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**The Role of Innovation Ecosystem in the New Business
Model for STSP Medical Companies**

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The Role of Innovation Ecosystem in the New Business Model for STSP Medical Companies

Executive Summary

In today's hyper-competitive market, innovation is considered a key factor for a successful industry. It is also the fundamental cause of transition from conventional economy to knowledge-based economy. In addition to new product development, a complete operation of the innovation ecosystem cannot be built up without a good profit model.

Due to the increase in the global aging population, as well as the rising awareness of the value of health, the medical device industry is thought to have a great development in the future. Various studies have estimated that medical devices could contribute approximately 300 billion US dollars per year in the global market between 2013 and 2018. There are a large number of medical device companies in Silicon Valley, which has an environment that favors the development of new ideas in the field, and has a well-developed support system for the commercialization of products. Ideas for high-quality and highly marketable products originate not from technology, but from the needs of physicians, as well as from the alliances and the cooperation developed among physicians and engineers. This connection between medicine and engineering is well developed in Silicon Valley. 50% of the top 30 medical device manufacturers are in the United States. The international companies' global marketing channels and physician training system also play an important role in marketing and promotion in this innovation ecosystem.

The innovation ecosystem comprises two separate economies: the knowledge economy, driven by fundamental research, and the commercial economy, driven by the marketplace. The Innovation ecosystem of medical devices in the STSP has been promoted since two years ago. Manufacturers have created many innovative and high-end medical apparatuses with physicians' collaboration. The medical device industry has three characteristics in the marketing model which are not easy to break. First, it's a relatively closed market in comparison with other markets, and it needs super brand marketing and expert endorsement strategies. Second, the marketing of medical devices is an experience economy. The products need instructions and operation to be understood. Third, clinical data should be collected to build up physicians' and patients' trust on medical device products.

However, it's difficult to change the physicians' habitual use of clinical approaches to treatment. Physicians are very cautious in using "NEW" medical devices. The situation as mentioned above causes a gap in the innovation ecosystem, which makes it hard to support the development of innovative products in STSP. Most of medical device companies in Taiwan are SMEs, which are limited by manpower, technology, equipment, and capital. As a result, they can only concentrate on their R&D process, and it's not easy for them to complete simulations, tests, and test production together at the R&D stage. To speed up innovation and maximize the value of the industry, professional knowledge provided by service platforms is required. Those service platforms are the driving factors of an innovative business model which allows manufacturers to profit and to be able to have more resources for innovation. For this purpose, three service platforms have been developed to support medical device companies developed in STSP.

1. Technology Matching Service Platform

To help manufacturers to be more involved in the global market and technological exchanges, better promote their innovative research products, and enhance their manufacturing strength, we invite international medical device companies, physicians and VCs to visit STSP, so that the manufacturers can enter the international innovation ecosystem. We also provide quick trial and testing services for innovative prototypes whose concepts come from the academia, physicians or manufacturers, in order to speed up the commercialization of the prototypes.

2. Clinical Experience Platform

Through communications between physicians and manufacturers, the manufacturers can obtain clinical information from the physicians, and such information will serve as a reference to develop innovative products. On the other hand, if the products meet physicians' clinical needs, they will be willing to use the products, and become the "Key Opinion Leader (KOL)" after the products are launched into the market. To establish the communication mechanism is one of the important factors of developing innovative medical device products. Besides, we also integrate the products from STSP manufacturers into the medical college training system. With this long-term training, medical students who may become KOLs in the future will have a better understanding of medical devices made in Taiwan; local and foreign KOLs will hence act as the advocates to endorse Taiwan medical devices. Such counter-corporation among physicians and suppliers can eventually elaborate market efficiency towards positive circulation.

