Orthopedic Industry Outlook Prompts Positive Market Sentiment

Amid a deteriorating macroeconomic backdrop, orthopedic industry stocks have shown resiliency relative to the broader public markets. This enables management teams to breathe a sigh of relief, driven in part by expectations for a long-awaited pickup in procedure volumes, as they and investors have watched valuations tumble over recent years due to COVID-19 headwinds, supply-chain backlogs, and other industry forces.

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While equity trends serve as a refreshing signal for the orthopedic industry's future prospects, day-to-day operating challenges remain unrelenting. Most significant is staffing shortages in hospitals, which surveys indicate as currently the largest impediment to procedural catchup. In a Canaccord Genuity Capital Markets October 2022 survey of 47 orthopedic surgeons, 47% of respondents noted their facilities are performing surgeries at 80% capacity or less. Some 30% of respondents cited staffing as the number-one bottleneck influencing market growth, up from 23% in June. Additional industry dynamics, such as supply-chain constraints, continue to weight on both stocks and market demand, as Stryker Chairman and CEO Kevin Lobo told analysts on the company's third-quarter earnings call on October 31, 2022.

"Our hip and knee businesses also delivered double-digit growth, reflecting the continued recovery of elective procedures and our worldwide *Mako* momentum...We are pleased with our strong sales growth, which would have been even higher if not for material shortages, mostly affecting medical [devices] and instruments," he said.

Lastly, 55% of the survey respondents cited negative macroeconomic factors as impacting patient demand, an increase of 10% from June.

Emerging Trends Drive Optimism

Robotics Are a Key Growth Opportunity

Although the orthopedic industry is facing many challenges, emerging trends provide optimism for both the near and long term. Over the past decade, robotics has become an integral driver of growth in the orthopedic market. A review in *BMC Musculoskeletal Disorders* (November 22, 2021), based on bibliometrics between 2000 and 2019, cited The *Journal of Arthroplasty* as publishing the most relevant and influential papers on robotic orthopedics, covering 14 systems, mostly indicated for knee and spine surgeries. The most widely adopted system has been **Stryker**'s *Mako*, which has been used in more than 615,000 knee and hip procedures since its commercial launch in 2015. Stryker is currently seeking FDA approval for *Mako*'s applications in spine and shoulder surgeries, with management expected to provide further guidance on timelines in January 2023.

The robotic knee system market is more fragmented, with Stryker, **Zimmer Biomet**, **Johnson & Johnson**, and **Smith+Nephew** collectively holding approximately 85% of the total market share, according to the business intelligence firm GlobalData. Despite the accumulation of research and availability of systems for certain indications, the market remains highly underpenetrated. Only 11% of the roughly three million knee reconstruction surgeries performed worldwide in 2020 involved robotic assistance. The volume is expected to reach 700,000 globally by 2030, marking plenty of runway for growth and innovation within the segment.

In spine surgery, **Medtronic** has the leading robotic guidance system, *Mazor*, following its acquisition of Mazor Robotics in 2018 for roughly $1.64 billion. Related, its acquisition of Medicrea in late 2020 for approximately $200 million further strengthens Medtronic's dominance in spinal solutions, with the addition of patient-specific, 3D-printed titanium spinal implants and an AI planning and prediction platform, *UNiD*. Medtronic now offers a fully comprehensive portfolio of integrated spinal solutions, utilizing AI-driven surgical planning, personalized spinal implants, and robotic-assisted surgical delivery to increase the quality and predictability of surgical procedures. Underscoring the power of this integrated strategy, Medtronic highlighted that its US core spine business rose in the mid-single digits year over year during its first-quarter fiscal year 2023, which ended July 29, 2022. Notably, the *UNiD* platform alone propelled double-digit sequential growth.

Note should be taken that other large strategics also are supplementing their advances into robotic and digital platforms, driving appetites for acquisition of enabling technologies. In addition to Medtronic, **Globus Medical**, **NuVasive**, and **Brainlab** are following this path and have made tuck-in acquisitions that position them competitively in the orthopedic surgery suite of the future.

