



STANDARD

Stock Symbol :1720

Standard Chem. & Pharm. Co., Ltd. (SCP)

Investor Roadshow

2020.04.15



生達化學製藥股份有限公司

STANDARD CHEM.& PHARM.CO.,LTD

免責聲明

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We do not undertake any obligation to publicly revise or update any forward looking statements for availability of new information, future events or otherwise. Real result probably differ substantially from those expected in these forward-looking statements.



Agenda



Introduction to Standard Group (SCP Group)

- Milestones
- Resource Integration
- Past Financial Performance



2019 Operating Results

- Consolidated Financial Statements
- Parent Company Only Financial Statements



Forward-Looking Strategies

- Future Development Direction
- Actions for Revenue Growth
- Forward-looking Strategy



Corporate Social Responsibility (CSR)

- Fan Dao Nan Foundation





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COMPLETE

Introduction to Standard Group (SCP Group)



International Accreditation



The first TW pharmaceutical company to be ISO9001 certified



The first TW company to pass **US** FDA inspection

SCP passed subsequent US FDA cGMP inspections without 483



SCP received **JP** PMDA's "Certificate of Foreign Drug Manufacturer"

Y2018 FDF Plant and API Plant passed PMDA GMP Audit



SCP's API plant passed **AU** TGA inspection



Y2010 SCP passed TW PIC/S GMP inspection

Y2012 SCP is certified GDP by the T-FDA

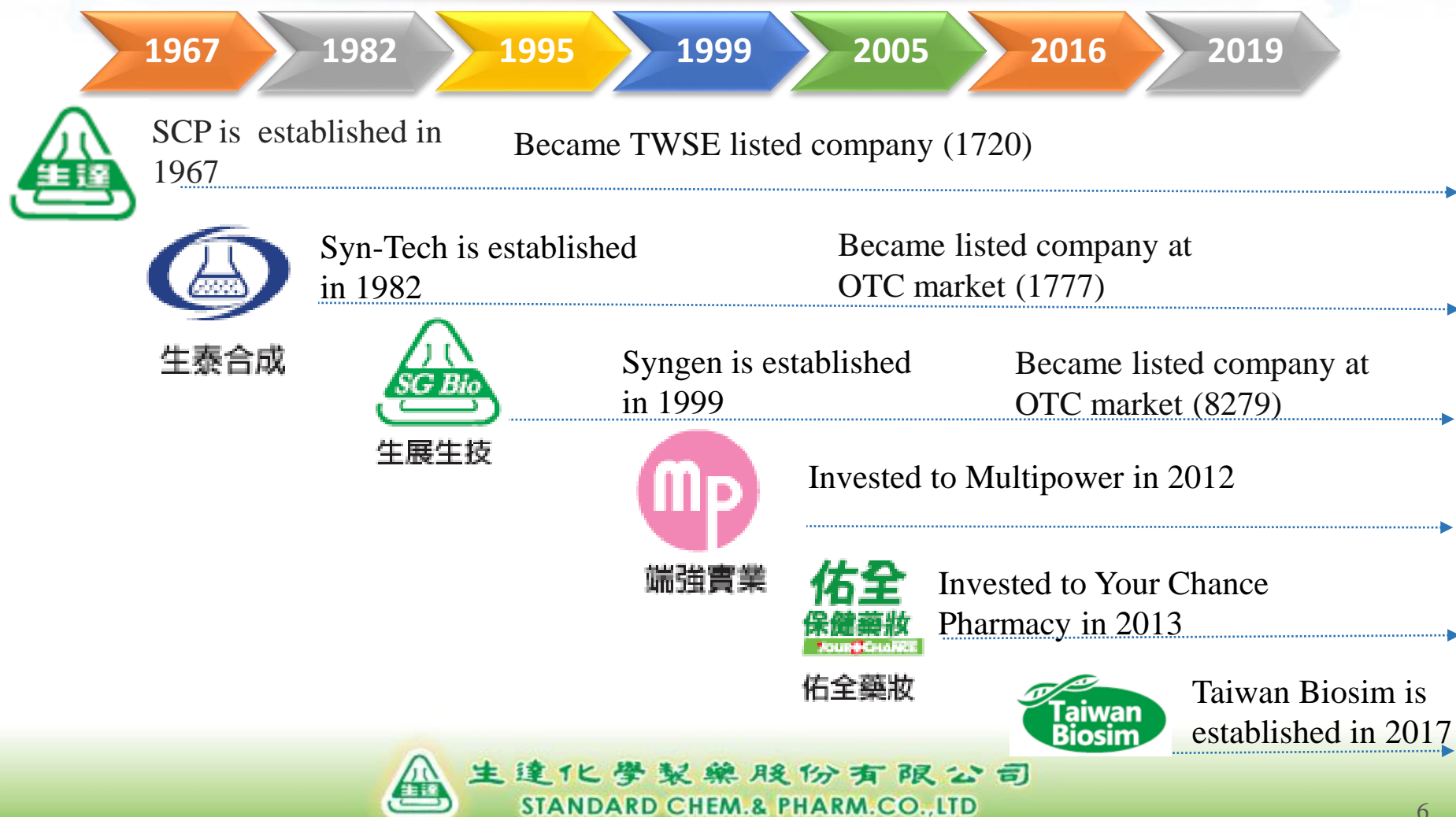


Y2012 SCP passed K-FDA inspection



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SCP and Related/Affiliated Companies



