

# VALUE FOCUS Medical Device Industry



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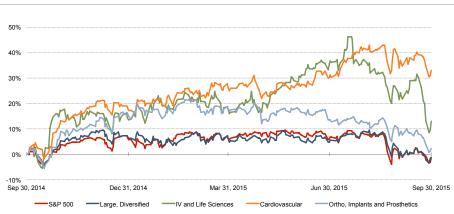
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# Stock Market Performance

Total investor returns across major medical device sectors saw mixed results amid a broader equity downturn between midyear and 3Q15. Cardiovascular companies escaped the pullback relatively unscathed, posting a 1.2% gain over the quarter. Other sectors saw declines ranging from 6.4% to over 17%. Year over year ("YOY") returns were more positive, with returns beating the S&P across all sectors. Valuation multiples contracted across sectors from the prior quarter with the exception of the orthopedic sector.

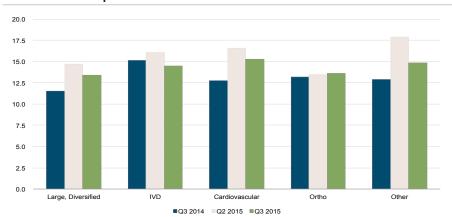
- » IVD companies had a tough quarter, declining 17.3% compared to the 7.6% decline for the S&P 500. Despite this decline, the sector saw gains of 13.1% from 3Q14. Multiple companies in the sector saw YOY gains offset by deep declines in 3Q15. Within the group, genetic testing companies also saw sharp declines in the quarter (17.0%; see page 3).
- » Cardiovascular companies returned a collective 33% over the year to 3Q15. Significant stock movers YOY within the group included Abiomed (281.9%), Thoratec Corporation (138.7%), and Edward Lifesciences Corporation (37.5%).
- » Orthopedic, implants and prosthetics companies saw a 10.0% decline from midyear, but returned a positive 2.2% from 3Q14. Zimmer Biomet Holdings saw a 6.0% decline YOY led by a 13.8% decline in 3Q15. Smith and Nephew and Integra Lifesciences saw gains of 7.2% and 32.5%, respectively from 3Q14.
- The larger diversified companies struggled over the year, falling 6.4% in the quarter and 1.1% over since 3Q14. Johnson & Johnson saw its stock fall 7.9% over the year, constituting a large portion of the sectors decline.

## Mercer Capital's Value Focus: Medical Device Industry



#### Total Shareholder Returns

Represents market capitalization weighted index for each group. Source: Bloomberg, Mercer Capital analysis



#### **EV/EBITDA Multiples**

Median EBITDA multiples from each MCM group. Data source: Bloomberg

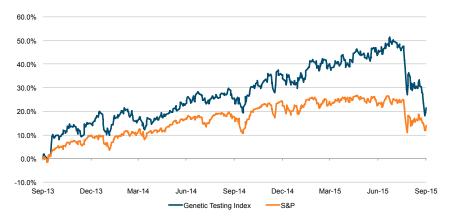
#### Mercer Capital's Value Focus: Medical Device Industry

#### Fourth Quarter 2015

# FEATURED SEGMENT Genetic Testing

Genetic testing consists of an analysis of genes to help predict the risk of disease, find medication that can help fight illnesses, and identify diseases before they become too serious. An increase in demand for personalized medicine has fueled much of the historical growth in genetic testing. As a result, the nature of the genetic testing market has changed from service-driven to product-driven, and this shift has led diagnostics companies to expand related offerings. Total market potential for genetic testing is expected to be on the order of \$25 billion for the United States and \$60 billion globally by 2021.<sup>1,2</sup>

The genetic testing market experienced sharp declines in stock performance over 3Q15, falling 17.0% in the period. General fears plaguing the broader biotechnology sector, along with Medicare reimbursement uncertainty regarding lab testing led to the decline. The following shows the stock price performance for seven companies that operate in the genetic testing market over the two years preceding 3Q15. Prior to the sell-off in 3Q15, these companies had collectively gained more than 50% since 3Q13.



#### Stock Price Performance of Select Genetic Testing Companies

Represents market capitalization weighted index for the group that includes AFFX, ABT, MYGN, A, QGEN and CPHD. Source: Bloomberg, Mercer Capital analysis

- "Global Genetic Testing Market Industry Analysis and Market Forecast 2014-2020", available online at http://www.marketwatch.com/story/global-genetic-testing-marketindustry-analysis-and-market-forecast-2014-2020-2014-10-09, accessed on June 4, 2015.
- <sup>2</sup> "Genetic Testing Market Outlook 2018," available online at http://www.researchandmarkets.com/reports/3007772/genetic-testing-market-outlook-2018, accessed on June 4, 2015.

# Venture Capital Funding & Exit Activity

Venture Capital funding in the medical device industry for 3Q15 totaled \$821.5 million, up 29.6% compared to 3Q14, and was the highest total since the 2Q11. Deal volume was down however, falling 12% from 3Q14 to 73 deals.<sup>3</sup>

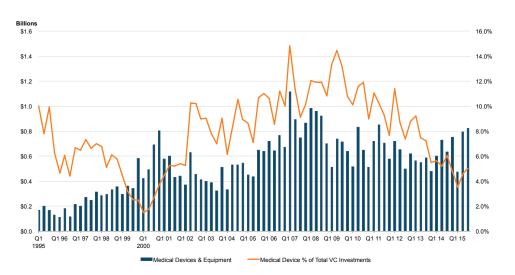
- » VC investments in medical device companies accounted for 5.0% of all VC investments during 3Q15, up from 4.6% in 2Q15 but down from 6.1% during 3Q14. While higher than the previous quarter, this still represented a 3.2% decline from the five-year average (8.2%).
- » Total VC funding for 3Q15 was \$16.4 billion, up 56.4% compared to 3Q14. Life Science investment funding (including biotechnology and medical devices) totaled a record high \$2.9 billion in 3Q15, up 60.4% from 3Q14.
- » Average deal size for medical device deals was \$11.3 million, up from \$10.4 million in 2Q15 and \$7.7 million in 3Q14. This was the highest average size since 1995.
- Medical device VC investments are generally perceived to be riskier due to the need to obtain both regulatory approval and payor coverage (reimbursement) in order to enable commercial success of the products. Consequently, later stage companies have tended to command a higher proportion of VC funding and deals. Seed and early stage medical device funding in 3Q15 increased 1.8% from 3Q14, but fell 7.9% from the previous quarter. Expansion and later stage funding increased 38.4% from 3Q14 and 8.2% from 2Q14.<sup>4</sup>
- » The impact of the longer-term decline in the VC investment share of medical device companies is tempered somewhat by investment interest from larger, more established companies seeking engagement earlier in the development cycle. During 2Q15, (strategic) corporate investments represented 5.5% of all VC investments in medical device companies.<sup>5</sup>

- 4 Ibid.
- <sup>5</sup> Data compiled in NVCA Corporate Venture Investment Report, available online at http://nvca.org/research/corporate-venture/, Accessed November 3, 2015.

<sup>&</sup>lt;sup>3</sup> Data compiled in the MoneyTree ™ report, available online at https://www.pwcmoneytree.com, Accessed November 3, 2015.

Exit activity for venture-backed companies was fairly robust during 3Q15.

