The 29th STAG Board Meeting

Topic 6: Biotech Industry

Presentation:
Taiwan Biotechnology Take-off Diamond Action Plan

Shuenn-Tsong Young
Researcher,
Science & Technology Advisory Group, (STAG)
Executive Yuan

Nov 4, 2009

Outline of Report

1. Introduction

2. Analysis of Industry Status

3. Strategies to Promote Development

4. Conclusion

1. Introduction

1.1- Introduction

- The government has aggressively promoted development of the biotech sector, helping to create an outstanding clinical research and healthcare system, a strong foundation for R&D, an environment conducive to production, and a respect for and protection of IPR. Taiwan now has the opportunity and conditions to become an Asian R&D cooperative partner within the global biotech community.

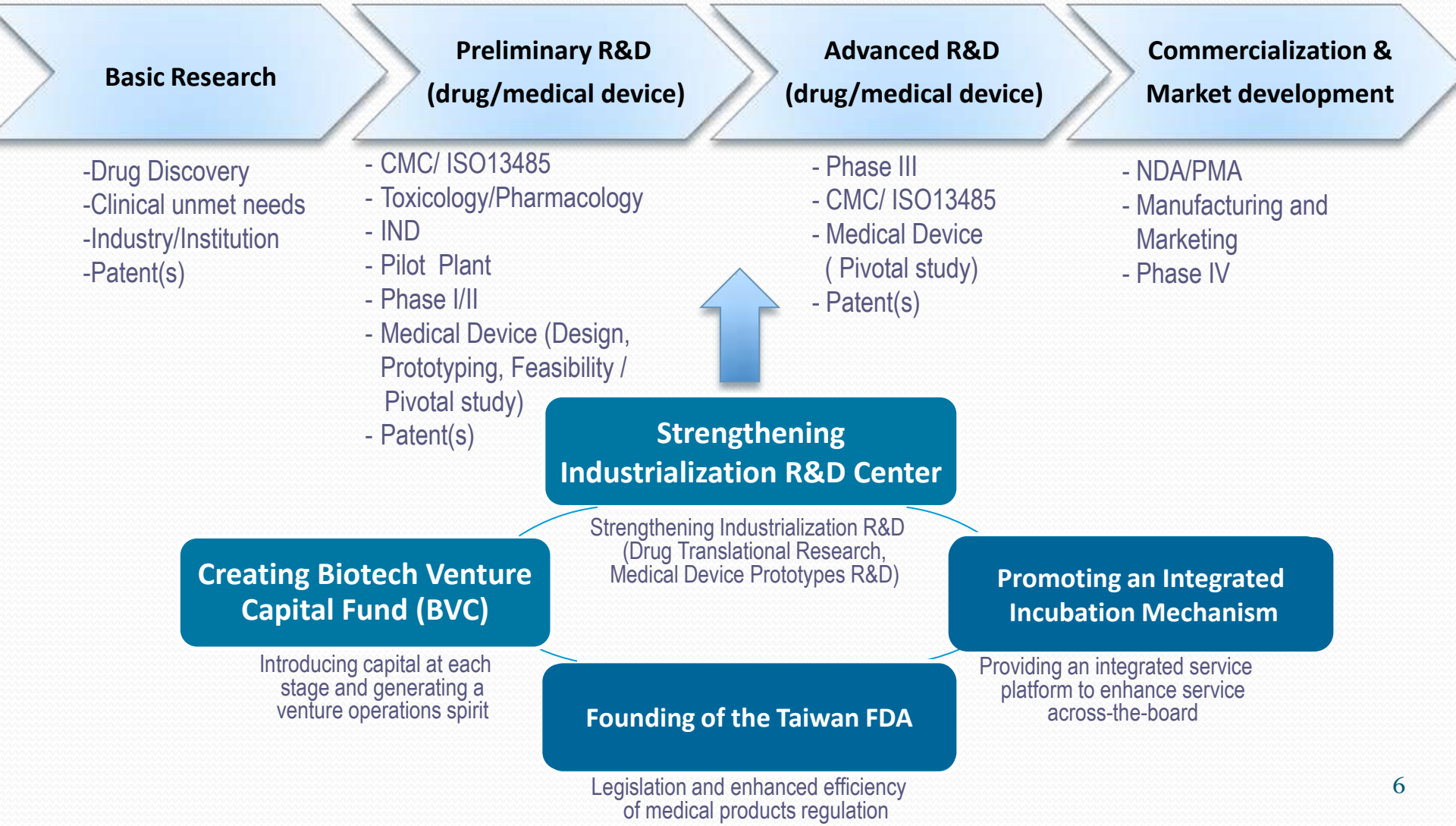
- The Executive Yuan, in an effort to create a well-rounded environment for industrial development and boost the competitiveness of Taiwan's biotech industry, drafted the "Taiwan Biotechnology Take-off Diamond Action Plan", based on the conclusions of the 2008 meeting of the BioTaiwan Committee. The plan aims to close gaps in the industrial value chain and spark the takeoff of the biotech industry here.

