

ORTHOKNOW®

STRATEGIC INSIGHTS INTO THE ORTHOPAEDIC INDUSTRY

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MEMBER SUCCESS STORY

Randall Huebner, Executive Vice President, Acumed LLC

The orthopaedic industry is enriched by selfless people who truly love their calling. Periodically, we seek to bring you closer to some of the orthopaedic power players, to learn what has helped them to be better at what they do.

Randall Huebner worked throughout college in various machine shops. In 1981, he graduated from Fairleigh Dickinson University with a B.S. in Mechanical Engineering Technology. Following that, he served as Senior Product Development Engineer at Howmedica from 1981 to 1988.

In 1988, Randy and Mary Huebner founded Acumed LLC. Randy served as President of Acumed until 1999, when the company was purchased by the Marmon Group. Currently, Randy holds the position of Executive Vice President in charge of Product Development.

We're honored that Mr. Huebner took time to share his experiences.

ORTHOKNOW (OK): *Who is your business "hero" or mentor? What was the most important lesson you learned from him or her?*

Randall Huebner (RH): I do not have one single mentor or "hero" in business, but I have been fortunate to have known many very good people over the last 30 years who have helped and taught me a great deal.

My father worked as a salesman in the plastics industry all of his life. He always tried to have a broad understanding of each of the pieces that were important to every sale and to each customer. He showed me that salesmen are one of several customers whom we needed to convince that we not only had good products, but would also be good business partners. A motivated salesforce that understands and believes in your mission makes a big difference

in the way that a company is able to present its products and services to surgeons and hospitals.

When my wife Mary and I were starting Acumed and had very little cash, my father taught us to be as self-sufficient as possible. Whether it was with legal matters or FDA, we learned that even if we could not do everything ourselves, but could understand the issues, we would at least reduce our costs and end up with a better result.

Early in Acumed's history I was fortunate to work with Dick Williams. He really understood and enjoyed orthopaedics on many levels. He was very good at looking at market segments and business pieces, and he helped me to appreciate many of the nuances of a business strategy.

Harry Kraus has been a friend of mine since my days at Howmedica. He is the consummate sales professional and I am grateful to him for helping me understand the real life challenges of sales in orthopaedics.

More recently, I have enjoyed working with Bob Pritzker. He is part of the Colson Group that oversees Acumed. His large and diversified experience in managing many companies has been invaluable.

OK: *Your mentors aside, to whom have you most often turned for inspiration throughout your orthopaedic career? What have they taught you?*

RH: My wife Mary and I started Acumed in 1988. She is an accountant and has been an excellent sounding board on both financial and business issues throughout my career. Acumed has always been self funded, forcing us to make cash a priority, especially in the early years.

Randall Huebner...

Mary is naturally frugal and managed our finances through what were sometimes difficult periods. She was great at looking at all of the small things that can affect cash flow while making sure that we had the ability to take risks and fund projects when we needed to. She showed me the value of paying attention to all of the small details that are often overlooked and can hurt a business.

OK: *In your experience, what are the key attributes of a successful businessperson?*

RH: Our industry is always changing, and over the years I have learned some of my most important lessons the hard way. It is very important to manage your cash carefully; especially the things that do not really matter to your business, so that you can be ready for an opportunity or resolve a problem when it arises.

Always question your plans. If a project or path is having trouble, it is better to take your medicine early. If a project does not feel right, chances are pretty good that there are problems ahead—even if you can't pinpoint them.

Every project has risks. On big projects it is important to measure and minimize them and, if possible, dip your toes before diving in head first. I worry over all of the details because it seems that it is rarely the big things that go wrong, but usually some small piece that seemed unimportant initially that comes back to haunt a project. I like to see the entire process, from R&D through sales and to the clinical outcomes. Each of these stages can have its own impact on determining the right product design and strategy.

It is important to have clear goals, but not too many of them. I also think that in orthopaedics, perhaps more than many other industries, things are cyclical and you need to have a good understanding of the history of the products that went before you.

OK: *What advice would you offer a young person entering the ranks of an orthopaedic company in marketing, sales or R&D?*

RH: Try to see and understand the entire product development, manufacturing and business cycle. It is important to be in surgery, be proficient with your products in the lab, understand what it is really like to sell, go out onto the fac-

tory floor and know your competitors. Concentrate on the important issues, think as an outsider and try to look at problems from several different perspectives. Understand all of the things that can affect the overall cost of a project.