3. Product Promotion Platform

The purpose here is to construct a promotion platform to boost the overall image of Taiwanese medical device industry. Through the pavilion of high-end products, oversea technology matching seminars, and oversea expansion, the visibility of Taiwanese medical device products has been enhanced. Furthermore, a brand mechanism shall be jointly created to achieve strategic alliances and joint Internet promotions among domestic brand leaders and medical device makers in STSP. At the same time, the cluster exhibition is designated in the medical device area to boost product visibility and increase matching opportunities for agents.

With the development experience of the medical device industry, Taiwan is successfully creating a series of innovative service platforms. However, there are several important mechanisms in this study that can serve as a reference for other countries. Future innovative marketing models will also facilitate the more complete ecosystem of STSP.

Keywords: Southern Taiwan Science Park (STSP), medical device, key opinion leader (KOL), innovation

1. Introduction

There are two approaches to increase economic output: (1) increasing the input in the production process, or (2) trying to acquire more output from the same amount of input. Generally speaking, the latter essentially means innovation via introducing new or improved products (commodities or service), procedures, organizational methods, marketing strategies, etc. Innovation is regarded as the foundation for creating wealth in an economy.^[1] In today's hyper-competitive market, innovation is considered a key factor for a successful industry. It is also the fundamental cause of transition from a conventional economy to a knowledge-based economy. In addition to new product development, a complete operation of the innovation ecosystem cannot be built up without a good profit model.

An innovation ecosystem is a conceptual framework used to describe market competition; it consists of key components, such as technology innovation, business model and organizational management innovation. In the value chain of a traditional industry, different companies are situated at different parts of the up-, mid- and downstream of the industry, where they enjoy their corresponding profit. In the innovation ecosystem of an emerging industry, whether or not a company is at the core position of the system becomes the key factor. The core companies share values from market competition with other companies and relevant institutions. In the innovation ecosystem, companies at the core position are not necessarily those with core technologies. Rather, they are often platform-oriented companies with the ability to integrate relevant innovation resources.

The innovation ecosystem of the medical device industry consists of the following elements^[2]:

- Fuelers: venture capitals (VCs), investors, open markets, etc.
- Innovation catalysts: small start-ups, large companies, incubation centers, etc.
- Regulators: Food and Drug Administration, Centers for Medicare and Medicaid Services (CMS), etc.
- Consumers: patients, physicians, hospitals, etc.

The innovation catalysts need resources to commercialize innovations of medical devices, and the resources come from the fuelers (such as VCs). When the products meet the standards of regulators, they will be launched into the market to the consumers (patients, physicians and hospitals). The incomes generated from the sale of the products will then be used as catalysts for the ideas and incentives of the fuelers.

However, the medical device industry has three characteristics in the marketing model which are not easy to break. First, it is a relatively closed market in comparison with other markets, and it needs super brand marketing and expert endorsement strategies. Second, the marketing of medical devices is part of an experience economy. The products need instructions and operation to be understood. Third, clinical data should be collected to build up physicians' and patients' trust in medical device products. Therefore, product safety, production costs and physicians' degree of trust need to be included within the development process of medical devices.

1.1 Safety of New Technologies

The most important topic of the medical device industry is product safety, and safety is the result of quality medical devices. Therefore, quality must also be considered during the research and development (R&D) process of medical devices; in addition, consumers' feedback is an important factor.

1.2 Development Costs of Medical Devices

Before a medical device acquires market approval, its development costs include those from proof of concept (such as laboratory tests and animal tests), studies on safety and clinical feasibility (such as small-scale human tests), and key experiments. The average cost from the proof of concept to the acquisition of market approval is around 73 million US dollars. The marketing costs after the acquisition of market approval are two to five times that of the development costs, about 136 million US dollars.

The key to ensure maximum effectiveness of development costs lies in continuous feedback of testimonies from the users (physicians or patients). This will allow the development of innovation to be based on clinical and scientific statistics, thus shortening the time required for the products to be launched into the market. Through communication between physicians and manufacturers, the manufacturers can obtain clinical information from the physicians; such information will serve as a reference to develop innovative products. On the other hand, if the products meet physicians' clinical needs, they will be willing to use the products, and become the "Key Opinion Leader (KOL)" after the products are launched into the market. Therefore, establishing a communication mechanism is one of the important factors of developing innovative medical device products.

