

## BIODESIGN GLOBAL SOURCEBOOK: INDIA OVERVIEW

Although small, India's medical device market is piquing investor interest. Global medical device companies now rank India among the top three emerging markets for direct investment.<sup>1</sup> Strong market growth, a rising middle class, expanding health insurance coverage, improving healthcare infrastructure, and better venture funding are among the factors enhancing the environment for med-tech investment and innovation in India.

This chapter provides an overview of the Indian healthcare system, the emerging medical device sector, and the potential for med-tech innovation in the country. It also summarizes the contents of the other chapters on India in this unit. (See Figure 1 for a map of India.)

### TOPICS

- Introduction
- Health System Overview
  - Health Trends
  - Healthcare Delivery
  - Healthcare Financing
- Medical Device Industry
- Innovation Potential
  - Funding Sources
- India Module Chapter Contents
- Endnotes

### HEALTH SYSTEM OVERVIEW

#### Health Trends

Leading health indicators in India continue to lag international averages. The average life expectancy of Indians at birth only reached 65 years in 2009, compared to the global average of 68 years. India also has some of the highest infant mortality and maternal mortality rates in the world, 44 per 1,000 births and two per 1,000 births respectively in 2012.<sup>2</sup>

At the same time, the prevalence of diseases linked to greater urbanization is growing. India's disease profile is traditionally associated with communicable diseases, such as malaria and

---

This chapter was prepared by Ritu Kamal and edited by Pamela Yatsko as part of a multi-chapter global series for use in Stanford University's Program in Biodesign. These papers can be used individually or as a set. References to other related chapters may refer to the Biodesign Textbook or others in this series.

*Copyright © 2013 by the Board of Trustees of the Leland Stanford Junior University. All rights reserved. To order copies or request permission to reproduce materials, e-mail the Stanford Biodesign Program. No part of this publication may be reproduced, stored in a retrieval system, used in a spreadsheet, or transmitted in any form or by any means — electronic, mechanical, photocopying, recording, or otherwise — without the permission of the Stanford Biodesign Program.*

tuberculosis, or tropical diseases, such as Japanese encephalitis and dengue fever. However, coronary heart disease, diabetes, asthma, and other chronic non-communicable diseases are on the uptick. Analysts predict some 60 percent of the world's heart patients will live in India by 2020.<sup>3</sup> While these trends pose challenges for the country's healthcare system, they also present significant opportunities for medical device companies.

**Figure 1 Map of India**



## Healthcare Delivery

Over the last half century, India's public sector has steadily given up market share to the private sector in providing healthcare to Indians. Less than 10 percent of care is delivered in public facilities. As of 2001, the private sector accounted for over 90 percent of all hospitals, 85 percent of doctors, 80 percent of outpatient care, and 60 percent of inpatient care.<sup>4</sup> Private health systems have basic clinics, multispecialty clinics (nursing homes), hospitals, and hospital chains. Public healthcare facilities are divided into primary health centers, district-level hospitals, and tertiary hospitals.

Vast disparities in the quality and availability of care characterize India's healthcare system. State-of-the-art Indian secondary and tertiary care institutions attract both domestic patients who can afford their world-class services and roughly half a million medical tourists each year.<sup>5</sup> However, healthcare facilities without adequate supplies, staff, or capacity to provide affordable care are responsible for serving most of the population. A significant percentage of existing infrastructure, both public and private, is non-functioning at any given time.<sup>6</sup> In rural settings, where the penetration of healthcare facilities has been low, patients often resort to traditional healers for healthcare.<sup>7</sup> These circumstances have deterred use of medical devices beyond those that are very basic and low cost. Disparities also exist between geographic regions. Southern states, such as Tamil Nadu and Karnataka, have far better infrastructure than Uttar Pradesh, Bihar, and other northern states.<sup>8</sup>

The good news is that India's economic growth story is propelling improvements in healthcare infrastructure. Corporate hospitals chains, such as Apollo and Fortis, are investing in cities outside major metropolitan areas and driving 15 percent annual growth in the hospital sector.<sup>9</sup>