- » During 3Q15, ten IPOs of venture-backed life science companies (biotechnology and medical device / healthcare) raised \$1.3 billion. Companies going public included Global Blood Therapeutics Inc., Aimmune Therapeutics Inc., Neos Therapeutics Inc., Penumbra Inc., Chiasma Inc., ProNAi Therapeutics Inc., Zynerba Pharmaceuticals Inc., Regenxbio Inc., Nabriva Therapeutics AG, and Natera Inc.<sup>6</sup>
- » 14 venture-backed life science companies entered into strategic M&A transactions during 3Q15. Aggregate transaction value for the ten deals with disclosed values totaled \$1.6 billion.<sup>7</sup>







- <sup>6</sup> Data compiled in NVCA Q2 2015 Venture-Backed IPOs Report, available online at http://nvca.org/research/exits/, Accessed November 3, 2015.
- "M&A Value Hits \$5.1 billion for Strongest Quarter This Year," available online at http://nvca.org/pressreleases/ma-value-hits-5-1-billion-for-strongest-quarter-this-year/, Accessed November 3, 2015.

#### Select Venture Funding Deals

	Recent	Financing		
Company	Amount (\$M)	Round	Founded	Notes
Mevion Medical Systems Inc	\$200	Later Stage	2004	Provides proton therapy systems for radiation treatment
Gynesonics Inc	\$43	Later Stage	2005	Gynesonics develops an ablation device for treating uterine fibroids
Ivenix Inc	\$42	Later Stage	2007	Develops products for intravenous infusion therapy
Veran Medical Technologies Inc	\$42	Later Stage	na	Medical device company that helps physicians diagnose disease and deliver therapies
Delphinus Medical Technologies Inc	\$40	Early Stage	2010	Develops and services breast cancer screening solutions
Reshape Medical Inc	\$38	Later Stage	2008	Develops non-surgical weight loss devices
Jenavalve Technology, Inc.	\$27	Later Stage	2006	Designs and develops trans catheter-delivered aortic valve systems
Gritstone Oncology Inc	\$26	Early Stage	na	Develops personalized cancer vaccines
Channel Medsystems Inc	\$24	Early Stage	2009	Develop proprietary cryo-ablation delivery technologies
MediBeacon Inc	\$22	Early Stage	2011	Optical diagnostic company
Vapotherm Inc	\$18	Later Stage	1999	Manufactures and sells respiratory care devices
Chrono Therapeutics Inc	\$18	Later Stage	2004	Disease and addiction management, programmable passive transdermal drug delivery (TDD)
Corvia Medical Inc	\$17	Early Stage	2009	Develops structural heart devices for the treatment of heart failure
TherOx Inc	\$17	Later Stage	1994	Focuses on heart attack patients
Pulsar Vascular Inc	\$16	Later Stage	2005	Endovascular platform to address the needs of bifurcation aneurysms
SetPoint Medical Corp	\$15	Later Stage	2006	Treats patients with inflammatory diseases using proprietary implantable neuromodulation devices
Ativa Medical	\$15	Early Stage	2008	Deliver diagnostic solution to decentralized healthcare settings
Baebies Inc	\$13	Early Stage	2013	Develops and commercializes digital microfluidic technology
Amphora Medical Inc	\$12	Expansion	2011	Develops medical devices for overactive bladder
Providence Medical Technology Inc	\$12	Expansion	2008	Cervical spine
Nalu Medical Inc	\$12	Startup/Seed	na	In vivo mini-robot surgery, minimally invasive colon resection and abdominal procedures
Virtual Incision Corporation	\$11	Later Stage	2006	na
Senseonics Inc	\$10	Later Stage	1996	Glucose monitoring products
Saluda Medical	\$10	Early Stage	2013	Personalized neuromodulation therapy

Data Source: MoneyTree Report, PwC/NVCA, Thomson Reuters; and, CrunchBase [http://www.crunchbase.com/] at TechCrunch.com. Medical Devices and Equipment funding rounds over \$10 million during 3Q15.

## Medical Devices Select Transactions Summary

(\$Millions)

		Est. Deal		FBITDA	EV /	EV/
Target	Date	Size (EV)	Sales Est.	Est.	Sales	EBITDA
NeuroFix Therapeutics, LLC	9/9/2015	458.0	NA	NA	NA	NA
Scioderm, LLC	8/31/2015	869.5	NA	NA	NA	NA
Cytovance Biologics, Inc.	8/24/2015	205.7	NA	NA	NA	NA
GeneWEAVE Biosciences Inc.	8/13/2015	425.0	NA	NA	NA	NA
Therakos, Inc.	8/9/2015	1,325.0	174.0	NA	7.61x	NA
Receptos, Inc.	7/14/2015	6,741.7	3.5	(175.6)	NM	NM
Baxalta Incorporated	7/10/2015	30,907.3	5,984.0	2,178.0	5.17x	14.2x
Audeo Oncology, Inc.	7/1/2015	16.0	NA	NA	NA	NA
CBR Systems, Inc.	6/29/2015	700.0	121.8	24.2	5.75x	29.0x
TEI Biosciences Inc.	6/26/2015	199.8	64.4	20.6	3.10x	9.7x
Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.	6/26/2015	11.0	NA	NA	NA	NA
InSite Vision Incorporated	6/8/2015	45.2	4.5	(11.1)	10.10x	NM
Bio-Reference Laboratories Inc.	6/3/2015	1,516.0	882.5	115.9	1.72x	13.1x
DARA BioSciences, Inc	6/3/2015	20.8	2.4	(9.0)	8.75x	NM
	NeuroFix Therapeutics, LLC         Scioderm, LLC         Cytovance Biologics, Inc.         GeneWEAVE Biosciences Inc.         Therakos, Inc.         Receptos, Inc.         Baxalta Incorporated         Audeo Oncology, Inc.         CBR Systems, Inc.         TEI Biosciences Inc.         Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.         InSite Vision Incorporated         Bio-Reference Laboratories Inc.	NeuroFix Therapeutics, LLC9/9/2015Scioderm, LLC8/31/2015Cytovance Biologics, Inc.8/24/2015GeneWEAVE Biosciences Inc.8/13/2015Therakos, Inc.8/9/2015Receptos, Inc.7/14/2015Baxalta Incorporated7/10/2015Audeo Oncology, Inc.7/1/2015CBR Systems, Inc.6/29/2015TEI Biosciences Inc.6/26/2015Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.6/26/2015InSite Vision Incorporated6/8/2015Bio-Reference Laboratories Inc.6/3/2015	NeuroFix Therapeutics, LLC         9/9/2015         458.0           Scioderm, LLC         8/31/2015         869.5           Cytovance Biologics, Inc.         8/24/2015         205.7           GeneWEAVE Biosciences Inc.         8/13/2015         425.0           Therakos, Inc.         8/9/2015         1,325.0           Receptos, Inc.         7/14/2015         6,741.7           Baxalta Incorporated         7/10/2015         30,907.3           Audeo Oncology, Inc.         7/1/2015         16.0           CBR Systems, Inc.         6/29/2015         700.0           TEI Biosciences Inc.         6/26/2015         199.8           Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.         6/26/2015         11.0           InSite Vision Incorporated         6/8/2015         45.2           Bio-Reference Laboratories Inc.         6/3/2015         1,516.0	Target         Date         Size (EV)         Sales Est.           NeuroFix Therapeutics, LLC         9/9/2015         458.0         NA           Scioderm, LLC         8/31/2015         869.5         NA           Cytovance Biologics, Inc.         8/24/2015         205.7         NA           GeneWEAVE Biosciences Inc.         8/13/2015         425.0         NA           Therakos, Inc.         8/9/2015         1,325.0         174.0           Receptos, Inc.         7/14/2015         6,741.7         3.5           Baxalta Incorporated         7/10/2015         30,907.3         5,984.0           Audeo Oncology, Inc.         7/1/2015         16.0         NA           CBR Systems, Inc.         6/29/2015         700.0         121.8           TEI Biosciences Inc.         6/26/2015         199.8         64.4           Icagen, Inc. 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NeuroFix Therapeutics, LLC         9/9/2015         458.0         NA         NA           Scioderm, LLC         8/31/2015         869.5         NA         NA           Cytovance Biologics, Inc.         8/24/2015         205.7         NA         NA           GeneWEAVE Biosciences Inc.         8/13/2015         425.0         NA         NA           Therakos, Inc.         8/9/2015         1,325.0         174.0         NA           Receptos, Inc.         7/14/2015         6,741.7         3.5         (175.6)           Baxalta Incorporated         7/10/2015         30,907.3         5,984.0         2,178.0           Audeo Oncology, Inc.         7/11/2015         16.0         NA         NA           CBR Systems, Inc.         6/29/2015         700.0         121.8         24.2           TEI Biosciences Inc.         6/26/2015         199.8         64.4         20.6           Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.         6/8/2015         45.2         4.5         (11.1)           Bio-Reference Laboratories Inc.         6/3/2015         1,516.0         882.5         115.9	Target         Date         Size (EV)         Sales Est.         Est.         Sales           NeuroFix Therapeutics, LLC         9/9/2015         458.0         NA         NA         NA           Scioderm, LLC         8/31/2015         869.5         NA         NA         NA           Cytovance Biologics, Inc.         8/24/2015         205.7         NA         NA         NA           GeneWEAVE Biosciences Inc.         8/13/2015         425.0         NA         NA         NA           Therakos, Inc.         8/9/2015         1,325.0         174.0         NA         761x           Receptos, Inc.         7/14/2015         6,741.7         3.5         (175.6)         NM           Baxalta Incorporated         7/10/2015         30,907.3         5,984.0         2,178.0         5.17x           Audeo Oncology, Inc.         7/1/2015         16.0         NA         NA         NA           CBR Systems, Inc.         6/29/2015         700.0         121.8         24.2         5.75x           TEI Biosciences Inc.         6/26/2015         1199.8         64.4         20.6         3.10x           Icagen, Inc. Prior to Merger with XRpro Sciences, Inc.         6/8/2015         45.2         4.5         (11.1)

