

MEDICAL DEVICE MANUFACTURING

MARKET UPDATE

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MEDICAL DEVICE MANUFACTURING MARKET UPDATE

MEDICAL DEVICE MANUFACTURING TRENDS

The medical devices industry plays a critical role in driving the U.S. economy, accounting for 3.4 percent of U.S. GDP in 2010. It is responsible for nearly two million jobs—equivalent to 1.4 percent of total U.S. employment. The Advanced Medical Technology Association (AdvaMed) shows the medical technology industry to be a strong and vibrant contributor to the U.S. economy. Medical devices are one of the fastest growing sectors within life sciences.

Over the past 12 months, the FDA has developed streamlined regulations for manufacturing compliance. These regulations, designated as 21 CFR Part IV, (a part of healthcare reform) have some top leaders in the industry saying “it will lead to increased deal making” for manufacturers. Another positive trend working in the Medical Device sector’s favor is the growing body of evidence that medical technology, while sometimes more expensive to implement up front, ultimately lowers healthcare costs in the long term. The most robust areas of investment have been within minimally invasive therapies that facilitate a faster recovery and better outcomes or target earlier diagnosis and treatment of chronic diseases. This determination is reflected in the fact that during 2009 and 2010 nearly 40% of the venture capital dollars going into healthcare were directed towards medical device innovation.

For more than a year, uncertainty surrounding the healthcare deal market increased the valuation gap between buyers and sellers. In 2010, the health care market produced 913 deals and generated over \$206 billion in deal value. While this figure represents a three percent decrease from the 945 deals announced in 2009, it remains well within the range of annual deal volume established over the past decade. Among individual sectors, Medical Devices had the highest total—165 deals worldwide—representing 18 percent of the health care industry’s total deal volume.

The passage of the Health Care and Education Reconciliation Act of 2010 in March eliminates much of the valuation gap between buyers and sellers. Healthcare reform will transform the U.S. healthcare delivery and payment system as changes are phased in over the next 10 years. These changes will create opportunity for investors. Many Healthcare businesses will need to find partners in order to meet strategic goals requiring new resources.

Industry Most Pressing Issues

- Cost Reduction
- Product Launch
- Growth Strategy
- Merger Integration
- R&D Transformation
- Portfolio Management
- Product Lifecycle Management
- Sales and Marketing Effectiveness
- Organization Change Management
- Pricing and Reimbursement Strategies

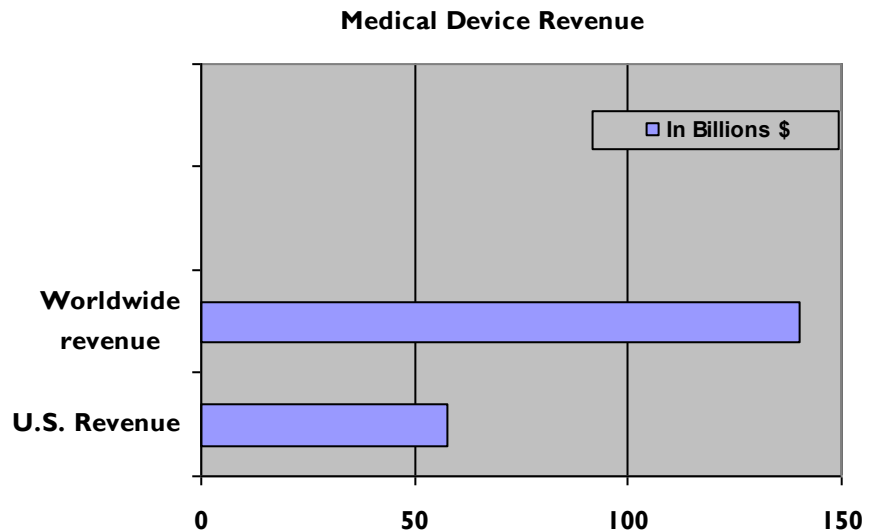
MEDICAL DEVICE MANUFACTURING MARKET UPDATE

MEDICAL DEVICE MANUFACTURING TRENDS

In the next few years, medical technology innovations will fundamentally transform the health care delivery system, providing new solutions with medical devices that will challenge existing paradigms and revolutionize the way treatments are administered. Already innovations that just a few years ago would have been seen as science fiction, are quickly becoming the standard of care.

With the convergence of many scientific and technological breakthroughs, the pace of medical invention is accelerating, inspiring hope for better clinical outcomes with less invasive procedures and shorter recovery times, all in lower cost settings.