## Healthcare Financing

Low spending levels plague India's healthcare system. Healthcare expenditure per capita was only US\$56 in India in 2010 compared to US\$208 in China and US\$964 in Brazil that same year.<sup>10</sup> Although the government plans to boost its healthcare outlays going forward, it only accounts for some 25 percent of total healthcare spending in India.<sup>11</sup> Individuals and institutions contribute the remainder, making India's healthcare system one of the world's most privatized.<sup>12</sup>

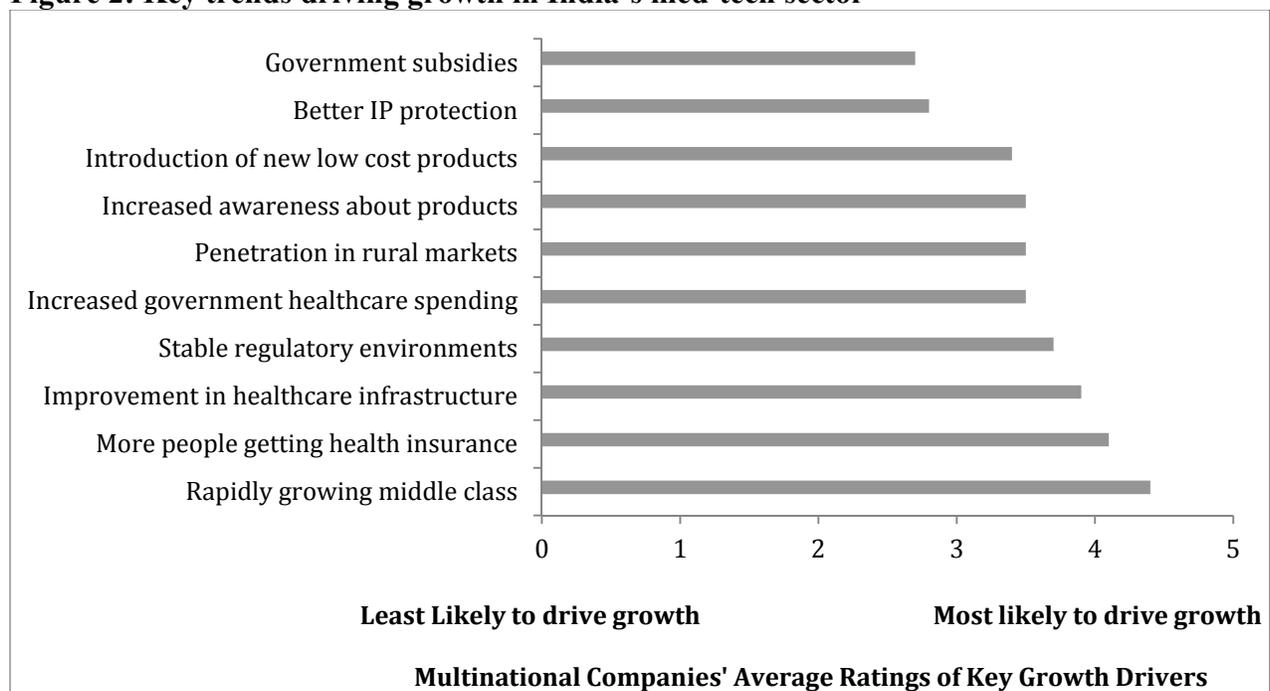
Health insurance is rare but growing. Only 55 million people had health insurance in 2003. By 2010, 300 million people, mostly below the poverty line, gained access to some partial form of health insurance. Still, only 3 percent to 5 percent of patients have full or substantial coverage.<sup>13</sup> Most Indians pay out-of-pocket for healthcare expenses and, hence, are extremely cost-conscious. Medical devices are reimbursed as part of a hospital procedure, if at all. (See **Business Models Basics** for detailed information about financing in India's healthcare system).