It is important to learn the history of the products and the business of orthopaedics. An understanding of past successes and failures will be valuable. Appreciate that most products in orthopaedics are evolutionary, and all of us are adding in some way to someone else's ideas.

OK: *What books have you read that you consider critical reading material for someone seeking success?*

RH: I very rarely read a traditional business book; I tend to read about businesses gone awry. No two businesses are alike and none has an exact formula. Many of these books highlight the important elements of people, good strategy and sticking to your mission in the success or failure of any business.

Regardless of the industry, I always find good real world lessons on innovation, risk, cash and knowing your strengths. Some of my favorites are an out of print book by David Halberstam, *The Reckoning*, which documents the American and Japanese auto industries over the last 70 years, and a financial book by Roger Lowenstein entitled *When Genius Failed: The Rise and Fall of Long-Term Capital Management*.

OK: *What do you consider to be keys to the success of Acumed in the marketplace?*

RH: Acumed has many great employees and salespeople who believe in our goals and have been with us for a long time. It helps that our mission has been essentially the same for the last 20 years. In a nutshell, we want to develop and deliver innovative trauma products that solve real problems and of which we are proud.

We have often gone into areas that may not have penciled out at first, but were clear spaces to which we thought we could bring innovation before anyone else. Not every product is a home run, and we have been happy with adding singles and doubles when we liked the product. We have also been patient with our strategy and have avoided the temptation to jump off track and follow the latest hot market segment.

Always question your plans. If a project or path is having trouble, it is better to take your medicine early.



Randall Huebner...

While good products are critical to any company's success, we have gradually evolved from an engineering-based company into one that has supported these products with good marketing and training tools.

OK: *Your engineering background is tied to the work you do with the Surgical Implant Generation Network (SIGN)—please explain.*

RH: As an engineer, this is one of the most rewarding projects on which I have worked. SIGN designs and manufactures trauma implants that are given away to developing countries. They combine this with detailed surgeon training and have created what is likely the world's largest database of femoral and tibial fractures. Most of these countries have unique issues ranging from a lack of C-arms and reliable power drills to fractures that are treated late and are often very severe.

Many products that we use here in the U.S., even if they were available in other regions, are not always the best choices in those environments. At its core, this means designing im-

plants that work easily in challenging and inconsistent situations, are inexpensive enough to give away, are extremely durable and have clinical results that are equal to those in the rest of the world. As an engineer, it seems impossible to not be motivated and inspired by this.

SIGN was founded and is driven by Dr. Lewis Zirkle. He is an example of how one person with a clear vision, lots of determination and a huge goal can have an impact on health-care around the world. It is a privilege to be a part of this.

OK: *Any final thoughts?*

RH: The orthopaedic industry has changed a lot in the last 30 years, but despite the challenges ahead I believe that this remains a great field in which to work. Innovation, creativity and excellent service are valued. Good companies survive, and we are able to have an impact on the health of millions of people around the world.

Special thanks to Pamela Davis for her assistance in bringing this article together.

*We have gradually evolved from an **engineering-based company** into one that has supported these products with **good marketing and training tools.***

CONFERENCE REVIEW

Highlights from New Orleans: AAOS and Canaccord Adams

The following is a summary of highlights and intel gathered at the AAOS Annual Meeting and the Canaccord Adams Musculoskeletal Conference in March. Visit these companies via the Device Company directory in ORTHOWORLD, and stay tuned to ORTHOFLASH for updates to these technologies.

APPLIED SPINE

www.appliedspine.com

- Stabilimax
 - Redesigned screw w/o gritblast finish; in holding pattern with FDA
 - ~150 patients at 18-24 months; 20 with new screw
 - Kinematic signature postop = that preop
- Seeks to validate technology and look for mergers & acquisition transaction

ASCENSION ORTHOPEDICS

www.ascensionortho.com

- Big push in shoulder market
 - To file IDE for PyC hemi humeral head

- To launch modular shoulder w/ and w/o PyroCarbon head in 2010 – metal shoulder in U.S. and PyC hemi in rest of world
- >30,000 PyroCarbon implants in 10 years
- Building direct salesforce for foot/ankle applications (15 reps now)
- ~70 distributors for hand and foot/ankle

AXIAL BIOTECH

www.axialbiotech.com

- Developing and commercializing DNA-based tests
- Degenerative Disc Disease (DDD) prognostic test
 - To confirm not only the likelihood of developing DDD but also the level of severity of the condition to allow earlier surgical intervention and treatment
 - Currently in clinicals with release scheduled for 2010
- Also developing tests for Spondylolisthesis, OA and osteoporosis



Conference Review...