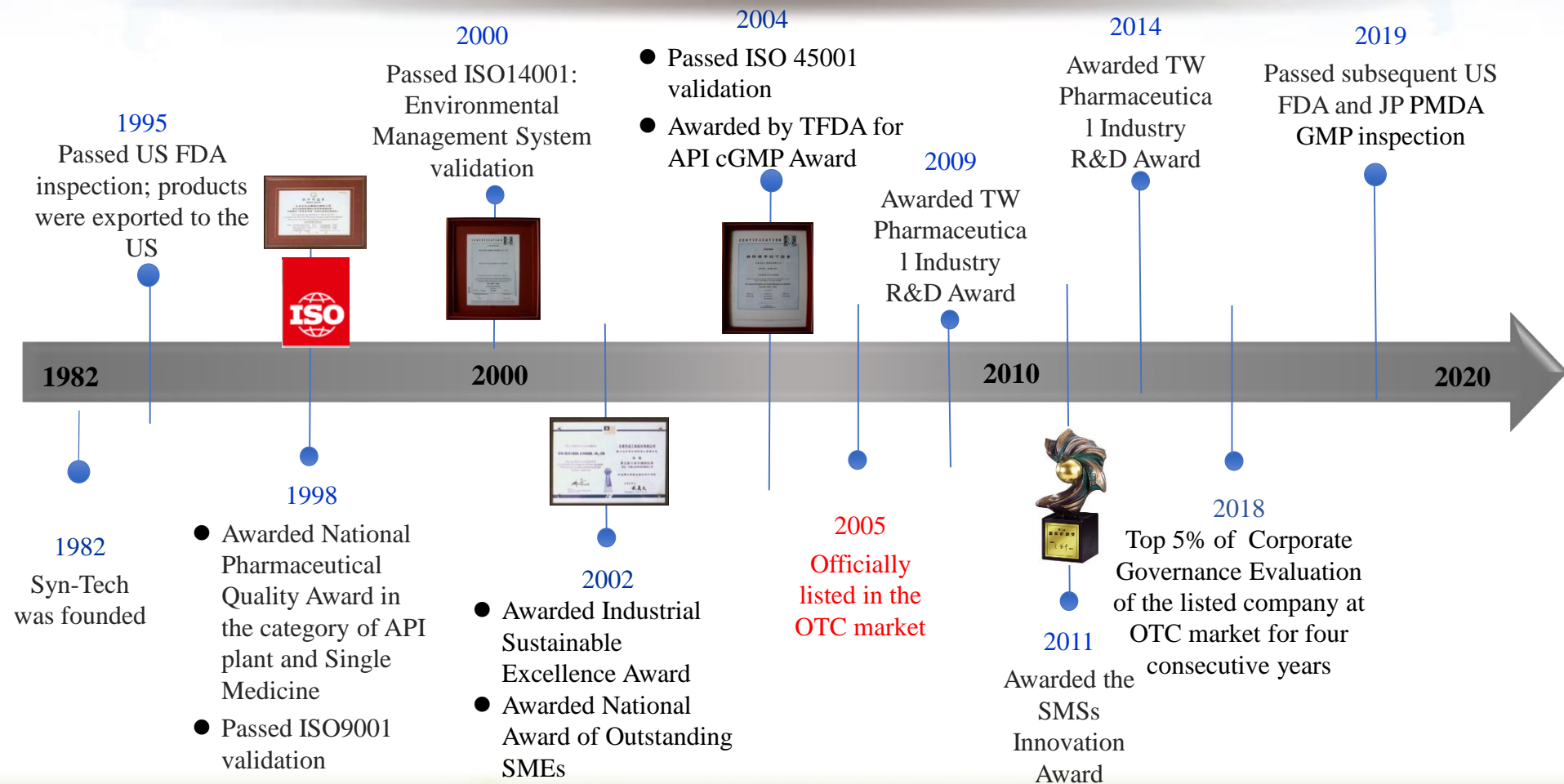


生泰合成



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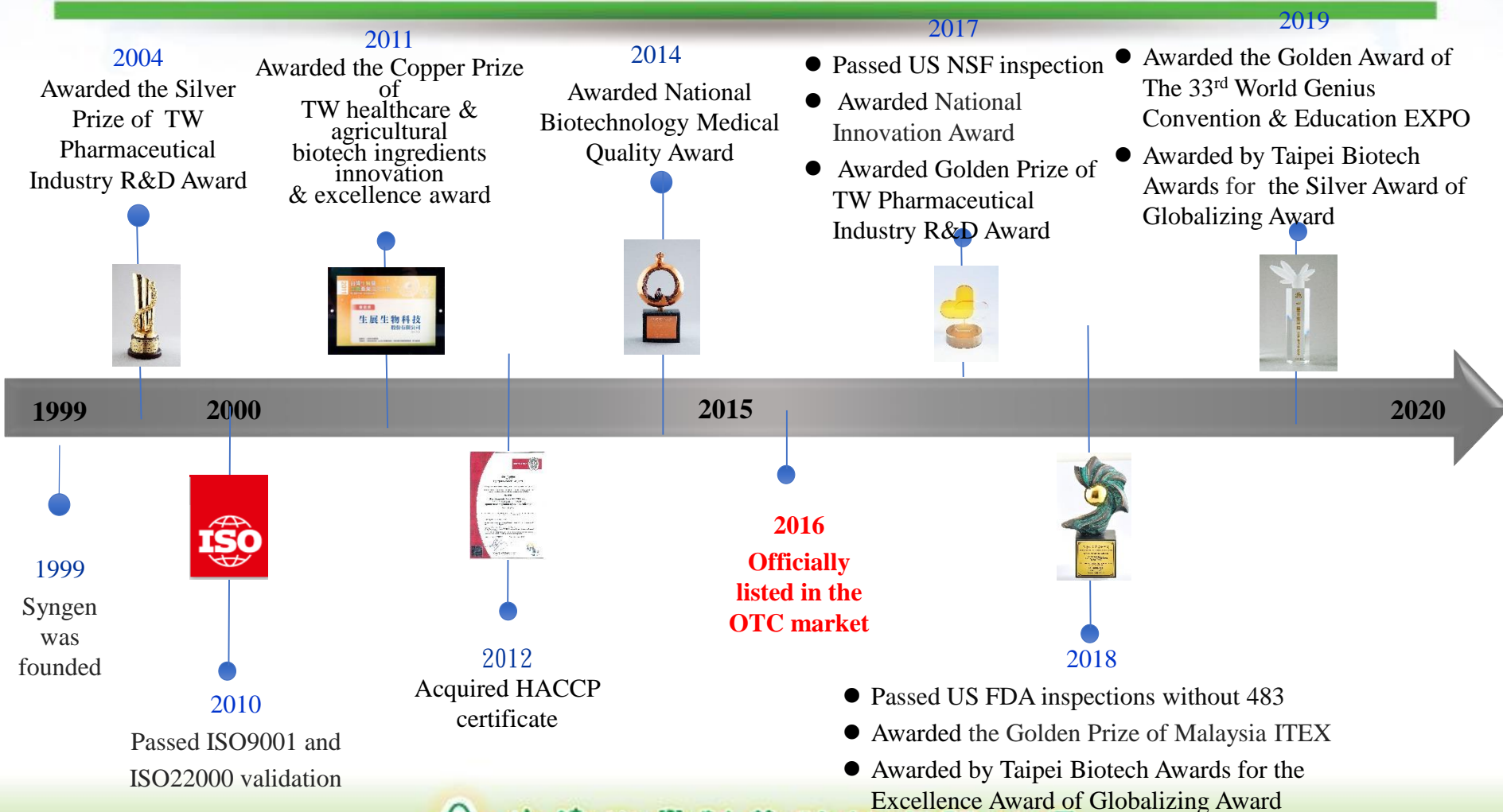
Syn-Tech⁽¹⁷⁷⁷⁾ Historical Milestone