1.3 Physicians' Attitudes

It is difficult to change physicians' habitual use of clinical approaches to treatment, as the physicians are very cautious in using "NEW" medical devices. Therefore, super brand marketing and expert endorsement strategy are required. It requires surgical assistants' help or clinical experience to understand the products. It also requires the establishment of clinical data to build up physicians' and patients' trust in medical device products. The above three factors are also keys for medical devices to be successfully launched into the market.

2. Innovation Ecosystem: Taking Silicon Valley as an Example

Due to the increase in the global aging population, as well as the rising awareness of the value of health, the medical device industry is thought to have a great future development potential. The value of the global medical device market was around 340.3 billion US dollars and is expected to reach 405.3 billion US dollars by 2017^[3]. The largest regional medical device market in 2014 was in the America with a share of 45.5% of the global market. It was followed by 26.8% of the western European region, 21.3% of the Asia-Pacific region, 4.1% of central and eastern European region, and 2.4% of the Middle East and Africa.

In the United States, there are over 6,500 medical device companies, most of which are small and medium enterprises (SMEs); 80% of these companies have fewer than 50 employees, and many small companies (especially innovative start-ups) have few or no sales incomes. 50% of the world's Top 30 medical device companies are based in the US (Chart 1). An analysis of the number of patents owned by these US medical device companies shows that more than 50% of these companies with patents have fewer than nine employees, and 25% of companies with patents have fewer than 50 employees^[4], thus demonstrating the high capacity of US start-ups in regard to their R&D ideas.

There are many medical device companies in Silicon Valley, which has an environment that favors the development of new ideas in the field, and has a well-established ecosystem for the commercialization of products. Ideas for high-quality and highly marketable products originate not only from technology, but also from the needs of physicians, as well as from the alliances and cooperation developed among physicians and engineers. Such alliances and cooperation are well-established in Silicon Valley. Physicians' participation is a key for product development. While some physicians start up their

own companies, others serve as instructors in start-ups under consulting contracts, stock options, or other forms of cooperation (Chart 2).

Moreover, there are numerous venture capital providers (VCs) and angel funders in Silicon Valley. Sand Hill Road in front of Stanford University is where the headquarters for the world's Top 10 VCs are based, around which there are many "angels." These VCs and angels are constantly looking for quality ideas in the laboratories of universities such as Stanford. They are in fact the driving force of the development of the US economy. Only with the angels and VCs can academic and research institutions have the opportunity to commercialize and industrialize their R&D results. ^[5]

These VCs and angels also play a role in facilitating communication between physicians and engineers, as they often organize meetings and social functions for the exchange of ideas between the medical and engineering communities. Of the medical device patents owned by US-based universities, 20% of them are owned by those in California, and mostly by the University of California and Stanford University. Both universities maintain close contact with top US medical institutions and outstanding engineering schools.

Silicon Valley has a favorable environment for turning original ideas or technology into commercialized or marketable products, which explains why there are so many medical device companies in Silicon Valley. Silicon Valley provides the plentiful resources and facilities required by medical device companies for each of the development phases, such as laboratories for animal tests, interdisciplinary technology integration (such as information and communications technology), consulting service for intellectual property protection, and government agencies for the management of medical devices. These incubation centers, along with peripheral supporting institutions, can accelerate the commercialization of ideas by: (1) providing resources needed by start-ups, (2) introducing experienced practitioners or physicians to serve as instructors for start-ups, and (3) facilitating cooperation between start-ups and advanced medical device companies. In the field of medical devices, ideas with the potential for commercialization and marketability are the most important part of planning in the first phase of start-ups.