Adoption of robotics benefits companies in capital raising, as well as in revenue generation. **THINK Surgical**, developer of the *TSolution*, a robotic system used for knee replacement surgeries, received a $100 million investment in October 2022 from KDB Investment Global Healthcare of Korea. The California-based company will use the proceeds to increase *TSolution*'s speed to market and build out a common planning solution that integrates across multiple robotic platforms along with implants from different manufacturers. THINK Surgical's agnostic capabilities differentiate it from competitors because, unlike other companies, its platforms work with multiple manufacturers' implants.

Robotic systems have demonstrated the potential to deliver value through myriad enhanced outcomes, including reduced complications and readmissions, increased patient satisfaction, and reduced payer costs of various procedure types.

Manufacturers Shift Ambulatory Surgery Center Strategies

Robotics and other enabling technologies are also facilitating the market shift to performance of increasingly complicated orthopedic procedures in outpatient settings. The most high-profile example of this is the routine performance of same-day robotic-assisted total knee replacement surgery. Ambulatory surgical centers (ASCs) were once on the periphery of major manufacturers' customer bases, but technological advances that improve the safety and effectiveness of minimally invasive surgeries, along with better reimbursement, present a more favorable outlook for them as alternatives to defaulting to hospital outpatient or inpatient facilities. In his remarks during Stryker's third-quarter earnings call, Kevin Lobo of Stryker observed that more than 10% of large-joint replacement surgeries are now done in ASCs.

Emerging Technology: NanoHive Medical

Commercializing an innovative 3D-printed spinal interbody fusion implant portfolio targeting multiple procedure approaches. The company utilizes a proprietary biomimetic *Soft Titanium* material for the manufacturing of novel, lattice structured implants, promoting best-in-class bone ingrowth and outgrowth, reduced stiffness, and improved visualization. NanoHive is currently the only company in the orthopedic industry offering implants with independent endplates, biologic injection channels, and a rhombic dodecahedron design. The company has recently received an undisclosed amount of growth capital and has shown considerable product adoption with minimal sales and marketing efforts to date.

> "[The numbers] keep going up, not at a rapid rate, but it's a steady climb. And to your point, the gating factor is just construction and refurbishment of these ASCs to enable more procedures. But every hospital system I talked to is preparing themselves for another—a new ASC. It's a trend that had started prior to COVID and has accelerated."

Other top orthopedics manufacturers are positioning for this shift as well. Smith+Nephew, for example, offers *CORI*, a handheld robotic surgical system ideal for ASCs due to its minimized footprint and ability to enhance surgery workflow. In January 2022, the company acquired Engage Surgical, a producer of the only cementless partial knee system commercially available in the US, for up to $135 million, contingent upon sales milestones. The deal added a differentiated product to the Smith+Nephew pipeline, offering the potential for better long-term fixation and shorter operating times than competing products. According to the related press release on January 19, 2022,

> "The *Engage Surgical Partial Knee System* is optimized for robotics and will have an application with *CORI* in the future. Engage Surgical's Partial Knee System also complements Smith+Nephew's focus on serving the growing outpatient market, with an increasing proportion of knee procedures performed in ASCs."

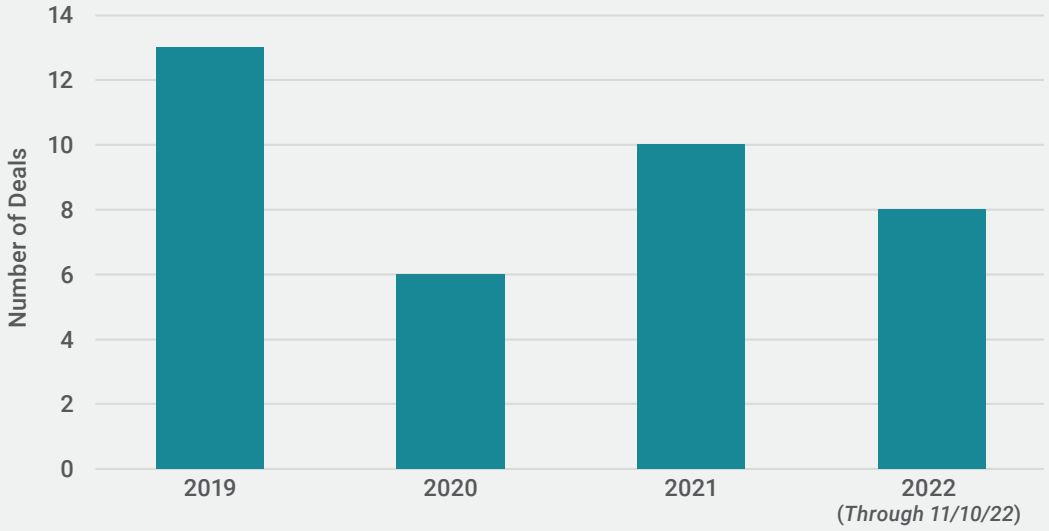
This acquisition emphasizes a strategic focus from Smith+Nephew to advance its robotic surgery capabilities while simultaneously enhancing its competitive position in the growing ASC market.

