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Industry Update

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Innovation remains intact: updates on 31 noteworthy private MedTech players

Eighteenth Annual Musculoskeletal Conference

We recently hosted the 2023 Canaccord Genuity Musculoskeletal Conference in Las Vegas leading up to AAOS. The conference showcased 31 innovative, privately held companies in our coverage universe primarily focused on orthopedics. Coming out of those meetings, we have increased conviction in the level of innovation emerging from the private companies and the potential for differentiated solutions to enter the market over the next several years (either through an IPO or M&A via the larger strategic players). We came away impressed with the level of innovation, clinical data, and commercial progress many of these companies have accomplished over the past year, particularly against the challenges of the pandemic. We note many of the technologies developed by these firms are disrupting the standard of care by focusing on striking a balance between clinical efficacy/outcomes while also reducing healthcare costs and improving economic outcomes. To that point, we suggest investors use this note highlighting the private companies at our Musculoskeletal Conference as an opportunity to identify key emerging companies across our coverage universe:

- **ABANZA:** Innovating in arthroscopic soft tissue repair, beginning with ACL fixation
- **AgNovos Bioscience:** Minimally invasive ortho implants for treatment of osteoporosis
- **Allay Therapeutics:** Analgesic technology for post-surgical pain relief
- **Arcuro Medical:** Knotless, all-suture meniscal repair system
- **Augmedics:** Augmented reality enabling technology for orthopedic procedures
- **Canary Medical:** Implant-based sensor technology to track a wide range of metrics
- **Caira Surgical:** Radar-based navigation for advanced joint replacement
- **CarIsmed:** A personalized medicine company creating optimal surgical plans and spine fusion devices
- **Carmell Therapeutics**: Plasma-based Bioactive Materials for tissue repair and growth
- **Catalyst OrthoScience:** Shoulder replacement with an innovative stemless implant design
- **Centinel Spine:** The largest privately held spine company focused on anterior column reconstruction
- **CoNextions Medical:** Novel tendon repair technique to improve outcomes and economics
- **CurvaFix:** Novel pelvic trauma technology to improve outcomes
- **DiscGenics:** Regenerative cell-based therapies for degenerative spine disease
- **Empirical Spine:** Novel solution for the treatment of degenerative spinal spondylolisthesis
- **Miach Orthopedics:** Bioengineered surgical implant for ACL repair
- **Moximed**: Implantable shock absorber to treat knee osteoarthritis
- **Onkos Surgical:** Surgical oncology solution targeting tumor, revision, and trauma
- **OnPoint Surgical:** Augmented reality guidance for orthopedic and spine procedures
- **OSSIO:** Bio-integrative ortho implants for soft-tissue-to-bone fixation
- **OrthAlign:** Surgical navigation to aid in precise alignment and tailored for the ASC
- **Premia Spine:** Joint replacement solution for spondylolisthesis and spinal fusion

For important information, please see the Important Disclosures beginning on page 19 of this document.

- **Providence Medical Technology:** Novel solution for high-risk posterior cervical fusion and other conditions
- **Relievant Medsystems:** Minimally invasive treatment for relief of chronic vertebrongenic low back pain
- **restor3D:** 3D-printed personalized implants and instruments by uniting biomaterials, biomechanics, and AI
- **Shoulder Innovations:** Glenoid fixation technology for shoulder replacement
- **Sonex Health:** Ultrasound-guided procedures for carpal tunnel release and trigger finger
- **Sparta Biomedical:** Chemically engineered cartilage-like implants to treat osteoarthritis
- **Theragen:** Pure play non-invasive therapeutic stimulation
- **THINK Surgical:** Active robotics for knee replacement surgery
- **Trice Medical:** Office-based technologies for visualization and treatment

Key takeaways (alphabetical order)

Source: Company Website

Innovating in arthroscopic soft tissue repair with ACL fixation

ABANZA

ABANZA aims to innovate in the field of orthopedics and arthroscopic soft tissue repair procedures. ABANZA's flagship WasherCap fixation system for ACL repair obtained CE Mark in 2021. Other solutions it is developing include its Loopcap technology for F&A applications as well as its ST Biomimetics technology for soft tissue healing.

Takeaways from the conference

- ABANZA's WasherCap technology features 1) cortical positioning to help prevent migration, 2) internal fixation of the graft, and 3) protection against damage and threading. It comes in four sizes that address ~95% of cases. ABANZA is also developing its WasherCap mini for meniscal root repair.
- The WasherCap 9mm has shown enhanced strength and improved residual displacement vs competitive solutions, performing the best of all devices tested at 708 Newtons strength and 0.6mm of residual displacement, beating DePuy's Intrafix 9mm, Zimmer's WasherLoc 9mm, Smith and Nephew's Biosure PK, and Arthrex's Delta Screw 9mm. For context, it has been shown that residual displacement of 3mm+ is correlated to ACL reconstruction failure.
- ABANZA sees its Loopcap technology in applications for F&A and shoulder and other soft tissue indications in the future. Its Biomimetics technology features an increased contact area of graft to bone, promoting enhanced probability of graft healing for indications in ACL, shoulder, and Achilles repair.
- ABANZA has received CE Mark, UKCA Mark, and FDA 510(K) clearance for its WasherCap. It anticipates the first US surgeries in Q2/23 and is currently building out its distribution network.

Source: Company Website

Minimally-invasive ortho implants for treatment of osteoporosis

AgNovos Bioscience

AgNovos is a regenerative medicine company focused on building hard tissue, initially pioneering novel treatments for osteoporosis. AgNovos' OSSURE LOEP (Local Osteo-Enhancement Procedure) has been clinically tested to show substantial increases in bone density and strength for at least seven years.