Only deals with available deal size information shown. | Data Source: Bloomberg and Capital IQ

## Medical Devices Select Transactions Summary (continued)

(\$Millions)

Acquirer	Target	Date	Est. Deal Size (EV)	Sales Est.	EBITDA Est.	EV / Sales	EV / EBITDA
Juno Therapeutics Inc.	X-BODY, Inc.	6/1/2015	42.8	NA	NA	NA	NA
NantPharma, LLC	IgDraSol Inc.	5/14/2015	1,290.1	NA	NA	NA	NA
Alexion Pharmaceuticals, Inc.	Synageva BioPharma Corp.	5/5/2015	8,245.0	5.8	(209.4)	NM	NM
PlasmaTech Biopharmaceuticals, Inc. (nka:Abeona Therapeutics Inc.)	Abeona Therapeutics LLC	5/5/2015	32.8	NA	NA	NA	NA
Celgene Corporation	Quanticel Pharmaceuticals, Inc.	4/27/2015	NA	NA	NA	NA	NA
Agenus Inc.	Celexion, LLC	4/7/2015	10.0	NA	NA	NA	NA
Fujifilm Medical Systems USA, Inc.	Cellular Dynamics International, Inc.	3/30/2015	254.7	16.7	(27.6)	15.26x	NM
Teva Pharmaceutical Industries Limited	Auspex Pharmaceuticals, Inc.	3/29/2015	3,340.9	NA	(50.2)	NA	NM
Horizon Pharma USA, Inc.	Hyperion Therapeutics, Inc.	3/29/2015	955.2	113.6	36.3	8.41x	26.3x
AbbVie Inc.	Pharmacyclics, Inc. (nka:Pharmacyclics LLC)	3/4/2015	19,063.4	816.1	112.8	23.36x	168.9x
Grifols, S.A.	Alkahest, Inc.	3/4/2015	78.8	NA	NA	NA	NA
Bristol-Myers Squibb Company	Flexus Biosciences, Inc.	2/23/2015	1,250.0	NA	NA	NA	NA
Vivione Biosciences, LLC	Trillium Diagnostics, LLC	1/26/2015	15.0	NA	NA	NA	NA
Abcam Plc	Firefly BioWorks, Inc.	1/21/2015	28.0	NA	NA	NA	NA

Only deals with available deal size information shown. | Data Source: Bloomberg and Capital IQ

## Medical Devices Select Transactions Summary (continued)

(\$Millions)

Acquirer	Target	Date	Est. Deal Size (EV)	Sales Est.	EBITDA Est.	EV / Sales	EV / EBITDA
Shire Pharmaceutical Holdings Ireland Limited	NPS Pharmaceuticals, Inc.	1/11/2015	4,862.3	224.1	8.4	21.70x	NM
Roche Holdings, Inc.	Foundation Medicine, Inc.	1/11/2015	1,596.7	61.1	(45.5)	26.14x	NM
Tekmira Pharmaceuticals Corporation (nka:Arbutus Biopharma Corporation)	OnCore Biopharma, Inc.	1/11/2015	391.2	NA	(5.1)	NA	NM
Amarantus Diagnostics, Inc.	DioGenix, Inc.	1/8/2015	14.3	0.2	(2.1)	62.43x	NM
Adaptive Biotechnologies Corporation	Sequenta, Inc.	1/7/2015	94.0	NA	NA	NA	NA
Merck & Co. Inc.	Cubist Pharmaceuticals Inc.	12/8/2014	8,404.1	1,164.5	203.5	7.22x	41.3x
Cocrystal Pharma, Inc.	RFS Pharma, LLC	11/25/2014	195.5	0.2	(2.4)	NM	NM
Valeant Pharmaceuticals International, Inc.	NicOx Inc.	11/17/2014	20.0	NA	NA	NA	NA
Research And Diagnostic Systems, Inc.	CyVek, Inc.	11/4/2014	110.0	NA	NA	NA	NA
Interpace Diagnostics, LLC	Interpace Diagnostics Corporation	10/31/2014	34.8	NA	NA	NA	NA
Actavis W.C. Holding Inc.	Durata Therapeutics, Inc.	10/5/2014	837.7	10.1	(63.4)	83.10x	NM
Janssen Pharmaceuticals, Inc.	Alios BioPharma, Inc.	9/30/2014	1,750.0	NA	NA	NA	NA

Only deals with available deal size information shown. | Data Source: Bloomberg and Capital IQ