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Syngen Biotech⁽⁸²⁷⁹⁾ Historical Milestone

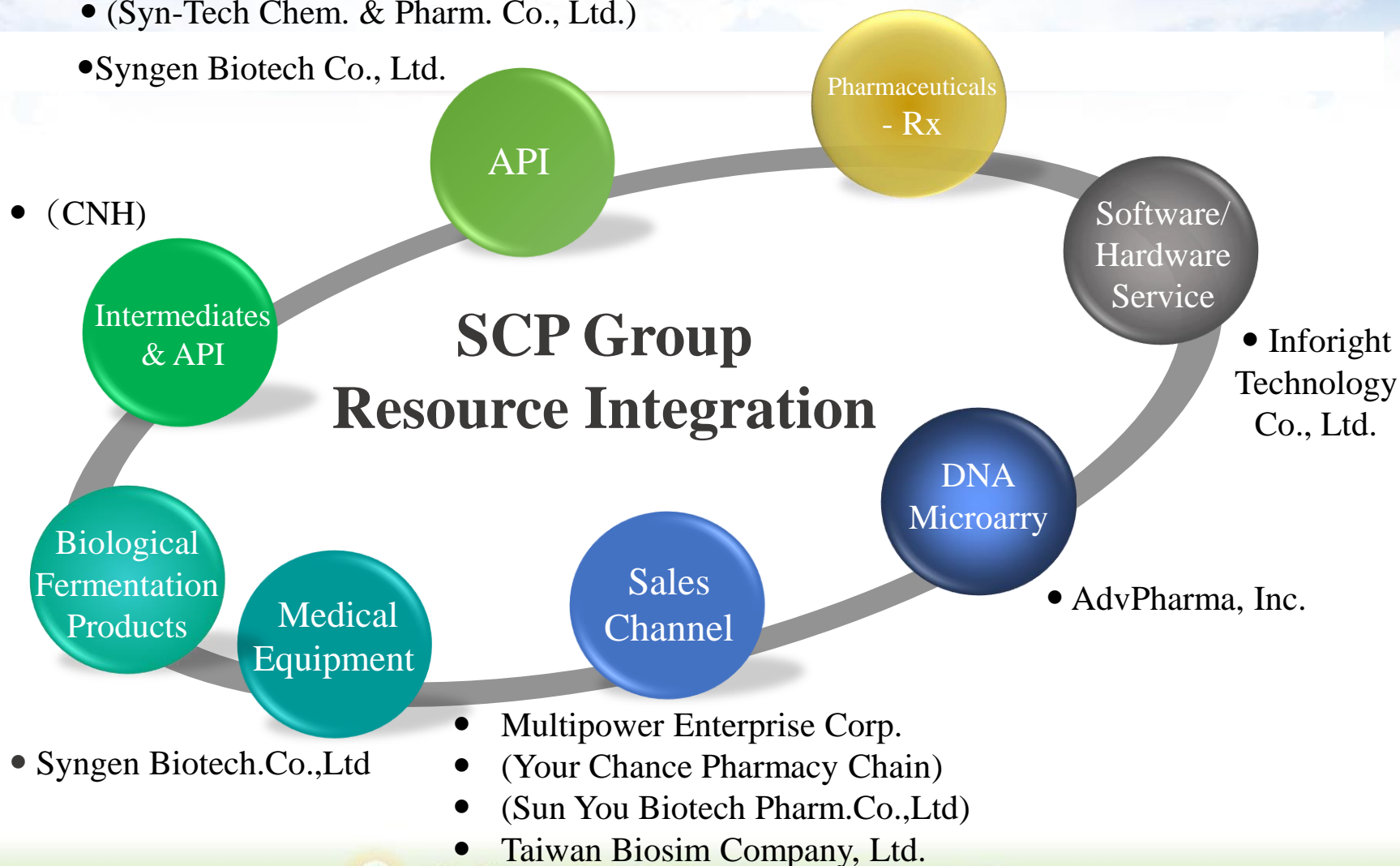


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- Standard Chem. & Pharm. Co., Ltd
- Souriree Biotech. Co., Ltd

- (Syn-Tech Chem. & Pharm. Co., Ltd.)
- Syngen Biotech Co., Ltd.

- (CNH)