Takeaways from the conference

- Its flagship solution LOEP is a local osteo-enhancement hip procedure where regenerative material is delivered minimally invasively as a targeted therapy to reduce fracture risk. The procedure has two use cases: 1) as a concomitant procedure to hip fracture repair ($4B estimated TAM) and 2) as a stand-alone, scheduled surgical procedure ($120B estimated TAM). AgNovos is pursuing a PMA pathway and expects approval at the end of 2025/mid-2026. It received a category 3 code at the most recent CMS meeting, with AgNovos anticipating a category 1 code 6-9 months post PMA approval. The procedure does have CE mark, but AgNovos is currently only commercializing the standalone procedure in Europe.
- Its second product, indicated for spine, will be a 510(K) De Novo pathway, with AgNovos currently conducting a clinical trial and targeting 2026 for FDA approval.

Source: Company Website

Analgesic technology for post-surgical pain relief

Allay Therapeutics

Allay Therapeutics is focused on treatments for post-surgical pain management and recuperation, employing proprietary non-opioid analgesic technology to deliver weeks-long pain relief.

Takeaways from the conference

- Allay's non-opioid platform delivers controlled pain relief lasting for weeks vs competitor products, which last for only 1-3 days. Its lead product ATX-101, a novel drug polymer, is designed for total knee arthroplasty, the largest segment of the estimated $10B post-surgical pain market at a $1B TAM.
- After a minutes-long "place and go" application by surgeons into the natural knee architecture, ATX-101 delivers diminishing doses of drug as the patient's pain wanes and then the polymer resorbs within 30-60 days. Each ATX-101 patch holds 500mg of drug, an unmatched density.
- A Phase 1b study for TKA showed a matched benefit vs competition for 2 days plus an extended benefit for the next 19 days, a clinically significant 1- to 2-point change in pain intensity with no or mild pain for 14 days and a 50-66% reduction in opioid use for its patients vs traditional TKA patients. Allay expects data from its phase 2a study later in 2023 and anticipates completing its Phase 2b study, which focuses on dosing, in the 1H/24 with data ready in 2H/24, while initiating a Phase 3 study at the end of 2024.
- While it will focus on building out ATX-101 as a lead product, Allay will extend its reach beyond TKA into total shoulder as well as spine. Further R&D projects include soft tissue products for procedures such as open inguinal hernia, abdominoplasty, and mammoplasty and 3-5 day injectables for treatment of peripheral nerve blocks, laparoscopic hernia, and gynecological procedures.

Source: Company Website

Knotless, all-suture meniscal repair system

Arcuro Medical

Arcuro is innovating the anatomic repair of the meniscus. Arcuro's SuperBall replaces hard polymer implants with soft flexible sutures, protecting the meniscus and articulating cartilage and leaving no knots in the joint space. The SuperBall launched in July 2020 across the US.

Takeaways from the conference

- Arcuro's SuperBall Mensical Repair system features a proprietary repair suture mesh and anatomic tensioning system with a depth limiter, ergonomic handle design, and low-profile crescentic needle. It is an all-suture, soft-repair, knotless implant with a novel tensioning mechanism meant to mimic the inside-out repair technique (which is the SOC).
- Arcuro's SuperBall is FDA-cleared with CE Mark, and Arcuro anticipates launching line extensions in Q3/23. Arcuro has 20 independent distributors in the US and sells its products in 11 markets OUS.
- Preliminary data from the Time Zero Study demonstrated successful deployment and tension of the device in >98% of cases.

Source: Company Website

Augmented reality enabling technology for orthopedic procedures

Augmedics

Augmedics is focused on enabling technologies for orthopedic procedures to improve surgical workflow and clinical outcomes. Augmedics' lead technology is its Xvision system, which is the first augmented reality navigation technology to be used in surgery. Xvision allows surgeons to see the patient's anatomy through skin and tissue as if they have "x-ray vision," enabling surgeons to navigate instruments and implants during procedures.

Takeaways from the conference

- Augmedics highlighted its Xvision augmented reality spinal navigation system, which received FDA 510(K) clearance in late 2019 and was commercialized in 2020. The company outlined plans to expand to indications beyond spine, including cranial surgery, joints, ENT, and robotics integration. Additionally, while US-focused for now, Augmedics plans to expand OUS in the near future.
- Augmedics believes the TAM for augmented reality navigation sits at ~$1.9B currently and expects it to expand to $4B total by 2025.
- The company follows a razor/razor-blade model with the headset/software sold as an initial purchase and sterile single marker sets sold for each individual surgery, enabling a strong gross margin profile and long-term optionality to use the technology across different surgery types.
- Augmedics generated $7M in 2022 revenues and, in Q1/23, introduced two AI applications. Moving forward, the company has two R&D projects underway: its next-gen headset, which it plans to debut next year, as well as CT fluoroscopy.

Canary Medical

Canary Medical is focused on combining digital (smart) technologies with implanted medical devices to measure clinically relevant parameters like activity/motion, pressure, and blood flow. Canary has partnered with Zimmer Biomet to integrate Canary's sensor technology into ZBH's flagship Persona knee system and plans on expanding into additional specialties such as hips, shoulders, and spine via partnerships with other market leaders.

Source: Company Website

Implant-based sensor technology to track a wide range of metrics

Takeaways from the conference

- Canary's sensor technology is capable of tracking a wide range of metrics, including range of motion, step count, cadence, distance traveled, and average walking speed. Additionally, Canary expects to be able to infer qualitative factors such as infection risk, step quality, and the ability to distinguish between activities. The data is then provided in a unique software dashboard for easy analysis and patient follow-up.
- Zimmer received De Novo 510(K) in August 2021.
- Canary began releasing recovery curves in late 2022 to help doctors put patient data into context and conduct patient monitoring. Further data collection will allow for predictive analytics. Since launching recovery curves, Canary has seen an over 200% increase in surgeon use post recovery curve training.
- Canary plans on moving into "smart" trauma/spine screw projects next, with management having noted in the past that a small sensor can fit inside most cannulated screws once the wire is removed.

Caira Surgical

Caira Surgical is inventing radar-based tracking technology and software for advanced joint navigated and robotic surgery. Its first product is a navigation system for knee replacement that employs novel, fast anatomic landmark registration to shorten procedure time and radar tracking to address line-of-sight interference inherent with existing technologies.

