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2022 Outlook: Insight for Building Relationships and Strategies

By Carolyn LaWell

In looking to 2022, we considered what might

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be the most significant opportunities and challenges for the orthopedic industry, and what advice we could offer orthopedic executives around those ideas. We asked regular commentators to weigh in on those questions. Among their replies: identify providers' needs and foster relationships with executives; understand the regulatory landscape and build well-thought-out strategies, and take advantage of a hot equity and M&A market to buy or sell.

Know Your Customer (Better than You Do Now)

Patrick Vega, Vizient

Somethings New

The ambulatory surgery center and ambulatory procedures for orthopedics and spine are becoming a new competitive ground for suppliers and manufacturers. Although the rate of migration of these cases from inpatient to ambulatory settings will wax and wane, driven largely by reimbursement policy and patient preference, they are inexorably moving in that direction.

In addition to their traditional suite of products, forward thinking orthopedic companies will produce products that are specifically focused on the ambulatory setting. Additionally, they may develop wraparound and value-added products such as software that support key business functions and web-based patient engagement tools and outcomes collection.

While certainly now a wide-open market space, there are risks for orthopedic companies. One risk in the ASC setting is

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eroding brand loyalty, especially in those ASCs that are wholly or partly owned by physicians, as higher priced products have a direct impact on their income.

Somethings Old

From my provider perspective and experience, it is yet to be seen if there will be breakthrough products that have substantial impact in the coming year. Certainly, joint replacement robotics has established a foothold with spine robotics emerging. Providers' enduring needs tend to be more mundane — products that address core needs and the most common requirements for implants, devices, and support.

From the standpoint of providers, there is a need to balance cost, proven quality and market performance, but especially cost. To the degree that orthopedic vendors can assertively address cost, they may be advantageously positioned to maintain and potentially grow business and market share.

My colleague, Reggie Knight, M.D., MHA, FAAOS, Senior Vice President, Chief Physician Executive for Bassett Healthcare Network, recently offered his insightful perspective, "… as a former spine surgeon, now hospital administrator, the pressing question remains, where does the cost savings come from — hospital, surgeon, or implant company? There needs to be shared savings to offset the shared risk to be successful."

I have consistently urged vendors and suppliers to seek more alignment with the strategic considerations of the orthopedic and spine service lines. While their long-standing relationship has been primarily with surgeons and hospital supply chain decision surgeons and hospital supply chain decision makers, the opportunity is to assertively expand this to include executive leadership. If this can be cultivated and sustained, it will provide additional insights and strategic access, potentially resulting in incremental business.

Patrick Vega, MS, is Consulting Director for Vizient Advisory Solutions. Mr. Vega consults to member hospitals, health systems and physicians in musculoskeletal services with a focus on high-value care by aligning cost, quality and performance.

The Evolution of Musculoskeletal Regenerative Medicine in 2022

Scott P. Bruder, M.D., Ph.D., Bruder Consulting & Venture Group, LLC

As the orthopedic industry emerges from the pandemic, and critical changes in the regulatory environment regarding human cell and tissue products (HCT/Ps), the next year will be one of substantial evolution. On the heels of FDA's cessation of "enforcement discretion" regarding the marketing of HCT/Ps, dozens of companies pulled their products in order to remain compliant with Federal Regulations, and only a subset of those have chosen to embark on a rigorous, expensive and risky BLA or PMA approval process.

This has left a void in some therapeutic segments that provides a competitive advantage for those firms who have been compliant in recent years, or whose orthobiologic products are not regulated as

HCT/Ps. At the same time, those small and medium sized firms who have wisely invested in tissue repair and regeneration technologies are becoming ripe for acquisition by larger strategic firms or private equity investors.

Although a considerable number of "bad actors" continue to illegally market unapproved products such as amniotic fluid, Wharton's Jelly, exosomes and "stem cells," pressure from conscientious physicians and law-abiding competitors is helping FDA and FTC to crack down on those who try to skirt the law. A growing number of multi-million dollar judgments against physicians and OEMs are also serving to highlight the risk of being associated with these illegal products.

For those companies bringing legitimate products to market, commercial success is highly dependent on navigating the reimbursement process. Therefore, advanced strategic planning, investment in collecting the necessary scientific and clinical data, and submission of applications to CMS to secure appropriate coding and coverage is essential. Oftentimes, consideration of the requirements necessary to obtain adequate payment begins too late in the product development cycle to optimize revenue recognition at the time of launch. For these reasons, in part, undertaking a wholistic and professional review of all aspects of commercialization early in development is a wise investment of time and money.

Dr. Bruder founded the Bruder Consulting & Venture Group in 2015 after 25 years in the industrial sector, serving in the C-suites of Stryker, BD and DePuy / Johnson & Johnson. In addition to his tenure through industry, Dr. Bruder has maintained an active academic

Bruder has maintained an active academic presence, serving as an Adjunct Professor of Biomedical Engineering at Case Western Reserve University since 2011, after 13 years as an Adjunct Professor in the Department of Orthopaedic Surgery.

Equity and M&A Appetites Will Remain Strong

Mike Evers, ORTHOWORLD

Charles Hamilton, a managing director within Piper Sandler's healthcare group, recently gave an address for the 2021 Musculoskeletal New Ventures Conference. Speaking of medtech broadly, he said both equity and M&A markets are paying peak valuations for growth above all other metrics. Investor appetite for disruptive business models is driving a steady inflow of capital based on growth stories.

The "unprecedented" market conditions include:

- Trading multiples near record levels for high-growth companies. These companies are trading at 13.8x forward revenue, while the 10-year average is 8.4x forward revenue
- Record IPO numbers and valuations. Median pricing is 7.3x forward revenue, an all-time high.
- M&A transactions are nearing all-time highs. Large strategic companies are remaining more disciplined compared to public markets. They are also partnering earlier in product lifecycles to assure a "seat at the table" when the product reaches commercialization.
- Venture capital and private equity deals are at record levels in both volume and

> are at record levels in both volume and dollar amount. A "war chest" of capital is sitting on the sidelines, waiting to be deployed as a lot of capital chases relatively few assets.

We saw three orthopedic companies go public in 2021, with others receiving new private equity backing. We expect investors will continue to find the orthopedic market attractive and well-positioned companies could benefit from new capital.

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