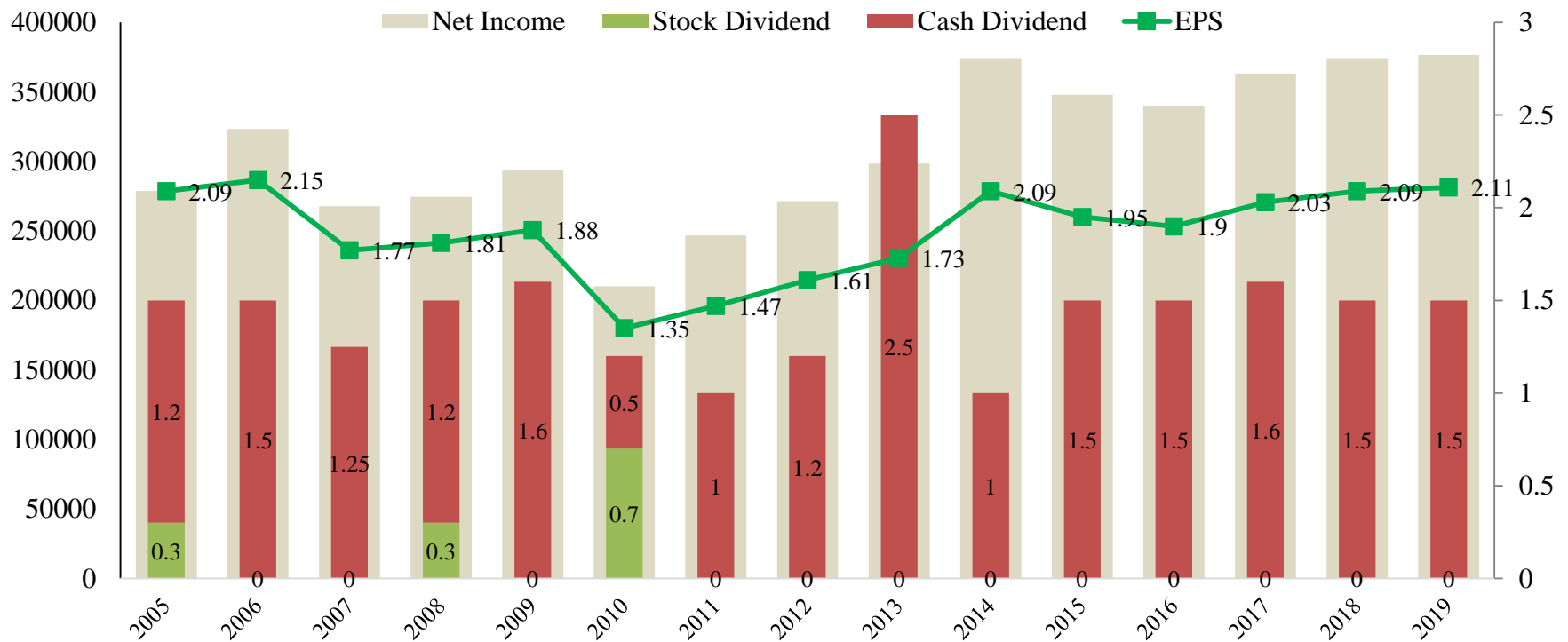
52 Years of Continuous Profit

(Profit and Dividend Performance in past 15 years)

An average cash dividend of NT\$1.46 per share was distributed for past 15 years

(Expressed in thousands of New Taiwan Dollars)

EPS





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2019 Operating Results

Income Statement (Consolidated)

(Expressed in thousands of New Taiwan Dollars)

	2019		2018		+	(-)	Growth Rate
	Amount	%	Amount	%	Amount	%	
Operating revenue	3,937,129	100	3,573,093	100	364,036		10
Operating cost	2,227,998	57	2,028,483	57	199,515		10
Gross profit	1,709,131	43	1,544,610	43	164,521		11
Operating expense	1,193,287	30	1,156,352	32	36,935		3
Operating profit	515,844	13	388,258	11	127,586		33
Non-operating income and expense	69,966	2	129,208	3	-59,242		-46
Income before tax	585,810	15	517,466	14	68,344		13
Net income	470,433	12	427,936	12	42,497		10
Net income attributed to Stockholders of the Parent Company	376,482	10	374,359	10	2,123		1
EPS (NT\$)	2.11		2.09		0.02		1



Balance Sheet (Consolidated)



(Expressed in thousands of New Taiwan Dollars)

	2019年12月31日		2018年12月31日	
	Amount	%	Amount	%
Cash and cash equivalents	1,556,352	22	1,305,141	20
Accounts receivable	911,021	14	931,257	15
Inventories	914,629	13	793,128	12
Investments	755,474	11	731,794	12
Property, plant, and equipment	2,116,644	31	2,134,253	33
Other current and non-current assets	673,884	9	543,540	8
Total Assets	6,928,004	100	6,439,113	100
Current Liabilities	1,813,056	26	1,687,530	26
Long-term debts	0	0	152,283	3
Other liabilities	468,527	7	352,988	5
Total liabilities	2,281,583	33	2,192,801	34
Total shareholder's equity	4,646,421	67	4,246,312	66
Total liabilities and shareholder's equity	6,928,004	100	6,439,113	100

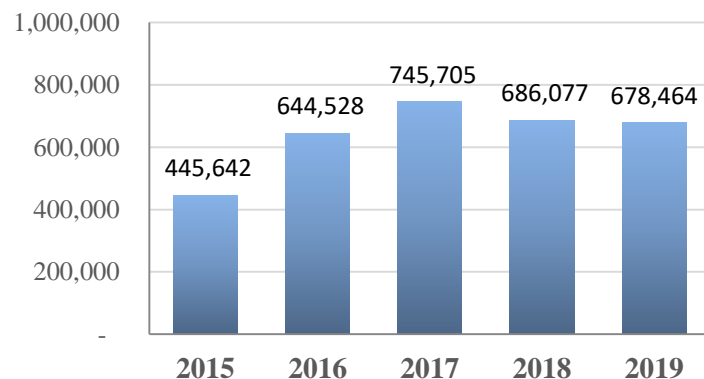


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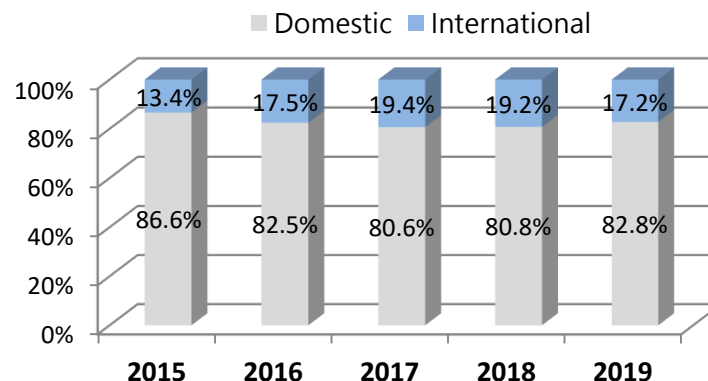
Global Revenue Ratio of past 5 Years (Consolidated)

(Expressed in thousands of New Taiwan Dollars)