Source: Company Website

Radar-based navigation system for advanced joint replacement

Takeaways from the conference

- Caira's current target market is total knee replacement, only 20% of which surgeries utilize advanced technology, with utilization broken down into 14% robotic assistance, 3% cutting guides, 2% custom implants, and 1% soft tissue. Long term, Caira looks to have a hand in

the total joint market, valued at $3B per year in the U.S and $13B per year WW.

- Caira's Radar Constellation is 75% less expensive than traditional systems, offers fast 90-second landmark registration, requires no additional incisions or bicortical pins, has a much shorter 5-case learning curve, and features patented radar tracking technology which eliminates line-of-sight interruptions. The company implements a comprehensive and unique ESG lifecycle, having the single-use instrument set shipped back to Caira after use for full decontamination and reprocessing rather than being kept at the hospital. This process reduces Caira's cost of goods by 10X and relieves hospitals and ASCs of their sterile processing tasks.
- The company collaborates with 23 surgeons at 13 joint replacement centers. It holds 4 granted patents, with 3 more in review and 6 in development. Before clinical release, Caira will implement both imageless knee and handheld scanner technologies. The company expects to receive 510(K) clearance in the Q4/23 or Q1/24. Management projects 2024 revenue will be $2.4M, with the goal of achieving profitability in 2027.

Source: Company Website

A personalized medicine company creating optimal surgical plans and spine fusion devices

Carlsmed

Carlsmed uses patient data and digital technologies to create optimal surgical plans and personalized spine fusion devices for each patient. Carlsmed's digital technologies help guide preoperative decisions to align surgeon and patient expectations and increase patient satisfaction. Carlsmed's Aprevo was developed to help surgeons achieve the desired correction during surgery with reduced complications and improved outcomes.

Takeaways from the conference

- Carlsmed asserts that 63% of spine surgeries end in malalignment, with 46% of adults with spine deformity experiencing post-op complications and 26% needing a revision. To solve for this, Carlsmed markets its Aprevo personalized spine fusion cages, the first and only patient-specific and surgeon-specific interbody fusion devices (the company sees an estimated $2.3B+ TAM). Aprevo was granted breakthrough designation and is 510(K) cleared for anterior, lateral, and transforaminal approaches. It features built-in alignment correction, supporting 1-5 level procedures and -/+ levels for flexibility.
- The process begins with the surgeon selecting imaging and surgical preferences based on the patient, with Carlsmed then creating a surgical plan utilizing prior outcomes data which it will send to the surgeon for approval. Subsequently, Aprevo is 3D printed/sterile packed and sent to the hospital with a lead time of 2-4 weeks. Surgery and post-op data is collected to enhance learning.
- Recently, a paper presented at the 2022 Congress of Neurological Surgeons demonstrated, through a 39-patient cohort, that patient-specific interbody implants can achieve and maintain post-operatively a predetermined alignment for the patient that drives better outcomes long term. Carlsmed's implant registry named COMPASS (Clinical Outcome Measures in Personalized Aprevo Spine Surgery) is more than 30% enrolled in its 200-patient cohort, with Carlsmed expecting to have an initial data read-out at the end of 2023.

Source: Company Website

Plasma-based Bioactive Materials for tissue repair and growth

Carmell Therapeutics

Carmell is focused on developing off-the-shelf Plasma-based Bioactive Materials (PBMs) for tissue repair or growth after injury, disease, or aging. PBMs are fresh frozen, platelet-enriched plasma and can be placed directly at the anatomical site in need of accelerated healing. Thus, Carmell is a platform technology aiming to deliver growth factors to the treatment site across multiple therapeutic applications.

Takeaways from the conference

- Carmell's flagship product, CT-101 Bone Healing Accelerant ("BHA"), was granted FDA Fast Track in 2020 and is currently in phase 2 trials for tibia fracture healing. Additional indications include foot/ankle fusion (phase 1 complete), bone void filler (CE Mark), spine fusion (pre-clinical), and dental (also pre-clinical).
- Its second product is a tissue healing accelerant with anticipated indications for hair loss and active tissue repair, both of which are currently in pre-clinical stages, but with Carmell expecting to submit an IDE for hair growth in 2023. Carmell also anticipates creating a product for the sports medicine market with a development partner, likely in an injectable form.
- Carmell is currently planning to merge with ALPHA Healthcare Acquisition Corp III, which is on track to finalize mid-2023.

Source: Company Website

Shoulder replacement with an innovative stemless implant design

Catalyst OrthoScience

Catalyst OrthoScience's goal is to make orthopedic shoulder surgery less invasive and more efficient for both the surgeon and the patient. Catalyst's flagship product is the Catalyst CSR, a single-tray shoulder arthroplasty system for patients with osteoarthritis or similar conditions.

Takeaways from the conference

- Traditional techniques require the removal of the top of the humerus so a "stem" can be inserted down the bone canal, while the Catalyst CSR system is fixated without a stem, thereby preserving more strong, healthy bone. The system also has a price point under $10K and requires the use of only one tray as compared to traditional techniques requiring multiple trays and costing far more – making it well suited for the outpatient/ASC environment.
- Catalyst soft launched a reverse design implant in April 2021 (called Archer R1 Reverse), which it estimates opens up ~60% of additional US market opportunity. The device is in limited launch with Catalyst expecting full launch in 2023. The company also has a 3D planning software which received 510(K) clearance in March 2022. The software is in extended limited release, with Catalyst preparing for full launch this year. Additional upcoming launches include convertible heads in 2023 and its fracture stem and subscap repair solutions in 2024.
- US TAM is estimated at ~$500M with the global market at ~$1B. The product has been on the market since 2016 and has been used in over 2,700 surgeries to date. It is hoping to expand OUS and receive CE Mark in 2024.