1.2- Project Objectives

～Taiwan Biotech Take-off Diamond Action Plan～

Integrating Resources, Cross-Disciplinary Coordination,
Introducing Entrepreneurial Spirit

1.3- Emphasis of Plan & Core Concepts



1.4- Developmental Visions

- To patch links in the industrial value chain, creating a strong foundation for translation research and paving the way for commercialization and industrial beachheads.
- To bolster entrepreneurial spirit, introduce private capital and invigorate the overall corporate mechanism.
- To overcome bottlenecks in Taiwan's biotech industry and spark the development of the biotech and healthcare sectors, thereby creating more jobs for highly trained talent.
- To attract large multinational companies to invest here and establish R&D centers, and to strengthen the international competitiveness of Taiwan's biotech industry.

2. Analysis of Industry Status

-Trends in the Global Biotech Industry

-Developmental Status of Taiwan’s Biotech Industry

Global Trends in Medical Treatment

- Increasing Health Awareness
- Aging Societies
- Individualized Treatment
- Micro and Digital Devices

- New therapies and drugs
- Innovative medical devices

• Health management becomes part of daily life
• Increase of integrated health management high-tech products and applications

• Use of technology to reduce manpower needs
• Alternative care models replace hospital care
• Reduced opportunities for illnesses and its complications

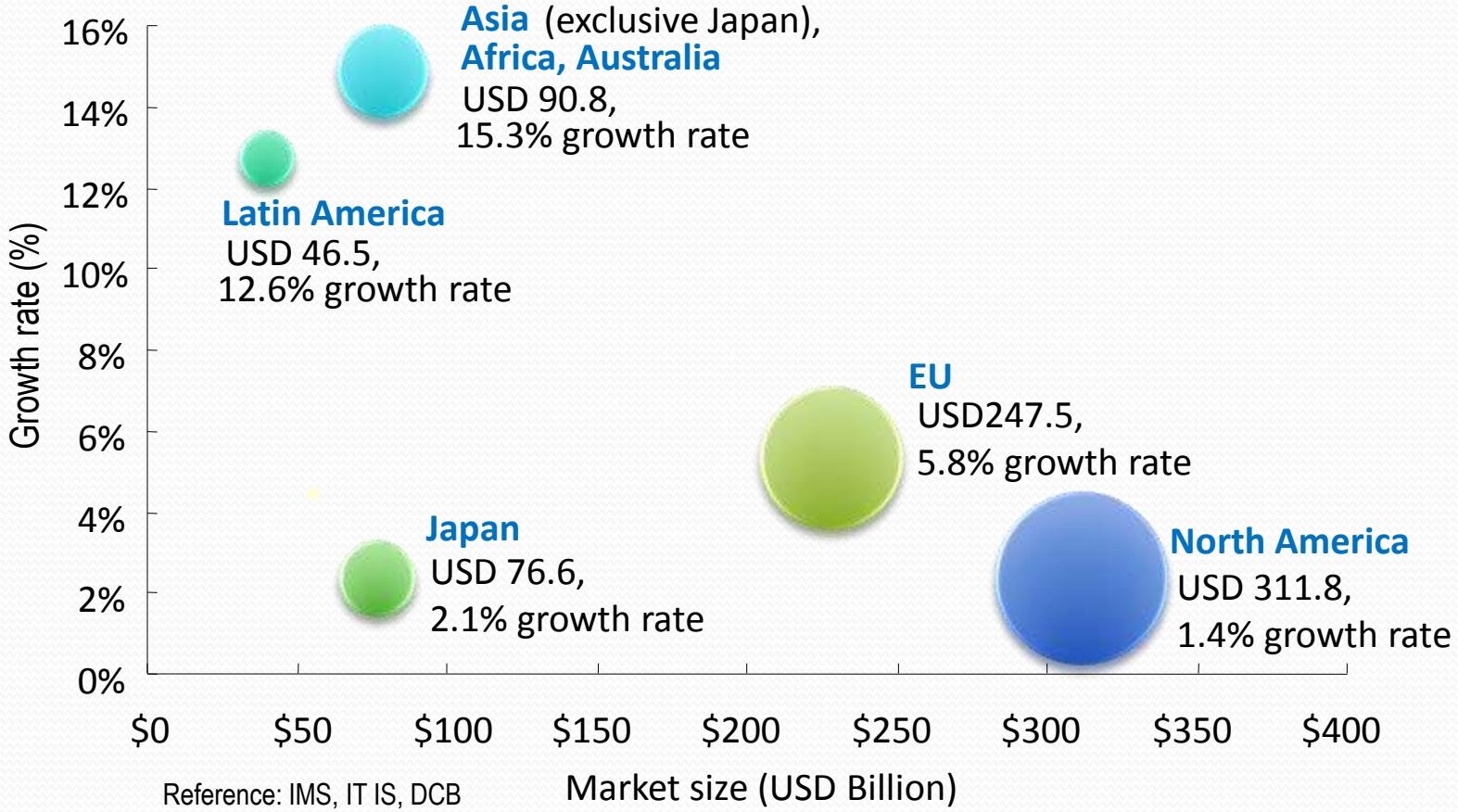
• Increase in premiums
• Increase in self-paid portion
• Reduced benefits