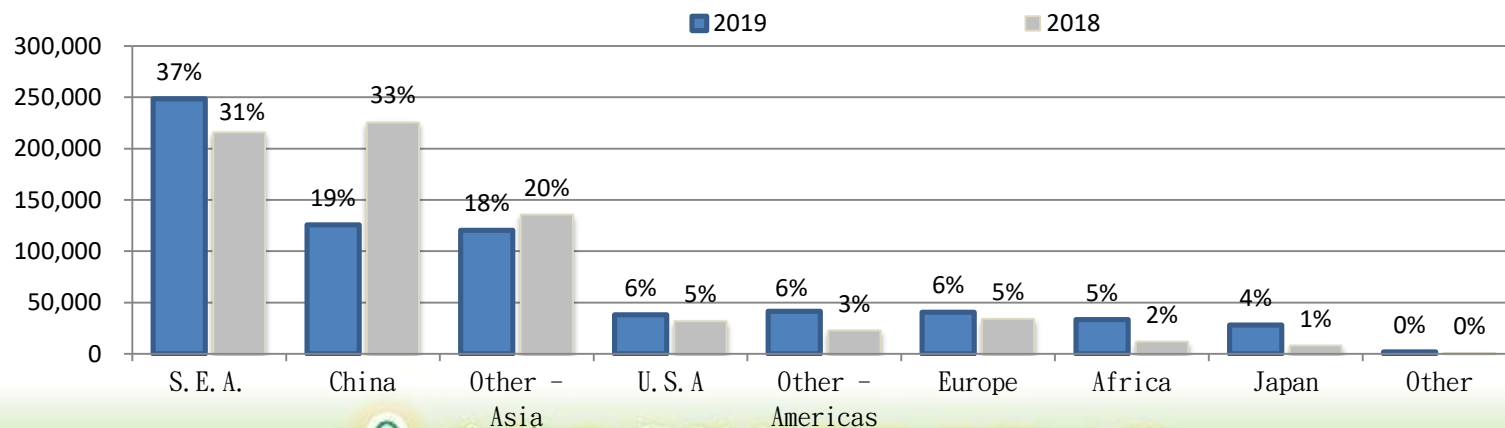
■ International Sales of past 5 years



■ Ratio of International-to-Domestic Sales of past 5 years



■ International Revenue (Ex-Taiwan)



Income Statement

(Parent Company Only)

(Expressed in thousands of New Taiwan Dollars)

	2019年		2018年		+	(-)	Growth Rate
	Amount	%	Amount	%	Amount		%
Operating revenue	2,403,678	100	2,385,819	100	17,859		1
Operating cost	1,318,348	55	1,287,252	54	31,096		2
Gross profit	1,085,330	45	1,098,567	46	-13,237		-1
Operating expense	735,177	31	739,224	31	-4,047		-1
Operating profit	350,153	14	359,343	15	-9,190		-3
Non-operating income and expense	89,853	4	88,618	4	1,235		1
Income before tax	440,006	18	447,961	19	-7,955		-2
Net income	376,482	16	374,359	16	2,123		1
EPS (NT\$)	2.11		2.09		0.02		1



Balance Sheet

(Parent Company Only)

(Expressed in thousands of New Taiwan Dollars)

	2019/12/31		2018/12/31	
	Amount	%	Amount	%
Cash and cash equivalents	837,940	15	976,973	18
Accounts receivable	673,731	13	683,451	13
Inventories	574,519	10	510,031	10
Investments	2,053,644	37	1,765,909	33
Property, plant, and equipment	1,069,039	20	1,141,224	22
Other current and non-current assets	272,831	5	242,364	4
Total Assets	5,481,704	100	5,319,952	100
Current Liabilities	1,408,520	26	1,227,480	23
Long-term debts	0	0	70,000	2
Other liabilities	308,972	5	341,247	6
Total liabilities	1,717,492	31	1,638,727	31
Total shareholder's equity	3,764,212	69	3,681,225	69
Total liabilities and shareholder's equity	5,481,704	100	5,319,952	100

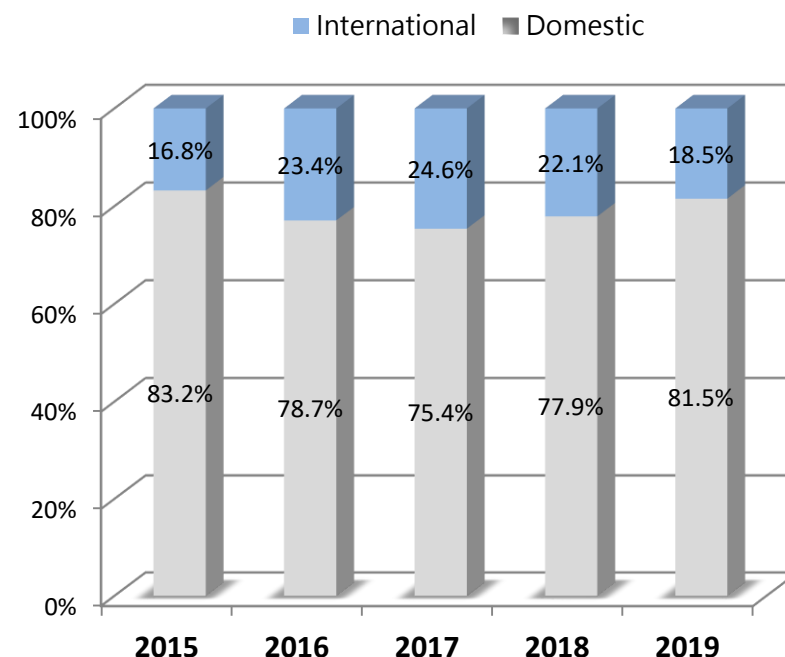
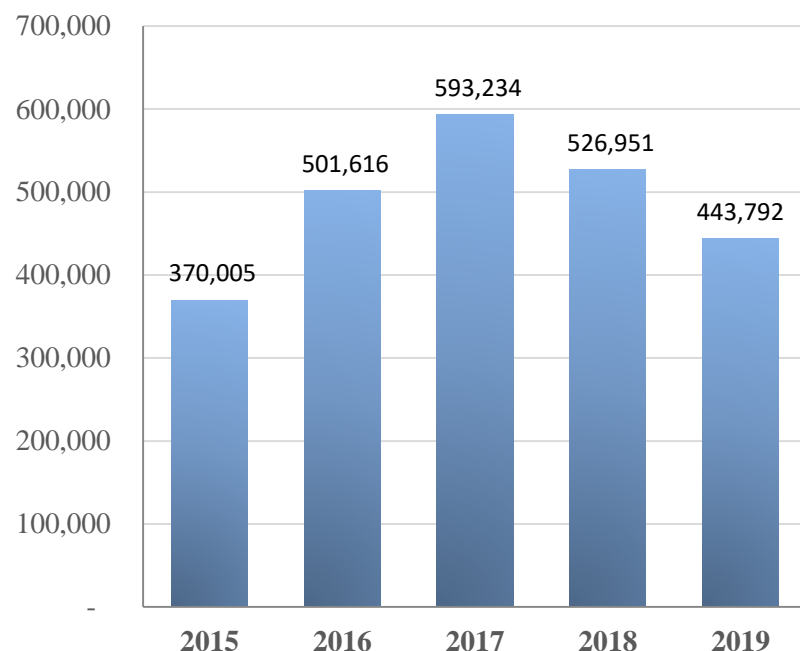


Global Revenue Ratio of past 5 Years (Parent Company Only)

