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Healthcare M&A – 10 factors that will affect 2012 activity… a U.S. perspective

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Merger and acquisition activity in the healthcare sector is directly related to the swirling currents pervading the sector generally. The sluggish world economy has obviously dampened the performance of most industries, with healthcare being no exception. Yet, there are unique challenges in the medical field, which us at the intersection of public policy, budget constraints, business issues, and personal welfare.

Underlying Healthcare Dynamics

These are 10 prominent factors that will affect the industry during 2012 and drive M&A activity.

1) Lower procedure volumes. High unemployment, the depressed housing market and other factors cause many people to forego medical procedures that were once considered non-discretionary. Declining procedure volumes are also due to high deductibles and co-pays that patients now pay as part of healthcare insurance plans. Lower procedure volumes lead hospitals to reduce inventory levels which, in turn backflows through the entire supply chain. Yet, as the economy improves — especially into 2013 — demand for healthcare is expected to grow significantly due to the expanding population over 65, longer lifespans, and more people engaging in active lifestyles.

2) Tighter government budgets. Compressed economies limits the funds governments can spend on medical care and innovation. Already, there is a widespread recognition that healthcare costs are out of control and the U.S. government is seeking to stem the tide by reducing Medicare and Medicaid payments. The U.S. has yet to come to terms with impending shortfalls in funds necessary to pay for how healthcare is currently delivered. Governments are financially strapped and cannot afford to pay for every procedure and technology proposed by doctors or sought by patients. The result will be lower reimbursement rates and margin compression, forcing many companies to seek out new higher growth, higher margin product lines, via R&D, in-licensing, strategic alliances and M&A activity.

3) Parts of the U.S. Healthcare Reform Law May Erode. In March 2012 the Supreme Court will hear arguments on the constitutionality of the individual mandate part of the Healthcare and Education Affordability Reconciliation Act

of 2010. To date, healthcare reform has failed to reduce healthcare costs and it is unclear how the expansion of healthcare coverage reflected in the law can be funded without the individual mandate. If a Republican wins the Presidential election, elements of the healthcare reform law are sure to fall, and in any event some 45 state legislatures have proposed legislation to limit, alter or oppose selected provisions. In a Presidential election year, uncertainty can be expected to continue. A 2.3% excise tax – effective in 2013 — looms over medical device companies and similar taxes apply to other healthcare sectors. As a possible harbinger of industry reaction to the tax, Stryker is closing the New York operations of its Gaymar subsidiary, leaving 160 out of work as part of its plan to cut 5% of its global workforce.

4) But Cost Containment and Reform are a Reality. Payors — public and private — will increasingly look toward bundled and value-based payments rather than fee-for-service payments. Reimbursements will center on treating a patient from a multi-disciplinary approach, not the current a la carte system. The healthcare reform law provides for Accountable Care Organizations (ACOs), as a measure to contain costs, and there will be inevitable movement in this direction. Physicians and institutional providers will be incented to join ACOs, as they can profit from yet-to-be determined savings from bundled reimbursement payments for comprehensive cost-effective treatment meeting certain quality stadards. Many physicians facing financial difficulties surviving in their own practices are joining hospitals as employees, while others are considering joining an ACO while remaining independent. Either way, economies of scale will matter at the provider level, at the distributor level and at the manufacturer level. Containing healthcare costs will benefit large companies that have made themselves lean and efficient. That means expect more consolidation.

5) Payors and Patients Favoring Less Invasive Treatments. Given the economy and sometimes unreliable surgical results, many physicians are recommending, and patients are opting for, less invasive approaches such as drugs instead of a medical procedure and physical therapy in lieu of surgery. This is especially the case in light of safety concerns with certain products, including "all-metal" artificial hips, certain implantable cardiac rhythm devices and a few pharmaceuticals. These problems result in a more cautious approach by the FDA and a lengthened R&D and testing process.

6) Confusion at the FDA. In late 2010 a survey of over 200 medical technology companies reflected widespread delays and inefficiencies at the FDA, prompting some optimism that these problems would be corrected and that approval pathways would be improved. But in July 2011, a group commissioned by the FDA to analyze regulatory approval procedures,, was highly critical of the 510(k) medical device clearance process and recommended a more stringent regimen. The FDA has backed off that position, but its regulatory approach and capabilities remain far from clear, obscuring corporate planning.

7) Newer Technologies will Gain Traction. New technologies will continue to win favor, especially those offering minimally invasive approaches, quicker recovery times, and lower procedure costs. Edwards Lifesciences is the leader in transcather heart valve replacement, and in February 2012 received CE Mark approval for its Intuity small incision and rapid valve deployment system. Medtronic's CoreValve transcatheter valve is under a US pivotal study scheduled for completion in mid-2012. The European market is more competitive with CoreValve, Germany-based JenaValve Technology and Switzerland-based Symetis having entries. Newer technological areas also include combination products integrating devices and drugs and devices and information technologies, as well as regenerative and tissue remodeling technologies.
In addition, niche areas are now being exploited by large companies. These areas used to be the province of only pioneering entrepreneurial players that sought less crowded markets. Medtronic, Boston Scientific and others, for instance, are increasing offerings for peripheral interventions and in the orthopedic areas, the extremities are now mainstream.