Source: Company Website

The largest privately held spine company focused on anterior column reconstruction

Centinel Spine

Centinel Spine is the largest privately held spine company focused on anterior column reconstruction. The company's leadership in anterior column reconstruction continues to demonstrate strength, and the Prodisc acquisition has quickly become a strong performer within the company's breadth of products, posting 7 consecutive quarters of growth. Management expects momentum to continue in 2023, with key product launches, commercial network expansion, and broader fusion and motion preservation procedure adoption as clear tailwinds for the business.

Takeaways from the conference

- The anterior column reconstruction space has a $1.1B US market, believed to reach $2B by 2029. Within spine, anterior spine, and anterior motion preservation boast much faster growth rates (7% and 11% CAGR, respectively) compared to overall spine. Management expects the TDR market to triple by 2029.
- Centinel is the only company to have cervical, lumbar, and two-level lumbar approval in the US. The company's portfolio boasts two industry-leading anterior franchises: Prodisc for motion preservation and STALIF for fusion, with Prodisc implanted over 225K times and STALIF implanted over 75K times globally. Prodisc features a fixed center of rotation which restores controlled, predictable motion and improves outcomes vs. variable center of rotation designs.
- Centinel recently received approval for 3 new endplate designs for one-level cervical TDR (Prodisc C Vivo, Prodisc C Nova, Prodisc C SK). In limited release of Vivo and SK, 650+ cases have been implanted and ~150 surgeons have adopted the technologies since September. The company is currently conducting two-level cervical TDR IDE trial and hit its patient enrollment goal in Dec 2022.
- Centinel posted +12% Y/Y growth for the FY/22. Management has seen +47% Y/Y growth YTD in 2023 accelerated by the Vivo and SK launches. Full launch of Vivo and SK anatomic fit discs in the US will continue through 2023. Management expects to train 600+ surgeons and reach EBITDA profitability in 2023.

Source: Company Website

Novel tendon repair technique to improve outcomes and economics

CoNextions Medical

CoNextions Medical is a company dedicated to improving patient outcomes and the economics of tendon repair. The company's flagship product, CoNextions TR, is an alternative to traditional suture repair techniques that involves using a handheld device to join the two severed tendon ends using a stainless-steel implant. In early clinical testing, the product has shown increased repair strength, superior glide performance, and a faster, more efficient procedure.

Takeaways from the conference

- Current suture techniques can be complex, time-consuming, unreliable, and difficult to learn. The 510(K) cleared CoNextions TR allows maximal coaptation site surface area, minimal bulk at the repair site, and improved mobility in a shorter time frame post-implantation. CoNextions TR is able to achieve a tensile strength of 90 Newtons in the repaired tendon vs 40 Newtons with traditional suture techniques, with repair only taking 90 seconds vs traditionally 4-5 minutes.
- Its Coronet Soft Tissue Fixation system is 510(K) cleared with an initial focus on F&A procedures. The system's unique design promotes simultaneous, strong, and secure fixation of soft tissue to bone.
- Currently, CoNextions has ~30 independent distributors consisting of over 400 orthopedic sales reps in the US, with four stocking distributors OUS. It anticipates a $5M annual revenue run rate by Sep 2023 and expects CE Mark in Q2/24.

Source: Company Website

Novel pelvic trauma technology to improve outcomes

CurvaFix

CurvaFix is a medical device company focused on pelvic fracture repair. The company's CurvaFix IM implant is the first new intramedullary pelvic trauma technology, designed to follow the natural bone shape and fill space within the pelvis. The device, unlike straight screws that cannot fit the natural curvature of intramedullary pathways (limiting use), provides a new state-of-the-art option for pelvic repair that results in immediate pain relief, early mobility, and faster recovery. The company launched its 7.5mm implant in the Q1/23 and has a dozen cases performed so far.

Takeaways from the conference

- CurvaFix aims to help with Fragility Fractures of the Pelvis (FFP) repairs. It estimates there are ~186K cases per year (growing at 9% per year), with ~10% surgically treated today vs the 82% of FFP that can be surgically treated. Non-operative treatment leads to lengthy hospitalizations (9-45 days), high nursing home admits (33-69%) and high 1-year mortality (18-25%).
- The company estimates its WW TAM at >$2.0B, broken down into $1.3B in pelvic fractures, $300M in pelvic adjacencies (complex reconstruction, musculoskeletal oncology), and $400M+ in new applications (extremities, pediatric rib fractures). To date, CurvaFix has treated >100 patients, with 49% of its commercial cases being FFP.
- Management is in the process of raising a Series C before initiating a full US launch in which it will target 239 L1 Trauma Centers and 263 L2 Trauma Centers while continuing efforts to scale through its existing network and patient referrals.
- CurvaFix reported ~$0.7M in revenue for FY/22 with expectations for $2.6M in 2023. Management expects revenue growth to continue to accelerate, projecting $11M in 2024 and $60M+ in 2027.

Source: Company Website

Regenerative cell-based therapies for degenerative spine disease

DiscGenics

DiscGenics is pioneering regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative spine disease. DiscGenics' first product candidate, IDCT (rebonuputemcel), is an allogenic (donor-derived) noninvasive cell therapy for treatment of adult patients with single-level mild to moderate symptomatic lumbar disc degeneration. This treatment is currently in late-stage clinical trials for use in the US and Japan.

Takeaways from the conference

- DiscGenics target patient population is ~2.5M annually in the US and defined as those that can have both partial and full thickness tears.
- The company received Fast Track from the FDA in 2019. Since then, DiscGenics has de-risked its clinical pathway by completing Phase I and II trials for its first product candidate, IDCT, and is currently planning a pivotal Phase III clinical study. The FDA granted regenerative medicine advanced therapy (RMAT) designation to IDCT in Jan 2023. The company has been approved for a comprehensive Type B meeting with the FDA which will occur in April 2023.
- Phase I/II of clinical trials have demonstrated rapid, durable, statistically significant, and clinically meaningful improvements in pain function, quality of life, and disc volumes sustained at two years post-injection. Specifically, opioid use decreased in the high-dose IDCT group and increased in the vehicle control group compared to baseline. Disc volume also substantially increased in high-dose, achieving statistical significance in 50 weeks post treatment.