■ International Sales of past 5 years

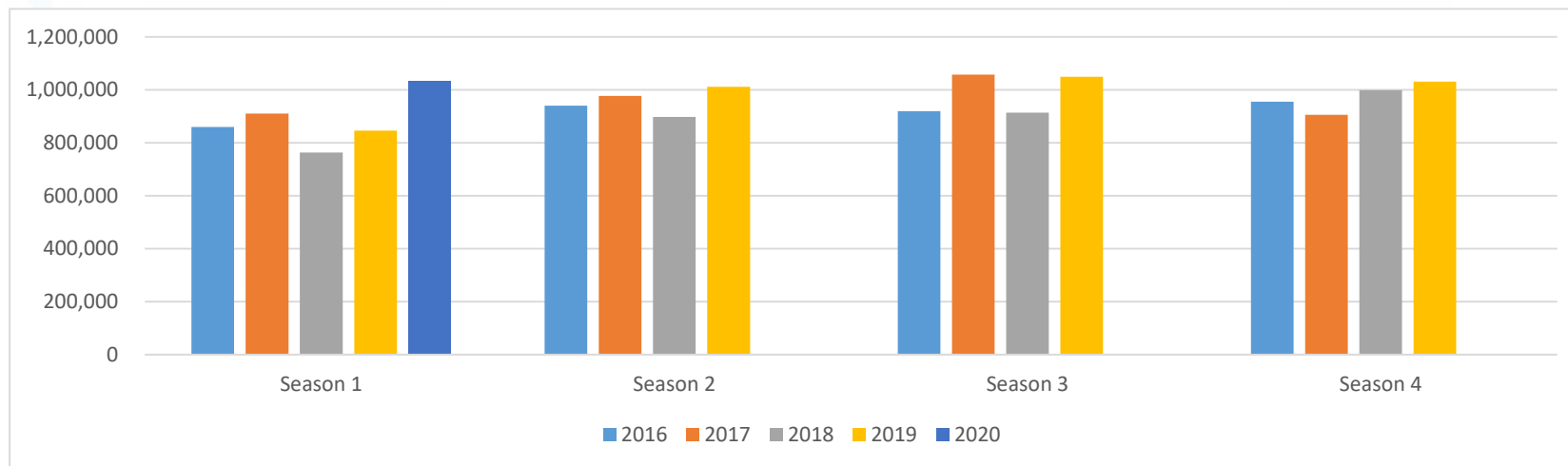
■ Ratio of International-to-Domestic
Sales of past 5 years

(Expressed in thousands of New Taiwan Dollars)



Comparison of Quarterly Revenue of past 4 years (Consolidated)

(Expressed in thousands of New Taiwan Dollars)



Consolidated Revenue	Season 1	Season 2	Season 3	Season 4	Annual Statistics
2016	859,024	940,238	919,663	954,876	3,673,801
2017	909,933	976,177	1,056,753	905,821	3,848,684
2018	763,261	897,693	913,353	998,786	3,573,093
2019	846,177	1,010,837	1,048,886	1,031,229	3,937,129
2020	1,304,408				1,304,408



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Forward-looking Strategy



Future Milestone



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Taiwan Generics

**International
Better than Generics**



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SCP – Major International Operations of the past 2 years

Taiwan

- Agent for Japanese Anti-psychotic brand drug Latuda®
- Agent for Herceptin®, a biosimilar anti-cancer drug
- Continues research & development for high technical threshold biosimilar drugs

China

- Continues export of antibiotic injection
- Continuous commercialized opportunities through Generic Quality Consistency Evaluation(GQCE)
- Active application for self-developed generic drug approval

Japan

- Export of Asthma product to Japan
- Launch of Anti-inflammatory Oral Solid Dosage in 2020



Revenue Growth Strategy - Taiwan

■ Taiwan as Base of Operations for Global R&D and Pharmaceutical Manufacturing

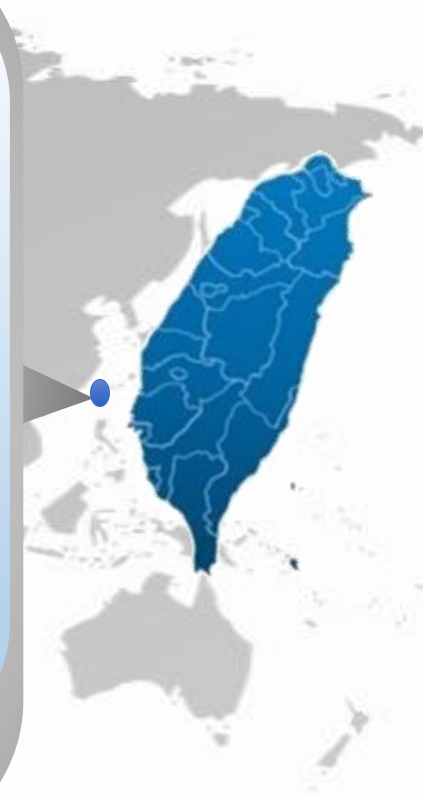
- Increasing export to Southeast Asia, China and Japan in 2020
- Maximizing market by new product launch in US, China, Japan, and ASEAN

■ Strengthen Manufacturing Capability

- Manufacturing line complies with international standards; have passed numerous international audits
- Production line simplification
- Continuing production expansion and upgrade equipments

■ In-licensing:

- Distribute Japanese brand psychiatric drug aiming at more than NT\$100 million revenue in 2020.
- Agent for 20 Mylan anti-cancer drugs in Taiwan; launch of second biosimilar drug in 2020.



Distribution of 20 Mylan anti-cancer drugs in Taiwan



■ 5 kinds of Macromolecules Biosimilar Drugs

- 3 ingredients, 5 drug licenses
- 3 drug licenses have been approved in Taiwan
- 2 drug was officially approved with NHIA reimbursement price

■ 15 kinds of Small Molecule Drugs

- 9 ingredients, 15 drug licenses
- 12 drug licenses have been approved in Taiwan
- 12 drug was officially approved with NHIA reimbursement price



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Mylan Ogivri

■ Herceptin

- The product is ranked 4th in global drug sales, and it has taken the first spot of cancer NHIA reimbursement for many years.
- The product was approved with NHIA reimbursement price in 2002, and the current NHIA reimbursement Price: NT\$46,895/dose; 2018 annual NHIA expenditure was NT\$2.206 billion with 5,030 applicants.