# Select Operating Metrics

	Gross M	argin	EBITDA M	argin	Operating	Margin	R&D / Revenue		
Segment	3Q15	2Q15	3Q15	2Q15	3Q15	2Q15	3Q15	2Q15	
Large, Diversified	65.7%	65.6%	26.4%	26.4%	14.1%	15.6%	7.9%	8.1%	
IVD & Life Sciences	57.1%	56.5%	15.9%	15.1%	6.6%	5.4%	10.7%	10.9%	
Cardiovascular	67.2%	67.6%	16.4%	15.9%	11.2%	12.4%	12.3%	12.3%	
Ortho, Implants & Prosthetics	74.5%	73.7%	18.0%	18.0%	7.8%	7.8%	6.4%	6.4%	
Other	53.9%	53.6%	4.0%	4.1%	3.1%	5.5%	7.6%	7.6%	
All Companies	61.0%	61.3%	15.6%	15.2%	7.5%	7.4%	8.1%	8.1%	

	Historica Grow		LT Fwd Op Ea	rn Grwth	Debt /	EV	Debt / EBITDA		
Segment	Quarterly	Annual	3Q15	2Q15	3Q15	2Q15	3Q15	2Q15	
Large, Diversified	0.6%	3.4%	10.7%	9.7%	19.5%	15.3%	2.8	2.5	
IVD & Life Sciences	1.6%	4.5%	14.5%	12.5%	8.6%	4.2%	1.8	1.6	
Cardiovascular	1.8%	7.6%	15.1%	15.3%	4.1%	4.2%	0.0	0.0	
Ortho, Implants & Prosthetics	0.0%	5.5%	14.0%	14.0%	15.2%	15.4%	2.2	2.3	
Other	2.2%	3.9%	15.4%	15.5%	2.9%	2.4%	0.2	0.3	
All Companies	1.6%	4.8%	15.0%	14.8%	7.3%	6.1%	0.9	0.9	

Median measures for each group. | Data Source: Bloomberg

## **Public Medical Device Companies**

		Price		∆ Stoc	k Price	EV	TTM Rev	TTM EBITDA	FWD E	BITDA	EV / Sales	EV / EBITDA		V / Ebitda
	3Q15	2Q15	3Q14	Qtrly	Annual	3Q15	3Q15	3Q15	FY 15	FY 16	3Q15	3Q15	2015	2016
arge, Diversified														
Abbott Laboratories	\$40.22	\$48.77	\$41.05	-17.5%	-2.0%	\$57,647.6	\$20,527.0	\$4,739.0	\$5,559.3	\$6,050.3	2.81	12.2	10.4	9.5
Baxter	\$32.85	\$38.26	\$38.06	-14.1%	-13.7%	\$25,492.0	\$16,326.0	\$3,958.0	\$1,664.6	\$1,891.4	1.56	6.4	15.3	13.5
Becton, Dickinson and Company	\$132.66	\$141.16	\$112.42	-6.0%	18.0%	\$39,475.3	\$9,424.0	\$2,662.0	\$3,492.1	\$3,777.2	4.19	14.8	11.3	10.5
Boston Scientific Corporation	\$16.41	\$17.81	\$11.92	-7.9%	37.7%	\$26,263.3	\$7,344.0	\$1,858.0	\$2,285.1	\$2,494.7	3.58	14.1	11.5	10.5
Medtronic, Inc.	\$66.94	\$72.90	\$61.09	-8.2%	9.6%	\$112,204.4	\$23,262.0	\$6,535.0	\$10,850.5	\$11,503.2	4.82	17.2	10.3	9.8
Johnson & Johnson	\$93.35	\$96.94	\$103.56	-3.7%	-9.9%	\$243,849.1	\$71,882.0	\$23,498.0	\$25,327.4	\$26,878.1	3.39	10.4	9.6	9.1
Stryker Corporation	\$94.10	\$95.02	\$80.34	-1.0%	17.1%	\$34,626.1	\$9,818.0	\$2,588.0	\$2,887.2	\$3,108.7	3.53	13.4	12.0	11.1
/D & Life Sciences														
Affymetrix, Inc.	\$8.54	\$10.70	\$7.98	-20.2%	7.0%	\$688.0	\$358.3	\$54.2	\$64.6	\$74.4	1.92	12.7	10.7	9.2
Bio-Rad Laboratories, Inc.	\$134.31	\$150.25	\$115.36	-10.6%	16.4%	\$3,617.2	\$2,107.8	\$349.9	\$317.0	\$312.0	1.72	10.3	11.4	11.6
Bruker Corporation	\$16.43	\$20.37	\$18.89	-19.3%	-13.0%	\$2,640.3	\$1,677.3	\$212.2	\$258.7	\$288.4	1.57	12.4	10.2	9.2
Enzo Biochem, Inc.	\$3.17	\$2.94	\$5.18	7.8%	-38.8%	\$134.6	\$96.8	\$0.0	(\$9.4)	na	1.39	nm	nm	nm
GenMark Diagnostics, Inc.	\$7.87	\$9.10	\$9.08	-13.5%	-13.3%	\$280.7	\$33.9	(\$37.8)	(\$44.9)	(\$30.6)	8.29	nm	nm	nm
Haemonetics Corporation	\$32.32	\$41.34	\$34.81	-21.8%	-7.2%	\$1,964.3	\$899.3	\$198.0	\$228.0	\$230.5	2.18	9.9	8.6	8.5
Hologic, Inc.	\$39.13	\$37.63	\$24.49	4.0%	59.8%	\$14,084.2	\$2,662.8	\$971.2	\$1,066.3	\$1,174.8	5.29	14.5	13.2	12.0
Illumina, Inc.	\$175.82	\$213.98	\$165.22	-17.8%	6.4%	\$25,234.0	\$2,071.0	\$716.7	\$915.2	\$1,088.5	12.18	35.2	27.6	23.2
Luminex Corporation	\$16.91	\$17.22	\$19.42	-1.8%	-12.9%	\$606.9	\$231.4	\$54.9	\$53.3	\$53.1	2.62	11.1	11.4	11.4
OraSure Technology	\$4.44	\$5.41	\$7.42	-17.9%	-40.2%	\$159.4	\$114.0	\$6.8	\$12.9	na	1.40	23.4	12.4	nm
Quidel Coporation	\$18.88	\$22.85	\$26.93	-17.4%	-29.9%	\$573.7	\$200.6	\$34.1	\$45.5	\$56.0	2.86	16.8	12.6	10.2
TECHNE Corporation	\$92.46	\$97.83	\$92.54	-5.5%	-0.1%	\$3,403.6	\$452.2	\$188.8	\$215.5	\$231.0	7.53	18.0	15.8	14.7
Trinity Biotech	\$11.44	\$18.02	\$18.34	-36.5%	-37.6%	\$262.6	\$103.3	\$0.0	\$23.7	\$29.0	2.54	nm	11.1	9.1
Vermillion, Inc.	\$2.00	\$2.08	\$1.83	-3.8%	9.3%	\$93.1	\$3.4	(\$9.0)	na	na	27.55	nm	nm	nm
Vermillion, Inc.	\$1.77	\$1.93	\$3.00	-8.3%	-41.0%	\$59.1	\$3.2	(\$4.2)	na	na	18.65	nm	nm	nm

(\$Millions, except per share figures)