Source: ITRI-IEK

Global Pharmaceutical Market

The global pharmaceuticals market in 2008 was US$773.2 billion.

Asia will be the center of growth in the pharmaceuticals market in the future.

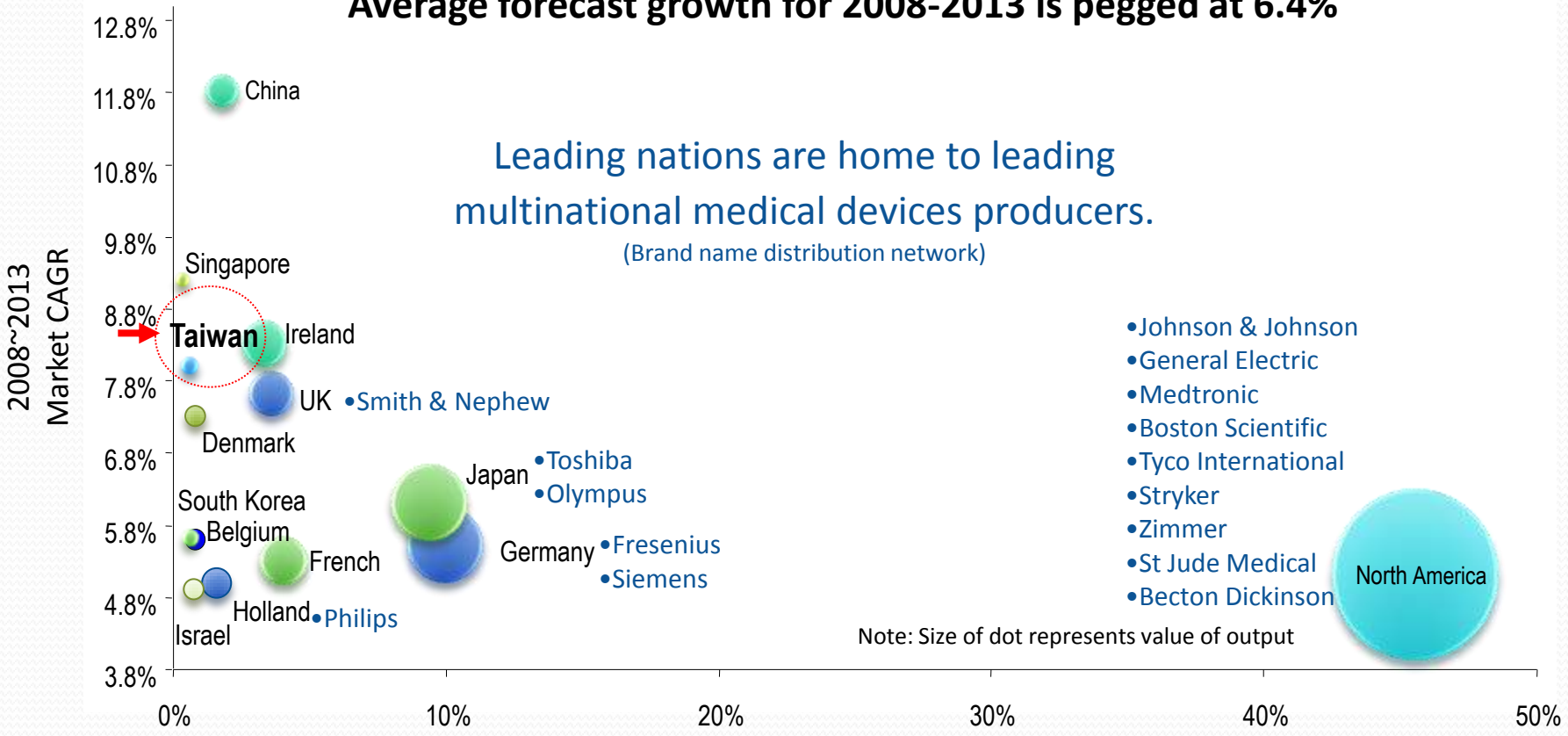


Reference: IMS, IT IS, DCB

Currency exchange rate: 32.39USD=1NTD (Oct 23, 2009)