Also driving ASC growth is the utilization of disposable surgical instruments. While elevated price points hinder widespread adoption in hospital usage due to large previous investments in sterilization systems, manufacturers are offering ACSs disposable instruments in prepackaged "bundles." These bundles include surgical robotic systems, disposable surgical equipment, and other instruments necessary to complete all aspects of ASC procedures. This synergistic relationship enables these facilities to compete with hospitals for certain kinds of procedure volume while providing orthopedic strategics with a new source of perpetual revenue.

Figure 1

Outcome Capital Orthopedic Index M&A Transactions, 2019-2022

(Excluding deals ≥$1B)



Source: PitchBook data curated by Outcome Capital

Industry heavyweights, such as Stryker and Medtronic, currently offer disposable instruments as part of their comprehensive orthopedic portfolio.

Advances in Additive Manufacturing and Innovative Materials

Additive manufacturing (AM) and 3D printing technologies have become widely accepted by strategics, enabling the introduction of new hybrid structures with complex geometries. By providing advantages over traditional processes, AM and 3D printing set new manufacturing standards.

> "Additive manufacturing makes it possible to produce geometries that cannot be achieved using traditional manufacturing methods. In addition, the parts have greater performance capacity or functional precision." – Alex Berry, Director, Sutrue, which makes robotic suturing devices that can be integrated into many manufacturers' robotic platforms.

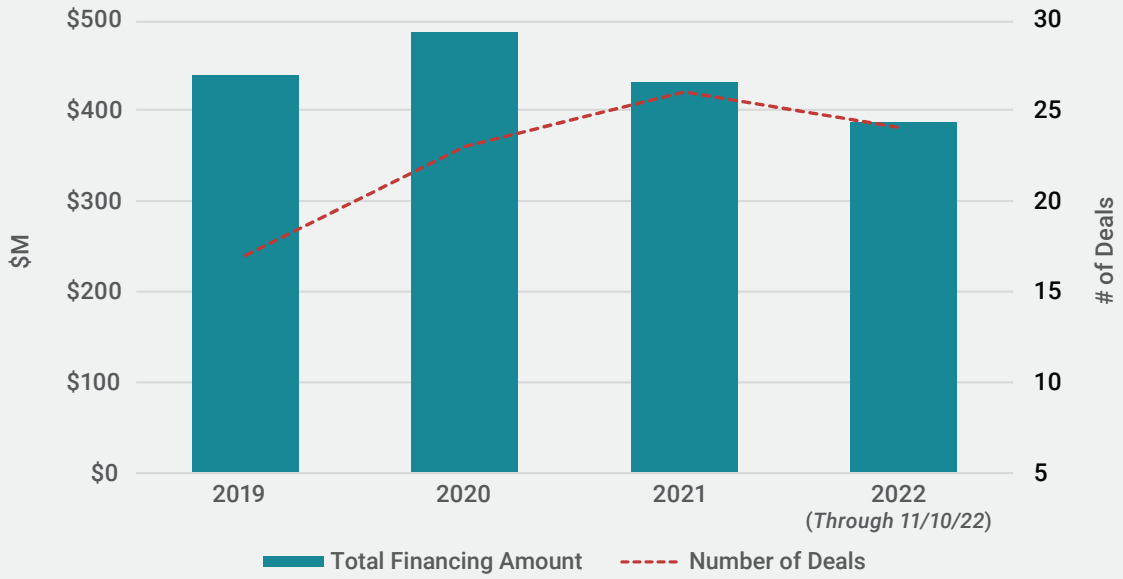
With conventional manufacturing, as the degree of complexity increases, costs also rise. AM provides a simplified method to manufacture customized structures with complex geometries at lower costs. Said differently, AM provides design innovation relative to standard manufacturing processes. Additionally, AM utilizes the same processes and materials for the manufacturing of prototypes as does the final product, thereby providing easy-to-interpret data points, rapid product development, and increased speed to market. Further potential benefits include customization of implants that allows for enhanced bone ingrowth and performance and durability improvements, as well as supply-chain optimization through inventory, waste reduction, and lead-time reduction.