Source: Company Website

Novel solution for the treatment of degenerative spinal spondylolisthesis

Empirical Spine

Empirical Spine is developing advanced solutions for the surgical treatment of degenerative spinal spondylolisthesis. The company's LimiFlex Dynamic Sagittal Tether was designed to provide stabilization without compromising spinal function for patients with degenerative lumbar spinal disorders requiring segmental stabilization, for which the current standard surgical option is spinal fusion.

Takeaways from the conference

- Of the 300K+ lumbar spine fusions in the US each year, around 50% are eligible for LimiFlex. Empirical outlined the US TAM as $1.1B in 2022, with the market growing to $1.8B in 2030 when it believes over 60% of the opportunity will be ASC/outpatient.
- Empirical's completed IDE clinical trial demonstrated significant benefits of LimiFlex compared to traditional transforaminal lumbar interbody fusion (TLIF). LimiFlex showed a 15-point improvement in ODI at 6 weeks compared to that of TLIF and continual improvement through 2 years. Limiflex resulted in 1 hour less operating time, ¼ of the blood loss, and no outpatient stay compared to the median 3-night stay for TLIF. In 90 days, 90% of patients returned to normal activity with Limiflex vs. 60% with TLIF.
- Empirical has submitted its full PMA module to the FDA, anticipating approval in Q4/23 and thus targeting 2024 for commercialization.
- LimiFlex's one-SKU, one-tray setup is a highly scalable and efficient solution. Additionally, its short learning curve (no cadaver lab needed) and high account-to-sales ratio position it favorably for ASC/outpatient adoption.

Source: Company Website

Bioengineered surgical implants for ACL repair

Miach Orthopaedics

Miach is dedicated to developing bioengineered surgical implants for connective tissue restoration. The company's initial focus is the Bridge-Enhanced ACL Repair (BEAR) Implant, which represents a paradigm shift in the treatment of ACL tears from reconstruction to restoration.

Takeaways from the conference

- ACL injuries total ~400K annually in the US, with ~200K ACL surgeries.
- The BEAR implant is indicated for skeletally mature patients at least 14 years of age with a complete rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair. The implant shields the blood from synovial fluid, promoting sustained clotting, and reabsorbs by 3 months post-op.
- The company entered into a soft commercial launch of the BEAR product in October 2021 after receiving De Novo approval from the FDA in December 2020, the first De Novo classification for sports medicine. With a full year of commercialization under its belt, results have been strong, with 147 facilities onboard and 650+ implants implanted. The company has a direct sales model with over 25 commercial reps selling the product. Additionally, it is leveraging existing reimbursement codes and has strong profit margins (80%+).

Source: Company Website

Implantable shock absorber to treat knee osteoarthritis

MoxiMed

Moximed is developing a novel, implantable shock absorber as a load management tool against knee osteoarthritis. Moximed's flagship product, the MISHA Knee System, can be placed under the skin, but outside of the joint itself, eliminating the need for bone cutting and making the procedure totally reversible. MISHA reduces load and pain on the knee, aiming to reduce peak forces on the knee by over 30% with every step.

Takeaways from the conference

- MoxiMed is initially targeting patients under 65 with mild-to-moderate OA that have activity-restricting pain, have failed non-surgical care, and are not yet ready for TKA, which it estimates at ~3M US patients.
- The procedure is especially suitable for the ASC/outpatient setting, with minimal inventory demands for these sites of care as MISHA features a disposable instrument set and only two implant sizes (L&R). MoxiMed has seen 91%+ of its US cases completed in an outpatient setting.
- The procedure features quick recovery and improved knee function, with its US pivotal study demonstrating patients were typically back to partial weight-bearing 2 days post-op and 100% of full weight-bearing activities 6 weeks post-op. At 2 years post-op, patients saw a 76% reduction in pain and 74% improvement in knee function. The study demonstrated superiority on its primary and secondary endpoints and essentially an equivalent safety profile to the control. The device received FDA breakthrough designation, and MoxiMed is pursuing a De Novo pathway, having submitted its data to the FDA and expecting a decision by 1H/23.

Onkos Surgical

Source: Company Website

Surgical oncology solution targeting tumor, revision, and trauma

Founded in 2015, Onkos Surgical is focused on innovating within the surgical oncology field. Through dedication and strategic partnerships, Onkos Surgical intends to advance surgical oncology solutions and advocate for and support the surgeons and caregivers who dedicate their lives to the surgical treatment of cancer.

Takeaways from the conference

- Onkos Surgical has products for complex limb salvage and reconstruction, patient-specific joint sparing, and regenerative biologics and osseointegration. Management described a broad commercial base with over 300 surgeons and a direct-selling organization of 15 focused on oncology (tumor surgeons), combined with over 115 distributors focused on revision and trauma.
- Management outlined several R&D pipeline efforts expected to come to market over the next 5 years, including the recent launch of the ELEOS Proximal Tibia with BioGrip technology and personalized pelvis reconstruction platform.
- Onkos revenue generated $27M in revenues in 2022, up from $18.5M in, and management outlined a plan to generate +$100M in the US in the next 5 years. The company plans to leverage its surgical planning platform to open up new market opportunities in periacetabular osteotomies, spinal deformity, and osteochondral defects.

OnPoint Surgical

Source: Company Website

Augmented reality guidance for orthopedics and spine

OnPoint Surgical is a privately held medical technology company pioneering augmented reality guidance for orthopedic and neurosurgical spine procedures, including minimally invasive and robotic surgery.

Takeaways from the conference

- OnPoint is targeting the broad $30B combined spine, neurosurgical, and orthopedic markets, with spine and knee being the two first applications. To date, the company has a seminal IP position for spinal AR guidance, holding 30 US patents and four Chinese patents with broad granted claims.
- The company's technology displays virtual holograms directly on the patient using AR optical see-through glasses, which superimpose CT scans or 3D models on the patient, allowing the surgeon to visualize

key anatomical landmarks, plan cases in real time, and visualize implants before deciding on size and location.
- Management describes key benefits of the technology being an improvement in surgical accuracy, reduction in OR and turnover time, and a reduction in intra-op imaging, without any disruption or change in current surgeon practice. Specifically, management asserts 2-5X more accurate placement than leading spinal navigation and robotic systems, with more data to be presented during the remainder of the year. The company expects cluster-based adoption to start in the H2/23.

