BARE BONES®

A MONTHLY EXECUTIVE SUMMARY OF KEY STRATEGIC ORTHOPAEDIC EVENTS

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Orthopaedic Strategic Initiatives

GLOBUS MEDICAL (GMED) acquired **EXCELSIUS SURGICAL**, developer of a next-generation **surgical robotic positioning platform** for **spine** and other applications.

The robotic Excelsius Surgical system supports **navigation, surgical access, implant sizing, positioning** and **placement**. GMED expects to obtain **FDA clearance** to market the system in **2015**, with **commercial sales** expected in **2016**.

(Globus Medical, Inc., 1/8/14)

MAZOR ROBOTICS signed an **agreement** with one of the **largest U.S. group purchasing organizations** for hospitals and freestanding surgical centers for supply of the **Renaissance**™ robotic guidance system for **spine surgery**. **Three member hospitals** under this GPO are **current Renaissance customers**.

(Mazor Robotics Ltd., 1/14/14)

STRYKER and **NEUROLOGICA** entered into an **exclusive agreement** to sell NeuroLogica's **BodyTom**® portable **full body computed tomography scanner** for **orthopaedic, spine, trauma and neurosurgery** with the **Stryker NAV3i**™ **Surgical Navigation** platform.

(Stryker Corporation, 1/6/14)

WRIGHT MEDICAL (WMGI) completed the **divestiture** of its **OrthoRecon** business to **MICROPORT**. (See *BARE BONES*, 6/13.) The transaction establishes **MICROPORT ORTHOPEDICS** as the **6th largest multinational hip and knee reconstruction company**, with global headquarters in Tennessee.

(Wright Medical Group, Inc., 1/9/14; MicroPort Orthopedics, Inc., 1/13/14)

WMGI acquired **SOLANA SURGICAL** for **US $90MM in cash and stock** and entered into a **definitive agreement** to acquire **ORTHOPRO** for up to **$36MM in cash**. The latter transaction is expected to close in **2/14**.

(Wright Medical Group, Inc., 1/30/14)

Orthopaedic Product/Company Performance

ACUMED introduced the **Scapho-Lunate Inter Carpal** (SLIC) **Screw** for **bone stabilization** during repair and healing of the **scapho-lunate interosseous ligament**.

The SLIC Screw features a **joint** that allows for **rotation** between the **scaphoid and lunate** and is designed to be **removed in 6 to 9 months** to **support soft tissue repair** and allow **more time for biological healing**.

(Acumed, 1/14/14)

AMXTEK received a Notice of Allowance for **U.S. Patent No. US2011/0196502**, Methods of Using **Water-Soluble Inorganic Compounds** for **Implants**.

The patent provides for the use of **bioactive glass** to **enhance osteostimulative bone ingrowth** and also **provide broad-spectrum antimicrobial implant prophylaxis**, with application in **spine, trauma, joint reconstruction and revision implants**.

(AMxTek LLC, 1/20/14)

ARTHROCARE (ARTC) entered into a **2-year Deferred Prosecution Agreement** (DPA) with the **U.S. Department of Justice** (DOJ) to resolve ongoing investigation regarding **allegations of securities and related fraud** committed under a previous management team, 1st announced in **2008**.

Pursuant to the DPA, ARTC has agreed to pay a **US $30MM fine** to the DOJ and to maintain a **compliance program** meeting certain criteria specified in the DPA.

(ArthroCare Corporation, 1/7/14)

AURORA SPINE (ASG) confirmed that the anticipated size of its **private placement** of common shares will be **CDN $10MM** (US $9.1MM), with shares issued at **CDN $3.15/share**.

Net proceeds will fund the **manufacturing, sales and marketing** of **ZIP**™ and other FDA-cleared products and for **general working capital**. The transaction closed on **1/15/14**.

(Aurora Spine Corporation, 1/15/14)

ASG announced the **sale** of the **100th ZIP Ultra MIS Interspinous fusion system** in **Italy**.

(Aurora Spine Corporation, 1/29/14)

BIOMEDICAL ENTERPRISES filed a **suit** against Solana Surgical, alleging **infringement** of **U.S. Patent No. 8,584,853** through sales of products such as the **FuseFORCE Fixation System**.