As aging demographics drive future demand for orthopedic procedures, strategics remain focused on research and development of innovative materials to utilize for interbody implants. The properties of an ideal implant material are as follows: elastic modulus close to that of bone; stable, load-bearing qualities, such as toughness, rigidity, creep resistance, and abrasion resistance; and optimal integration and compatibility with radiological imaging. Currently, titanium alloy and polyetheretherketone (PEEK) are the most common materials used in orthopedic implants, each with differentiated advantages and limitations. Titanium has an elastic modulus that is much higher than bone, which can lead to stress shredding and the eventual loosening of implants due to a loss in bone density. At the same time, titanium has fantastic osseointegrative properties, enabling early bony fusion and stable fixation, resulting in favorable resistance to shear forces and increased recovery times. In comparison, PEEK has an elastic modulus much closer to that of bone, but is limited in use due to a lack of necessary biological properties. Attributable to advancements in manufacturing, variations of these materials are available that address the aforementioned drawbacks and limitations.

Beyond titanium and PEEK, innovative techniques exist that optimize mechanical and biological properties of implants to improve porosity, surface roughening, and surface coating. Improved orthopedic implant porosity, for example, provides desirable benefits such as optimal elastic modulus and osteoblast adhesion and migration. Another applied method, surface roughening, enables better clinical outcomes by decreasing the likelihood of implant loosening or dislodgment

Figure 2

Orthopedic Industry Venture Financing Overview, 2019-2022



Source: PitchBook data curated by Outcome Capital

Due to the mature nature of the orthopedic industry, consolidation is anticipated to persist, as large strategics with healthy balance sheets deploy capital-seeking inorganic growth opportunities.

due to increased friction. Additionally, surface roughening promotes enhanced biological integration of implants. Lastly, surface coatings can optimize biological properties of interbody implants. As an example, titanium alloys coated with hydroxyapatite have been clinically proven to enhance bony integration.

In September 2022, **SeaSpine** launched the 3D-printed *WaveForm TO Interbody System*, based on an AM 3D-printed process. The implant is approved for use in transforaminal lumber interbody fusion (TLIF) procedures and is designed to optimize sagittal alignment and endplate support.

> "With the goal of fusion, WaveForm's sheet-like structure provides more surface area for bone to crawl in and across compared to other 3D-printed architectures and features an endplate porosity of 65% proven to maximize the potential for early stability."

In parallel, the implant is constructed using a titanium alloy material and manufactured with multiple footprints and lordotic options available, providing surgeons with the ability to intraoperatively address specific anatomical needs without disrupting workflow.

Transaction Activity

Slight Slowdown in M&A, Longer-Term Confidence

While the orthopedic industry continues to look for stability in a post-COVID world, large orthopedic franchises provide encouraging guidance. However, M&A deal volume remains below normal levels, when referencing 2019 as the base year, as measured by the Outcome Capital Orthopedic Index as a proxy for industry M&A activity (*see Figure 1*). The total deal volume captured in Figure 1 represents all transactions with deal values less than $1 billion, in addition to deals with undisclosed values.

All transactions represented in Figure 1 with disclosed deal values can be categorized as middle market transactions defined as deals less than $1 billion; within this search parameter, all deals with disclosed values coincidentally were less than or equal to $500 million. (Although counted in the total deal volume, it is not confirmed that undisclosed transactions fall into this value range.) For reference, middle market activity has accounted for more than $3.8 billion of total deal value over the sample period, with about a third of the 37 deals captured in Figure 1 having undisclosed deal values. In general, with some exceptions, the orthopedic M&A market remains healthy and poised for further robust activity as strategic players pursue bolt-on acquisitions to bolster current pipelines and establish attractive market positioning.