Global Medical Devices Market

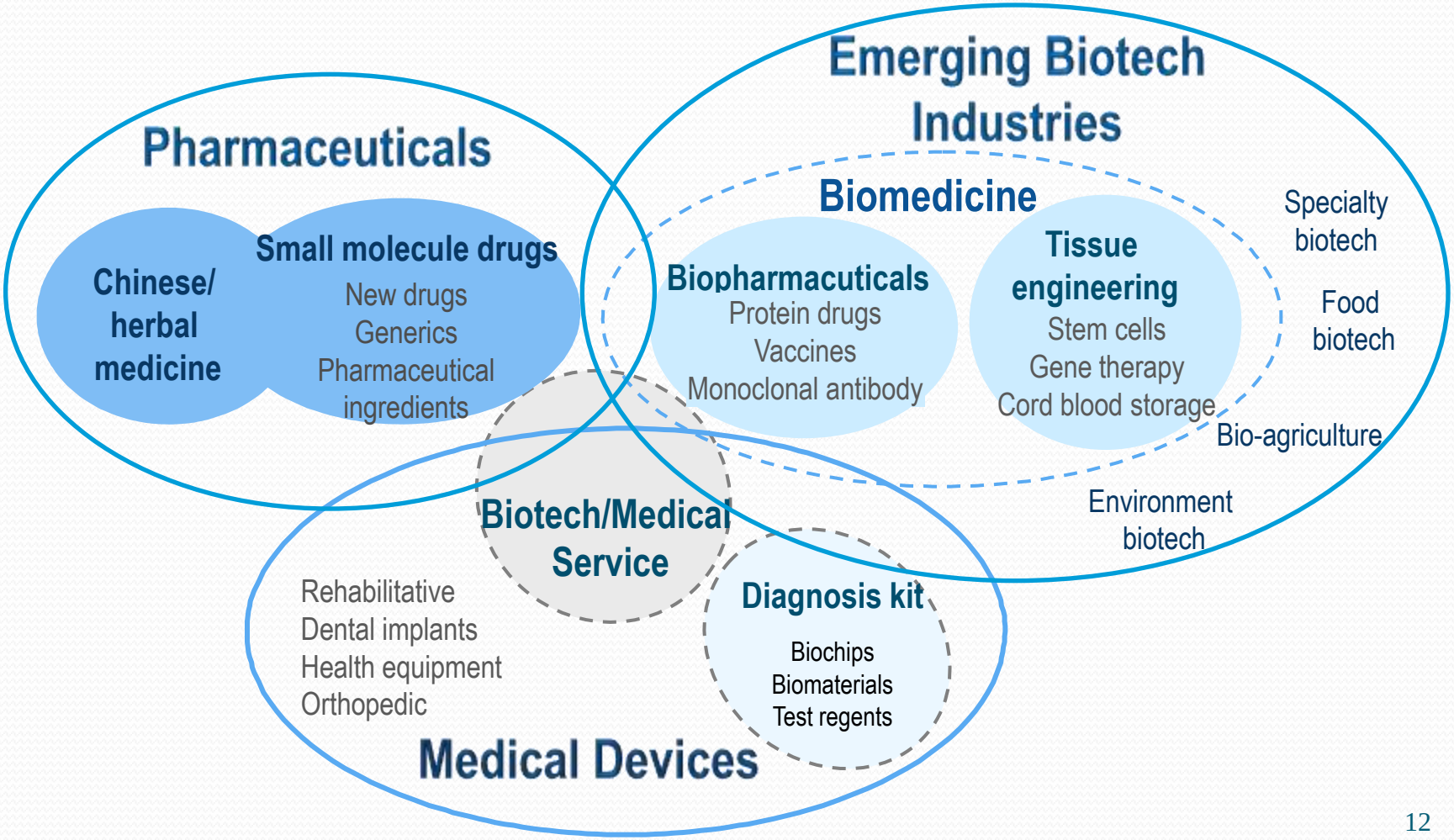
The global medical devices market in 2008 was US$210.2 billion.
Average forecast growth for 2008-2013 is pegged at 6.4%