		Price		∆ Stoc	k Price	EV	TTM Rev	TTM EBITDA	FWD E	BITDA	EV / Sales	EV / EBITDA		V / Ebitda
	3Q15	2Q15	3Q14	Qtrly	Annual	3Q15	3Q15	3Q15	FY 15	FY 16	3Q15	3Q15	2015	2016
Cardiovascular														
ABIOMED, Inc.	\$92.76	\$65.33	\$25.03	42.0%	270.6%	\$3,744.5	\$254.9	\$48.0	\$81.3	\$112.7	14.69	77.9	46.1	33.2
CR Bard Inc.	\$186.31	\$170.71	\$142.61	9.1%	30.6%	\$14,125.6	\$3,376.7	\$1,054.8	\$1,094.4	\$1,191.6	4.18	13.4	12.9	11.9
CardioNet Inc.	\$12.24	\$9.29	\$6.77	31.8%	80.8%	\$341.5	\$175.0	\$26.9	\$39.7	\$51.4	1.95	12.7	8.6	6.6
Cardiovascular Systems, Inc.	\$15.84	\$26.56	\$25.14	-40.4%	-37.0%	\$428.8	\$181.5	(\$30.3)	\$6.3	na	2.36	nm	68.1	nm
CryoLife, Inc.	\$9.73	\$11.13	\$10.08	-12.5%	-3.5%	\$253.4	\$143.6	\$12.5	\$17.7	na	1.77	20.3	14.3	nm
Cyberonics, Inc.	\$60.78	\$59.61	\$52.82	2.0%	15.1%	\$1,411.0	\$300.6	\$111.4	\$133.0	na	4.69	12.7	10.6	nm
Edwards Lifesciences Corporation	\$142.17	\$142.35	\$103.17	-0.1%	37.8%	\$14,476.8	\$2,432.5	\$663.3	\$747.3	\$855.2	5.95	21.8	19.4	16.9
Greatbatch, Inc.	\$56.42	\$53.54	\$43.22	5.4%	30.5%	\$1,552.0	\$677.6	\$117.8	\$154.0	na	2.29	13.2	10.1	nm
HeartWare International, Inc.	\$52.31	\$72.96	\$79.43	-28.3%	-34.1%	\$840.8	\$285.4	(\$8.6)	\$3.0	\$14.4	2.95	nm	277.3	58.6
LeMaitre Vascular, Inc.	\$12.19	\$11.50	\$6.60	6.0%	84.7%	\$196.6	\$75.0	\$6.8	\$15.6	\$18.2	2.62	29.0	12.6	10.8
Merit Medical Systems, Inc.	\$23.91	\$21.12	\$12.00	13.2%	99.3%	\$1,253.6	\$529.2	\$86.8	\$95.3	\$103.5	2.37	14.4	13.2	12.1
St. Jude Medical, Inc.	\$63.09	\$72.52	\$60.12	-13.0%	4.9%	\$20,606.3	\$5,566.0	\$1,695.0	\$1,825.4	\$1,969.2	3.70	12.2	11.3	10.5
The Spectranetics Corporation	\$11.79	\$23.75	\$26.64	-50.4%	-55.7%	\$700.3	\$240.8	(\$6.9)	(\$8.2)	\$5.4	2.91	nm	nm	129.8
Thoratec Corp	\$63.26	\$44.41	\$27.41	42.4%	130.8%	\$3,192.0	\$483.8	\$69.5	\$135.0	\$157.5	6.60	46.0	23.6	20.3
Vascular Solutions, Inc.	\$32.41	\$34.24	\$24.67	-5.3%	31.4%	\$525.6	\$137.7	\$32.6	\$33.6	na	3.82	16.1	15.7	nm
Vascular Solutions, Inc.	\$30.32	\$27.35	\$25.57	10.9%	18.6%	\$489.3	\$130.8	\$29.8	\$27.6	\$33.6	3.74	16.4	17.7	14.6

(\$Millions, except per share figures)

#### ттм EV / EV / EV / Price **∆ Stock Price** E٧ TTM Rev EBITDA FWD EBITDA EBITDA **FWD EBITDA** Sales 3Q15 2Q15 3Q14 3Q15 3Q15 3Q15 FY 15 **FY 16** 2015 Qtrly Annual 3Q15 3Q15 2016 **Ortho, Implants and Prosthetics** Alphatech Holdings -80.8% \$104.0 \$21.3 0.52 \$0.33 \$1.38 \$1.72 -76.1% \$199.9 \$33.5 na 4.9 3.1 nm \$43.8 Exactech, Inc. \$17.43 \$20.89 \$23.77 -16.6% -26.7% \$251.9 \$244.1 \$48.4 \$51.1 1.03 5.7 5.2 4.9 Globus Medical, Inc. \$20.66 \$25.58 \$19.64 -19.2% 5.2% \$1,682.9 \$511.8 \$175.2 \$201.7 \$218.4 3.29 9.6 8.3 7.7 Intergra LifeSciences Holdings \$59.55 \$60.99 \$45.31 -2.4% 31.4% \$2,694.2 \$959.6 \$198.4 \$240.0 \$272.0 2.81 13.6 11.2 9.9 NuVasive, Inc. \$48.22 37.7% \$2,429.6 \$789.5 \$167.7 \$217.2 \$247.1 \$47.60 \$35.02 1.3% 3.08 14.5 11.2 9.8 Orthofix International N.V. 8.2 \$33.75 \$32.95 \$31.13 2.4% 8.4% \$580.3 \$392.0 \$42.1 \$71.1 \$78.7 1.48 13.8 7.4 RTI Surgical Inc. \$5.68 \$6.24 \$5.06 -9.0% 12.3% \$442.2 \$275.7 \$37.8 \$49.7 \$49.5 1.60 11.7 8.9 8.9 Wright Medical Group, Inc. \$20.39 \$24.80 \$24.12 -17.8% -15.5% \$1,064.2 \$340.4 \$30.4 \$17.8 \$48.4 3.13 35.0 59.8 22.0 Zimmer Holdings, Inc. \$93.93 \$109.04 \$100.64 -13.9% -6.7% \$29,270.1 \$4,630.9 \$1,916.2 \$3,038.6 \$3,232.2 6.32 15.3 9.6 9.1 Wright Medical Group, Inc. \$1,409.1 \$25.80 \$27.11 \$30.51 -4.8% -15.4% \$304.9 \$0.9 (\$25.4) \$0.3 4.62 1,501.1 4,909.8 nm Zimmer Holdings, Inc. \$114.13 2.8% 26.4% \$19,760.3 \$4,646.2 \$1,848.4 \$2,404.6 \$3,029.9 10.7 8.2 \$117.29 \$92.78 4.25 6.5

## Public Medical Device Companies (continued)

(\$Millions, except per share figures)