Source: Company Website

Bio-intergrative ortho implants for soft-tissue-to-bone fixation

OSSIO

OSSIO seeks to replace traditional metal implants with natural, bio-integrative implants featuring intelligent bone regeneration technology. OSSIO is a proprietary technology platform combining fixation strength with bone growth/implant replacement and no adverse biological effects. The technology is both stronger than bone and traditional bioreabsorbables. OSSIO targets an estimated $15B+ global orthopedic fixation market and has 7 received FDA clearances since 2019.

Takeaways from the conference

- Its OSSIOfiber intelligent bone regeneration technology features a novel fiber matrix including the same organic minerals found in bone, enabling early bone attachment, measured bone & tissue ingrowth, and complete integration without inflammation & weakness. It comprises 50% natural mineral fibers, for increased strength and fluid flow, and 50% polymer, for more certain integration sans inflammation.
- OSSIO has five major product platforms: hammertoe, a trimmable fixation nail, a 4.7mm suture anchor, a compression screw, and a compression staple. The suture anchor broadens OSSIO's reach into sports medicine from foot & ankle, while its compression staple is the first and only non-permanent compression staple. In addition to sports, in 2023, OSSIO anticipates entering the hand & wrist markets.
- OSSIO grew by +100% in 2022 to reach over $11M in revenues. To date, OSSIO has seen 15K implantations in the US, and its approach employs existing reimbursement and surgical methods. In terms of commercialization efforts, the company launched a direct-to-patient campaign in 2022 and has seen significant traffic to its website. The commercial team stands at 200 independent sales reps.

Source: Company Website

Surgical navigation to aid in precise alignment and tailored for the ASC

OrthAlign

OrthAlign is a medical technology company providing surgical navigation products to aid in the precise alignment needs for orthopedic procedures. Its products include handheld navigation devices that provide real-time data for precise positioning of implant components during knee and hip arthroplasty surgeries, as well as tibial and femoral alignments.

Takeaways from the conference

- The company launched its Lantern product in Q4/21, which delivers accurate, individualized alignment to any patient with a single-use handheld smart tool that can be used across implant platforms and surgical techniques.
- The company received approval for its Lantern knee application last year and, over time, plans to pursue additional indications and expand product breadth to include next-generation hip alignment, pre-operative planning, limb alignment, and eventually post-operative wearables.

- OrthAlign posted revenues of over $40M in 2022 and YTD is up 50% Y/Y. Currently, it is involved in 5% of US total knee procedures.

Source: Company Website

Joint replacement solution for spondylolisthesis and spinal stenosis

Premia Spine

Premia Spine offers an alternative solution to spinal fusion for patients who suffer from lumbar spinal stenosis and degenerative spondylolisthesis. Premia's flagship product, TOPS, is a mechanical implant device that replaces bony and soft tissues removed during spinal decompression surgery. Placed at a single level between L2 through L5, TOPS stabilizes the spine by blocking sheer forces while allowing for motions in all directions (flexion, extension, lateral bending, axial rotation).

Takeaways from the conference

- Premia outlined a $4.3B lumbar stenosis and spondylolisthesis market with significant unmet needs for the TOPS product, with half of the opportunity fusion conversions and the other half decompression surgery.
- TOPS recently received FDA breakthrough device status, and the company unblinded its full IDE clinical trial in 2022. The IDE study included 302 patients and concluded prematurely due to its overall success. Data demonstrated a composite overall clinical success (meeting all 6 points: no re-op or lumbar injection, ODI reduction > 15 points, no new or worsening neuro deficit, no fusion status failure, and no major device adverse event) for 76% of patients with TOPS vs 25% of patients with fusion. Premia submitted for premarket approval (PMA) and expects FDA approval in April 2023.
- Premia recently hired Peter Wehrly to lead its commercial launch, aiming for a quick build-out of its sales management team with independent regional distributor partners. The company will focus on target surgeons from the IDE study for a controlled first-wave release and expects to see the first cases in June 2023, with management guiding to a full launch in 2024. Additionally, Premia expects to see an NTAP for the product starting in Oct 2023.

Source: Company Website

Novel solution for high-risk posterior cervical fusion and other conditions

Providence Medical Technology

Providence Medical Technology is focused on solutions for cervical spinal conditions. The company's flagship product is the CORUS spinal system, a posterior cervical fusion instrument set with the largest instrument smaller than a dime (reducing patient trauma), along with complementary Cavux cervical cages and Ally screw systems which provide powerful stabilization and decompression. The system has been studied extensively (15 clinical publications), demonstrating significant symptom improvement as well as high fusion and low complication rates.

Takeaways from the conference

- Providence management described the company's focus on the high-risk cervical market, with a total opportunity estimated at over 72K circumferential procedures annually, representing ~$865M of annual TAM. Since 2010, The company has implemented its technologies in 16K+ cases in 2K+ hospitals with 900+ surgeon users.
- The REVISE study was completed in 2022 and included retrospective data and prospective case reviews of 191 patients. These patients had a failed anterior cervical discectomy and fusion treatment (ACDF) and received circumferential cervical fusion with Providence's products. After 38 months, 96% of patients fused successfully, 92% had a greater than 2° range of motion score, and 75% had CT-verified bridging bone. Compared to anterior and posterior (LMS) methods, Providence's treatment had significantly lower operative time, hospital

stay, no complications, and no third operation. The company received 510(K) clearance in Dec 2022, making Providence the first company to be approved for spinal revision surgery.
- Providence kicked off a prospective, multi-center randomized clinical trial in 2020 (the "FUSE" clinical study) evaluating superiority in circumferential cervical fusion in high-risk patients and would be a significant catalyst for sustainable market penetration. To date, 220 patients have enrolled, and management expects to enroll the full 300 patients by 1H/23. The company is planning to file for 510(K) clearance in Q1/24.
- Providence generated $30M in revenue for FY/22, its second year of +20% Y/Y growth. The company reported gross margins of 84% and noted expectations for further improvement. Management forecasted accelerated growth and profitability through 2026, expecting $100M+ in revenue by 2025.