Source: Espicom, Frost & Sullivan, ITRI-IEK

Currency exchange rate: 32.39USD=1NTD (Oct 23, 2009)

2.4 Scope of Taiwan's Biotech Industry



2.5-Developmental State of Taiwan's Biotech Industry (1)

~ Pharmaceuticals Industry Structure ~

Pharmaceuticals Industry

- Output in 2008 was US$1.78 billion.
- A total of 153 companies have passed CGMP standards to produce Western medicines, with most production centering on generic drugs. Products are mainly for the domestic market and are particularly used in the national health insurance system.
- A total of 23 companies have passed GMP standards to produce pharmaceutical ingredients (60% is sold domestically, and 40% is exported),e.g. ScinoPharm Taiwan, Yung Shin, Everlight Chemical, and Yung Zip Chemical are among the firms whose technology and quality have been recognized internationally.
- Taiwan fully instituted Chinese herbal medicine GMP standards starting in Sep 2005. To date, 117 makers of Chinese herbal medicines meet these requirements.
- ***The output value of Taiwan's pharmaceuticals market is less than 0.5% of world output.***

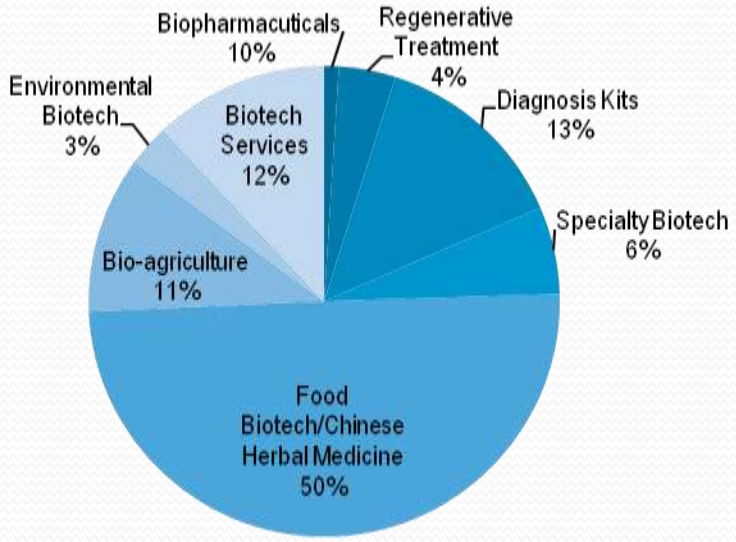
Currency exchange rate: 32.39USD=1NTD (Oct 23, 2009)

2.5-Developmental State of Taiwan's Biotech Industry (2)

~ Emerging Biotech Industry & Medical Devices Industry ~

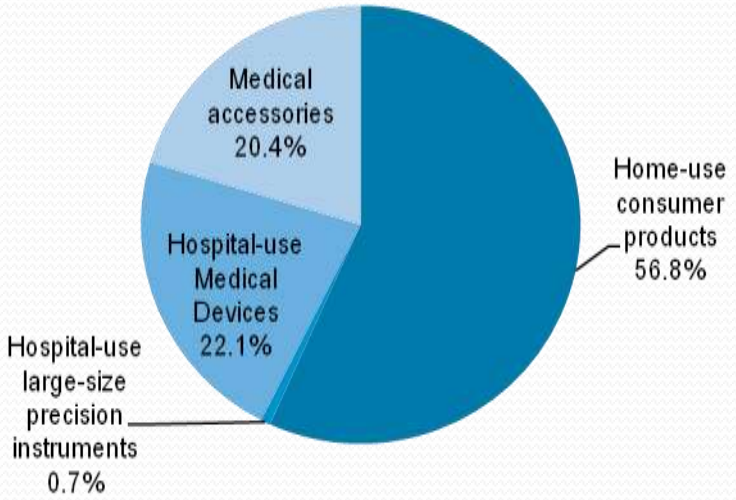
Emerging Biotech Industry

Output in 2008 was US$1.22 billion; Companies were mostly involved in food/Chinese herbal medicine biotech and agri-biotech**. This industry is still in the early growth stage.**



Medical Devices Industry

Output in 2008 was US$1.65 billion; The largest portion was home-use consumer products, while hospital-use large-sized precision instruments accounted for only 0.7**%. Taiwan's medical devices industry accounts for about 1% of global output. However, the structure of the industry is significantly different from that of leading nations.**