		Price		∆ Stoc	k Price	EV	TTM Rev	TTM EBITDA	FWD E	BITDA	EV / Sales	EV / EBITDA		EV / Ebitda
-	3Q15	2Q15	3Q14	Qtrly	Annual	3Q15	3Q15	3Q15	FY 15	FY 16	3Q15	3Q15	2015	2016
Cosmetics														
Cutera, Inc.	\$13.08	\$15.98	\$10.26	-18.1%	27.5%	\$118.6	\$85.9	(\$6.9)	\$2.8	\$4.7	1.38	nm	42.0	25.2
Cynosure, Inc.	\$30.04	\$38.51	\$21.43	-22.0%	40.2%	\$553.9	\$316.4	\$50.0	\$64.3	\$84.6	1.75	11.1	8.6	6.5
PhotoMedex, Inc.	\$0.52	\$1.47	\$6.44	-64.6%	-91.9%	\$8.4	\$140.7	(\$10.4)	na	na	0.06	nm	nm	nm
Dental														
Align Technology, Inc.	\$56.76	\$61.65	\$53.12	-7.9%	6.9%	\$3,948.5	\$796.1	\$211.7	\$249.9	\$316.0	4.96	18.7	15.8	12.5
DENTSPLY International	\$50.57	\$51.26	\$45.65	-1.3%	10.8%	\$8,172.5	\$2,781.6	\$586.0	\$684.3	\$694.3	2.94	13.9	11.9	11.8
Sirona Dental Systems, Inc.	\$93.34	\$100.05	\$76.83	-6.7%	21.5%	\$4,874.1	\$1,146.4	\$325.2	\$370.6	\$391.4	4.25	15.0	13.2	12.5
Obesity Treatment														
EnteroMedics Inc.	\$0.26	\$0.97	\$1.23	-73.2%	-78.9%	\$23.9	\$0.1	(\$25.8)	(\$23.3)	(\$13.0)	302.08	nm	nm	nm
ZELTIQ Aesthetics, Inc.	\$32.03	\$29.79	\$23.30	7.5%	37.5%	\$1,193.0	\$212.4	\$8.5	\$37.6	\$66.2	5.62	140.6	31.8	18.0
Pediatric Medical Devices														
Natus Medical Incorporated	\$39.45	\$42.06	\$29.18	-6.2%	35.2%	\$1,232.0	\$365.2	\$71.8	\$87.1	\$99.4	3.37	17.2	14.1	12.4
Surgery and Life Support Devices														
AtriCure	\$21.91	\$24.09	\$14.66	-9.0%	49.5%	\$570.8	\$118.6	(\$14.8)	(\$11.8)	(\$5.3)	4.81	nm	nm	nm
Intuitive Surgical, Inc.	\$459.58	\$483.78	\$464.72	-5.0%	-1.1%	\$15,451.7	\$2,273.0	\$750.1	\$974.3	\$1,062.8	6.80	20.6	15.9	14.5
Misonix, Inc.	\$10.73	\$9.75	\$12.16	10.1%	-11.8%	\$73.5	\$22.2	(\$0.3)	na	na	3.31	nm	nm	nm
NxStage Medical, Inc.	\$15.77	\$14.49	\$13.10	8.8%	20.4%	\$974.8	\$315.0	\$8.4	\$22.6	\$42.0	3.09	116.3	43.1	23.2
Stereotaxis, Inc.	\$0.93	\$1.46	\$2.45	-36.4%	-62.1%	\$34.4	\$37.8	(\$3.4)	na	na	0.91	nm	nm	nm
SurModics Inc.	\$21.84	\$23.34	\$18.71	-6.4%	16.7%	\$228.3	\$59.9	\$22.3	\$21.3	na	3.81	10.2	10.7	nm
Synergetics USA, Inc.	\$6.57	\$4.69	\$3.39	40.1%	93.8%	\$160.2	\$72.2	\$8.7	\$9.9	na	2.22	18.4	16.1	nm
Teleflex, Inc.	\$124.21	\$134.75	\$105.36	-7.8%	17.9%	\$5,961.7	\$1,814.7	\$414.9	\$541.7	\$603.5	3.29	14.4	11.0	9.9
Teleflex, Inc.	\$120.19	\$115.28	\$103.82	4.3%	15.8%	\$5,805.6	\$1,830.7	\$422.2	\$498.3	\$568.3	3.17	13.8	11.7	10.2

(\$Millions, except per share figures)

		Price		∆ Stoc	k Price	EV	TTM Rev	TTM EBITDA	FWD E	BITDA	EV / Sales	EV / EBITDA		:V / EBITDA
-	3Q15	2Q15	3Q14	Qtrly	Annual	3Q15	3Q15	3Q15	FY 15	FY 16	3Q15	3Q15	2015	2016
General Hospital Devices and Supp	olies													
CONMED Corporation	\$47.74	\$57.60	\$37.23	-17.1%	28.2%	\$1,520.0	\$728.9	\$121.0	\$143.2	\$154.4	2.09	12.6	10.6	9.8
Digirad Corporation	\$3.74	\$4.23	\$3.77	-11.5%	-0.8%	\$50.7	\$57.4	\$3.7	\$6.7	\$7.2	0.88	13.7	7.6	7.1
Dynatronics Corporation	\$3.10	\$3.23	\$4.02	-4.0%	-22.9%	\$13.7	\$29.1	(\$0.2)	na	na	0.47	nm	nm	nm
FONAR Corporation	\$13.41	\$10.50	\$11.20	27.7%	19.8%	\$83.3	\$69.1	\$12.4	na	na	1.21	6.7	nm	nm
Intuitive Surgical, Inc.	\$459.58	\$483.78	\$464.72	-5.0%	-1.1%	\$15,451.7	\$2,273.0	\$750.1	\$974.3	\$1,062.8	6.80	20.6	15.9	14.5
Masimo Corporation	\$38.56	\$38.55	\$21.07	0.0%	83.0%	\$2,024.9	\$616.2	\$122.2	\$114.1	\$160.0	3.29	16.6	17.8	12.7
Opko Health, Inc.	\$8.41	\$15.49	\$8.64	-45.7%	-2.7%	\$4,437.5	\$117.8	(\$143.5)	\$68.5	\$310.3	37.66	nm	64.8	14.3
STERIS Corporation	\$64.97	\$64.23	\$53.72	1.1%	20.9%	\$4,384.9	\$1,877.5	\$366.4	\$441.0	na	2.34	12.0	9.9	nm
Varian Medical Systems, Inc.	\$73.78	\$83.60	\$81.20	-11.7%	-9.1%	\$6,769.0	\$3,093.4	\$660.2	\$686.4	\$725.2	2.19	10.3	9.9	9.3
Home Health and Consumer Device	es													
Invacare Corporation	\$14.47	\$22.02	\$12.24	-34.3%	18.2%	\$495.8	\$1,214.0	\$1.9	\$33.6	na	0.41	265.8	14.8	nm
Mine Safety Appliances Company	\$39.97	\$48.52	\$49.15	-17.6%	-18.7%	\$1,681.7	\$1,133.2	\$183.4	\$208.8	na	1.48	9.2	8.1	nm
ResMed Inc.	\$50.96	\$55.14	\$48.97	-7.6%	4.1%	\$6,744.1	\$1,678.9	\$493.3	\$591.0	\$648.3	4.02	13.7	11.4	10.4
Span-America Medical Systems, Inc.	\$17.25	\$18.20	\$17.45	-5.2%	-1.2%	\$45.4	\$59.6	\$4.5	na	na	0.76	10.1	nm	nm
Syneron Medical Ltd.	\$7.15	\$10.79	\$10.39	-33.7%	-31.2%	\$170.5	\$271.2	\$11.5	\$38.3	na	0.63	14.9	4.5	nm

(\$Millions, except per share figures)

