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The rise of Medtech: How and why the medical technology industry grew over the last decade and where it will continue to grow

Introduction

The medical device sector experienced unprecedented growth in revenue and earnings over the last decade. While sales and profits in most industries lagged due to worldwide recessions, medical device companies rewarded their investors with handsome returns.

Long viewed as the smaller sibling to Big Pharma, the medtech industry now generates more than $200 billion in annual revenue worldwide, excluding sales of diagnostics.[1] The United States market accounts for just under 50% of the worldwide market with total sales of $95 billion in 2010.[2]

Over the last 10 years, we witnessed a sea of change in the role that devices play in the health care marketplace. Diversified companies that once relied on pharma to bolster their earnings began looking to devices for sustained growth. Investors who shifted their portfolio accordingly were treated well. Case in point: Had a savvy financier invested $100 in the S&P 500 Medical Equipment Index on New Year's Eve, 1999, that investment would have been worth $173 on December 31, 2009, a 6% annualized return. Had he invested in the S&P 500 Pharmaceuticals Index, the investment would have been worth just $83, a 2% annualized *loss*.[3]

Potential barriers to innovation

Will medical device companies and their investors continue to prosper? Innovation is the key concern. Medical device manufacturers worry that studies on comparative effectiveness may soon become an integral part of clinical trials, a change that will add time and expense to medical device development. Additionally, the Institute of Medicine recently released a study calling into question the effectiveness of the FDA's 510(k) clearance route and recommending that the process be abandoned. Concerned that

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1 Comparative Effectiveness Hits Medical Devices, [online] (Irvine, CA: Medtech Insight, 2010) [cited 17 June 2010]; available from Internet: http://www.medicaldevicestoday.com/2010/06/comparative-effectiveness-hits-medical-devices.html.

2 US Medical Device Market Estimated at $94.9 Billion in 2010, [online] (Princeton, NJ: Espicom) [cited 18 April 2010]; available from Internet: www.espicom.com/Prodcat2.nsf/Product_ID_Lookup/00000110?OpenDocument.

3 Bloomberg closing prices for Bloomberg tickers: S5HCEP, SPX, S5PHAR.

changes to the 510(k) process could significantly alter approval rates and approval timelines, most device manufacturers and industry groups have condemned the report.

Nonetheless, medtech still holds great promise. A close look at regulatory trends for medical devices compared to pharmaceuticals demonstrates that medical device entrepreneurs are more likely to realize return on their investment than their pharmaceutical counterparts. Although few medical devices can produce the kind of sales that blockbuster drugs are known for, devices require less development risk and are easier to bring to market than drugs.

The regulatory pathway for pharmaceuticals has become increasingly challenging. Only five in 5,000 compounds entering preclinical testing will make it to human testing, and only one of those five will be approved for sale.[4] In contrast, the FDA receives thousands of medical device submissions each year, the vast majority of which are 510(k)s and PMA supplements as opposed to original PMAs for new devices. The United States Government Accountability Office reports that from 2003 to 2007, FDA reviewed 13,199 submissions for Class I and II devices via the 510(k) process, clearing 11,935 (90%) of these submissions. The agency reviewed 342 submissions for Class III devices through the 510(k) process, clearing 228 (67%) of these submissions. Furthermore, it reviewed 217 original and 784 supplemental PMA submissions for Class III devices and approved 78% and 85%, respectively.[5]

Approval timelines and regulatory trends provide justification for continued medical device innovation. As such, investment in devices could continue to provide a less costly and more predictable alternative to investment in pharmaceuticals.

(A more complete description of medical device and pharmaceutical clinical trial costs and timelines is included in the full-length article, originally published in the July 2011 issue of *MD+DI, Medical Device + Diagnostic Industry* magazine, online at **http://www.mddionline.com/article/rise-medtech**.)

Areas of future growth

Percutaneous heart valves

The onset of transcatheter heart valves, also known as percutaneous heart valves, represents the largest developing opportunity within the cardiac surgery device market. Percutaneous valves are expected to replace at least some of the mechanical and tissue heart valves currently implanted using open surgical procedures. These devices are also expected to expand the patient population eligible for heart valve surgery, opening up valve procedures to less stable patients who are considered high-risk for open heart surgery.