■ Mylan Ogivri

- The product was approved and launched in the U.S. in December 2017, and also approved in Taiwan in December 2018; the sale is commenced in 2020.
- NHIA reimbursement Price: NT\$ 39,860/dose, one dose usage for every 3 weeks, around 18 doses each year
- Indication: EBC、MBC、MGC

■ Breast Cancer Patients

- Breast cancer takes the first place of Taiwan female cancer, with the third spot of leading cause of death .
- Breast cancer patients are increased 12,000 every year in Taiwan



Mylan Fulphila

■ Original Drug: Neulasta

- Indication : to help reduce the chance of infection due to a low white blood cell count, while non-myeloid cancer patient receive anti-cancer medicines that can cause fever and low white blood cell count.
- Short-acting, 3~10 injections per therapy
- Long-acting, 1 injection per therapy

Product Name	Dosage	NHIA Price (NT\$)	2018 NHIA Volume
Short-acting: Filgrastim inj. (Filgrastim)	75µg	\$694	14,863 inj.
	150µg	\$1,462	24,150 inj.
	300µg	\$1,835	155,671 inj.
Long-acting: Neulasta inj. (Pegfilgrastim)	6mg	\$18,497	1,309 inj.

■ Mylan Long-acting: Fulphila(Pegfilgrastim)

- NHIA Price: NT\$15,722 (effective from April 2020)



Revenue Growth Strategy - China



SCP Competitiveness

- SCP has successful experience with U.S. and Japan regulatory dossiers
- SCP to continue to specialize expertise in BE design and execution



Mid-Term Goals

- Increase technology in-flow
- Increase revenue from profit-sharing



Collaboration Model

- Tech-transfer
- Co-development
- BE Collaboration
- Profit-sharing Partnerships



NMPA review of importation

- Continuous export of antibiotic injection products
- Diabetes products passed the BE test. Application for review is expected to be submitted in 2020 Q2



NMPA Consistency Evaluation

- 8 contracts signed and in execution.
- Flexible adjustment of strategy due to COVID-19 and 4+7 tender policy changes.



Results

- Emphasize export and tech transfer simultaneously.
- Increase the number of cooperative projects and pharmaceutical companies

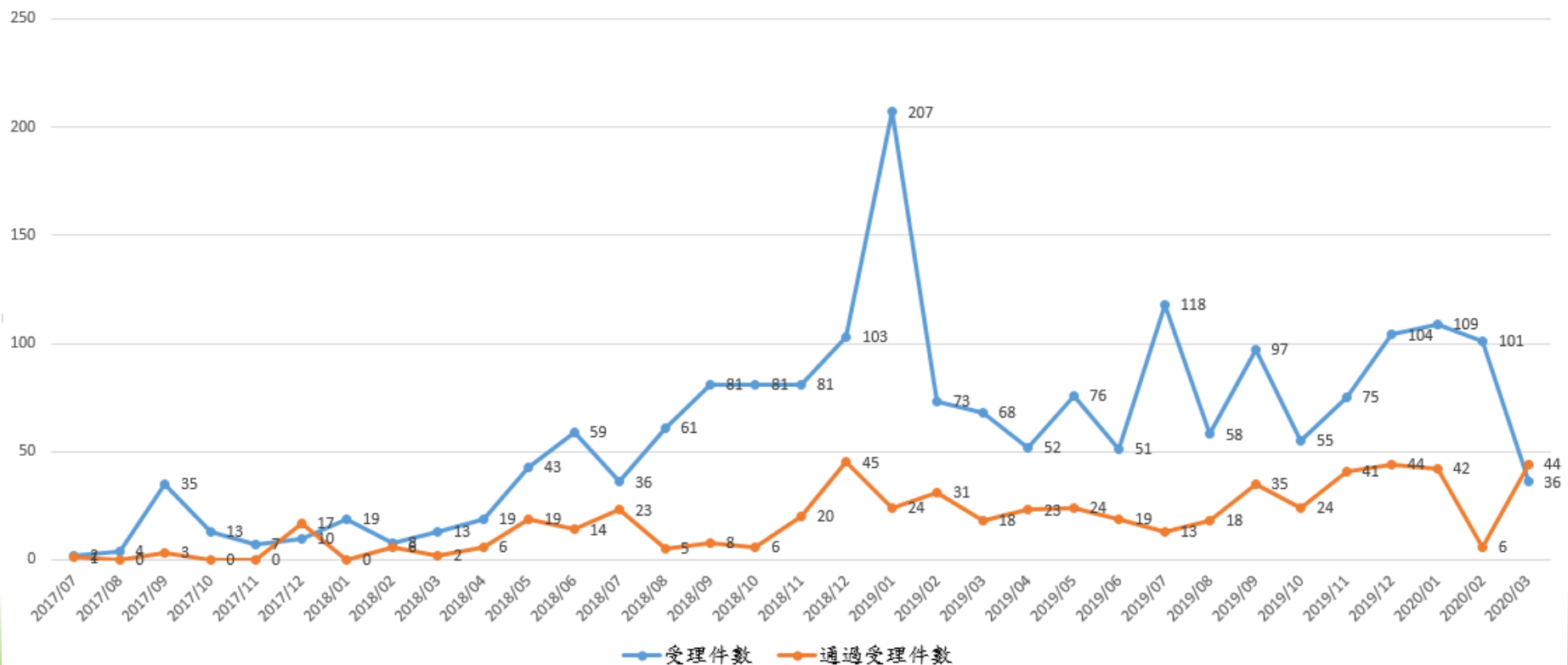


NMPA Reforms: Consistency Evaluation

Total received & approved submissions

- 2017.07~2020.03 1,955 submissions were received in total, 581 submissions were passed.

2017.07-2020.03 一致性評價送件與核准數量比較圖



NMPA Reforms: Consistency Evaluation

Total received & approved submissions

■ Revised status of GQCE

Period	Received #	Approved #
2017	71	21
2018	604	154
2019	1,034	314
2020 Jan. to Mar.	246	92
Total	1,955	581

■ Cost of Research and Development

- According to Pharmcube's statistic, during Jan. 2018 to Oct. 2019, there were 65 Consistency Evaluation items. The ceiling and bottom of R&D expenditure among those 65 items were \$20.11 and \$1.54 million, respectively. Expenditures between \$1.54 ~ \$5.00 million consisted of 28% of total items; over \$15million consisted of 3% of total items. Midian=\$6.78 million.



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Procurement by Volume Policy Implementation: in 4+7 cities

■ Decrease of drug prices via Procurement by Volume Policy

- On Nov. 14, 2019, “Pilot Program for Centralization Drug Procurement by National Organization” was approved by China
- Announcement of purchase volume while bidding; the lowest bidder gets the procurement contract for one year period.
- Through the Procurement by Volume tender to achieve drug price reduction.