## MEDICAL DEVICE INDUSTRY

India's medical device market was worth US\$3 billion in 2010, growing roughly 15 percent over the previous year.<sup>14</sup> It is expected to expand at a 16 percent compounded annual clip during the 2010-2015 period,<sup>15</sup> far better than the 2 percent to 3 percent growth forecast for this sector in the United States and Europe. As a result, global medical technology firms view India as one of the most promising emerging markets for direct investment.<sup>16</sup>

Driving their enthusiasm is the rise of India's middle class (see Figure 2), which has benefitted from the Indian economy's robust growth. India's gross domestic product (GDP) expanded 6 percent or more per year on average over the last decade<sup>17</sup> to reach US\$2 trillion in 2012.<sup>18</sup> India's new and demanding middle class is expected to grow rapidly in coming years, from roughly 50 million people to nearly 600 million between 2007 and 2025.<sup>19</sup> Improvements in India's regulatory environment, healthcare infrastructure, and health insurance coverage are among the other trends spurring the med-tech sector's strong growth.

**Figure 2: Key trends driving growth in India's med-tech sector<sup>20</sup>**



Companies are pursuing the market in a number of ways. Most companies view India as a market for products developed elsewhere. To date, 23 of the largest global med-tech firms by revenue have established sales and marketing offices in India.<sup>21</sup> However, some multinationals now also see the country as a base for product development, clinical trials, and manufacturing. Some are setting up wholly owned subsidiaries, while others are acquiring local capabilities. For instance, Smith and Nephew, a major multinational player in the orthopedic space, recently bought Indian med-tech company Sushrut Medical.<sup>22</sup>

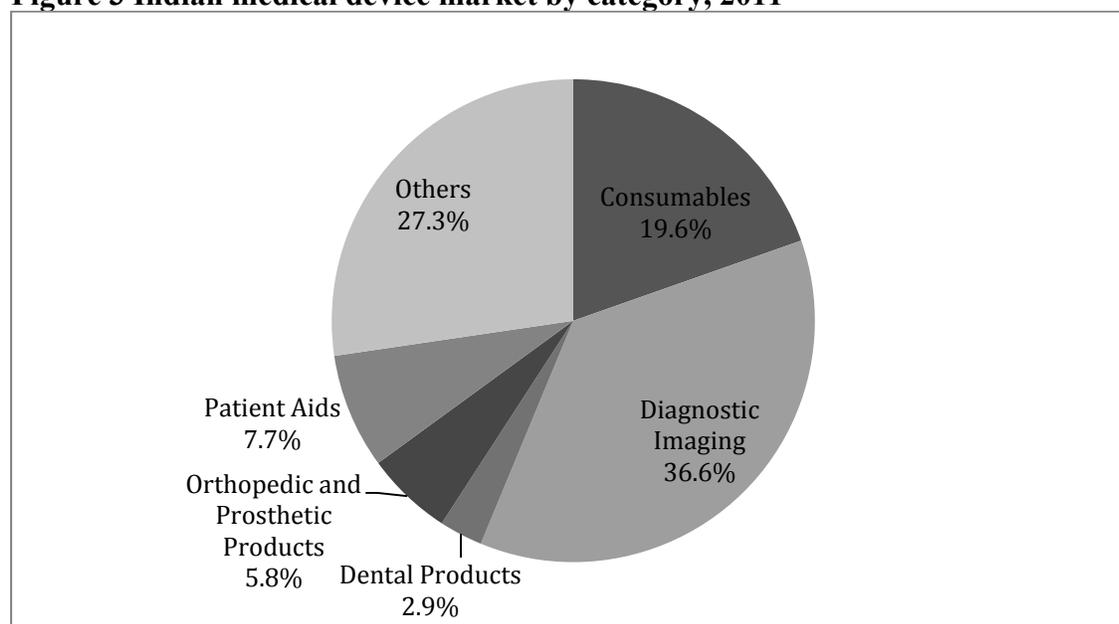
Other companies, such as Siemens, Philips, Stryker, and J&J, are investing in large product development labs in India. These labs are often clustered around Bangalore, Delhi, Mumbai, and other major metropolitan areas, usually in government-designated high-tech parks. For example, GE developed a handheld ultrasound device intended for resource-constrained markets at its Bangalore campus. This device, called V-Scan, launched globally in 2010.<sup>23</sup>