Due to the mature nature of the orthopedic industry, consolidation is anticipated to persist, as large strategics with healthy balance sheets deploy capital-seeking inorganic growth opportunities. For example, in October, SeaSpine and **Orthofix** announced a merger of equals. The new company, to be named after the transaction closed on January 5, 2023, would have approximately $700 million in annual revenues. Based on terms outlined in the agreement, the transaction will be completed as an all-stock deal, granting SeaSpine stockholders 0.4163 shares of Orthofix in exchange for each share of SeaSpine. The deal premium to be received by SeaSpine shareholders at deal closing is currently around 20%, using the stock price of SeaSpine on the day of the announcement as reference.

An important consideration in evaluating M&A transactions is the deal structure. Traditional finance assumes stock should be used when a buyer wants to share the risk of a transaction, foregoing some potential future upside. Alternatively, all-cash considerations shift risk and future upside to the buyer almost entirely. Lastly, the earn-out components associated with tuck-in acquisitions serve as a proxy for the risk appetite from strategic perspectives.

Venture Capital Equity Financing

In capital markets, roughly 24 financings occurred in US orthopedics year to date, as of mid-November.[1] The pace of transactions is expected to match or exceed that of 2021, an encouraging sign for management teams seeking capital. However, uncorrelated to the number of deals, total investment amount and average investment amount per round have dipped over the past few years (*see Figure 2*). Industry dynamics

partly explain this, as companies require less capital to arrive at attractive value inflection points, and strategics rely on the acquisition of innovative technologies for growth. Alternatively, macroeconomic headwinds could be prompting risk-averse investors to sit on the sidelines for the time being.

As an example of a typical successful deal this year, **Accelus**, a privately held, Florida-based orthopedic company, closed a $12 million Series D equity financing in July. Accelus offers a diversified portfolio of spinal implant solutions, biologics, and a robotic navigation system. The funds are intended to drive US commercialization and adoption of the company's robotic-enabled, minimally invasive portfolio in hospitals and ASCs. Accelus has shown strong traction in the market to date with $27.5 million in revenue last year, up 63% from 2020. Sustained growth of this magnitude will likely gain the attention of strategics, making Accelus a prime acquisition target in the near future.

Given industry dynamics and attractive valuations, we expect an increase in investment activity as we head into 2023 and beyond. Technologies prioritized by investors include personalized implants, minimally invasive solutions, and differentiated innovations applied to existing solutions.