\$122.28 \$129.29 \$121.42

-5.4%

0.7%

		Price		∆ Stoc	k Price	EV	TTM Rev	TTM EBITDA	FWD E	BITDA	EV / Sales	EV / EBITDA		V / EBITDA
-	3Q15	2Q15	3Q14	Qtrly	Annual	3Q15	3Q15	3Q15	FY 15	FY 16	3Q15	3Q15	2015	2016
Other Medical Device														
Accuray Incorporated	\$5.00	\$6.60	\$7.40	-24.3%	-32.5%	\$457.3	\$379.8	\$0.3	\$36.3	\$45.0	1.20	nm	12.6	10.2
Allied Healthcare Products, Inc.	\$1.15	\$1.47	\$2.00	-21.8%	-42.5%	\$7.2	\$35.5	(\$0.4)	na	na	0.20	nm	nm	nm
Arrhythmia Research Technology, Inc.	\$6.24	\$6.37	\$6.99	-2.0%	-10.7%	\$21.9	\$23.3	\$0.7	na	na	0.94	30.9	nm	nm
Dehaier Medical Systems Limited	\$1.41	\$2.65	\$5.01	-46.8%	-71.8%	na	\$8.3	\$0.0	na	na	nm	nm	nm	nm
Escalon Medical Corp.	\$1.16	\$1.42	\$1.48	-18.3%	-21.6%	\$7.2	\$13.1	(\$1.0)	na	na	0.55	nm	nm	nm
Hansen Medical, Inc.	\$3.76	\$8.80	\$11.90	-57.3%	-68.4%	\$63.8	\$17.8	(\$38.8)	(\$42.6)	na	3.59	nm	nm	nm
IRIDEX Corporation	\$7.61	\$8.29	\$7.12	-8.2%	6.9%	\$63.9	\$41.7	(\$0.1)	na	na	1.53	nm	nm	nm
Navidea Biopharmaceuticals, Inc.	\$2.28	\$1.63	\$1.33	39.9%	71.4%	\$387.4	\$9.4	(\$20.9)	na	na	41.11	nm	nm	nm
ThermoGenesis Corp.	\$0.53	\$0.84	\$1.18	-37.2%	-55.1%	\$18.2	\$16.0	(\$10.9)	na	na	1.13	nm	nm	nm
Congentix Medical, Inc.	\$1.24	\$1.68	\$4.82	-26.2%	-74.3%	\$49.3	\$27.2	(\$6.1)	na	na	1.81	nm	nm	nm
Other Diversified Cos with Med-Tec	h Compon	ents												
Agilent Technologies, Inc.	\$34.33	\$38.63	\$40.45	-11.1%	-15.1%	\$10,960.1	\$4,808.0	\$1,102.0	\$977.3	\$1,074.9	2.28	9.9	11.2	10.2
Danaher Corporation	\$85.21	\$84.61	\$75.34	0.7%	13.1%	\$58,131.6	\$20,287.9	\$4,514.4	\$5,568.1	\$6,027.9	2.87	12.9	10.4	9.6
General Electric	\$25.22	\$26.40	\$24.52	-4.5%	2.8%	\$266,919.9	\$139,122.0	\$24,000.0	\$23,192.5	\$25,268.0	1.92	11.1	11.5	10.6
PerkinElmer, Inc.	\$45.96	\$52.76	\$43.73	-12.9%	5.1%	\$6,005.7	\$2,241.2	\$360.7	\$501.8	\$521.8	2.68	16.6	12.0	11.5

\$61,980.2

\$16,853.9

\$4,109.6

\$4,520.8 \$4,865.9

3.68

15.1

13.7

(\$Millions, except per share figures)

Thermo Fisher Scientific Inc.

Data Source: Bloomberg

12.7

## SPECIAL SUPPLEMENT

# Five Trends to Watch in the Medical

**Device Industry** 

by Sujan Rajbhandary, CFA sujanr@mercercapital.com

The medical device manufacturing industry in the U.S. produces a range of products designed to diagnose and treat patients. Medical devices range in nature and complexity from simple tongue depressors and bandages to complex programmable pacemakers and sophisticated imaging systems. The medical device industry includes a variety of primary products, including surgical instruments, medical supplies, electro-medical equipment, in-vitro diagnostic equipment and reagents, irradiation apparatuses, and dental goods.

## **Medical Device Overview**

Although medical devices are essential healthcare products, the recession hurt industry profitability considerably, as industry revenue plunged 25.6% in 2009. Medical device end-users struggled to raise capital for large assets and delayed the purchase of the industry's premium and larger devices. However, the economy has improved, increasing demand for medical devices in the years since the recession. According to estimates, industry revenue has grown an annualized 3.6% since 2009. Revenue in the industry grew 6.7% in 2014 to total \$37.6 billion, and is expected to increase at an average of 7.1% per year to \$52.9 billion by 2019.<sup>1</sup>

The following outlines five structural factors and trends that have, and will likely continue to influence demand and supply of medical devices and related procedures.

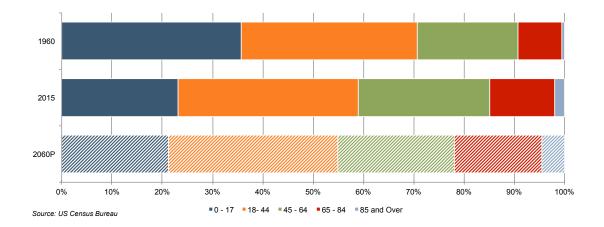
## Demographics

Besides general economic growth, the aging population represents a major demand driver for medical devices. The elderly population (persons 65 and above) in the United States, approximately 48 million in 2015, accounted for about one third of total healthcare consumption. The Census Bureau estimates that the elderly will number 92 million by 2060, approximately 22% of the total population.

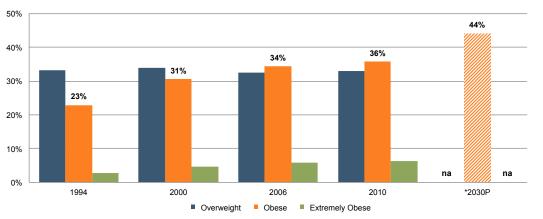
According to United Nations projections, the global population of elderly people will triple by 2050, growing from 500 million in 2010 to 1.5 billion by 2050 (16% of projected total global population). In addition to the greying population, the prevalence of unmet medical needs and increasing incidence of lifestyle diseases (see the chart "US Adult Obesity Rates" on the following page) are likely to drive continued growth in the demand for medical devices.

## Mercer Capital's Value Focus: Medical Device Industry

## SPECIAL SUPPLEMENT



#### US Population Distribution by Age Group



#### **US Adult Obesity Rates**

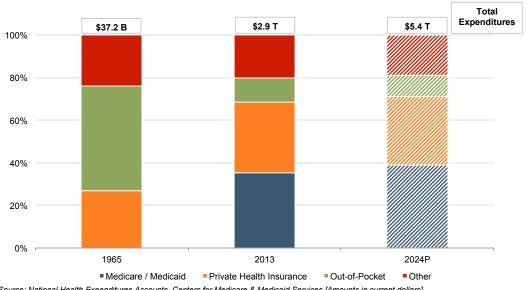
Source: Centers for Disease Control and Prevention; Trust for America's Health, Robert Wood Johnson Foundation Mercer Capital Analysis

## SPECIAL SUPPLEMENT

## **2** Legislative Landscape in the U.S.

Since inception, Medicare has accounted for an increasing proportion of total US healthcare expenditures. Medicare currently provides healthcare benefits for an estimated 55 million elderly and disabled Americans, constituting an estimated 14% of the federal budget in 2014. Medicare accounted for 22% of total health spending in 2013, 26% of hospital spending, and 22% of physician services.<sup>2</sup>