(BME, Inc., 1/31/14)

BONUTTI SKELETAL INNOVATIONS entered into an **agreement** with **SMITH & NEPHEW** (SNN) to **resolve litigation** pertaining to **suture anchors** that was pending in a U.S. District Court.

(Acadia Research Corporation, 1/6/14)

COMPANY FINANCIALS† 2013 vs. 2012

Company/ Ticker Symbol	Sales ($MM)	vs. Prior
Implanet	~$9.1‡	+1%
Hips	~$2.4	+3%
Knees	~$5.5	-6%
Spine	~$1.1	+153%
Johnson & Johnson	$9,509.0	+23%
Hips		+4%
Knees		+3%
Trauma		+4%
Spine		-3%
Sports Medicine		+4%
Mathys	~$142.4§	+9%
Medicrea	~$31.2*	+11%
SpineVision	~$14.3††	+27%
SYK	$9,021.0	+4%
Recon	$4,004.0	+7%
Neuro/Spine	$1,658.0	+8%
MedSurg	$3,359.0	+4%
Vexim	~$8.3‡‡	+123%
ZMH	$4,623.0	+5%
Hips	$1,330.0	+1%
Knees	$1,910.0	+5%
Extremities	$194.0	+12%
Trauma	$316.0	+5%
Spine	$202.0	-3%
Surgical/Other	$432.0	+21%

FISCAL 2Q14 vs. 2Q13
ended 11/30/13

Biomet	$825.7	+5%
Hips	$167.7	+4%
Knees	$264.0	+8%
S.E.T.	$160.3	+7%
Spine/Bone Healing/ Microfixation	$104.9	+2%
Cement/Biologics/Other	$58.3	+3%

†Orthopaedic product sales only unless indicated. Constant currency.
‡€6.6MM
§CHF 128.8MM
*€22.9MM
††€10.5MM
‡‡€6.1MM

(Please see Stock Watch on page 4 for company names that correspond to ticker symbols listed here.)

(Company news releases, 1/14)

CARDINAL SPINE raised **US $0.3MM** of a planned **$1.25MM** offering. The company's products include the **STGC vertebral body replacement** and **STCC cervical cage**, both **FDA-cleared**.

(Form D/A for Cardinal Spine, LLC., SEC.gov, 1/3/14; Mass Device, 1/7/14)

Long-term study data demonstrated the **effectiveness** of **CARTIVA**'s **Synthetic Cartilage Implant** for up to **8 years** in the treatment of **focal knee cartilage injuries**.

At final follow-up, **85%** of patients indicated **improvement and satisfaction** with the results. The **polyvinyl alcohol hydrogel** product is designed to **mimic natural cartilage**.

(Cartiva, Inc., 1/13/14)

CYTORI THERAPEUTICS received **Investigational Device Exemption** approval from **FDA** to commence a **prospective clinical trial** of **adipose-derived regenerative cells** to treat **hamstring injuries**.

The **RECOVER** trial will enroll **10 initial patients**, to be followed by expansion to a **multi-dose, multi-center, double-blind, placebo-controlled trial**.

(Cytori Therapeutics, 1/13/14)

DEPUY SYNTHES SPINE and **DEPUY SYNTHES BIOMATERIALS** commenced **U.S. launch** of **CONFORM SHEET**™, a hydrated, pliable demineralized **cancellous bone matrix** for use in **posterolateral spinal fusion**.

The allograft, which is processed by the **MUSCULOSKELETAL TRANSPLANT FOUNDATION**, claims both **osteoinductive and osteoconductive properties**.

(DePuy Synthes, 1/6/14)

GENZYME withdrew an **appeal** filed in a U.S. Court relative to a **patent infringement suit** against **SEIKAGAKU** concerning **Gel-One®** single-injection treatment for **knee osteoarthritis pain**.