Source: Company Website

Minimally-invasive treatment for relief of chronic vertebrongenic low back pain

Relievant Medsystems

Relievant aims to transform the diagnosis and treatment of chronic vertebrogenic low back pain. Relievant's flagship product, the Intracept Procedure, is a minimally invasive procedure that targets the basivertebral nerve (BVN) for long-term relief. In February 2023, the North American Spine Society (NASS) announced a formal coverage recommendation for BVN ablation as a treatment for chronic vertebrogenic low back pain.

Takeaways from the conference

- Relievant outlined a $30B TAM for its Intracept system, which includes a population of ~5.3M patients with vertebrogenic pain and Modic Type 1 and 2 changes. To date, Intracept has been used to treat >10K patients commercially.
- Relievant's two randomized controlled trials have been followed out to 3 and 5 years and show sustained pain and function improvements. Intracept treatment resulted in >75% pain reduction in 50% of patients and reduction in opioid use, with 74% fewer patients actively taking opioids after treatment and nearly half of patients stopping opioids completely.
- Management highlighted its disciplined sales approach with strong emphasis on physician on-boarding and practice integration. It requires physicians to commit early to the process, getting their patients in the portal from the beginning so that these patients are approved for treatment as physicians complete training. Relievant is targeting early adopter interventional pain management physicians before expanding to most physicians with an upcoming Gen 3 launch.
- The company generated $37M in revenue for FY/22 and looks to carry its commercial momentum into 2023. Category 1 CPT codes for Intracept went into effect in Jan 2023. The company also announced that it established a coverage policy with Palmetto in March 2023 and is currently engaged with >500 payors.

Source: Company Website

3D-printed personalized implants and instruments by uniting biomaterials, biomechanics, and AI

restor3d

Restor3d offers tailored, patient-specific 3D-printed implants with superior anatomical fit and bio-integration through AI/ML-assisted design. Restor3d's TIDAL Technology creates implants with high-strength, optimized porous architecture that is designed for osseointegration. In 2021, restor3d merged with Kinos Medical, a company specializing in total ankle replacement, to accelerate restor3d's reach in the extremity arthroplasty markets.

Takeaways from the conference

- Restor3d is targeting the opportunity within the underutilization of CT scans in orthopedic procedures, for which there are 28M orthopedic procedures a year but only 1% of these procedures are planned with CT data and an even lesser 0.1% of these procedures design personalized implants using CT data for diseased anatomy.
- Restore3d uses CT scans and works with the surgeon to design, print, and ship 3D-printed, personalized implants. The company also offers patient matched solutions featuring off-the-shelf implants and a procedure plan for the surgeon. Since 2018, the company has printed 3.4K implants for use all over the body. Restore3d holds 32 US patents and over 1K data sets of orthopedic anatomy.
- The company is currently targeting products in shoulder and ankle arthroplasty, fusion, and talus and upper extremities bone replacement. Management expects expansion to spine, foot, ankle, and upper extremity through 2024-2025. Restor3d is expanding its R3ID platform to its patient base at the end of Q1/23.
- Restor3d has achieved top line growth of low triple digits in 2020, 2021, and most recently posted +102% Y/Y growth in the FY/22. Management asserts that its current manufacturing facility can support over $75M in revenue.

Shoulder Innovations

Source: Company Website

Glenoid fixation technology for shoulder replacement

Shoulder Innovations has developed inset glenoid fixation technology to address one of the more significant issues in shoulder arthroplasty: unreliable fixation of the glenoid component. The company's Total Shoulder System utilizes this technology to significantly strengthen the fixation by up to 40X, greatly improving glenoid stability. The company features a comprehensive portfolio including glenoid fixation, glenoid augmentation, humeral short stem, reverse stem, and stemless solutions.

Takeaways from the conference

- Its flagship InSet product received 510(K) clearance in Q4/19 and is applicable to ~85% of total shoulder procedures in the OR. It is the first and only FDA-cleared device which solves glenoid loosening, the #1 problem in anatomic shoulder arthroplasty.
- Since launching its InSet system, Shoulder Innovations has expanded its portfolio, including the addition of reverse and stemless systems, seeing first surgeries with its reverse and stemless systems in Sep 2021 and Sep 2022 respectively. Additionally, Shoulder Innovations also features a 3D AI surgical planning technology meant to streamline pre-op planning, with AI-based CT scans.
- The company boasts a more efficient model with fewer trays/SKUs to offer a competitive advantage in the ASC/outpatient setting vs larger incumbents, saving an estimated $1K-$3K per procedure.
- The company saw ~$10M of revenues in 2022, projecting a revenue CAGR of nearly 80% through 2026, with gross margins remaining ~80%.

Sonex Health

Source: Company Website

Ultrasound-guided procedures for carpal tunnel release and trigger finger

Sonex is focused on minimally invasive carpal tunnel release and trigger finger treatments through ultrasound-guided procedures. Sonex's UltraGuideTFR gives physicians real-time anatomical landmarks and allows them to perform procedures with local anesthesia and in their office or procedure room. Sonex announced full market release of UltraGuideTFR to treat trigger finger in April 2022 and completed patient enrollment in an RCT for carpal tunnel syndrome indication in Feb 2023.