Moreover, large medical device companies also acquire products from start-ups to expand their product lines at the marketing end. The international companies' global marketing channels and physician training system also play an important role in the marketing and promotion in this innovation ecosystem. In Silicon Valley, successful entrepreneurs also establish incubation centers, VC companies or consulting companies to further support new generation entrepreneurs, thus allowing the innovation ecosystem of Silicon Valley to continue to exert its beneficial effects.

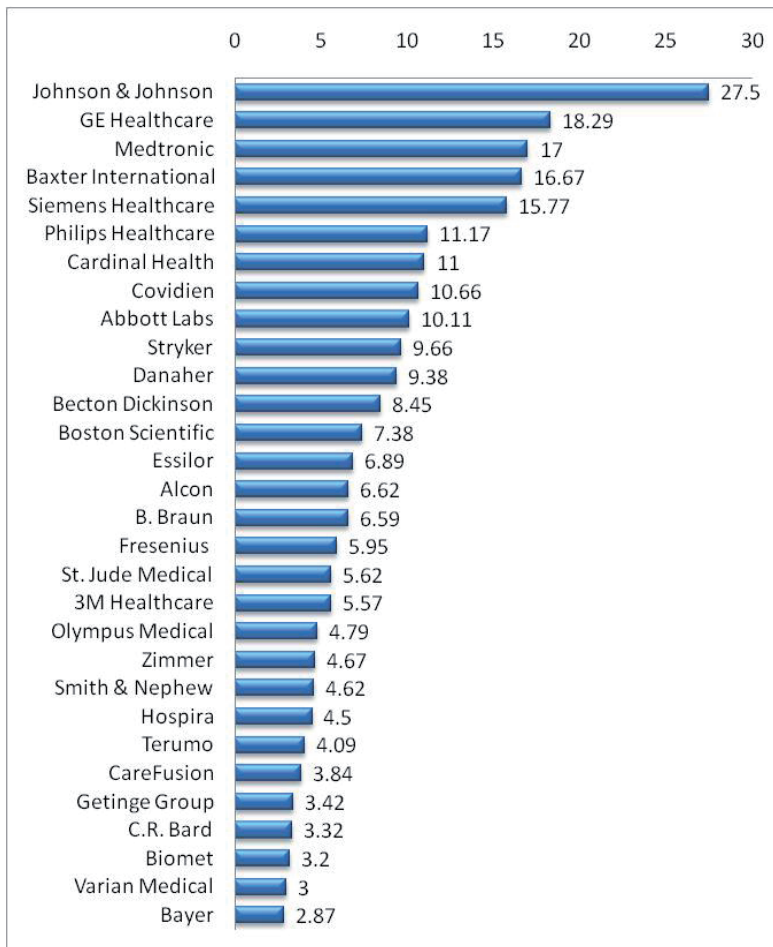


圖 1:
器材
Chart
(unit:
Chart
of

2014 全球銷售額前 30 醫療
廠商^[6] (單位: billions)

1: World's Top 30 Medical
Manufacturers in 2014^[6]
billions)

2: Innovation Ecosystem
Silicon Valley^[4]

With Silicon Valley as a basis of reference, this chart identifies eight indices of a successful innovation ecosystem environment^[7]:

Startup Output	This index assesses the intensity of startup output based on the area covered and population in the area.
Funding	This index assesses the investment of the capital market in start-ups and the risks they take.
Company Performance	This index assesses the performance and potential of start-ups with a combination of factors (such as revenues, jobs they create and potential growth).
Talent	This index assesses a combination of qualities of the entrepreneurs (such as age, educational background, experience, professional knowledge, the ability of risk assessment and the probability of success)
Support 支持系統指數	支持創業的周邊系統，如導師、相關專業服務及多元籌資管道 This index assesses supporting peripheral systems, such as instructors, relevant professional services and diverse funding channels.
Mindset 觀念及認知指數	綜合考量創業者素質(例如願景、韌性、風險承擔能力、誠信及問題解決能力)

	This index considers a combination of qualities of the entrepreneurs (such as vision, resilience, the ability to take risks, credibility and problem-solving ability).
Trendsetter	This index assesses whether or not the start-up ecosystem can rapidly introduce new technology and a management process, as well as grasp the latest global trends.
Differentiation from SV	This index assesses how the start-up ecosystem differentiates itself from Silicon Valley as well as its competitiveness.