MDDI, WTN News, Health Care M&A Monthly, and others agree that in spite of a weak national economy, today's market for medical devices is one of the largest and most stable sectors. The diversity of the device market, an industry that offers products from commodities such as gloves and bandages to high-tech equipment like pacemakers and surgical lasers, has outperformed many other U.S. and international business segments. Medical device production in this country appears strong. Healthcare M&A estimates place the U.S. Medical Device market at \$57.6 billion in revenue, boosted by a solid eight percent compound annual growth rate. Compare this U.S. market value with a worldwide device market of \$140 billion.



The United States produces 41 percent of the world's medical devices and consumes approximately 40 percent of the world's output. Not surprisingly, the market is highly concentrated. According to WTN News, the 17 largest medical device manufacturers, defined as companies with revenues exceeding \$500 million, account for some 65 percent of total U.S. revenue. There are approximately 6,000 medical device manufacturers of all sizes, and those companies employ about 400,000 people. Still, about 80 percent of those 6,000 employ fewer than 50 people and 98 percent have fewer than 500 employees. However, even if the revenue deck seems somewhat stacked in favor of large concerns, it is believed that medium and small companies can still be highly profitable.

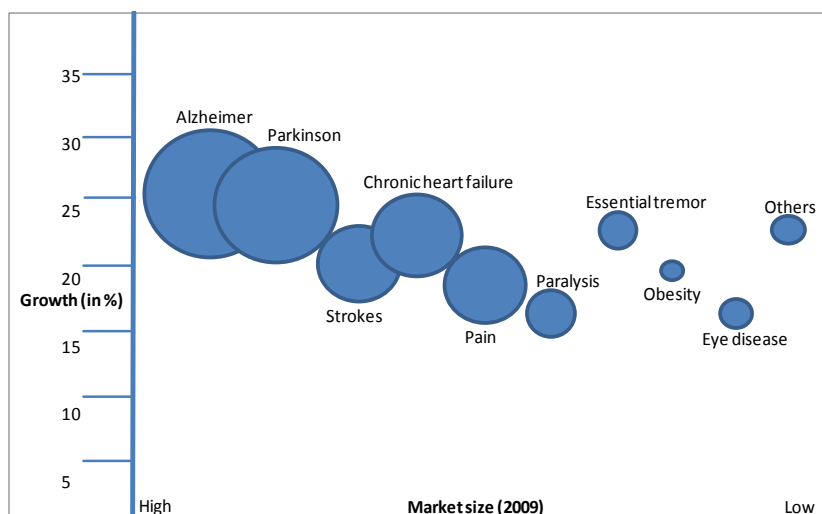
MEDICAL DEVICE MANUFACTURING MARKET UPDATE

EMERGING GROWTH AREA—NEUROSTIMULATION

The global market for neurostimulation devices was valued at about \$1.85 billion in the year 2009. It is expected to reach \$4.9 billion by 2016 with a Compound Annual Growth Rate (CAGR) of 15 percent from 2009 to 2016. The major growth segment within the neurostimulation devices category is Spinal Cord Stimulators (SCS) which are expected to grow to \$3.8 billion by 2016 with a CAGR of 16 percent. The market sizes for Deep Brain Stimulators (DBS) and Vagus Nerve Stimulators (VNS) are forecast to reach \$643m and \$481m, respectively, by 2016. Growth will mainly be driven by sales in SCS. The SCS market size is almost 75 percent of the overall market for neurostimulators.

Globally, there is a huge population suffering from various neurological diseases such as Parkinson's disease, dystonia, essential tremor, chronic pain, Failed Back Surgery Syndrome (FBSS), epilepsy, depression, and others. It is estimated that currently there are about 50 million people worldwide who suffer from epilepsy alone. The prevalence of Parkinson's disease is estimated to be around 1 percent of the total world population. About 80 percent of people across the globe have suffered from pain at some point in their lives. With the increase in the aged population (the population which is 60 years or above), the prevalence of diseases such as Parkinson's and chronic pain is expected to increase.

In addition, the existing treatment methodologies for some neurological diseases have not proven effective in many patients. Hence the demand for alternate treatments such as neurostimulation, which can ease the disease symptoms and improve the quality of life for the patient.