In contrast to the products traditionally sold in India, which are simplified versions of products sold in Western markets, firms have started to develop and customize medical devices specifically for the Indian market. Since such products tend to be lower priced, they permit companies to venture beyond well-heeled Tier 1 cities and tertiary hospitals into non-premium markets in rapidly growing Tier 2 cities and secondary level clinics.<sup>24</sup>

Business model innovation is critical to commercial success in India. For instance, dialysis equipment provider B. Braun has successfully navigated the Indian market by setting up a partnership with the government of Andhra Pradesh to run a dialysis service.<sup>25</sup>

Despite growing investor interest in India, imports currently dominate India's med-tech sector, accounting for approximately 75 percent of the devices sold in the country.<sup>26</sup> GE Healthcare, Siemens, J&J, and other multinational corporations, which normally have extensive sales and service networks, lead India's technology-intensive and high-cost device markets. Indian manufacturers suffer from a perceived lack of quality and traditionally have had trouble entering these markets. Domestic companies are highly competitive in the markets for medical supplies and consumables (sutures, catheters, etc.), which are particularly price sensitive due to low labor and manufacturing costs.<sup>27</sup> Small and medium enterprises manufacture some 60 percent of indigenous devices.<sup>28</sup>

Of the medical devices sold in India, the largest category by value is diagnostic imaging equipment, such as MRI and ultrasound machines (see Figure 3). Suppliers sell the bulk of these high-cost items to the private healthcare sector, which is more likely to have sophisticated infrastructure capable of generating revenue to pay for the devices.

**Figure 3 Indian medical device market by category, 2011<sup>29</sup>**

## INNOVATION POTENTIAL

The Indian medical device industry's growth is not only sparking interest from large multinational companies, but also from entrepreneurs, investors, incubators, and the Indian government. Several Indian medical device start-ups, such as Biosense<sup>30</sup> and Consure Medical,<sup>31</sup> have received venture capital funding in the last two years. Other promising start-up companies are developing novel technologies for the Indian market, giving rise to an active entrepreneurial medical technology community in India. Numerous incubators, including Villgro,<sup>32</sup> IKP Knowledge Park,<sup>33</sup> and HealthStart,<sup>34</sup> are focusing on healthcare companies and have taken on medical device companies as incubatees. To encourage technological innovation and entrepreneurship in India generally, the government is increasing spending on scientific research from 0.9 percent<sup>35</sup> in 2011 to 2 percent of GDP by 2017<sup>36</sup> and is providing funding through various grant-in-aid and loan schemes.<sup>37</sup> Declaring 2010 to 2020 the "Decade of Innovation," it will release a new science, technology, and innovation policy in 2013.<sup>38</sup>

## Funding Sources

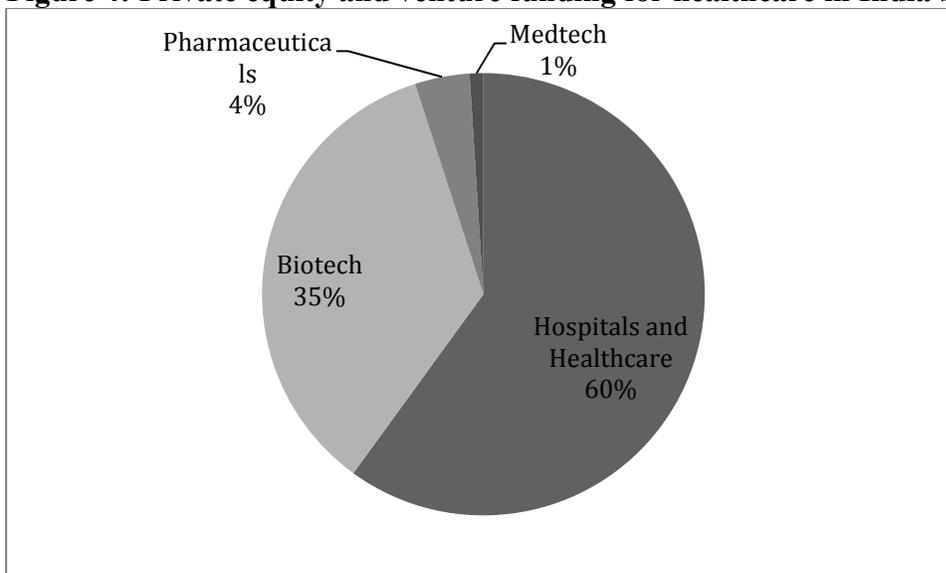
Med-tech entrepreneurs in India still struggle to access capital, but the government and the private sector have increased the avenues available for early stage funding in the healthcare sector.