8) Personalize Medicine and Companion Diagnostics will Increase, but Slowly. There is significant activity by diagnostic and pharmaceutical firms to target certain therapies to those patients pre-screened to likely benefit from a given treatment. Over 72 companion products are on the market or in development, but the list of FDA-approved companion diagnostics is short — only 1% of currently marketed drugs have companion diagnostics and these are mostly cancer treatment such as Gleevec, Tarceva, Iressa, Camptosar, Erbitux and Herceptin.

9) Competition will Remain Intense. Generics will gain more market share in view of patent expirations on branded drugs, the need to contain costs and questions about the marginal benefits of some pharmaceuticals. Branded drugs are also fighting with each other for share in challenging markets. Medical device companies are seeing extreme competition in such areas as orthopedics, spine and coronary.

10) Europe will be Complicated but Opportunity Continues in Emerging Markets. Given the sovereign debt turmoil and weak economic conditions, the European market will remain challenging. Yet, emerging markets will continue to offer promise as a widening middle class develops and the overall population requires higher levels of care. However, China and India are encountering implementation and quality issues, and there is an ever-present risk of overheating and speculation.

Strategies for Growth and the M&A Picture

Several companies are meeting the foregoing challenges with growth strategies that include:

- Restructuring internal operations, shedding non-performing assets, pruning organizational bloat and increasing margins via productivity gains and more creative approaches
- Diversifying product portfolios to moderate the harsh effects of any one technology faltering
- Prudently penetrating emerging markets to strengthen platforms for future expansion
- Pursuing strategic acquisitions to supplement organic growth, to diversify product lines and geographical markets and to obtain new high growth, high margin technologies.

With accumulated cash reserves, large companies will increasingly look to M&A activities to re-position themselves. Examples are set forth in the last section of this article.

Middle market and smaller companies will have a tougher time gaining access to key healthcare call points without a proven and sizeable sales force armed with a battery of products to gain the time and interest of providers. They may need to align with larger players to fulfill the promise of worthy technologies.

For smaller companies the challenging healthcare landscape puts a premium on having sufficient financial wherewithal to fund regulatory and sales and marketing requirements (i.e., “feet on the street”, marketing muscle and relationships with key opinion leaders). This is especially the case in the current tight economic climate where access to capital can be difficult. Given stricter regulatory requirements and the functional need for a substantial sales organization to properly commercialize new products, smaller companies — especially those with new technology — will find remaining independent to be more expensive and risky and many will evaluate the benefits of combining with a larger concern. Those firms should realistically assess their future and devise strategies for obtaining value for investments that have yet to hit stride in the market.

Changes in tax rates may also hasten M&A activity in 2012. If a new law does not pass by December 31, the maximum U.S. rate on capital gains will rise to 20% and the top rate on dividends will jump to 39.6%, its level prior to

the 2001 Bush tax cuts. In addition, the healthcare reform law imposes an extra 3.8% Medicare tax on investment income starting in 2013. With the prospect of capital gains rates rising to nearly 24%, 2012 may be a good time to sell.

Deals that Tell the Story

The following table sets forth a few M&A transactions that reflect the points made above.

Sector	Value	Acquiror / Target	Rationale
Orthopedics	$21.3b 5.8x Revs 16.4x EBITDA	**J&J / Synthes**	Strengthens DePuy's trauma line; manifests weakness in joint replacement market.
	$316m 3.3x Revs 113x EBITDA	**Stryker / Orthovita**	For bone grafts and vertebral augmentation. Previously bought BSX' neuro-vascular business for $1.5b.
Cardio-vascular	$225m pre-rev	**Boston Scientific / Sadra**	BSX enters the transcatheter aortic valve implantation (TAVI) market I competition with Edwards and Medtronic.
	$800m pre-rev $350m	**Medtronic / Ardian** **Invatec**	Investigational catheter-based treatment for uncontrolled hypertension – est. market >$1b plus market. Stents and balloons geared toward peripheral vascular disease, a market estimated at $2b annually and growing >10% per year.
	$225m	**C.R.Bard / Lutonix**	Drug coated balloons for peripheral angioplasty applications
Regenerative Medicine	$6.3b 3.0x Revs 9.8x EBITDA	**Apax Parnters / Kinetic Concepts** (KCI)	Leader in Negative Pressure Wound Therapy; plus, ulcer repair tissue matrix and regenerative medicine.
	$750m 5.1x Revs	**Shire / Advanced BioHealing**	Dermagraft -- leading bio-active diabetic foot ulcer treatment with attractive reimbursement; other indications under trial
Cancer Diagnostics -- Personalized Medicine	$470m 3.2x Revs 10x EBITDA	**Novartis / Genoptix**	Adds key "companion diagnostics" technology, enabling a more personalized medical approach.
Diagnostics -- General	$3.5b 6.7x Revs $2.1b 4.9x Revs 20x EBITDA	**Thermo Fisher / Phadia AB** **Dionex**	Allergy and Autoimmune Diagnostics Enhances Thermo Fisher's mass spectrometry business. (detecting the composition of samples of liquids)
BioPharma – Cancer	$5.7b 5.2x Revs 18.5x EBITDA	**Roche / Illumina**	Hostile takeover -- Illumina competes with Life Technologies and Affymetrix in personalized medicine gene-decoding machines.
	$20.1b 5.0x Revs 23x EBITDA	**Sanofi-Aventis / Genzyme**	Completed hostile takeover. Genzyme provides Sanofi with a stronger presence in the U.S.on the biotech and research side, considered a Sanofi weakness.
BioPharma –Generics	$460m 0.9x Revs	**Teva / Taiyo Pharmaceuticals (Japan)**	Increases generics franchise in Japan market