- Launched Scolio-Score, predictive test for children diagnosed with Adolescent Idiopathic Scoliosis (AIS) - multi-gene test that provides a qualitative and quantitative assessment of the likelihood of spinal curve progression for patients who have been diagnosed with AIS
- Generated \$5MM in 2009; expects revenues of >\$210MM in 2014
- Expects total number of tests run to reach >133,000 by 2014 (up from 927 in 2009)

AXIOMED

www.axiomed.com

- Freedom one-piece viscoelastic disc replacement
- Features CarboSil polymer core (silicone polycarbonate urethane thermoplastic elastomer); elastomer developed with DSM
- 50 patients out 2 years, with average age of 39
- On the market in EU through market evaluation
- Showed significant improvement in ODI, VAS and psychologic test scores
- Pivotal IDE study – >136 patients enrolled (to get 350 at up to 15 sites) – comparing to Pro-Disc; should complete enrollment by year’s end
- Pivotal to include economic analysis – hospital and surgeon costs, pain and disability, prescription and over-the-counter medical use, and return to work
- In discussions with distributors in Australia and New Zealand
- Lateral disc underway
- To begin biomechanical testing on cervical device and file CE for cervical in 2010

CARTICEPT MEDICAL

www.carticept.com

- Closed \$20MM financing round early March
- Cartiva
 - PVA hydrated polymer synthetic cartilage repair implant; in Europe since 2002
 - In pivotal trial vs. fusion for OA of 1st metatarsophalangeal (MTP) joint; 250 patients at 10 sites in UK and Canada with follow-up of 2 years
 - CMC underway in Brazil
 - Also looking at knee applications
 - Provides immediate rehab (almost immediate weight-bearing capability)
 - 20 minute OR time
- Navigator
 - For delivery of intra-articular injections with ready-to-use/premixed fluid delivery

- module with disposable cassette and ultrasound guidance
- 30MM potential patients annually in U.S.
- Transfers data automatically to electronic medical records
- +\$181.87 in surgeon reimbursement for ultrasound guided injections
- To launch 2010

CASTCOOLER

www.castcooler.com

- Very cool technology and, if you’ve ever had a cast on, you know this would feel great
- Connect to a vacuum hose, turn on vacuum – air flow gets directed through the lining into the cast – removes moisture and, hence, itch and smell

CAYENNE MEDICAL

www.cayennemedical.com

- >30,000 Aperfix, IFix and Crossfire implanted by >1,000 surgeons
- Future technologies: tenodesis anchor system and shoulder instability
- Should be in shoulder instability by year’s end
- Soon to be in 20 countries (now in 18)
- Mostly using independent agents; seeks to double feet on the street in 2010

CORESPINE TECHNOLOGIES

www.corespinetech.com

- Xtend-ST Nucleus Removal System
 - Articulating and extendable tip to “get around the corner”
 - Removes all nucleus in 10 minutes or less
 - Extracts soft tissue without harming endplates
- Xtend CR – gets cartilage off bone (as in endplates)

DGIMED ORTHO

www.dgimedortho.com

- Distalock Drill System
 - 30+ human implants
 - Expects mid-2010 launch of general drill and stainless steel nail in U.S., CE Mark 12/10
 - Uses Nitinol wire with inside out technique
 - Claims to reduce OR time by 70%, while also decreasing xray exposure
- Targeting non-teaching generalists
- ASP ~\$1,405
- To also develop titanium nail

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- ◆ Visit the upgraded Members Forum
- ◆ Register for OMTEC 2010
- ◆ Request Daily ORTHOFLASH® by Email

Have questions? Need help? Julie Vetalice is at your service. Call today: 440.543.2101, or email julie@orthoworld.com



Conference Review...