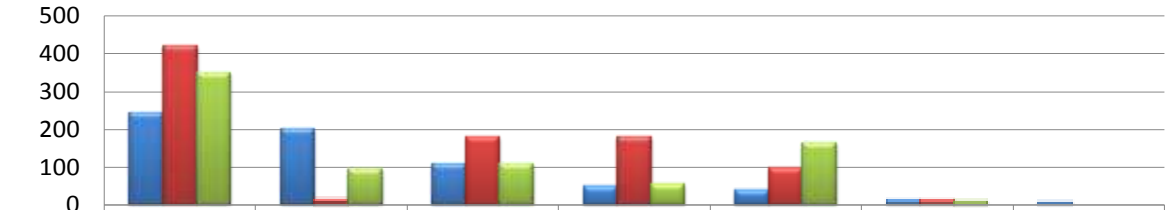
Source: DCB, IT IS: ITRI-IEK
Currency exchange rate: 32.39USD=1NTD (Oct 23, 2009)

2.5-Developmental Status of Taiwan's Biotech Industry (3)

~ Private Investment ~

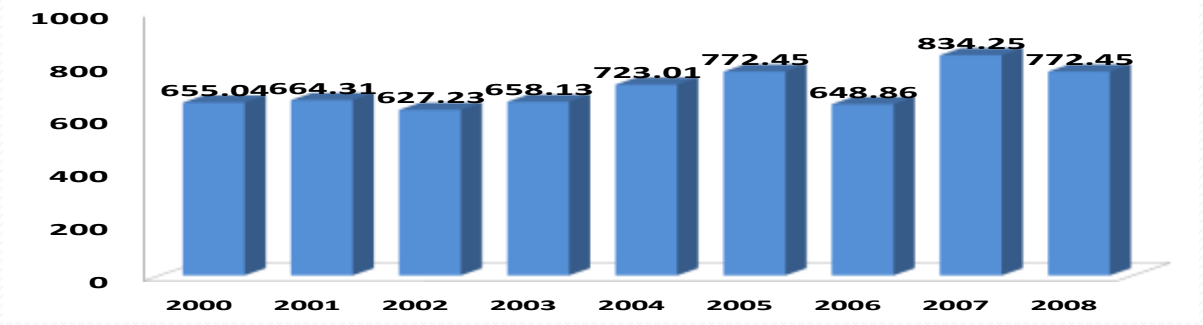
- Investment first exceeded US$618 million in 2001 and since then has surpassed that amount annually.
- Investment is primarily in pharmaceuticals, development of new drugs, medical devices and health foods.

Amt. of Investment (US million)



	Pharmaceuticals	Health Products	Medical Devices	Contract Services	Bio-ariculture	Test Regents	Enviroment Biotech
2006	241.47	199.19	106.58	47.10	38.81	9.89	6.03
2007	420.92	12.98	177.96	177.20	94.17	10.26	–
2008	347.60	92.69	108.14	54.07	162.21	7.72	–

Amt. of Investment (US million)



Source: The Biotechnology and Pharmaceutical Industries Program Office

Currency exchange rate: 32.39USD=1NTD (Oct 23, 2009)

2.5-Developmental Status of Taiwan's Biotech Industry (4)

-Encouraging Development of New Drugs that Create Value and High-end Medical Devices-

- Criteria for biotech companies to list on the Taiwan Stock Exchange or the Gre Tai Securities Market were eased in June 2001. As of the end of 2008, 39 biotech companies had listed.
- Sub-laws of the Statute for the Development of Biotechnology New Drug Industry were announced in 2008, including measures providing for investment tax credits for shareholders of companies in the biotech new drug industry, and tax credits for expenditures associated with the training of personnel involved in biotech new drug R&D. As of the end of May 2009, 23 companies qualified under the Statute, with most engaged in the development of new drugs.
- AbGenomics, Panion & BF Biotech, and Medigen Biotechnology are some of the firms that are successful collaborating with multinational drug firms via strategic alliances.
- ApexBio, Bioptik, and Health & Life have already secured a place in the global blood glucose monitor market.

2.6- Key Issues Facing the Industry's Development

- Taiwan's academic and research sectors exhibit strength in basic research. However, they have yet to develop highly profitable products or patents.
- Taiwan still lacks a well-rounded foundation for drug R&D. In addition, R&D themes lack marketability or clearly laid-out plans for commercialization.
- Amid the trend towards regional strategic alliances (on the line of a common market), regional regulatory harmonization is urgently needed in order to overcome international isolation.
- Biotech industrial clusters need to better share resources and engage in operational planning.
- Taiwan lacks highly attractive biotech industrial clusters and management teams able to recruit and coordinate the use of capital. It also needs to strategically attract foreign firms to invest in Taiwan.
- Taiwan desperately needs senior operations personnel with international strategic experience and persons well-versed in multiple disciplines.

