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STRATEGIC INSIGHTS INTO THE ORTHOPAEDIC INDUSTRY — AUGUST 2011

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Those who adapt best to these challenging times and complex issues will win.

ARTICLE

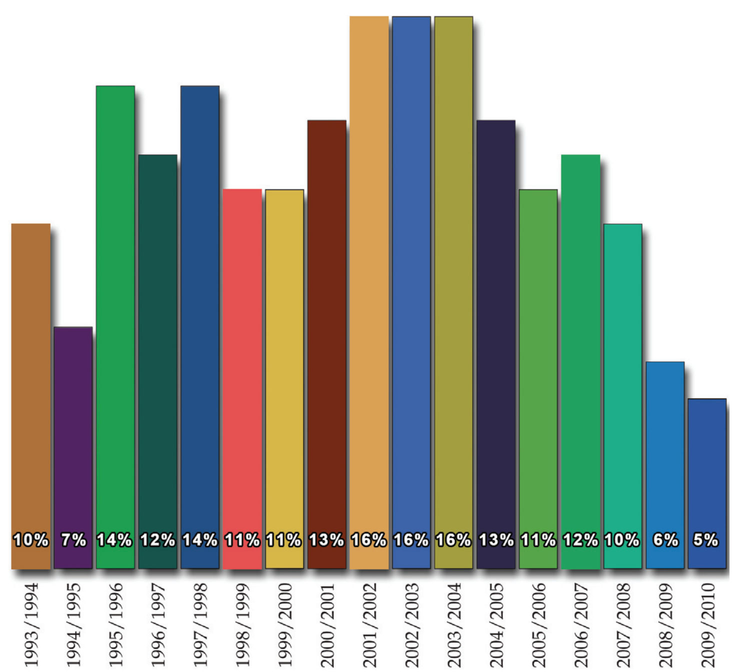
The Global Orthopaedic Industry: A High Altitude View

By Don Urbanowicz, Urbanowicz Consulting

Executive Summary

As can be seen in this year's installment of *THE ORTHOPAEDIC INDUSTRY ANNUAL REPORT®*, the global orthopaedic industry is facing a most challenging time, in which implant sales growth is proving to be increasingly difficult. (See Exhibit 1, excerpted from the Annual Report.)

EXHIBIT 1
ORTHOPAEDIC MARKET GROWTH: 1993 TO 2010



Source: ORTHOWORLD estimates.

That is, maturing markets, product commoditization and steady price degradation have become a reality. Although demographics remain favorable, making unit growth inevitable, the "traditional" innovation model: incremental product improvements driven by physician collaboration, a predictable and timely path to commercialization and reimbursement, the ability to secure a higher end-market price with minimal clinical data—is being severely scrutinized and receiving pushback by regulators, payers, physicians and hospitals. Further, industry continues to feel a profound impact from a slowdown in procedure volumes coupled with uncertainties and delays at FDA, proposed health care reform, an evolving hospital/surgeon/device company relationship and a looming excise tax.

In an effort to find new sources of growth and achieve cost savings, orthopaedic companies have more aggressively pursued acquisitions. However, structural changes affecting the way business is (or will be) done may also require companies to experiment with new R&D and business models, consider diversifying and pursue collaborations with non-traditional partners in an effort to remain innovative and relevant. Maintaining the status quo will simply not be an effective go-forward strategy.

Although dollar growth in hips, knees and spine has slowed to the low- to mid-single digit range, growth in the trauma, extremities, sports medicine and biologics segments remains strong to robust. Emerging markets, especially China, India and Brazil, continue to offer growth potential. Those who adapt best to these challenging times and complex issues will win.

Let's review the current and future landscapes to some of the abovementioned challenges.

Global Orthopaedic Industry...

Regulatory/Reimbursement

Current Situation

Innovation has been negatively impacted as the FDA 510(k) review process has become more deliberate, less predictable and less transparent

Burden-of-proof now required to demonstrate substantial equivalence for 510(k) products

Increasing need for clinical evidence:

- ~12% of 510k's submitted in 2010 included some form of clinical data
- Device innovation ex-U.S. is becoming a more attractive product development pathway
- Companies seek to bypass FDA by generating sales and building clinical experience ex-U.S.
- Comments heard with greater frequency: "It's easier to get into a European country (or countries), secure clearances and commercialize a product" and, "if you want to generate value, go to Europe first"

What to Look For in the Future

Technologies/products that have the potential to improve patient outcomes cost effectively, hospital process/efficiencies or reduce error rates will achieve the greatest commercial success. Potentially disruptive technologies will face a more complex commercialization and reimbursement path.