Several government agencies under the Department of Science and Technology (DST) offer research grants, fellowships, and soft loans or equity to technology entrepreneurs. For instance, the Department of Biotechnology (DBT) has established a Biotechnology Industry Partnership Program (BIPP) for public-private partnerships and a Small Business Innovation Research Initiative (SBIRI). These programs encourage innovators and companies through soft loans, grants-in-aid, and partnerships. Individual grant amounts can reach up to Rs500 million (US\$1:Rs63.37).<sup>39</sup> To bridge the gap between invention and commercialization, DBT recently

launched a new fund under its Biotechnology Industry Research Assistance Council (BIRAC) scheme. Named Biotechnology Ignition Grant (BIG), the fund provides entrepreneurs up to Rs5 million for 18 months.<sup>40</sup>

Venture capital (VC) and private equity (PE) firms have significantly increased their activity in India over the last decade.<sup>41</sup> Focusing at first on IT companies, VC/PE funds in India have expanded their scope to include clean energy, services, and healthcare. Their investment in healthcare has totaled roughly US\$268 million to date. Figure 4 shows the percentage of PE/VC funding allocated to the healthcare sector by category in 2011. Although medical technology still accounts for a small portion of the total, investment levels are rising.<sup>42</sup> For example, med-tech start-up Consure Medical in August 2012 closed a Series A funding round of about US\$8 million.<sup>43</sup>

**Figure 4: Private equity and venture funding for healthcare in India by category, 2011**<sup>44</sup>



## INDIA MODULE CHAPTER CONTENTS

The chapters in this module will discuss three topics most pertinent to medical device innovators developing new products for the Indian market: intellectual property protection, regulatory environment, and business model basics. **Intellectual Property Basics** provides innovators with information about the IP landscape in India, the process of applying for a patent, and the status of patent litigation in the country. **Regulatory Basics** outlines India's evolving medical device regulations and includes information about conducting clinical trials and establishing appropriate quality management systems for product development. **Business Model Basics** introduces the innovator to India's healthcare market and provides background on different market sectors, sales and distribution strategies, viable business models, reimbursement structures, and doing business in India. Innovators should note that some of the information provided in these chapters could change as the Indian medical device sector matures.