- Raised \$6.5MM from angels; now in B round (\$12MM)
- 3-6 reps to be hired but won't ramp until 2011 when tibial nail expected
- Expects to have 25-35 reps in 2012

FXDEVICES

www.fxdevices.com

- Pogo Screw and Lagwire
 - Looks like a Pogo stick
 - For dynamically applied constant compressive fixation of fractures

ISTO TECHNOLOGIES

www.istotech.com

- Using juvenile cartilage cells with proprietary technology – one donor can treat 3,000 patients
- DeNovoET
 - Cell-based scaffold-free living cartilage graft
 - In late stage clinicals
 - Focus on knee
 - To be distributed as part of partnership with Zimmer
- NuQu
 - Cell-based injectable of juvenile chondrocytes targeting low back pain
 - 1st cell therapy in clinical trials
 - Percutaneous delivery system with fibrin carrier for disc degeneration
 - Just initiated Phase I clinicals: 15 patients, with IRB approval at three sites; should complete enrollment by year's end
 - Outpatient procedure
- InQu
 - PLGA + hyaluronic acid bone graft extender
 - Focused on spine
 - Distributed through independent reps

LDR

www.ldrholding.com

- Mobi C
 - Approved in Europe, Asia and South America
 - >7,000 patients since 11/04
 - Cervical PMA submission expected 2Q10, with potential approval to begin trial by 2Q11
- Artificial discs in >10,000 worldwide
- Completed single and 2-level enrollment for lumbar disc
- Launched VerteBridge in U.S., EasySpine in Japan

- PEEK Interbody Devices: ROI-A (ALIF) Oblique 100 cases in Europe; should release in U.S. in 3Q
- ROI-A Lateral launch 4Q in U.S.; would be the only company with standalone lateral cage in U.S.
- Future products: C-plate (posterior cervical) 2010, with polyaxial screw end Q1 2010
- Anticipates IPO in 2011
- Generated ~\$35MM in 2009, achieved profitability; expects to generate \$65-70MM in 2010
- Selling in 30 countries
- Sells through 47 independent agents, 3 direct reps and 6 area VPs in U.S.
- >70,000 patients treated worldwide since 2003

MEDSHAPE SOLUTIONS

www.medshapesolutions.com

- Introduced FDA cleared devices manufactured from shape memory polymers based on PEEK (polyetheretherketone) and PMMA (polymethylmethacrylate) chemistries; deployable via thermal or mechanical activation
- MORPHIX Anchor
 - Utilizes PEEK Altera shape memory technology (can be deployed into different shapes with minimal force)
 - Features small insertion footprint
 - Preloaded with multiple sutures
- To launch technologies/products to distribution network by end of April

ORTHODYNAMIX

www.orthodynamix.com

- ArthroSteer
 - Steerable instrumentation – punch, grasper and cautery
 - Bend 180 degrees in one plane; lock the bend; rotate the jaw or electrode 360 degrees

PARCUS MEDICAL

www.parcusmedical.com

- From Latin: sparing, economical
- Titanium and PEEK CF (carbon fiber composite) suture anchors and interference screws
- Graft fixation and traction kits, as well

PEAK SURGICAL

www.peakurgical.com

- PEAK PlasmaBlade + PULSAR Generator pulsed plasma radiofrequency energy
 - Family of disposable, low-temperature cutting devices



How Can We Help Today?

For help *finding orthopaedic power tools*

or to get a *just-for-members tour* of ORTHOWORLD.com

...contact Julie Vetalice at 440.543.2101 or julie@orthoworld.com

Conference Review...

- Targeting total joints
- 49% less narcotic consumption by patients
- Provides faster/stronger healing with reduced blood loss
- Reduces OR time by 12% (saves \$500) and hospital stay by 17%
- Mostly disposables; ASP of \$275
- CE Mark approved
- Has capacity for 100,000 units
- 20% of business in orthopaedics (fastest growing part of their business)
- ~130 accounts with ~13-14 blades/month/account
- One salesforce 14 direct and 50 independent
- Established 10 ex-U.S. markets
- \$42MM raised to date
- Generated ~\$5MM in 2009; projecting for \$13-15MM in 2010

PROCHON BIOTECH

www.prochon.com

- BioCart Cartilage Regeneration System
 - For repair of cartilage defects (without periosteal flap or suture to secure)
 - In Phase II clinicals in the U.S. in the knee vs. microfracture – 20 patients enrolled by end 3/10
 - >85 patients treated, some at 4 years post-op
 - Expects to begin pivotal Phase III in 2011 and complete in 2012
- CartiMate Scaffold
 - In development for microfracture and small defects
 - Uses Fibroblast Growth Factor (FGF) as reagent
 - Demonstrated cell proliferation from 5-8 weeks to 2 weeks
- Also developing FGF2V (variant) platform, CartiMate without cells for augment microfracture and FGF on CartiMate + stem cells
- Manufacturing established in Israel and Italy; soon in North America