This action **leaves intact** a **previous ruling of non-infringement** by Seikagaku and **ZIMMER** (ZMH). Seikagaku and ZMH will continue collaboration to **market Gel-One in the U.S.**

(Seikagaku Corporation, 1/14/14)

ILLUMINOSS MEDICAL launched the **Photodynamic Bone Stabilization System** in **Spain** and **Israel** through **PRIM ORTOPEDIA** and **TRIMACO**, respectively.

The minimally invasive system enables **fracture repair** using a **light-curable polymer** contained within an expandable **balloon catheter** to achieve bone stabilization.

(IlluminOss Medical, Inc., 1/30/14)

INTELLIROD SPINE secured **debt financing** of **US $1.6MM** from the Ohio Third Frontier's Commercial Acceleration Loan Fund. The award will support **commercialization** of the **Intellirod™ Sensor** and related **lumbar fusion implants**.

Specifically, Intellirod will pursue **CE Mark approval** and **FDA clearance**, add a **companion pedicle screw** to its technology offering and hire **additional staff**.

(Intellirod Spine, 1/21/14)

K2M confidentially submitted a **draft registration statement** to the **U.S. Securities and Exchange Commission** relating to the **proposed initial public offering** of its common stock. The **number of shares and price range** for the proposed offering has **not yet been determined**.

(K2M, Inc., 1/25/14)

In **limited launch**, **MEDSHAPE**'s **DynaNail® TTC Fusion System** has been **successfully implanted** in **>100 tibiotalocalcaneal fusion procedures** to date.

Further, a large number of **high-risk patients** have reportedly **experienced fusions** with DynaNail, including many requiring **bone allografts**. **Full release** of the system will occur in **1/14**.

(MedShape, Inc., 1/7/14)

Results from a **100-patient Phase II clinical trial** of **MESOBLAST**'s proprietary allogeneic **Mesenchymal Precursor Cells** (MPCs) in the treatment of **chronic moderate to severe discogenic lower back pain** indicate that a **single injection** of MPCs into degenerating discs **reduced pain and improved function** for a minimum of **12 months**.

Compared to control, MPC patients used **less opioids**, exhibited **greater disc stability** and underwent **fewer additional surgical and non-surgical treatment interventions**.

(Mesoblast Limited, 1/29/14)

Early results from **limited commercial release** of **NEXTREMITY SOLUTIONS' Re+Line Bunion Correction System** indicate **faster healing**, **earlier weight bearing** and **less post-op pain** vs. other techniques and implants. The FDA

cleared device complements the company's **Nextra Hammertoe Correction System**.
(Nextremity Solutions, Inc., 1/28/14)

Results from use of Nextremity Solutions' **Nextra** implant in **hammertoe correction** demonstrated **control and flexibility** in **adapting** to the **patient's anatomy** and support of an **inter-digital surgical approach** to **conceal suture scars** post-op. The technique capitalizes on the **adjustable/reversible features** of Nextra's proprietary **RevLock technology**.
(Nextremity Solutions, Inc., 12/27/14)

A **Federal court** denied **NUVASIVE**'s **motion** to **dismiss** a **patent infringement case** brought by **ANGLEFIX TECH** regarding the **Helix Anterior Cervical Plate**, ruling that **claims construction** was **premature** at this stage of the case.
(Law360, 1/15/14)

ORTHALIGN announced **successful completion** of **>13,500 KneeAlign® Total Knee Arthroplasty cases globally**, to date. KneeAlign provides **tibial and distal femoral navigation** in a **palm-sized device** that is compatible with **all implant systems**.
(OrthAlign, Inc., 1/6/14)

ORTHOCOR MEDICAL selected The **Andrews Research & Education Institute** to receive a **grant** to support a **randomized, double-blind, placebo-controlled study** of the **Active Knee System**, a **pulsed electromagnetic field and heat-based treatment** for **knee osteoarthritis**.
(OrthoCor Medical, Inc., 1/16/14)

PROVIDENCE MEDICAL TECHNOLOGY (PMT) was issued **5 U.S. patents** in the past **12 months** for its **DTRAX®** technologies, including **U.S. Patent No. 8,623,054**, "**Vertebral Joint Implants** and **Delivery Tools**," describing methods and instruments for **minimally invasively routing an implant** into the **spinal facet joint** via a **posterior approach**. To date, **7 U.S. patents** have been issued to PMT.
(Providence Medical Technology, Inc., 1/13/14)

SI-BONE's **iFuse Implant System®** has been used in **>10,000 procedures worldwide** to date, utilizing **>29,000 iFuse implants**.

