on intended uses, capabilities, performance
- Published positive clinical results on Osteo-Sponge SC for regeneration of subchondral bone
- Closed US $25MM financing
Quarterly Review...

**EXHIBIT 1**

**ORTHOPAEDIC SALES¹ INCREASES BY PRODUCT SEGMENT: 3Q12 VS. 3Q11**

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<th>Company</th>
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<th>Extremities</th>
<th>Fixation</th>
<th>SportsMed</th>
<th>Spine</th>
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**NOTES TO EXHIBIT 1**

¹ Orthopaedic products; constant currency, pro forma growth.
² Includes biologics.
³ For the quarter ended 8/31/12; includes Dental. Spine includes Bone Stim and Biologics; Bone Stim reflects all Bone Healing sales. Excludes trauma acquisition.
⁴ Excludes Synthes acquisition.
⁵ For the quarter ended 10/26/12.
⁶ Spine
⁷ For the quarter ended 9/30/12.
⁸ Extremities: extremities + fixation combined; Endoscopy: endoscopic + communications, most of which is orthopaedic; Spine: neuro + spine. Total growth excludes Patient Handling.
⁹ ORTHOWORLD estimates.
MEDTRONIC (for 2Q13 ended 10/26/12)
$782MM, -5% (U.S. $549MM, -8%; ex-U.S. $233MM, +2%)
- Core Spinal $649MM, -2% (U.S. $430MM, -4%; ex-U.S. $219MM, +3%; U.S. Navigation +35%)
- BMP $133MM, -19% (U.S. $119MM, -20%; ex-U.S. $14MM, -7%)
- Other Biologics experienced double-digit growth
- No significant sequential changes observed in procedure trends, price pressure or competition
- U.S. spine market continued to show signs of stabilization
- U.S. spine procedures down in low single digits, positive mix offset pricing declines
- Anticipating results from Yale Infuse study in early 2013
- Sales to China significantly affected by decreased revenue from Weigao joint distribution venture following announcement of China Kanghui acquisition (terminated joint venture in 4Q)
- Solaris system at 70% of set capacity
- Launched ACD instrument set for insertion of Bryan cervical disc, >100 procedures performed, >300 surgeons trained
- Launched implants acquired from AMT, Capstone CONTROL, etc.

TIGENIX
ChondroCelect €1.1MM (~US $1.4MM), +175%
- Growth supported by continued uptake in Belgium, The Netherlands
- Obtained regulatory approval to manufacture ChondroCelect at European plant
- Predicts positive decision in coming months on national reimbursement in France, Germany and Spain

TRANS1
$3.2MM, -32% (U.S. $2.9MM, -10%; AxiaLIF 1L and 1L+ $1.2MM, AxiaLIF 2L $0.7MM; ex-U.S. $0.3MM, -12%)
- Non-AxiaLIF revenue includes $0.5MM from VEO direct lateral access/interbody fusion; $0.2MM posterior fixation; Bi-Ostetic bone void filler $0.2MM
- 164 U.S. AxiaLIF cases, 46 AxiaLIF 2L
- Average revenue per case at all-time highs, driven by higher mix of AxiaLIF 1L+ and higher ancillary product use

- VEO case count grew 25% sequentially, 15 new surgeons performed 1st cases in 3Q
- Entered into distribution agreement with Jade Sunshine for all AxiaLIF products in People’s Republic of China (except Hong Kong, Macau and Taiwan)
- Distributors represented ~20% of business in quarter
- Gained positive coverage for AxiaLIF from Capital Blue Cross Blue Shield (~900,000 covered lives in Pennsylvania) and Avera Health (<100,000 covered lives in South Dakota); >36MM total lives now under coverage
- Announced CMS approval of valuation of Category I CPT code 22586 for pre-sacral interbody single level spinal fusion at L5-S1, effective 1/1/13
- Code applies to AxiaLIF 1L+ bundled lumbar arthrodesis procedure that includes bone graft, posterior instrumentation and fixation
- In 4Q, commenced relaunch activities for AxiaLIF line
- OIG subpoena update: no claims made; resolution could come in 1Q13

Sources: Company press releases, earnings calls, filings with the Securities and Exchange Commission

Julie A. Vetalice is Content Coordinator for ORTHOWORLD Inc. She can be reached at 440.543.2101 or julie@orthoworld.com.