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BIODESIGN GLOBAL SOURCEBOOK: SG.01 SINGAPORE OVERVIEW

Singapore is an increasingly attractive venue for medical technology innovation in the Asia-Pacific region. Robust growth in Asian medical device markets, a clustering of medical device companies and services, a central location in Asia, and innovation-friendly government policies are some of the forces behind the citystate's growing appeal.

This chapter will discuss these developments, highlight some defining features of Singapore's healthcare model, and summarize the contents of other chapters on Singapore in this module.

INNOVATION-FRIENDLY ENVIRONMENT

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The same strengths that attract multinational companies generally to Singapore also draw players in the med-tech field. Singapore's attributes include an abundance of skilled labor, an emphasis on education, an efficient bureaucracy, and a lack of corruption. These assets have helped make the country Asia's most competitive economy, according to the World Economic Forum's 2011-2012 Global Competiveness Report.¹ Within six hours flying time of most Asian cities (see Figure 1), Singapore's location appeals to companies looking for a convenient regional base, such as international contract research organization Quintiles.²

The Singapore government has also launched a variety of initiatives to create an innovation-friendly environment. Since 2000, the government has invested over S\$5 billion (US\$1:S\$1.26) to enhance the city-state's innovation and R&D capabilities.³ It recently committed S\$16.1 billion for the 2011-2015 period, designating S\$3.7 billion of that amount for the biomedical industry.⁴ The government offers simplified tax compliance

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procedures, a network of Free Trade Agreements, and other financial incentives to encourage innovators to base their operations in Singapore.⁵ (See Appendix 1 for links to websites of relevant government agencies in Singapore.)

Funding Opportunities

A variety of funding schemes are available to help fuel biomedical start-ups and transform technology ideas into viable businesses. Spring Singapore, an enterprise development agency under the Ministry of Trade and Industry, has allotted S\$40 million for a Biomedical Sciences Accelerator (BSA) and has established the Technology Enterprise



Figure 1 Singapore's location in Asia

Commercialization Scheme (TECS), which offers grants for early stage ideas. TEC's Proof of Concept (POC) and Proof of Value (POV) grants provide qualifying start-ups as much as S\$250,000 and S\$500,000 respectively. Beneficiaries include Biobot Surgical, which developed a prostrate biopsy robot, and Clearbridge Biomedics, which develops medical research tools and diagnostic products.⁶ Singapore's Agency for Science Technology and Research (A*STAR) similarly offers a Biomedical Engineering Program (BEP) grant for POC and POV projects to encourage clinicians, engineers, and scientists to collaborate on solutions to clinical problems.

The Ministry of Health (MOH) and its hospitals provide funding and internal hospital infrastructure for clinical research, which fosters innovation by incentivizing companies to conduct clinical trials in Singapore. MOH's National Medical Research Council (NMRC) has set up the Translational and Clinical Research (TCR) Flagship program to convert basic science research into clinical research. The program focuses on "cancer, cardiovascular/metabolic disorders, neurosciences, infectious diseases, and eye diseases," awarding S\$25 million in grants over five years in each of these fields.⁷ Companies and innovators can also set up clinical trails, such as Bayer's electrocardiogram study,⁸ through National University Hospital's (NUH's) Investigational Medicine Unit (IMU), which offers facilities and services.

These and other innovation-friendly policies are making a difference for homegrown innovators. Take HealthSTATS International, which the World Economic Forum selected as a Technology Pioneer in 2007.⁹ Founded in Singapore in 2000 by Dr. Ting Choon Meng and two partners, HealthSTATS invented the first medical device for continuous monitoring and 24-hour remote analysis of blood pressure. Ting credits Spring Singapore and government trade promotion agency International Enterprise Singapore with boosting HealthSTATS branding capabilities and intellectual property.¹⁰

Strengthened Intellectual Property and Regulatory Regimes

The government is in the process of bolstering Singapore's regulatory and intellectual property regimes. The Health Sciences Authority (HSA) oversees medical device regulation in Singapore and in recent years has started to assert more regulatory control over medical devices. HSA has gained a reputation as a thought leader for regulatory affairs in Southeast Asia, potentially

making Singapore an attractive starting point for inventors seeking to penetrate Southeast Asian markets. (See **Regulatory Basics** for details on Singapore's regulatory regime.)

Singapore's Intellectual Property Office is reviewing Singapore's patent system to reform the application process. The World Economic Forum ranked Singapore second best globally for intellectual property protection in 2011-2012, which includes measures to prevent counterfeiting.¹¹ (See **Intellectual Property Basics** for more on Singapore's IP regime.)