Over 700 surgeons have performed the procedures that are designed to treat **degenerative sacroiliitis** and **sacroiliac joint disruptions**.
(SI-BONE, Inc., 1/6/14)

SNN is **withdrawing** the **femoral implant component** of the **Journey Bi-Cruciate Stabilized knee** from the **Australian market** following indications that the system's **femoral implant/tibial baseplate combination** is having a **higher than expected revision rate** vs. all other primary total knee replacements.

Following this action, Journey BCS will **no longer be available** in Australia as a **primary total knee replacement** system.
(Hazard Alert, TGA.gov, 1/6/14)

TITAN SPINE was awarded **5 new U.S. patents** addressing the design of **Endoskeleton® interbody devices**, as well as aspects of **composite devices** featuring a **combination of metal and polymer** (e.g., polyetheretherketone).
(Titan Spine, LLC, 1/21/14)

X-BOLT ORTHOPAEDICS completed an **equity investment round** of **€1.8MM** (~US $2.5MM). Funds will support **FDA clearance** of a **hip fracture fixation product** in the U.S. and **fast track commercialization** to the **global market**. In the **last 3 years**, the company has raised **~$4.5MM**.
(Silicon Republic, 1/16/14)

ZIPLINE MEDICAL closed a **Series C financing round** of **US $4.3MM**. The company is developing noninvasive **surgical skin closure devices** for **suture-like outcomes** with application in a variety of specialties, including **orthopaedics**.
(ZipLine Medical, ziplinemedical.com, 1/21/14)

KEY STRATEGIC 510(K)S JANUARY 2014

- Kiva VCF Treatment System (BENVENUE MEDICAL)
- Distalock Tibial IM Nail (DGIMED ORTHO)
- Small Fragment Locked Plate; Small and Large Non-locking Fragment Plate (EMERGE MEDICAL)
- I-Hip System, Gradual Transitioning (ICONACY ORTHOPEDIC)
- Aversion Pedicle Screw (K7)
- Santis Pedicle Screw (LANTERNA MEDICAL)
- Titanium Suture Anchor (MTP SOLUTIONS)
- Polyscrew Pedicle Screw (SPINESELECT)
- Digifix External Fixation System (VIRAK ORTHOPEDIC RESEARCH)

(FDA 510(k) Releasable Database, 1/14)

A current listing of all orthopaedic 510(k)s issued since 1/1/00 can be found in www.orthoworld.com, available exclusively to Members of ORTHOWORLD®.

Orthopaedic Reimbursement/Regulatory News

BENVENUE MEDICAL received **FDA 510(k) clearance** for the **Kiva® vertebral compression fracture** (VCF) treatment system. In **clinical studies**, Kiva was shown to **meet or exceed** the performance of **balloon kyphoplasty**, the **current standard of care** in treating VCFs.

The Kiva System received **CE Mark approval** in **2008** and is distributed by **ZIMMER SPINE** in **Europe**.
(Benvenue Medical, Inc., 1/28/14)

DALLEN MEDICAL received **FDA 510(k) clearance** for its individually packaged, sterile **Compressyn™ Staple** implants.
(Dallen Medical, 1/20/14)

In **draft guidance**, the U.K.'s **National Institute for Health and Care Excellence** supported use of **ELLIPSE TECHNOLOGIES' MAGEC** (Magnetic Expansion Control) device to treat **scoliosis** in **children aged 2 to 11** for whom **conventional treatments** have **failed**. **Consultation** on the guidance is slated to **close in 2/14**.

(*The Belfast Telegraph*, NICE Guidance, NICE.org.uk, 1/28/14)

ICONACY ORTHOPEDIC IMPLANTS received **FDA 510(k) clearance** to market the **I-Hip GT Femoral Stem**, comprising **porous coated femoral stem** and **acetabular cup** components for **cementless, press-fit fixation**.