3. Strategies to Promote Development

3.1- Promotion Framework

Supra Incubator Center

Software resources --
- To provide legal, IPR, technical, and operations services and assistance
- To bridge the academic and industrial communities, and offer a specialized technology assessment mechanism

Hardware resources —
- Hsinchu Biomedical Science Park (medical devices)
- Southern Taiwan Science Park (medical devices)
- National Biotech Development Park in Nangang (pharmaceuticals)
- Natioanl Laboratory Animal Center

Associated plans —
- The southern Taiwan biomeidcal devices industry cluster development plan

Regulatory process (transparency & efficiency)

Aiding industrial development

Regional regulatory harmonization

Strengthening of translational research --
- Creation of pre-clinical research platform (toxicology, PK and other translational research)
- Rapid trial production of medical devices

Associated plans and resources —
- National science & technology program for biotech
- Medical Devices cross-division development project

TFDA
(DOH)

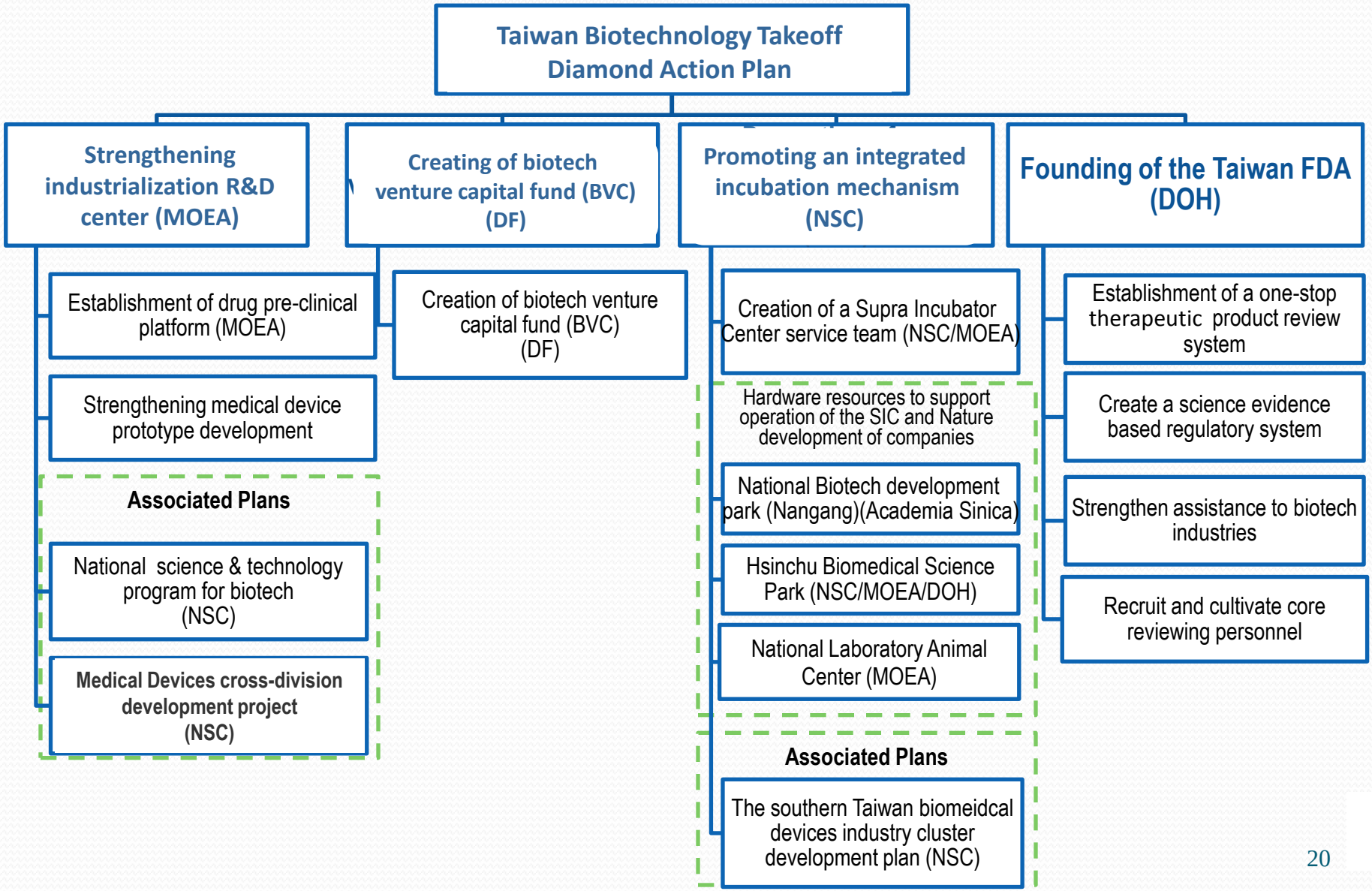
Industrialization R&D Center
MOEA (DCB, ITRI, MIRDC)