Owing to the growing influence of Medicare in aggregate healthcare consumption, legislative developments can have a potentially outsized effect on the demand and pricing for medical products and services. Benefits to the four parts of Medicare totaled \$597 billion in 2014, and Medicare spending is expected to reach \$826 billion by 2020.3



#### Health Consumption Expenditures // Payor Mix

Source: National Health Expenditures Accounts, Centers for Medicare & Medicaid Services [Amounts in current dollars]

The Patient Protection and Affordable Care Act ("ACA") of 2010 incorporated changes that are expected to constrain annual growth in Medicare spending over the next decade and beyond by curtailing increases in Medicare payments to healthcare providers, and establishing several new policies and programs designed to reduce costs. On a per person basis, Medicare spending is projected to grow at 4.1% annually between 2014 and 2024, compared to 7.0% growth from 2000 to 2010. <sup>4</sup>

As part of ACA legislation, a 2.3% excise tax was imposed on the sale of certain medical devices by device manufacturers, producers, or importers. The 2.3% levy is expected to net nearly \$30 billion over a decade into the early 2020s. The tax became effective on December 31, 2012, and has met resistance from industry participants and policy makers. In July of 2015, the U.S. House of Representatives voted to repeal the medical device tax. The repeal will be next heard in the U.S. Senate, which is expected to vote on the measure by 2015 year end. <sup>5, 6</sup>

## **3** Third-Party Coverage and Reimbursement

Third-party payors (both private and government programs) are keen to reevaluate their payment policies to constrain rising healthcare costs. Several elements of the ACA are expected to limit reimbursement growth for hospitals, which form the largest market for medical devices. Lower reimbursement growth will likely persuade hospitals to scrutinize medical purchases by adopting i) higher standards to evaluate the benefits of new procedures and devices, and ii) a more disciplined price bargaining stance.

The transition of the healthcare delivery paradigm from fee-for-service models to value models is expected to lead to fewer hospital admissions and procedures. In January 2015, the Department of Health and Human Services (HHS) announced that by 2016 it aims to have 85% of provider payments under a value-based system as opposed to the traditional fee-for-service system. Ultimately, lower reimbursement rates will likely limit pricing gains for medical devices and equipment.

Similar reimbursement issues face the medical device industry globally. A number of countries have instituted price ceilings on certain medical procedures, which could deflate the reimbursement rates of third-party payors, forcing down industry product prices. Whether third-party payors consider certain devices as medically reasonable or necessary for operations presents a hurdle that device makers and manufacturers must overcome in bringing their devices to market.

## 4 Competitive Factors and Regulatory Regime

Historically, much of the growth for medical technology companies has been predicated on continual product innovations that make devices easier for doctors to use and improve health outcomes for the patients. Successful product development usually requires significant R&D outlays and a measure of luck. However, viable new devices can elevate average selling prices, market penetration, and market share.

Government regulations curb competition in two ways to foster an environment where firms may realize an acceptable level of returns on their R&D investments. First, firms that are first to the market with a new product can benefit from patents and intellectual property protection giving them a competitive advantage for a finite period. Second, regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotions, sales and distribution, export and import, and post market surveillance.

#### **Regulatory Regime in the U.S.**

In the U.S., the FDA generally oversees the implementation of the second set of regulations. Some relatively simple devices deemed to pose low risk are exempt from the FDA's clearance requirement and can be marketed in the U.S. without prior authorization. For the remaining devices, commercial distribution requires marketing authorization from the FDA, which comes in primarily two flavors.

- » The premarket notification ("510(k) clearance") process requires the manufacturer to demonstrate that a device is "substantially equivalent" to an existing device that is legally marketed in the U.S. The 510(k) clearance process may occasionally require clinical data, and generally takes between 90 days and one year for completion.
- The premarket approval ("PMA") process is more stringent, time-consuming and expensive. A PMA application must be supported by valid scientific evidence, which typically entails collection of extensive technical, preclinical, clinical and manufacturing data. Once the PMA is submitted and found to be complete, the FDA begins an in-depth review, which is required by statute to take no longer than 180 days. However, the process typically takes significantly longer, and may require several years to complete.

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#### **Regulatory Overview in Europe**

The European Union (EU), along with countries such as Japan, Canada, and Australia all operate strict regulatory regimes similar to that of the U.S. FDA, and international consensus is moving towards more stringent regulations. Stricter regulations for new devices may slow release dates and may negatively affect companies within the industry.

Medical device manufacturers face a single regulatory body across the EU, the Company's second largest end market behind the U.S. In order for a medical device to be allowed on the market, it must meet the requirements set by the EU Medical Devices Directive. Devices must receive a Conformité Européenne (CE) Mark certificate before they are allowed to be sold on the market. This CE marking verifies that a device meets all regulatory requirements for the EU, and that they meet EU safety standards. A set of different directives apply to different types of devices, and the device must be compliant with the directive that purviews it.<sup>7</sup>

### **5** Emerging Global Markets

Global medical devices sales were estimated to total over \$360 billion in 2014. The industry is expected to expand approximately 3% annually through 2018, reaching \$427 billion. The United States is the largest medical device market in the world, accounting for approximately 40% of global revenue.

Emerging economies are claiming a growing share of global healthcare consumption, including medical devices and related procedures, owing to relative economic prosperity, growing medical awareness, and increasing (and increasingly aging) populations. Sales to countries outside the U.S., including emerging economies, represent a potential avenue for growth for domestic medical device companies.

	% of GDP	Per Capita	Growth, Ann.	2012 Payor Mix	
	2012	2012	2005-12	Gov't	Private
Region <sup>1</sup>					
United States	18%	\$8,895	4%	46%	54%
Africa	6%	\$147	7%	52%	48%
Americas ex US	7%	\$733	10%	58%	42%
Eastern Mediterranean	5%	\$525	9%	53%	47%
Europe	8%	\$2,349	5%	67%	33%
South-East Asia	4%	\$129	11%	50%	50%
West Pacific	7%	\$982	8%	72%	28%
Select Countries					
Australia	9%	\$6,014	10%	66%	34%
Brazil	9%	\$1,056	15%	46%	54%
Canada	11%	\$5,741	8%	70%	30%
China	5%	\$322	22%	56%	44%
France	12%	\$4,690	3%	77%	23%
Germany	11%	\$4,683	4%	76%	24%
India	4%	\$61	10%	33%	67%
Israel	8%	\$2,289	6%	62%	38%
Japan	10%	\$4,752	7%	82%	18%
Mexico	6%	\$618	4%	52%	48%
Norway	9%	\$9,055	5%	85%	15%
Republic of Korea	8%	\$1,703	8%	54%	46%
Russian Federation	6%	\$887	18%	61%	39%
Singapore	5%	\$2,426	13%	38%	62%
United Kingdom	9%	\$3,647	2%	83%	17%

#### **Global Healthcare Expenditures**

<sup>1</sup> Expenditures (US Dollars) and share statistics shown are averages for the regions. Growth rates are medians for the regions

Data Source: Global Health Expenditures Database, World Health

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#### Summary

Demographic shifts underlie the long-term market opportunity for medical device manufacturers. While efforts to control costs on the part of the government insurer in the U.S. may limit future pricing growth for incumbent products, a growing global market provides domestic device manufacturers with an opportunity to broaden and diversify their geographic revenue base. Developing new products and procedures is risky and usually more resource intensive compared to some other growth sectors of the economy. However, barriers to entry in the form of existing regulations provide a measure of relief from competition, especially for newly developed products.

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