Of the eight indices, “support,” which means peripheral systems supporting the operation of start-ups, such as instructors, relevant professional service, commercialization channels and diverse funding channels, is an area where governmental agencies can provide assistance to the development of the medical device industry.

3. Business Model of STSP Innovation Ecosystem

There are three science parks in Taiwan for the development of high-tech industry. Covering the biggest area, the Southern Taiwan Science Park (STSP) consists of two parks: one in Tainan, and the other in Kaohsiung. In Taiwan, science parks are run by the public sector through administrations subordinate to the Ministry of Science and Technology of the Republic of China, which has three major missions: formulating technology regulations, supporting academic research and developing the science parks. Taiwan’s science parks enjoy world-wide fame with their comprehensive facilities and environment.

Under global competition, the medical device industry requires a long journey from generating ideas to developing the ideas into products. There are many challenges regarding regulations, testing and certification standards to break through and overcome. In order to form a cluster of the medical device industry in Southern Taiwan, the STSP provides necessary incentives by offering R&D subsidies to encourage cooperation between academia and enterprises. With the promotion of the STSP Bureau, the Southern Taiwan Biomedical Devices Industrial Cluster Establishment Project has successfully helped traditional industries upgrade their technology in the first phase (2009-2012). With “upgrading traditional industries” as its major strategy, the Project has successfully attracted 36 manufacturers to move into and establish factories in the STSP. The manufacturers have since then gradually built up their own brands, and the output values in 2013 reached 24.8 million US dollars. An industrial cluster is therefore taking shape.

In the second phase (2013-2016), the STSP has adopted a promotion strategy consisting of two aspects: marketing products and marketing know-how. The STSP has been helping the industry to develop brands, build up reputation and explore the market. With its cooperative relationship with peripheral research hospitals, the STSP has created an environment for innovation cooperation to motivate more ideas for clinical application, so that basic research results can be successfully commercialized. The function of marketing know-how is to satisfy a variety of demands, such as product certification and talent training, for the benefit of the industry.

In this regard, the focus of the second phase is on the establishment of a clinical innovation ecosystem. The environment of this innovation ecosystem consists of six critical elements: talent training, technology integration, incubation centers, consultation of medical device regulations and product tests, venture capital, and government resources. New concepts of medical device products often emerge from the exchanges between R&D personnel and clinical physicians; therefore, the STSP Bureau has designed a series of training programs for R&D personnel and physicians for the acquisition of the latest technologies and knowledge. The integration of clinical needs and technologies is also a key element for innovative medical devices. The establishment of incubation centers aims to provide business consulting and guiding

services for start-ups. Before medical device products are launched into the market, they need to go through the process of consultation of regulations and product tests. In addition, venture capital and government resources further support the development of innovative medical device products. Hence, the aforementioned six elements constitute the clinical environment of an STSP innovation ecosystem.

To successfully launch products into the market with efficacious marketing is the uppermost objective of developing medical devices. The marketing model of the medical device industry requires: (1) super brand marketing and expert endorsement strategies, (2) instructions and operations to understand the products, and (3) clinical data to build up physicians' and patients' trust in the medical device products. However, most of medical device companies in Taiwan are SMEs with limited manpower, technology, equipment and capital. As a result, they can only concentrate on their R&D process; it is not easy for them to complete simulations, tests and pilot runs. This situation causes a gap in the innovation ecosystem, which makes it hard to support the development of innovative products in STSP.