Comparative Effectiveness will increase the scrutiny on existing and potential future treatments and products

- Data collection will be mandatory
- Implant registries will gain traction in the U.S.
- Reimbursement will continue to be challenging (and likely further reduced)

Lack of data will translate directly into lack of payment

FDA will accelerate enforcement of off-label use; continued investment will be required by device companies to ensure robust quality systems and processes are in place on the manufacturing side (captive and outsourced)

Device companies will integrate key departments (marketing, operations, development, clinical/regulatory, reimbursement) at earliest stages of product development to drive out costs and ensure an agreed upon go-forward strategy

Hospital and Physicians

Current Situation

Share of U.S. hospital-owned physician practices increased from 30% in 2003 to 55% in 2010; ~20% of orthopaedic surgeons were working directly for hospitals, medical centers and academic institutions in 2010

Hospitals are positioning themselves for a new voluntary business model for organizing and delivering health care – Accountable Care Organizations (ACOs)

- Objective is to have physicians and hospitals organize in an attempt to reduce Medicare costs and improve care; reducing costs is critical as Medicare enrollment is expected to increase by 33 million from 2010 to 2030 (vs. only 13 million from 1990 to 2010), with an unfunded liability of > $25 trillion over the lifetime of those in the program
- The healthcare provider shares the financial benefits of any new efficiencies with hospital and physician (and the risks, as well)
- Early feedback from hospitals and physicians suggest that proposed rules may be overly prescriptive, operationally burdensome and costly; "the financial rewards are too limited and the risks are too high"

Physicians are realizing potential benefits of being direct employees of hospitals (guaranteed salary, focus on patient care, no partnership issues); however, benefits come with a cost (no equity, diminished role as a key opinion leader, fewer product options)

Vendor consolidation, slower product adoption and pricing pressures continue to squeeze device companies, especially smaller ones

What to Look For in the Future

Physicians will continue selling out to hospitals: ~ 70% overall and ~ 35-40% for orthopaedic surgeons by end 2015; bond between surgeons and sales reps/device companies will continue to diminish

Delivery incentives will change

- Team-based care (partnerships with primary care physicians, specialists, non-physicians, hospitals) will be incentivized
- Quality outcomes will be reimbursed (versus volume)
- Outcomes data will be more transparent (providers performance will be measured)

Larger hospital organizations will gain greater leverage, force additional price reductions and limit product options

Patient length-of-stays will be further reduced

Global Orthopaedic Industry...

Device companies will be proactive in driving cost out of the development and manufacturing processes

- Focus will be on simpler, easier-to-use, better and less expensive products

Generic implants/products (priced ~50% below the "standard," but with an alternative distribution model) and/or those designed for ex-U.S. markets will penetrate a small but growing segment of the U.S. market

M&A, Early-Stage Deals and Start-Ups

Current Situation
Orthopaedic M&A is on the rebound with the potential for above-average year in 2011

Strategics with large cash balances have become comfortable with revenue-generating tuck-ins as they look to "move the revenue dial and increase share across hospitals"

- ~14 material orthopaedic deals were announced/concluded through May 2011 (record of 37 was achieved in 2007)

The percentage of companies without revenue that were acquired by strategics has dropped in each of the past three years

Series A investments by VCs in 2010 dropped for a third straight year; however, select companies with good technologies were still being funded

The VC MedTech model showing cracks

- Absence of an IPO market
- Shortage of capital resulting in focus on existing portfolio companies
- Movement to later (vs. earlier) stage investing
- Admission of longer road to liquidity (10+ years)
- Preference for 510(k) products/technologies that don't require human clinicals

Start-ups, unable to secure early-stage VC funding, seek non-traditional sources of capital, including angels, corporate VC arms, corporate partners, state innovation funds and the military

Providers of medical care have been active acquirers of late as they look to cut costs; Wellpoint acquired CareMore (26 clinics in 3 states); Humana bought Concentra (clinics in 40 states); and Highmark recently purchased the second largest hospital chain in Pittsburgh

What to Look For in the Future
Early-stage VC investing will take time to return, creating a void; VC-backed companies will be more "reasonably priced" to ensure an exit/liquidity

Revenue-generating tuck-ins will continue to be preferred by strategics as they seek to diversify product portfolios and protect margins; ex-U.S. acquisitions will increase, as large companies have substantial overseas earnings offshore

Strategics will continue to be more selective in their pursuit of pre-revenue/technology opportunities

First-mover advantage will increase in importance, especially given regulatory and payer push-back and expected scrutiny on incremental product enhancements

Select boutique pharma companies, looking to "take ownership of a disease" (treat patient from head to toe, beginning to end), will emerge as serious contenders in device acquisitions

The Consumer's Impact

Current Situation
Consumers (patients) affecting unit trends as they less-aggressively consume healthcare