Favorable Regional Market Trends

These developments, in combination with promising market trends, are helping Singapore become a regional hub for med-tech activity despite its small indigenous market (estimated at US\$575 million in 2010).¹² Whereas the medical device sector worldwide is forecast to grow at a roughly six percent compound annual growth rate between 2011 and 2013, the Asia-Pacific market should expand more than 10 percent (CAGR) over the same period. Worth an estimated US\$55 billion in 2011, it accounts for some 25 percent of the global medical devices market.¹³

Med-Tech Manufacturing and Services Growth

Key global med-tech companies such as Abbott, Boston Scientific, Edwards Lifesciences, and Siemens Healthcare have already established either international or regional headquarters in Singapore.¹⁴ The city-state has also become a leading med-tech manufacturing site as foreign and domestic firms make use of the country's existing electronic manufacturing and precision engineering services for medical device production. Companies include ST Microelectronics, Biosensors, and contract manufacturers Beyonics Technology and Venture Corp. Manufacturing output of medical devices in Singapore doubled from S\$1.5 billion in 2000 to about S\$3 billion in 2008.¹⁵ The city-state in 2009 accounted for some 50 percent of global production of microarrays and thermal cyclers, and 10 percent of world contact lens supply.¹⁶

Firms are increasingly conducting research and development for medical devices in Singapore. Some 30 global med-tech companies, including 3M, AB Sciex, and Becton Dickinson, had established R&D functions in the country as of 2011.¹⁷ Welch Allyn, for instance, developed its CP50 electrocardiograph machine for emerging markets in Singapore.¹⁸

Singapore is becoming a base for regional clinical trials as well. Leading international contract research organizations (CROs), such as Quintiles, Covance, PPD, and ICON, have set up shop in the city-state. They help manage clinical trials from Singapore through various stages (preclinical, clinical, and post-approval) and offer services such as data management, biostatistics, regulatory expertise, and consulting.¹⁹ For innovators in Singapore, this clustering of medical device companies and services spells more opportunity to develop and commercialize their concepts.

SINGAPORE'S HEALTHCARE MODEL

Innovators wishing to make the most of Singapore's attributes should note some defining characteristics of the city-state's healthcare model. The government emphasizes personal responsibility among residents to tamp down healthcare costs, but offers subsidies to keep basic

healthcare affordable.²⁰ Private general practitioners (GP's) account for 80 percent of the country's primary healthcare services. Government polyclinics supply the remainder. The public sector meanwhile provides 80 percent of more costly hospital care services. This model has worked well for the city-state. According to the World Health Organization, Singapore's total expenditure on health as of 2008 was 3.4 percent of its GDP, whereas it was 16 percent in the United States. (See **Reimbursement Basics** for a more detailed description of Singapore's healthcare model.)

SINGAPORE MODULE CHAPTER CONTENTS

The chapters in this module will discuss the fundamentals of three issues that bear on innovators' selection of a medical device need and design for the Singapore market: intellectual property protection, regulatory processes, and reimbursement for medical devices. **Intellectual Property Basics** provides inventors a basic understanding of Singapore's IP regime and how to seek patent protection. **Regulatory Basics** guides inventors through Singapore's product registration process to help them understand how to obtain the regulatory approval needed to sell their device legally in Singapore. **Reimbursement Basics** explains how healthcare is delivered and financed in Singapore, how healthcare providers negotiate prices and make purchasing decisions, and how reimbursement for medical devices works in Singapore. Innovators should note that the Singapore government is reforming and refining policies in all these areas, and they will subsequently need to keep abreast of changes as they occur.

Appendix 1 Links to Relevant Major Government Authorities in Singapore

Agency for Science, Technology & Research (ASTAR) http://www.astar.edu.sg

Health Sciences Authority http://www.has.gov.sg

International Enterprise Singapore (IE Singapore) http://www.iesingapore.gov.sg

Ministry of Finance http://www.mof.gov.sg

Ministry of Trade & Industry http://www.mti.gov.sg

Ministry of Trade & Industry – Information on Singapore Free Trade Agreement <u>http://www.fta.gov.sg</u> Economic Development Board Singapore (EDB Singapore) http://www.sedb.com

Intellectual Property Office of Singapore (IPOS) http://www.ipos.gov.sg

Monetary Authority of Singapore (MAS) http://www.mas.gov.sg

Ministry of Health <u>http://www.moh.gov.sg</u>

SPRING Singapore http://www.spring.gov.sg

Endnotes

¹ World Economic Forum, "e Global Competitiveness Report 2011-2012," pp. 11-12,

http://www3.weforum.org/docs/WEF GCR Report 2011-12.pdf (July 30, 2012).