To help STSP manufacturers to speed up innovation and maximize the value of the industry, the STSP has to build service platforms to provide professional knowledge. These service platforms are the driving factors for an innovative business model, which allows manufacturers to profit from more resources for innovation. For this purpose, the STSP has developed three service platforms to support the operation of the medical device manufactures: a technology matching service platform, a clinical experience platform and a product promotion platform. Each of the three platforms is designed to solve possible problems during industrialization.

3.1 Technology Matching Service Platform

The purpose of this service platform is to link STSP manufacturers to all possible resources, so as to derive and create maximum value for the entire ecosystem. The resources include government subsidies and grants, academic talents and basic research results, clinical research resources of hospitals, ideas for clinical application, core research facilities of the National Applied Research Laboratories, product certification service, etc.

This service platform helps manufacturers to combine research capacity of domestic medical device R&D institutions and academia to form a comprehensive technology matching service network, so that STSP manufacturers can quickly receive help regarding R&D resources to accelerate product development. In addition, we facilitate intra- and cross-industry cooperation among STSP manufacturers, and match up- and downstream manufacturers to form R&D coalitions. We also organize technology or R&D result matching conferences to facilitate cooperation between manufacturers, academia and the research community, hold product or technology forums and symposiums, and invite domestic and international well-known medical device manufacturers or academic research institutions for cooperation opportunities between STSP manufacturers and international manufacturers. Moreover, we invite international well-known distributors and manufacturers to visit the STSP and engage in exchanges with STSP manufacturers. This will facilitate R&D interaction, help STSP manufacturers to obtain more orders and increase the international visibility of the STSP products.

3.2 Clinical Experience Platform

Channels for medical device products are relatively conservative and closed. With regard to the procurement process of new products in hospitals, clinical physicians usually propose their procurement requests, which are then evaluated by hospital superintendents and relevant inspectors before they are handed over to professional procurers. In general, the process goes from proposing requests, evaluating (costs and effectiveness) and procuring, to negotiating prices. During the evaluation, hospitals give consideration to factors such as product quality, function, price, size, convenience of use, ease of

operation, repair and maintenance, after-sales service, and feedback in the medical community. Other factors, including brand, quality reliability and whether or not there will be maintenance engineers to provide troubleshooting consultation, all serve as reference for the evaluation. Therefore, medical device manufacturers need to be able to provide these services when trying to enter the supply system of medical devices.

This service platform will establish clinical data and provide experience service for STSP medical device products by the following measures: 1. Providing project-based subsidies to enable medical institutions to conduct clinical research on STSP products launched into markets, in order to ensure their trust in using the products; 2. Establishing an experience project in which both students from schools of dentistry and dentists can experience products from all STSP clusters in advance so that they will trust and purchase them for future medical practice, with the output values also increased accordingly; 3. Conducting international clinical education and training, in which domestic and international physicians will observe and gain experience regarding the use of the products, and will thus be more willing to use the products, thereby raising the output value in a short period of time. This, however, could not be achieved through the conventional approach of product manufacturers alone earning trust from potential users.

The abovementioned measures can help the manufacturers introduce their products to domestic hospitals for trial, as well as to educational and research institutes affiliated to the hospitals. By reaching out to the domestic market, STSP medical device products will have the opportunity to exploit the 'home market effect'; this will, in turn, increase the international competitiveness of Taiwanese medical device products. Besides, we also integrate the products of STSP manufacturers into the medical college training system, and work with the hospitals to establish an international medical training mechanism. With this long-term training, domestic and international medical students and physicians who may become KOLs in the future will gain further understanding of, and be willing to use, medical device products made in Taiwan.

3.3 Product Promotion Platform

The purpose of the product promotion platform is to boost the overall image of Taiwan's medical device industry. The STSP provides a location, known as the show room, to display medical device products from all STSP clusters. Moreover, the STSP finances the manufacturers' participation in international exhibitions every year. Through the pavilion of high-end products and overseas technology matching seminars, the visibility of Taiwanese medical device products has been enhanced. Furthermore, we have jointly created a brand mechanism to establish strategic alliances, so that domestic leading brands and STSP medical device manufacturers can combine their promotion efforts.