SALIENT SURGICAL TECHNOLOGIES

www.salientsurgical.com

- Transcollation
 - RF + electrically conducted fluid – able to change the molecular structure of collagen
 - Seals tissue planes
 - 400,000 patients treated to date
 - Used in 1 of every 9 TJR patients in 2009 and 35% of US hospitals
 - For surgeon: improves visibility and reduces surgery time; is more predictable

- For patient: improves ROM, decreases pain and swelling and speeds rehab
- For hospital: reduces transfusion costs, postop complications and LOS
- ASP north of \$500
- Generates direct cost savings of \$493/case with total cost savings of \$710/case
- Generated ~\$50-60MM in 2009; expects to generate \$72-\$77MM in 2010
- Cleared in Japan; expects to launch there in 2nd half
- Uses direct salesforce of 75 reps; ~\$700,000 each
- Launched trauma application early in 1Q10
- Expects to launch Aquamantys3 (cutting + Transcollation) in 2011

SKELETAL DYNAMICS

www.skeletaldynamics.com

- Developed 4 products (all Ⓢ); awaiting FDA clearance
- Akro-Vu Videoscopic Carpal Tunnel Release System
 - Procedure in a box
 - Miniature videoscope with handpiece and a monitor; can be placed within the sterile surgical field
 - Handpiece with videoblade containing camera, light source and blade assembly
- Internal Joint Stabilizer – Elbow I.J.S.
 - For internal, temporary stability between humerus and ulna of patients with elbow instability
 - Permits early, active mobilization and function of the elbow; also allows for osteosynthesis and soft tissue healing
- Align Radial Head System
 - Customized solution for each patient's anatomic orientation
- IMplate - Wrist Arthrodesis Nail
 - Features 3-piece construction that facilitates installation and a threaded slot allowing for compression and position (you've got to see it to "get" it)

SOTEIRA

www.soteira.com

- Kyphoplasty technology
 - Braided Nitinol with PET mesh shield
 - 102 levels in clinical study
 - 2 year pilot + 2 year follow-up
 - Averages 15 minutes OR time
 - Results: pain, quality of life = that in control and literature; leak frequency (using CT



Conference Review...

- measure) superior to control, as was leak volume
- Loss of height better than with vertebroplasty
- Expects to generate ~\$2.5MM in 2010

SPINAL KINETICSwww.spinalkinetics.com

- M6 Discs
 - Progressive resistance in motion quality + 6 degrees of freedom = M6 disc
 - Features fiber polymer construct – artificial nucleus and annulus
 - >5,250 cervical and 300 lumbar discs to date (lumbar 1st in 4Q09)
 - Completed cervical pilot with 30 patients; 1 year submitted at end of 2009 – all endpoints met
 - Received conditional approval for cervical pivotal; preparing for trial
 - Received CE Mark for cervical in 2006, lumbar in 2009
 - Focusing on Germany with 1Q09 limited launch; claims to have #2 position in market there
 - Launching lumbar in Germany now

SPINALMOTIONwww.spinalmotion.com

- Kineflex discs
 - >3,500 patients treated; commercial success in South Africa and Sweden
 - Lumbar 510 patients @ 25 sites vs. Charite – higher composite success score (faster pain relief, lower repeat procedure rates and adverse events; >90% satisfaction rate); average patient age of 39; submitted PMA 4Q09
 - Cervical 330 patients at 23 sites – demonstrated statistically superior to fusion (1cc less blood and just one night in hospital); average patient age 43; expects to submit PMA 1Q10
 - Anticipates clearance for both discs 2011
 - Developing MRI imaging friendly (PEEK with thin titanium endplate) discs; starting pilot 2Q10 and collecting data to support IDE
 - Lateral lumbar clinical study underway (pilot started 3Q09); CE Mark expected mid-2010
 - Also developing lower height cervical device

STRYKERwww.stryker.com

- Mobile bearing hip
 - Anatomic dual mobility acetabular system + X3 Advanced Bearing Technology
 - Addresses dislocation w/o metal-on-metal; dual points of articulation for greater range of motion
 - Demonstrated 97% reduction in volumetric wear vs. conventional polyethylene