## Endnotes

- <sup>1</sup> Nicholas Donoghue, Ajay Gupta, Rob Linden, Palash Mitra, and Ingo Beyer, “Medical Device Growth in Emerging Markets: Lessons from other Industries,” *In Vivo*, June 2012, p. 1.
- <sup>2</sup> “India: Health Profile,” World Health Organization, May 2012, <http://www.who.int/gho/countries/ind.pdf> (February 22, 2013).
- <sup>3</sup> David Kohn, “Getting to the Heart of the Matter in India,” *The Lancet*, Volume 372, Issue 9638, pp. 523-524, August 16, 2008.
- <sup>4</sup> “Private Sector in Healthcare Delivery in India,” National Commission on Macroeconomics and Health, 2005, p. 1, [http://www.nihfw.org/WBI/docs/PPP\\_SessionBriefs/PPP%20Course%20sessions/Need%20and%20Scope%20for%20PPP/Private%20Sector%20in%20Health%20Care%20Delivery%20in%20India.pdf](http://www.nihfw.org/WBI/docs/PPP_SessionBriefs/PPP%20Course%20sessions/Need%20and%20Scope%20for%20PPP/Private%20Sector%20in%20Health%20Care%20Delivery%20in%20India.pdf) (February 22, 2013).
- <sup>5</sup> “Medical Tourism in India,” Trak.In, May 23, 2011, <http://trak.in/tags/business/2011/05/23/medical-tourism-india/> (February 22, 2013).
- <sup>6</sup> “High Level Expert Group Report on Universal Health Coverage in India,” Planning Commission of India, November 2011, p. 189, <http://uhcforward.org/publications/high-level-expert-group-report-universal-health-coverage-india> (February 22, 2013).
- <sup>7</sup> Srinath Reddy, K. Srinath Reddy, Vikram Patel, Prabhat Jha, Vinod K. Paul, A. K. Shiva Kumar, and Lalit Dandona, “Towards Achievement of Universal Healthcare in India by 2020: A Call to Action,” *Lancet*, 2011, 377:760-68, <http://cghr.org/wordpress/wp-content/uploads/Towards-achievement-of-universal-health-care-in-India-by-2020-a-call-to-action-2011.pdf> (February 22, 2013).
- <sup>8</sup> Ibid.
- <sup>9</sup> Ibid.
- <sup>10</sup> “Taking Advantage of the Med-tech Market Potential in India,” PWC, 2012, p. 9, [http://www.pwc.com/en\\_GX/gx/pharma-life-sciences/publications/asia-pharma-newsletter/assets/taking-advantage-of-the-medtech-market-potential-in-india.pdf](http://www.pwc.com/en_GX/gx/pharma-life-sciences/publications/asia-pharma-newsletter/assets/taking-advantage-of-the-medtech-market-potential-in-india.pdf) (September 3, 2013).
- <sup>11</sup> Parvathi K. Iyer and Dinesh Abrol, “Science and Technology Financing,” *India Science and Technology*, 2008, <http://www.nistads.res.in/indiasnt2008/t2finance/t2fin2.htm> (February 22, 2013).
- <sup>12</sup> Nishant Jain, “Analysis of Public Expenditure on Health Using State Level Data,” IIM Ahmedabad, June 2004, p.4, <http://www.iimahd.ernet.in/publications/data/2004-06-08rbhat.pdf> (February 22, 2013).
- <sup>13</sup> “Government Sponsored Health Insurance in India: Are you covered?” World Bank, October 11, 2012, <http://www.worldbank.org/en/news/2012/10/11/government-sponsored-health-insurance-in-india-are-you-covered> (February 22, 2013).
- <sup>14</sup> “India: Medical Device Market,” Espicom Report 2012, <http://www.espicom.com/india-medical-device-market> (March 5, 2013).
- <sup>15</sup> “Taking Advantage of the Med-tech Market Potential in India,” op. cit., p. 9.
- <sup>16</sup> Ibid.
- <sup>17</sup> World Bank, “GDP Growth,” <http://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG> (February 22, 2013).
- <sup>18</sup> World Bank, “GDP,” 2012, <http://data.worldbank.org/indicator/NY.GDP.MKTP.CD> (March 5, 2013).
- <sup>19</sup> “Taking Advantage of the Med-tech Market Potential in India,” op. cit., p. 4.
- <sup>20</sup> Ibid.
- <sup>21</sup> “Top 100 Medical Device Companies,” PharmaLive.com; company websites, <http://www.pharmalive.com/> (July 1, 2013).
- <sup>22</sup> “Smith & Nephew to Acquire Indian Trauma Business,” Smith and Nephew Press Release, May 2, 2013, <http://www.smith-nephew.com/news-and-media/news/smith--nephew-to-acquire-indian-trauma-business/> (July 1, 2013).
- <sup>23</sup> GE Healthcare, “VScan,” <https://vscan.gehealthcare.com/gallery/a-quick-look-at-vscan> (February 22, 2013).
- <sup>24</sup> Taking Advantage of the Med-tech Market Potential in India,” op. cit., pp. 7-8.
- <sup>25</sup> T. K. S. Ravindran, “Public Private Partnerships in Maternal Health Services,” *Economic and Political Weekly*, November 26, 2011, Vol. XLVI, No. 48, p. 43, [http://www.epw.in/system/files/pdf/2011\\_46/48/PublicPrivate\\_Partnerships\\_in\\_Maternal\\_Health\\_Services.pdf](http://www.epw.in/system/files/pdf/2011_46/48/PublicPrivate_Partnerships_in_Maternal_Health_Services.pdf) (July 8, 2013).
- <sup>26</sup> “Introduction to Medical Devices in India,” Pacific Bridge Medical, <http://www.pacificbridgemedical.com/business-services/medical-device-consulting/india/> (February 22, 2013).