- CIGNA and Humana had superb Q1/11 earnings due to "decelerated use of healthcare" by consumers
- Consumers remain deeply concerned about uncertain employment outlook, higher deductible healthcare plans, expiration of COBRA benefits
- Percentage of the population employed (58.2%) is lower than when the recession officially ended in June 2009 (59.4%)
- Employment within healthcare looking less robust; healthcare sector feeling pressure pushing hospitals and health systems to cut costs

What to Look For in the Future
Procedure volumes will remain soft as long as the economy and consumer confidence continue to stall

Economists have downgraded the prospects for the growth of the U.S. economy for 2H11; belt-tightening from the implant companies will be the norm through year-end

Every healthcare system in the world will seek to cut additional going-forward costs due to austerity measures

Overview of Orthopaedic Market

Favorable Take-Aways
- Demographics remain favorable
- ~32 million individuals will soon be insured

*Generic implants (priced ~50% below standard, but with an alternative distribution model) and those **designed for ex-U.S. markets** will penetrate a small but growing segment of the U.S. market.*

For reprints or subscription information, please contact Julie Vetalice by phone, 440.543.2101 or email, julie@orthoworld.com.

ORTHOWORLD Inc.
8401 Chagrin Road, Suite 18
Chagrin Falls, Ohio 44023
www.orthoworld.com

Global Orthopaedic Industry...

- Unit growth is inevitable
- Capital spend environment has improved
- Hospitals still willing to pay for technology

Less-Favorable Take-Aways

- The "traditional model" and value proposition of products are severely challenged
- Commoditization is a reality; product mix becoming less significant
- Steady price degradation, including a sequential price step-down
- The economy and consumer confidence have stalled, impacting short-term procedure volumes
- Newer alignment between surgeon and hospital is diminishing the bond between surgeon and sales rep/device company
- 2.3% excise tax looming

2010 Worldwide Market Growth and 2011-2012 Projections

85% of total 2010 worldwide dollar market comprised recon, spine, trauma and arthroscopy; worldwide revenue growth +5% in 2010

Hip and knee revenue growth declined from double-digits in 2006 to low single-digits in 2010; five companies accounted for ~95% of 2010 worldwide sales

Hips +3.5% worldwide and +2.5% in the U.S. in 2010, but only +1% in 1Q11; projected sales growth +3% to 4% in 2011 and 2012, respectively
Current hot topics:

- Movement toward traditional bearing surfaces
- Anterior approach gaining traction
- New product launches are continuing
- >50% of cases in 2011 will be performed on patients <65

Knees +4.5% worldwide and +4% in the U.S. in 2010, -1% in 1Q11; projected growth +3% to 4% in 2011 and 2012
Current hot topics:

- Patient-specific cutting blocks gaining in popularity
- Robotics continue to create buzz

Spine +2% worldwide and +1.5% in U.S. in 2010, +3% in 1Q11; projected growth 4% to 5% in 2011 and 2012 (or more in line with hips and knees); 9 companies accounted for ~90% of worldwide 2010 sales
Current hot topics:

- Intense pricing pressures
- Continued private payer pushback/preauthorization requirements (lumbar fusion)
- Clinical value questions
- Shift toward less disruptive, MIS procedures

Items For Consideration

The biggest challenges facing orthopaedics today include the ability to remain innovative, demonstrate value and ensure growth. Maintaining the status quo will no longer be good enough.

Orthopaedic companies may address these issues by considering diversification, new business models (including outside incubators, less expensive delivery/distribution), more creative deal-making (outlicensing, selling off non-growth lines, VC arms) and relationships with non-traditional partners (including payers, pharma and other large medical device companies).

Products/technologies that focus on repair and prevention vs. intervention will be preferred.

Specific orthopaedic business segments/technologies that will remain attractive include extremities, sports medicine and biologics.

Healthcare reform may favor faster, less expensive diagnostics.

With increasing pressures in the more established healthcare markets, device companies will look to emerging markets like China, India and Brazil to fuel future growth. MedTech markets in China and India are expected to grow between 15% to 25% over the next decade.

Final Thoughts

Whether you agree or disagree with my views, I'd encourage you to identify your own take-aways, trends, implications and future views, incorprate them into your company's strategic planning process and confirm whether they validate, alter or completely change your go-forward strategy.

The winners in orthopaedics have always been those who adapted best to the changing environment.

Urbanowicz Consulting (UC) is a medical device advisory firm with a musculoskeletal focus seeking to enable clients to achieve strategic and transaction-related goals by capitalizing on market opportunities.

UC offers a unique perspective on how large global companies approach strategy, valuation, negotiations, due diligence and integration, and a thorough understanding of achieving success throughout all phases of the transaction process. Please learn more online at www.urbanowiczconsulting.com, and contact Don Urbanowicz at durbanowicz@du-llc.com.