■ 4+7 Cities :

- Consisted of 4 municipality and 7 provincial capital
- 4 Municipality: Beijing, Tianjin, Shanghai, Chongqing
- 7 Provincial: Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an.



Impact of Procurement by Volume Policy



■ No Guarantee Market

- There is no guarantee to win the Procurement by Volume tender even after approval of Consistency Evaluation

■ Vicious Price Competition

- Dramatic price drop after Procurement by Volume policy
- Entecavir (for Hepatitis B) price dropped by 96%; Irbersartan (antihypertensive drug) price dropped by 60%

■ Survival Competition for Pharmaceutical Entities

- Decrease in number of bidder and bidding items.
- Before the Policy, 207 applications were submitted to the Consistency Evaluation; after the Policy, only 110 applications were submitted to.



Revenue Growth Strategy - Japan



Collaboration Model

- Japanese Distribution Partner
- Contract Development, and Manufacturing
- License Holder



Raw Material Strategy

- Strategic alliance with API manufacturer.
- API Vertical Integration with Syn-Tech.



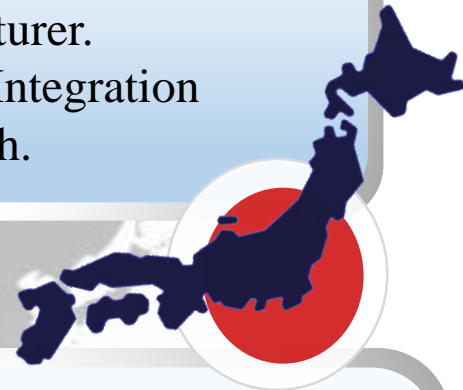
Current State

- Obtained marketing license for Montelukast (Asthma), expected export of NT\$20million

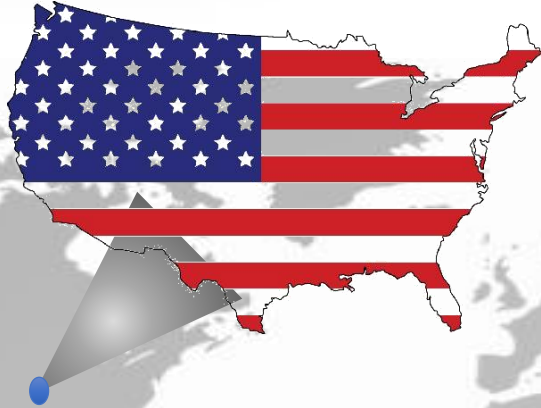


On Going

- License received for Nonsteroidal Anti-inflammatory Drug (NSAID) in Feb. 2020.
- Expected export of NT\$30million.



Revenue Growth Strategy – U.S.A.



U.S.A. Market

- Largest Rx Market
- Characterized by lengthy review timelines and costly compilation and filing work
- Part of SCP's long term goals



Strategy

- Strategic alliance with API manufacturer.
- API Vertical Integration with Syn-Tech.



Current Status

- Export of one diabetic treatment
- One approval, pending patent settlement terms
- Obtained Muscle Relaxant license in 2019 Q4 for Amyotrophic lateral sclerosis(ALS) symptom.



Forward-looking Strategy Layout



- Increase international business resources
- Recruit international talents



- Utilize Taiwan's cutting-edge R&D technology to enhance potential revenue .



- Stable foundation
- Rapid revenue creation
- Step-by-step optimization for minimization of loss
- Focus on market knowledge and business acumen
- Establish strategic partnerships for mid- and long-term goals





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Corporate Social Responsibility

Fan Dao Nan Foundation



Fan Dao Nan Foundation

- Established in 1987
- Endowment Fund: NT\$196 Million
- Annual Budget: NT\$12 Million

Principal Activities

- Cultural and educational development activities
- Scholarships and Talent Cultivation
- Non-profit education
- Sponsor R&D and Innovation



Rewards and Honors Received

- 2011: Special Recognition Award – Dept. of Education
- 2012: Tainan City Govt. Grant for Scholarship Program
- 2013: National Special Selection Award for After-School Program – Dept. of Education



Corporate Social Responsibility



Scholarships

- University (related fields): 2 universities/5 students
- High school: 8 schools/108 students
- Middle school: 57 schools/797 students
- Elementary school: 226 schools/2,626 students

Scholarship Total – NT\$5.86MM



Hope After-school Class

- Weekday afternoons
- 22 schools
- 1,806 students

Scholarship Total – NT\$1.75MM



Sunflower Wednesdays

- Every Wednesday afternoon
- 6 schools
- 300 students

Scholarship Total – NT\$400KK



Other Sponsorships

- Sponsorship to 17 non-for-profit organization for cultural and educational advancement

Grant Total – NT\$950KK



Meal-Assistance

- In 2019, provided 6,000 meals to students during winter and summer vacation.

Assisted Total – NT\$360KK



Charity



- SCP Children's Drawing Competition
- SCP National Table Tennis Competition

Prize Total – NT\$1.6MM



The First Senior Gym in Taiwan – The Center of Athletic Training and Health



- Intelligence analysis of health test results; customized design for sports course
- Provide a comfortable and professional health promotion place for middle-aged and senior people
- The first center was opened in July 2019. At the end of the year, the total user count is about 1,800.
- By Dec. 2020, 10 additional new athletic centers are expected to be set up; 3,000 user counts were estimated.



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Public Service Activity: Bone Mass Measurement



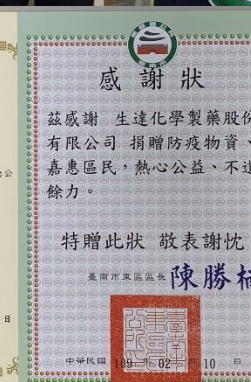
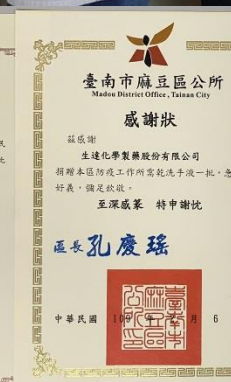
- Cooperate with medical institution, local community, and pharmacy for conducting public service activity: bone mass measurement.
- The activity were hold 48 times in 2019; 4,600 people in total were measured.



Infection and Prevention Control: COVID-19



- Within 3 months of COVID-19 epidemic, over 1,000 liters of alcohol(75%) in different container sizes were donated to publics.
- Alcohol were donated to donees, including general public, elementary schools, kindergartens, police station, fire departments, and district office, etc.





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Q & A



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