² Quintiles, "Singapore," http://www.quintiles.com/locations/asia/singapore/ (July 30, 2012).

³ Singapore Economic Development Board, "Singapore-The Biopolis of Asia," 2010.

⁴ Singapore Economic Development Board, "Biomedical Sciences Factsheet 2012,"

http://www.sedb.com/etc/medialib/downloads/industries.Par.44136.File.tmp/Biomedical%20Sciences%20Factsheet <u>%202012.pdf</u> (April 6, 2012).

⁵ Financial incentives include "greater overseas income flexibility in foreign tax credit claims and reduced Singapore taxes on remitted foreign income and simplified tax compliance procedures." See speech by Lim Hng Kiang, Singapore's Minister for Trade and Industry, at Medtronic Singapore Operations Opening Ceremony, March 10, 2011. Singapore also has 18 Free Trade Agreements, with countries such as China, Japan, South Korea, India, Australia, and the United States, 61 double taxation avoidance agreements, and 34 investment guarantee agreements.

See Singapore Economic Development Board, "Singapore - The Biopolis of Asia," op. cit.

⁶ See Spring Singapore, "Biomedical Sciences Accelerator (BSA),"

http://www.spring.gov.sg/entrepreneurship/fs/fs/pages/biomedical-sciences-accelerator.aspx (July 27, 2012); Spring Singapore, "Technology Enterprise Commercialization Scheme (TECS),"

http://www.spring.gov.sg/Entrepreneurship/FS/FS/TECS/Pages/technology-enterprise-commercialisationscheme.aspx (July 25, 2012); and "Overview of Singapore's Medical Technology Industry," Singapore Medical Engineering & Technology Guide 2010.2011, p. 13,

http://www.medtechsingapore.com/pdf/Overview of Singapore Medical Technology %20Industry.pdf (July 30, 2012).

⁷ National Medical Research Council, "Translational and Clinical Research (TCR) Flagship Program," http://www.nmrc.gov.sg/content/nmrc internet/home/our research/tcr flagship programme.html (July 30, 2012).

⁸ Baver's electrocardiogram study seeks to validate electrocardiogram data collected from a prior trial related to the drug Moxifloxacin. See National University Health System, "On-going studies in IMU,"

http://www.nuhs.edu.sg/research/core-facilities/investigational-medicine-unit-imu/ongoing-studies-in-imu.html (July 30, 2011).

⁹ World Economic Forum, "List of Technology Pioneers 2007," http://www.weforum.org/content/pages/listtechnology-pioneers-2007 (July 25, 2012). ¹⁰ HealthSTATS International, "HealthSTATS Touts Intellectual Property Assets,"

http://www.healthstats.com/en/investor-related/hs-touts-intellectual-property-assets.html (July 31, 2012). ¹¹ World Economic Forum, "The Global Competitiveness Report 2011-2012," op. cit., p. 391.

¹² Ames Gross and Arthur Chyan, "Updates on Singapore's Transition to Medical Device Regulation," Today's Medical Developments, October 20, 2010, http://www.onlinetmd.com/medical-device-design-manufacturingsingapore-102010-tmd.aspx (July 30, 2012).

¹³ Ames Gross, "Asian Regulatory Update: Asia-Pacific Medical Device Market Gets Healthier," www.massdevice.com, March 3, 2011, http://www.massdevice.com/blogs/ames-gross/asian-regulatory-update-asiapacific-medical-device-market-gets-healthier (July 25, 2012). ¹⁴ "Overview of Singapore's Medical Technology Industry," op. cit., p. 10.

¹⁵ "Remarks by S. Iswaran, Senior Minister of State for Trade & Industry and Education at the Med-Tech Manufacturing Consortium," October 13, 2009, http://app.mti.gov.sg/default.asp?id=148&articleID=20142 (June 19, 2011).

¹⁶ Ibid.

¹⁷ Singapore Economic Development Board, "Singapore - The Biopolis of Asia," op. cit, p. 12.

¹⁸ "Overview of Singapore's Medical Technology Industry," op. cit., p.11.

Quintiles, "Singapore," http://www.quintiles.com/locations/asia/singapore/ (July 30, 2012).

²⁰ Gordon G. Liu, Takashi Fukuda, et. al. "Evidence-Based Decision-Making on Medical Technologies in China, Japan, and Singapore," Value in Health, volume 12, supplement 3, 2009.