Percutaneous Aortic Valves

Percutaneous aortic valve replacement (PAVR) allows a synthetic valve to be transported to the heart via a transfemoral catheter inserted in the patient's leg. PAVR is performed to treat aortic valve stenosis (AVS), the most common valve abnormality in the United States. AVS affects an estimated 2.5 million people, most of whom are over 60 years old. Some estimate that as many as half of these patients are not referred for surgery because they are considered high-risk.[6]

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[4] PhRMA, "New Drug Approvals in 2009," [online] [cited 28 March 2011]; available from Internet: www.phrma.org/sites/default/files/422/nda2009.pdf. Note: This is a 2010 article citing 2007 Study by the Tufts Center for the Study of Drug Development.

[5] "Medical Devices: FDA Should Take Steps to Ensure that High-Risk Device Types Are Approved through the most Stringent Premarket Review Process," [online] US Government Accountability Office, cited 28 March 2011; available from Internet: www.gao.gov/products/GAO-09-190.

[6] Mary Thompson, "Heart Valve Market: PAVR Posed for Growth," *Medtech Insight*, January 2009.

Recognizing the opportunity, approximately 20 companies are competing to develop PAVR technology, with Edwards Lifesciences and Medtronic apparently leading the way. Edwards' SAPIEN valve was approved by the FDA in November 2011 and is currently the only FDA approved PAVR technology.[7] Current competitors estimate that the global market for percutaneous aortic valves could reach $2.5 billion by 2014.[8] Edwards expects its first four quarters of sales in the United States following launch to reach $150 to $250 million.[9]

Percutaneous mitral valves

It is suggested that the percutaneous mitral valve market has the potential to surpass the percutaneous aortic market in terms of procedures and revenues.[10] However, the percutaneous mitral valve market is still earlier in development and may ultimately require several valve approaches, including both mitral valve repair and mitral valve replacement.

The percutaneous mitral valve opportunity is focused on mitral regurgitation (MR), when the mitral valve's leaflets fail to create a tight seal and blood begins to flow backward into the left atrium. MR puts an added burden on the left ventricle and lungs and may cause stroke, congestive heart failure, irregular heartbeat, or sudden death.[11] MR is the most common type of heart insufficiency in the United States, affecting approximately 4 million people with annual incidence of 250,000; however, only about 50,000 people are currently treated each year.[12]

At least 10 companies are competing to develop mitral valve replacement and repair technology. Abbott's MitraClip device appears to be the clear leader, and is currently under review for approval by the FDA. The potential market opportunity in the United States for percutaneous mitral valve technology is estimated to be at least $2 billion.[13]

(Additional areas of future growth include peripheral stenting, peripheral angioplasty and robotic surgery. A more complete description of these opportunities is provided in the full-length article at **http://www.mddionline.com/article/rise-medtech**.)

Conclusion

Over the last 10 years, medtech innovation transformed the standard of care within many disease categories. Traditionally viewed as an option for only the most severe patients, devices have taken center stage, competing with and in some cases supplanting drug therapy as the optimal mode of treatment. The onset of minimally invasive, endovascular technologies has decreased the stigma associated with having a medical procedure performed. Open surgical procedures that result in long recovery periods and significant discomfort are being replaced by minimally invasive procedures that allow patients to resume normal living within days.

We expect to see medical device innovation continue to grow in the coming years, as evidenced by the pool of development stage companies investing in device innovation. Major markets that are currently

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[7] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278348.htm

[8] Edwards Lifesciences investor presentation, December 10, 2009.

[9] Edwards Lifesciences investor presentation, December 13, 2010.

[10] Mary Thompson, "Percutaneous Heart Valve Technology, The Mitral Challenge," *Medtech Insight*, February 2009.

[11] Abbott Vascular website, http://www.abbottvascular.com/int/mitraclip.html#learn-more, accessed March 28, 2011.

[12] Abbott Vascular website, http://www.abbottvascular.com/int/mitraclip.html#learn-more, accessed March 28, 2011.

[13] Mary Thompson, "Percutaneous Heart Valve Technology: The Mitral Challenge," *Medtech Insight*, February 2009.

undeveloped or underdeveloped will increase the overall size the medtech industry. Capital will, without question, continue to flow into the hands of the right entrepreneurs and the industry will continue to grow. The task at-hand is identifying those entrepreneurs who are capable of grasping the opportunity.

Contact
Kevin O'Keeffe
Associate Principal
+1-617-425-6533
kokeeffe@crai.com

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A longer version of this article was originally published in the July 2011 issue of *MD+DI, Medical Device + Diagnostic Industry* magazine. To view the full article, please visit **http://www.mddionline.com/article/rise-medtech**.

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