SIC
(NSC/Private Organizations)

BVC
(CEPD)

- Jointly comprised of capital from the government (40%) and private sector (60%)
- Top quality venture capital investment team
- US$0.3bln of capital to be raised in first phase
- Goal of US$1.85 bln of capital, which is dependent on performance and capital raised at various stages

3.2-Implementation Strategies and Responsibilities of Agencies



3.3- Status of Implementation (1)

Strengthening Industrialization R&D Center

- Utilizing the infrastructure of research institutions as the basis from which to strengthen translational research of drugs.
- Promoting the coordination of national projects on genomic medicine and pharmaceuticals, as well as helping to bridge efforts between the industrial and academic sectors and introducing a mechanism to take stock of results. The NSC is working in coordination with the MOEA and the DOH in planning and implementing the Medical Devices cross-division development project. The agencies are promoting projects to develop medical devices needed at various stages through life.

3.3- Status of Implementation (2)

Promoting an Integrated Incubation Mechanism

- A service team has been established to provide technical market assessment, regulatory and patent analysis, commercialization and incubation cooperation services.
- Three large biotech parks are being planned and established (Hsinchu Biomedical Science Park, Southern Taiwan Science Park, and National Biotechnology Development Park). Resources will be integrated to foster the development of industrial clusters.

3.3- Status of Implementation (3)

Founding the Taiwan Food and Drug Administration

- The Organic Act for the Food and Drug Administration, Department of Health, Executive Yuan, was passed by the Legislative Yuan and was promulgated by the president on Jun 3, 2009. The agency is expected to formally commence operation on Jan 1, 2010.
- The Department of Drugs & Biologics and the Department of Medical Devices and Cosmetic Products will be established under the TFDA and will be responsible for related products and operations.

Creating of Biotech Venture Capital Fund

- The management committee of the National Development Fund on Sep 8, 2009 approved rules governing the screening and management of the biotechnology venture capital fund. The Development Fund will contribute US$740 million to the biotech venture capital fund, with capital to be invested in stages to diversify risks

4. **Conclusion**

- Future Direction of Initiatives
- Expected Benefits

4.1-Emphasis of Future Work

～2009 BTC Important Conclusions and Suggestions～

- Carefully select innovative medical devices and drugs for development that are needed in market, strengthen a market-driven forces mechanism, and boost the level of participation by the industry.
- Work in conjunction with Taiwan's existing ICT industry to form industrial clusters, provide innovative services, and hasten the development of high-end medical devices.
- Encourage the academic, research and industrial communities to engage in mission-oriented R&D to increase the output of lead drugs; draft a mechanism to strengthen the bridge in drug research between the industry and academia, and promote the commercialization of R&D.
- Strengthen the use of international resources (including technology, personnel, clinical trials, capital, and market distribution networks); strengthen international cooperation; appropriately close gaps in Taiwan's industrial value chain.
- Establish a drug reviewing process and assistance mechanism that will underpin the industry's development.
- Promote drug and clinical trial regulatory harmonization.

4.2- Anticipated Benefits

2008

Output Value: NT$150.6 bln
Workforce: 42,000 People
Amt. of Investment: NT$25 bln

Benefits

Qualitative Benefits

- Generating momentum for Taiwan's drug translational research and medical device prototype development; creating a well-rounded drug R&D chain; promoting the commercialization of upstream R&D achievements.
- Strengthening review efficiency; promoting regulatory harmonization; introducing common market concepts; expanding Taiwan's drug market.
- Providing an integrated biotech incubation services platform; introducing highly talented personnel; assisting in the commercialization of R&D successes.
- Industrial clusters and biotech parks will gradually take root in a decade's time, sparking the creation of peripheral industries and employment opportunities.

Quantitative Benefits

- **Output value of the biotech industry will multiply within five years (to 2013), rapidly pushing the sector towards becoming a trillion dollar industry.**
- **Private sector investment in the biotech industry is expected to reach at least US$1.67 billion annually in 2013 (double the present level).**

End of Briefing

Your suggestions and advice are appreciated