TORNIERwww.tornier.com

- ArthroTunneler arthroscopic transosseous tunneling device
 - For rotator cuff repair
 - Allows surgeon to place precise intersecting tunnels and pass multiple sutures through bone with the same instrument
 - Complete arthroscopic transosseous rotator cuff repair without anchors
- Also markets Insite suture anchors and Piton knotless fixation for sports medicine applications

VERTEBRAL TECHNOLOGIESwww.vti-spine.com

- Interfuse Interbody System
 - Features intraoperative assembly; typically uses 5 modules
 - Posterior system, one incision, large footprint
 - Used in >600 cases by 50 docs
 - 1st 40 consecutive patients: 100% fusion with no subsidence, no migration and no loosening
 - Reduces tissue dissection, nerve root retraction
 - In U.S. commercialization phase
 - Also developing anterior, transforaminal and lateral versions
- InterCushion Disc Nucleus
 - PEEK inner with soft polyurethane outer; in development
 - On track to start ex-U.S. feasibility trial in 2010
 - Completed cyclic testing to 10MM without failure
- Generated \$500,000 to ~\$700,000/Q in 2009, seeing 2010 revenues of >\$1MM in 1Q to nearly \$3MM in 4Q
- Expects to raise \$5-10MM in 2011



YEAR IN REVIEW

Here are the remaining performance highlights for companies that had not published at press time in March.

AAP IMPLANTATE

- €33.1MM (US \$44.6MM), +4%
- Transferred dental sales to an exclusive distributor; focusing R&D on core ortho, trauma and spine
- In 2010, will sign 2 semi-exclusive license agreements for project development with partners

ACCELLENT

- For 4Q, endoscopy +1%, orthopaedic -37%
- Hearing positive feedback from customers and a general pick-up in inventory restocking

ANIKA THERAPEUTICS

- Joint Health (ORTHOVISC and MONOVISC) \$22.8MM, +22%
- Filed final module of PMA for MONOVISC; on track for 2H10 launch
- Will sell MONOVISC via direct distribution in U.S. (~10 salespeople)
- CIGNAL launch delayed due to focus on Fidia acquisition, minor technical issues; will evaluate how CIGNAL fits into overall strategy

ARTHROCARE

- \$230MM, +3%
 - Sports Medicine \$209.7MM, +5%
 - Spine \$20.3MM, -13%
- In Sports Med, will focus on expansion of arthroscopic markets
- Spine will not contribute to growth in 2010

MAKO SURGICAL

- \$34.2MM
 - Procedures \$7.5MM
 - RIO Systems \$14.7MM
 - TGS Systems \$11.3MM
 - Service/Other \$0.6MM
- 1,602 MAKOpasty procedures performed
- 27 MAKOpasty salespeople in the field
- RIO ASP averaged \$775,000 for year
- Average monthly utilization per commercial system = 5.6 procedures

ORTHOVITA

- \$92.9MM, +21% (Cortoss and Aliquot \$1.1MM)
 - U.S. Vitoss +23%
 - U.S. Biosurgery +14%
- 151 active Cortoss accounts; of those, 76% placed reorders
- Seeing some tightening up on pricing in spinal fusion; procedure volumes are fine

- Hospitals approving product in larger quantities, can offer pricing flexibility (particularly in 1-level 5cc kit)
- Developing Cortoss delivery devices to reduce number/complexity of plastic disposables
- Will initiate *in vivo* studies on new, unspecified indication for Cortoss
- Working to penetrate hospital outpatient settings to access higher volume VCF surgeons
- 106 reps selling Cortoss
- Strong demand for Vitoss bioactive foam, has cannibalized part but not all of classic foam; bioactive priced at ~20% premium to classic
- Plans to launch another version of Vitoss in 2011

TIGENIX

- ChondroCelect €46,000 (US \$62,000)
- Other Revenue €986,000 (US \$1.3MM, comprises mostly grant funding for meniscus/osteoarthritis research)
- Acquired Orthomimetics at year-end, thus adding 2nd commercial product to pipeline (ChondroMimetic resorbable implant)
- FDA requested additional study before filing a Biologic License Application for ChondroCelect, invited company to seek Special Protocol Assessment
- Company presented protocol for European follow-up study to FDA; initial feedback is positive and outline of study could be used for U.S.

Sources: Company earnings calls, press releases

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