The above figure illustrates the relative market shares and growth for the various neurostimulation applications in 2009. Alzheimer's and Parkinson's applications have relatively high market size and high growth rate, thereby promising a huge potential market for the major market players. Pain, chronic heart failure, and the strokes applications markets have an average market share but relative high growth rate, and are thus witnessing an increased number of new entrants. Obesity and other neurodisorders (incontinence and gastroparesis) applications currently have low market shares but very high growth rates; while the essential tremors and eye disorder applications have low market shares and low growth rates.



MEDICAL DEVICE MANUFACTURING MARKET UPDATE

PACIFIC NORTHWEST REGIONAL OUTLOOK

Washington Gets Active on Deal Front – Nationally, Washington’s deal activity saw the third straight quarter of increases slotting it fifth on a number-of-deals basis. The state’s primary investments are in the Internet sector so dollars remain relatively smaller. The Pacific Northwest has a strong base of researchers at institutions like the University of Washington that often see the problems and complications associated with a number of invasive medical procedures. The PNW also has a growing base of local talent to draw upon for early-stage device companies—the presence of high-quality incubators may help develop the next generation of medical-device companies that will keep the Pacific Northwest at the forefront of innovation.

Companies like Spiration, Inc.; Vertis Neuroscience, Inc.; Northstar Neuroscience; and Calypso Medical Technologies, Inc. have continued to raise significant venture rounds in recent years. Recent transactions in the PNW Medical industry involved Alcon, OSI Pharmaceuticals, Facet Biotech, Millipore, etc. These transactions are not particularly surprising since according to industry experts, the market for M&A among medical device manufacturers remains strong despite the ongoing credit crunch. However, the industry has not been immune to the recent economic slowdown, which could have noteworthy implications for medtech M&A going forward.

Although most other industry sectors experienced significant declines in the first quarter, investment in “other medical devices” remained stable at \$409 million on a national basis, indicating that the medical-device category now represents a larger piece of the venture capital pie. In the Pacific Northwest, this increase is evident: during the three year period from 1997 to 1999, 16 medical-device companies raised a total of \$37 million. So far this year, twice as much has been raised by just three companies.

In addition to medical device manufacturing, more than 120 biomedical device companies engage in research and development of new technologies in Washington State. The majority of these companies are located in the Puget Sound region, although some exist in cities outside such as Richland, Pullman, Spokane, Cashmere, and others.



IsoRay Medical, Inc., which manufactures and distributes cesium-131 isotopes to treat prostate and other cancers, has seen a financial increase from \$7 million to about \$22 million over the past years and has expanded its workforce of 69 employees to meet increasing demand.



Cadwell Laboratories, Inc., which designs, manufactures, and markets neurodiagnostic medical devices, was awarded three Group Purchasing Organization contracts. These contracts with Premier, Magnet, and Amerinet list Cadwell as a preferred vendor for approximately 50 percent of hospitals nationwide.



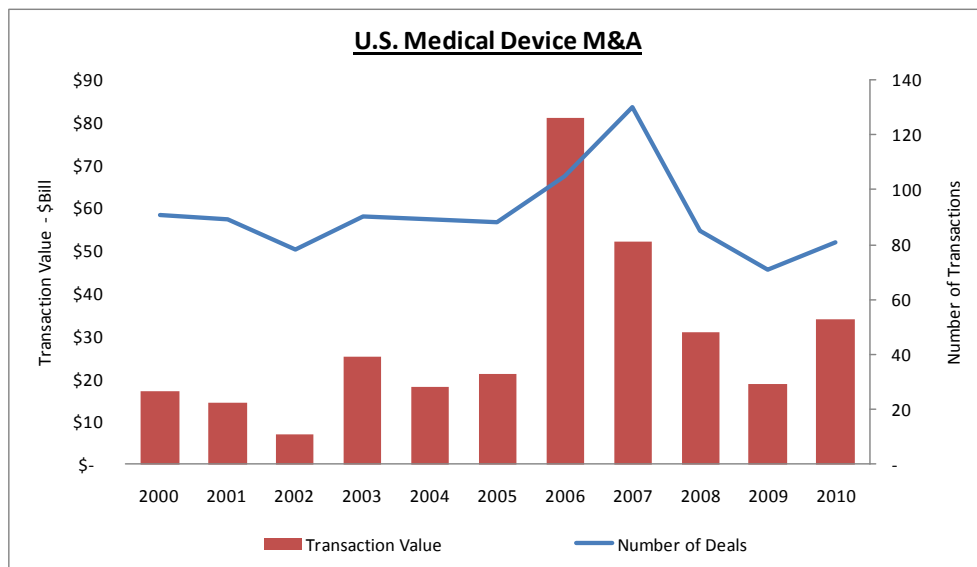
Da Vinci - Robotic surgery is the use of robots in performing surgery. Three major advances aided by surgical robots have been remote surgery, minimally invasive surgery, and unmanned surgery. Some major advantages of robotic surgery are precision, miniaturization, smaller incisions, decreased blood loss, less pain, and quicker healing time.