Ongoing Industry Restructuring

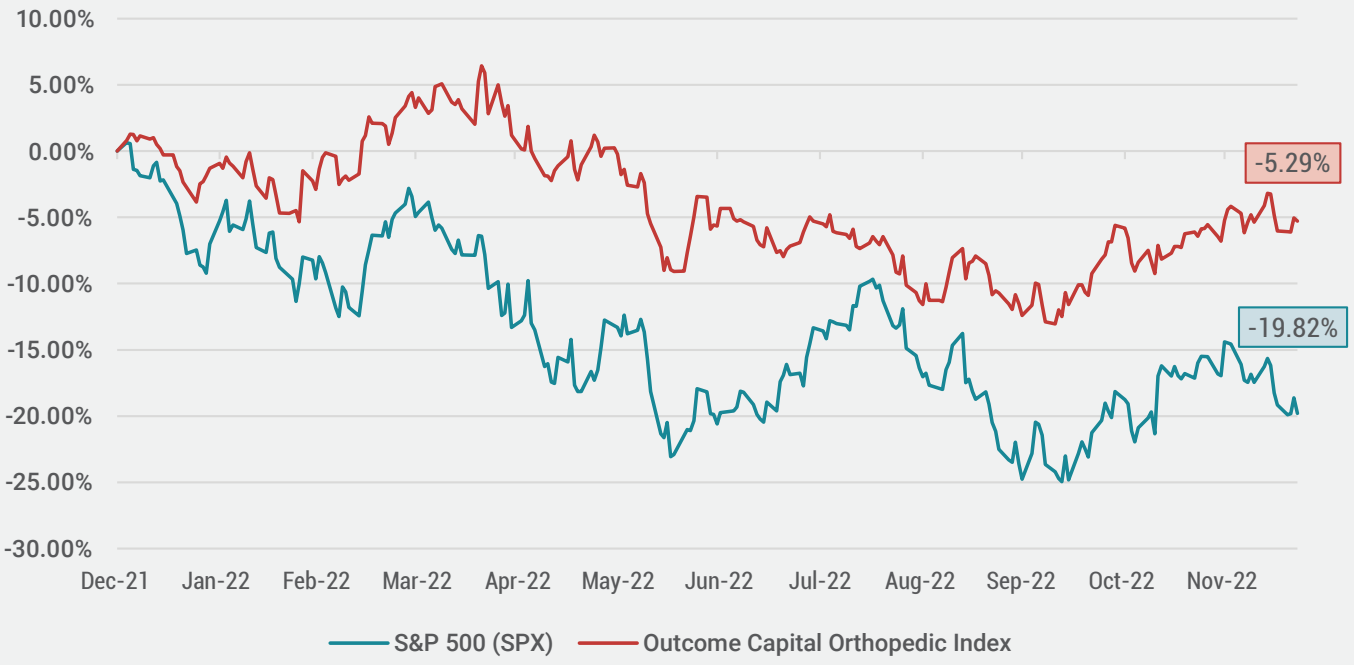
The orthopedic market saw major spin-off transactions in 2022, a dynamic promoting middle market transaction activity as companies implement targeted business plans and seek inorganic growth. Earlier in 2022, Zimmer Biomet spun off its dental and spine business resulting in the formation of **ZimVie**. This transaction creates two leading stand-alone orthopedic firms, marking a major milestone for the strategic positioning and go-forward strategy of both companies. Additionally, **Enovis**, previously named Colfax, opportunistically spun off its fabrication technology business into an independent, publicly traded company, **ESAB**, in April 2022. The spin-off positions Enovis as a leading orthopedic company with a top-in-class portfolio and clear path for growth potential. The company recently completed several strategic bolt-on acquisitions, strengthening and expanding its position in attractive market segments including extremities reconstruction.

The above-mentioned spin-off transactions highlight a more targeted business strategy, optimize resource allocation, and accelerate long-term growth, in turn, promoting further middle market transaction opportunities.

Figure 3

S&P 500 vs. Outcome Capital Orthopedic Market Index

(YTD as of 12/22/2022)



Source: Capital IQ data curated by Outcome Capital Orthopedic Index: CNMD, SYK, ZBH, JNJ, SN, MDT, NUVA, GMED, ENOV, OFIX

Going Forward: Strategic Considerations

As quarterly earnings were released throughout 2022, orthopedic strategics continued to report solid top-line growth in conjunction with optimistic forward-looking guidance. Despite challenges, the overall outlook for the orthopedic industry has remained positive. Year to date, the Outcome Capital Orthopedic Index has outperformed the broader market by around 9% on a relative basis, using the S&P 500 as a benchmark (see *Figure 3*). This dynamic is par for the course on a historical basis, as healthcare and medtech companies are typically somewhat insulated from volatile moves associated with the other sectors (e.g., technology, consumer discretionary).

Although a small number of orthopedic strategics control a lion's share of the market, these companies traditionally lack innovation. Their recourse is to acquire or invest in external innovation. This dynamic bodes well for middle market transaction activity. Middle market companies therefore would do well to focus on the development and adoption of differentiated technology, as opposed to allocating resources toward expanding sales and marketing efforts.

Related, as procedural volumes increase, Outcome Capital anticipates the number of transactions to move in lockstep. Further, as the industry begins to stabilize and revenues become more predictable, management teams are likely to make strategic transactions, given greater transparency of their competitive advantages and desired market positioning.

Additionally, we expect an uptick in venture financings on a similar premise.

Robust transactional activity, in turn, bolsters investors' confidence in favorable exit scenarios. As the industry continues to accelerate, Outcome Capital anticipates a related uptick in investor sentiment, with consequent increased capital flow into the segment. In closing, the orthopedic industry appears primed for sustained growth as procedural volumes increase, emerging technologies are developed and adopted, and M&A activity perseveres. MTS

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