(ICONACY Orthopedic Implants LLC, 1/20/14)

K2M received **FDA 510(k) clearance** to market **CAYMAN® Minimally Invasive**, a **single-level lateral plate** featuring **tifix® Locking Technology** that **obviates** the need for an **additional locking mechanism**.

CAYMAN Minimally Invasive enables preservation of the **position of the lateral implant** and **insertion of the plate** without **repositioning** the **RAVINE® Lateral Access retractor**.

(K2M, Inc., 1/8/14)

The **Centers for Medicare & Medicaid Services** released a **final Decision Memorandum** allowing **Coverage with Evidence Development** (CED) for **Percutaneous Image Guided Lumbar Decompression** for **Spinal Stenosis**.

Following this Memorandum, Medicare coverage for the **VERTIFLEX Totalis™ Direct Decompression System** will be available for **lumbar spinal stenosis** patients **enrolled in an approved CED study**.

(VertiFlex, Inc., 1/14/14)

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STOCK WATCH

(Based on close of business, 1/31/14)

Company	*Ticker Symbol*	*52-Wk High*	*52-Wk Low*	*Close*	*Chg vs. Prior Mo.*	*Chg vs. Prior Yr.*
aap Implantate †	AAQ	3.38	1.55	3.31	13.0%	77.0%
Alphatec Spine	ATEC	2.41	1.55	2.17	8.0%	25.4%
ArthroCare	ARTC	49.95	31.56	45.38	12.8%	24.6%
Aurora Spine	ASG	4.64	1.75	4.64	34.1%	n/a
Bacterin International	BONE	1.45	0.37	0.54	8.0%	-60.3%
Baxano Surgical	BAXS	2.67	0.92	1.27	25.7%	-49.0%
co.don †	CNW	2.44	0.95	1.70	-24.4%	24.1%
ConMed	CNMD	45.57	29.1	41.95	-1.3%	42.8%
curasan †	CUR	4.25	2.93	3.24	-3.0%	-17.3%
Exactech	EXAC	25.14	17.68	22.28	-6.2%	16.1%
Globus Medical	GMED	23.95	12.50	23.40	16.0%	83.1%
Japan MDM‡	7600	3.89	2.16	3.16	6.0%	15.8%
LDR	LDRH	28.23	17.79	26.42	11.9%	n/a
NuVasive	NUVA	38.79	16.77	37.44	15.8%	117.3%
Orthofix	OFIX	39.58	19.35	20.55	-9.9%	-46.1%
RTI Surgical	RTIX	4.95	2.77	3.10	-12.4%	-37.0%
Smith & Nephew	SNN	74.85	52.52	72.24	0.7%	25.3%
Stryker	SYK	79.24	61.59	77.60	3.3%	23.9%
Symmetry Medical	SMA	12.83	7.44	9.72	-3.6%	-9.2%
TiGenix †	TIG	1.36	0.20	1.17	125.0%	0.0%
Tornier	TRNX	21.87	15.17	18.19	-3.2%	5.5%
Wright Medical	WMGI	32.52	21.10	30.41	-1.0%	43.9%
Zimmer	ZMH	97.86	72.24	93.97	0.8%	26.0%
***BARE BONES* Index[1]**					1.8%	29.1%
Biologicals Index[2]					-0.2%	-34.0%
Devices Index[3]					3.6%	28.4%
Supplier Index[4]					-3.6%	-9.2%

[1]*BARE BONES* Index = average of all STOCK WATCH stocks.
[2]Biologicals Index = average of AAQ, BONE, CNW, CUR, RTIX and TIG.
[3]Devices Index = average of 7600, ASG, ATEC, ARTC, BAXS, CNMD, EXAC, GMED, LDRH, NUVA, OFIX, SNN, SYK, TRNX, WMGI and ZMH.
[4]Supplier Index = SMA.

†Euro to USD; 1€ = 1.35 USD ‡Yen to USD, 1¥ = 0.0085 USD

In order for a company to qualify for inclusion in the *BARE BONES* Stock Watch, orthopaedics must represent at least 60% of its revenues.