- <sup>27</sup> Espicom 2012, loc. cit.
- <sup>28</sup> E. Saneesh, "The Emerging Role of Small and Medium Enterprises in the Indian Medical Devices Market," *Frost and Sullivan*, September 17, 2012.
- <sup>29</sup> Espicom 2012, loc. cit.
- <sup>30</sup> "Medical Devices Start-Up Biosense Secures Funding," Reuters, March 21, 2013, <http://in.reuters.com/article/2013/03/21/medical-devices-startup-biosense-secures-idINDEE92K0DO20130321> (July 1, 2013).
- <sup>31</sup> "India Innovation Fund, IAN Invest In Consure Medical," DealCurry, August 31, 2012, <http://www.dealcurry.com/20120823-India-Innovation-Fund-IAN-Invest-In-Consure-Medical.htm> (July 1, 2013).
- <sup>32</sup> Villgro, [www.villgro.org/](http://www.villgro.org/) (July 1, 2013).
- <sup>33</sup> IKP Knowledge Park, <http://www.ikpknowledgepark.com/index.php> (July 1, 2013).
- <sup>34</sup> HealthStart, <http://healthstart.co.in/> (July 1, 2013).
- <sup>35</sup> "Annual Global Funding Forecast 2012," *Battelle*, December 16, 2011, <http://www.battelle.org/media/news/2011/12/16/battelle-r-d-magazine-annual-global-funding-forecast-predicts-r-d-spending-growth-will-continue-while-globalization-accelerates> (March 6, 2013).
- <sup>36</sup> R. Koul, "Public Funding in the Lifescience Zooms," *Biospectrum*, October 8, 2012.
- <sup>37</sup> Ministry of Science and Technology India, Annual Report 2011-2012, [http://www.dst.gov.in/about\\_us/ar11-12/default.htm](http://www.dst.gov.in/about_us/ar11-12/default.htm) (July 1, 2013).
- <sup>38</sup> Indian Ministry of Science and Technology, "Decade of Innovation," Department of Science and Technology Press Release, March 10, 2010, [http://www.dst.gov.in/whats\\_new/press-release10/pib\\_10-3-2010.htm](http://www.dst.gov.in/whats_new/press-release10/pib_10-3-2010.htm) (March 6, 2013).
- <sup>39</sup> This exchange rate is for U.S. dollars to Indian rupees on September 13, 2013. Bloomberg.com, September 13, 2013, <http://www.bloomberg.com/quote/USDINR:CUR> (September 13, 2013).
- <sup>40</sup> BIRAC, "Programs," <http://www.birac.nic.in/programmes.php?prg=big> (March 6, 2013).
- <sup>41</sup> R. Jai Krishna, "India Private Equity Investments Up 24 Percent in 2011," *WSJ Deal Journal India*, January 12, 2012, <http://blogs.wsj.com/dealjournalindia/2012/01/12/india-private-equity-investments-up-24-in-2011/> (March 6, 2013).
- <sup>42</sup> Ibid.
- <sup>43</sup> "Consure Medical Secures Funding for Novel Device," *MedtechInsider*, September 24, 2012.
- <sup>44</sup> Koul, "PE Investments in Biosciences," *Biospectrum*, October 8, 2012.