Takeaways from the conference

- Sonex sees a $3.5B market opportunity for UltraGuideTFR, serving the total carpal tunnel and trigger finger syndrome markets. In 2022, UltraGuideTFR was used in 17K+ carpal tunnel release cases in the US.
- The company asserts the advantages of ultrasound guided procedures over open and endoscopic approaches, such as the use of local anesthesia, a much smaller 4-5mm wrist incision, comprehensive FOV of all critical anatomy, minimal scarring, and faster return to activity/work.
- Sonex generated $6M in revenue in FY/22 and has 114 total active physicians that perform 5-6 procedures per month (81% total physician retention rate). Management presented a 5-year revenue plan with a 98% revenue CAGR through 2027 and long-term low 80% gross margins, driven by production scaling, flat spending, and the release and commercialization of its Gen 2 product. Gen 2 UltraGuideTFR will likely be released in the 2H/23 and used in Sonex's application for CE Mark.

Source: Company Website

Chemically engineered cartilage-like implants to treat osteoarthritis

Sparta Biomedical

Sparta is developing cartilage-like implants to address cartilage degeneration in osteoarthritis. Sparta is developing Galene, a multi-indication platform aimed to cover all the important joints in the body, and, unlike traditional cartilage regeneration technologies which take months/ years to regrow strong cartilage, mimics hyaline cartilage at time zero. The Ormi implant combined with Galene intends to treat chondral and osteochondral lesion of the femoral condyle and is currently in pre-clinical development.

Takeaways from the conference

- Its first implant, Ormi, is a knee implant which mimics native cartilage and replaces only damaged cartilage, allows for immediate weight bearing, enables bone ingrowth, is implantable in less than 10 minutes, features proprietary reusable instrumentation, and has been granted breakthrough designation by the FDA. Ormi is 3X stronger than cartilage based on third party testing, with a pilot animal study demonstrating device safety.
- In the future, Sparta will look to expand its technology to other areas such as partial knee, patella, shoulder, elbow, thumb, trochlea, hip, ankle, and toe.

Source: Company Website

Pure play non-invasive therapeutic stimulation

Theragen

Theragen is focused on non-invasive, therapeutic energy-based treatments for pain and tissue healing. Its ActaStim-S product addresses lumbar spine fusion therapy with capacitive coupling technology, its Kneehab XP addresses quadricep strengthening via neuromuscular electrical stimulation (NMES), and its Recovery Back treats low back pain via either NMES or transcutaneous electrical nerve stimulation (TENS).

Takeaways from the conference

- Theragen offers various products for the NMES and bone growth stimulation (BGS) markets, both of which have established reimbursement codes and CMS coverage. Theragen is the market leader in NMES quadriceps rehab with its Kneehap XP product, while its ActaStim-S product, launched in 2021, features first-mover digital technology to drive patient engagement and is the most compact spine BGS on the market.
- The company's products are portable and non-invasive, with a mobile engagement app including a patent-protected algorithm enabling data

collection with the goal to drive patient engagement and compliance to improve outcomes.

- Theragen's spine BGS level 1 clinical data for its original FDA submission featured two primary endpoints: radiographic healing and function. The data showed a 20% increase in combined radiographic and clinical outcomes with a 31% improvement in expected success. All patients were included in the findings, with compliance ranging from 1.5-24 hours/day.
- Through its ActaStim Sync companion app, patients can track activity and journal/track pain in real-time, while providers can see compliance data, activity levels, and patient-entered data such as real-time pain/goals.

THINK Surgical

THNK Surgical develops, manufactures, and markets active robotics for knee replacement surgery. The TSolution One Total Knee Application performs automated preparation of the bone and joint surface and supports a versatile, open platform providing surgeons the flexibility of using a variety of implants. The TSolution One system is comprised of TPLAN, the 3D pre-surgical workstation, and TCAT, the active robot that helps the surgeon execute each patient's individual pre-operative plan with consistent results. In addition, THINK is launching two new products, the TMINI and TMAX, that provide surgeons with more optionality in size and system costs, with both also fully integrated with TPLAN.

Source: Company Website

Active robotics for knee replacement surgery

Takeaways from the conference

- THINK believes that its product selection of the TSolution One, TMINI and TMAX, will help accelerate surgical robotics uptake by offering a robotic ecosystem with an open platform that can accommodate surgeon implant choice and match surgeon operating preferences. The company offers an open implant platform with 7 existing implant partners currently addressing 40% of the knee implant market, with the ability to add more potential implant partners to the platform.
- TMINI is a compact, 6lbs system, with cameras looking down to provide a full range field-of-view while not disrupting surgeon and staff movement. TMAX is a large, fully autonomous device that performs a surgical task without direct control/intervention of the surgeon. This is compared to the "semi-active" platforms in which the robot acts as a tactile feedback system that augments the surgeon's ability to control the tool. THINK plans to launch TMINI in the Q2/23 with clearance by the end of April/May 2023, with TMAX on the docket for late Q1/24.

Trice Medical

Trice has pioneered fully integrated camera-enabled technologies that provide a clinical solution optimized for the physician's office. Trice's two primary platform technologies, mi-eye (direct endoscopic visualization) and mi-ultra (ultrasound), enable office-based treatment and diagnosis of some of the most common soft tissue disorders.

Source: Company Website

Office-based technologies for visualization and treatment

Takeaways from the conference

- Trice Medical participates across a $20B TAM which includes tendinopathy, diabetic foot ulcer, carpal tunnel, disposable arthroscopes, and diagnostic arthroscopy/MRI. Its technologies have resulted in over 50K procedures performed in 2022.
- Its 25-degree mi-eye 3 needlescope, launched in 2022, offers 16X more information over a 0-degree camera which has been the standard of care in arthroscopy.

- Since 2021, Trice has made acquisitions to gain share in therapeutic procedure markets. The Seg-Way acquisition (2019) opened opportunities in the carpal tunnel, plantar fascia, gastric release, and cubital tunnel markets. The Tenex acquisition (2021) introduced Trice to the tendinopathy market.
- With its recent development partnership with Clarius Mobile Health in late 2022, Trice will focus on continued innovation and indication expansion. Together, Trice and Clarius aim to deliver the world's first platform that enables orthopedic physicians to use high-definition wireless ultrasound and a single-use handheld arthroscope on one tablet.

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Investment Recommendation

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