Over the past year, we have organized a dental clinical observation and invited domestic clinical physicians to deliver preclinical introduction and keynote speeches on odontology (such as dental implantation and 3D digitization). The clinical physicians also performed on-site dental implant surgery. Through their explanation of the process, participants were able to understand the connection between clinical practices and innovative R&D. The on-site clinical observation also facilitated exchanges among physicians, R&D personnel and clinical physicians. Following the same approaches mentioned above, we also invited dentists of the Central Stomatology Hospital of Hanoi, Vietnam, to visit the STSP to facilitate the procurement cooperation between STSP manufacturers and hospitals in Vietnam. Currently, some of the STSP products are in Vietnam for inspection and registration before being launched into the market.

Moreover, we also invited international distributors or manufacturers from Russia, Vietnam, Thailand, Hong Kong, the Czech Republic, Australia and Korea to visit the STSP. Currently, the Russian-based CORAL Company serves as an agent for the products of Codent Technical Industry Co., Ltd. in the STSP, a

Vietnamese company promoting the products of Kuang Yeu Medical Co. Ltd., a Hong Kong-based company promoting the products of General Biologicals Corporation, and an Australian company and a Czech company promoting the products of EPED Inc. We also helped to facilitate an investment of over 1 million US dollars in Excelsius Medical Co., Ltd. by a Korean company.

With the development experience of the medical device industry, the STSP in Taiwan has successfully created a series of innovative service platforms. There are several important mechanisms in this study that can serve as a reference for other countries, and future innovative marketing models will also facilitate the creation of a more complete ecosystem. With the STSP Bureau's efforts over the years, by June 2014, there are currently 50 active manufacturers in the medical device cluster in the STSP, including 13 medical implant manufacturers, 19 medical equipment manufacturers, and 18 manufacturers of other medical devices. The investment value is 9.206 billion dollars, and the dental product line is the most comprehensive of all products. The STSP has created jobs for 814 people, helped the STSP manufacturers acquire 54 domestic patents and 16 international patents, and nurtured 332 masters and doctors.

4 Conclusion

In the past, due to the incomplete product line, Taiwan was considered in an inferior position in the medical device industry. It mainly resulted from the fact that during the group procurement process, hospitals preferred to purchase from large international medical device companies for the sake of price negotiation, convenience and better service. Continuing to face global competition, the STSP will move toward completing its product line.

In the future, the STSP will focus on "STSP product integration modules" for the promotion of innovative technology. The effort will include the "exhibition and joint marketing-based," "clinical experience-based" and "personalized experience-based" marketing modules. The aim is to provide clients with a total solution regarding appearance, structures, software, hardware and firmware of products, as well as a one-stop-service system. With regard to the procurement of STSP products, we will transform and upgrade the procurement from a business service model for products only to a marketing service-oriented model that focuses on product system integration modules. In so doing, in addition to supplying products only, the STSP manufacturers will also act as units that provide R&D, application and solution services.

Moreover, in line with the Taiwanese government's "one center one alliance" strategy, we strive to form an R&D alliance for the STSP medical devices and help the STSP manufacturers introduce their products into (1) trial channels and (2) educational and research channels of medical centers or hospitals. Products introduced to the trial channels will comply with standards required by the physicians. For manufacturers failing to meet the standards, we will help them develop R&D plans. With the product line developed after the establishment of the alliance, we will work with domestic hospitals to build a domestic product center and carry out clinical marketing for these products. Furthermore, in accordance with the STSP medical device experience project, we will first of all organize experience programs for domestic physicians and students to allow them to gain familiarity with and trust in domestic products. We will then arrange experience programs for international physicians and students along with educational marketing.

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