MEDICAL DEVICE MANUFACTURING MARKET UPDATE

M&A TRENDS IN MEDICAL DEVICE MANUFACTURING

M&A

M&A transactions, which include changes in ownership and control of companies or assets, experienced a huge increase from 2009 to 2010. During 2009 and the first half of 2010, nearly 40 percent of the venture capital dollars going into health-care were in the medical device arena, and this trend is expected to continue in the future. Strong venture capital funding will now assist in strengthening merger and acquisition transactions in the future.



2011 should continue to show strength in transactions as consolidators seek growth through acquisitions with a record amount of cash on their balance sheets. 2010 recorded 43 billion-dollar deals in the health-care sector, worth a combined total of \$134.9 billion. Forty deals were announced with price tags in the range of \$500 million up to \$1 billion, with a combined total value of \$27.8 billion. In the range of \$100 million up to \$500 million, 141 deals were announced worth a combined total of \$35.5 billion. This trend demonstrates that deal makers still favor the middle market rather than mega-deals that keeps the health care M&A market out of the mainstream media and general public.

CLOSING THOUGHTS

The near-term impact of health care reform stems from the medical device industry tax, of 2.3 percent excise tax on device sales scheduled for introduction in 2013. The impact on large-cap device companies may end up being quite manageable, and calculations show it will affect earnings for companies negatively by about 3 percent or 4 percent. Some of this reduction gets offset, however, by the benefit of expanding coverage to an additional 32 million Americans. Analysis shows that expanding coverage could grow the revenue base of large med tech markets, like orthopedic or cardiovascular implants, from 3 percent to 7 percent. Combined, there may be a net negative impact of a couple percentage points to the bottom line for these companies.

Healthcare still remains the largest single sector for venture money. Experts say that executives who are readying their companies for acquisition need to pay attention to fundamentals as well as current trends.

ABOUT EXVERE INC.

SERVICES

Exvere represents private companies in major capital transactions (partially listed below). Exvere Directors work closely with their clients to target and strategically select qualified financial counterparties, employing time-tested processes to maximize value for clients, throughout the entire transaction process, from the first conversation to a timely and efficient closing.

TRANSACTION TYPES

- Acquisitions
- Business Sales (Stock & Assets)
- Business Unit Divestitures
- Equity Placements
- Management Buy-Outs
- Merger of Equals
- Private Equity Recapitalizations
- Structured Financings

INDUSTRIES SERVED

- Aerospace & Defense
- Building Products
- Computer Hardware
- Construction
- Consumer Products
- Distribution
- Energy Efficiency
- Food & Agribusiness
- General Business Services
- Healthcare Services & Medical Devices
- Manufacturing
- Telecommunications
- Wine & Beverage

THE EXVERE EDGE

Founded in Seattle, WA in 1991, Exvere has served as adviser in over 100 capital transactions. In 2006, Exvere formed Exvere Securities, LLC, a FINRA broker-dealer, in order to expand the range of services it offers to Northwest business owners.

Strategic Assessments - Many owners haven't prepared comprehensive, operational, or exit plans for their businesses. Exvere assists with producing near and long-term strategic direction in order to maximize exit values, utilizing their extensive analytical and research capabilities. Exvere also helps business owners assess timing considerations by examining the entire process through the eyes of a potential acquirer or target. The Strategic Assessment identifies company strengths and weaknesses in order to provide third-party insight and direction, which results in a higher valuation at the chosen time of exit.

Valuation Expertise - Exvere's professional staff includes an Accredited Valuation Analyst (AVA), ensuring quality and accuracy in valuations and fairness opinions.

FINRA Member - Exvere, through its wholly owned subsidiary, Exvere Securities, LLC, is a FINRA broker-dealer. As such, we are subject to rigorous regulatory compliance and financial standards. This qualification allows Exvere to provide a greater array of options to their clients, such as partnering with international and domestic investment banks, sharing extensive research resources, and providing the broadest potential market exposure.

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