

元大證券
東生華營運說明會

2019/07/30

致力於提升慢性病患者之生活品質

免責聲明

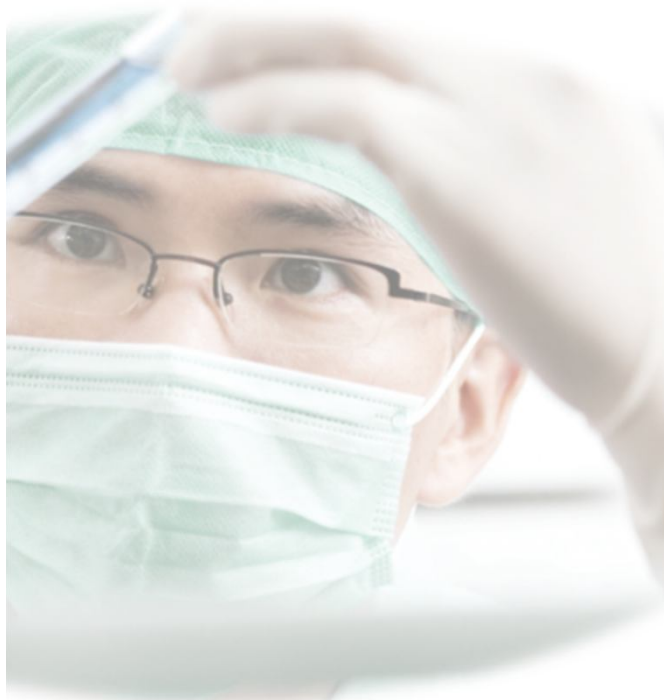
本簡報及同時發佈之相關訊息所提供之預測性資訊包括營運展望、財務狀況以及藥品開發規劃等內容，乃是建立在本公司從內部與外部來源所取得之資訊基礎。本公司未來實際所可能發生之營運結果、財務狀況以及藥品開發結果，可能與這些明示或暗示之預測性資訊有所差異。其原因可能來自於各種因素，包括但不限於政府政策、競爭情勢、國際經濟狀況、市場需求以及其他本公司無法掌控之風險等因素。

本簡報中對未來之展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司並不負責隨時再度提醒或更新。此簡報及其內容未經本公司書面許可，任何第三者不得任意取用。

Welcome!!



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2 Growth Strategy

3 RD Pipeline

4 In Progress Status

5 Financial Disclosure

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TSH Biopharm Co., Ltd.,



設立日期 / 實收資本額:
99年9月1日
新台幣3.84億元



專業領域：
Cardiovascular、Gastrointestinal、
Auto-immune、Critical Patient Care



產業：
生技醫療



核心能力：
新案源評估, 資源整合, 專案管理,
臨床試驗, 策略法規, 區域市場行銷



組成:
董事長：張志猛
總經理：楊思源
員工人數：約80人



基本資訊:
公司地址：
台北市南港區園區街3之1號3樓之1
辦公室：台北、台中、高雄
統一編號：53093421
官方網站：www.tshbiopharm.com

TTY Group



- A Taiwan-based biopharmaceutical company focuses Oncology, anti-infection, and healthcare.
- Major oncology products including Lipo-Dox®, UFUR®, THADO®, TS-1®, Tynen, and PAINKYL.
- Distribution channels: hospitals.
- Market cap: US\$613mn.



- A NRDO and network-pharma model adapted biopharmaceutical company.
- Focuses on the new drugs development for cancer and Asian prevalent diseases.
- Pipelines includes ONIVYDE™, PEP503, and PEP06 in development.
- Market cap: US\$518mn.



- A specialized biopharmaceutical company focuses on chronic diseases including cardiovascular, gastrointestinal, and autologous immune.
- Distribution channels: hospitals and GP
- Market cap: US\$90mn.



- A biotech company focuses on *Lactobacillus* related health food development.
- Distribution channels: GPs and drug stores.
- Market cap: US\$19mn.

Market cap is estimated by the closing price on 2019/1/2

TSH Vision and Mission



Vision

To be committed to improving the quality of life
of patients with **chronic diseases**

Mission

Focusing

To focus on the development of **patentable & high barrier specialty** drugs
with Pharmaco-economic profile.

Specializing

To specialize in establishing portfolio of **chronic disease**.

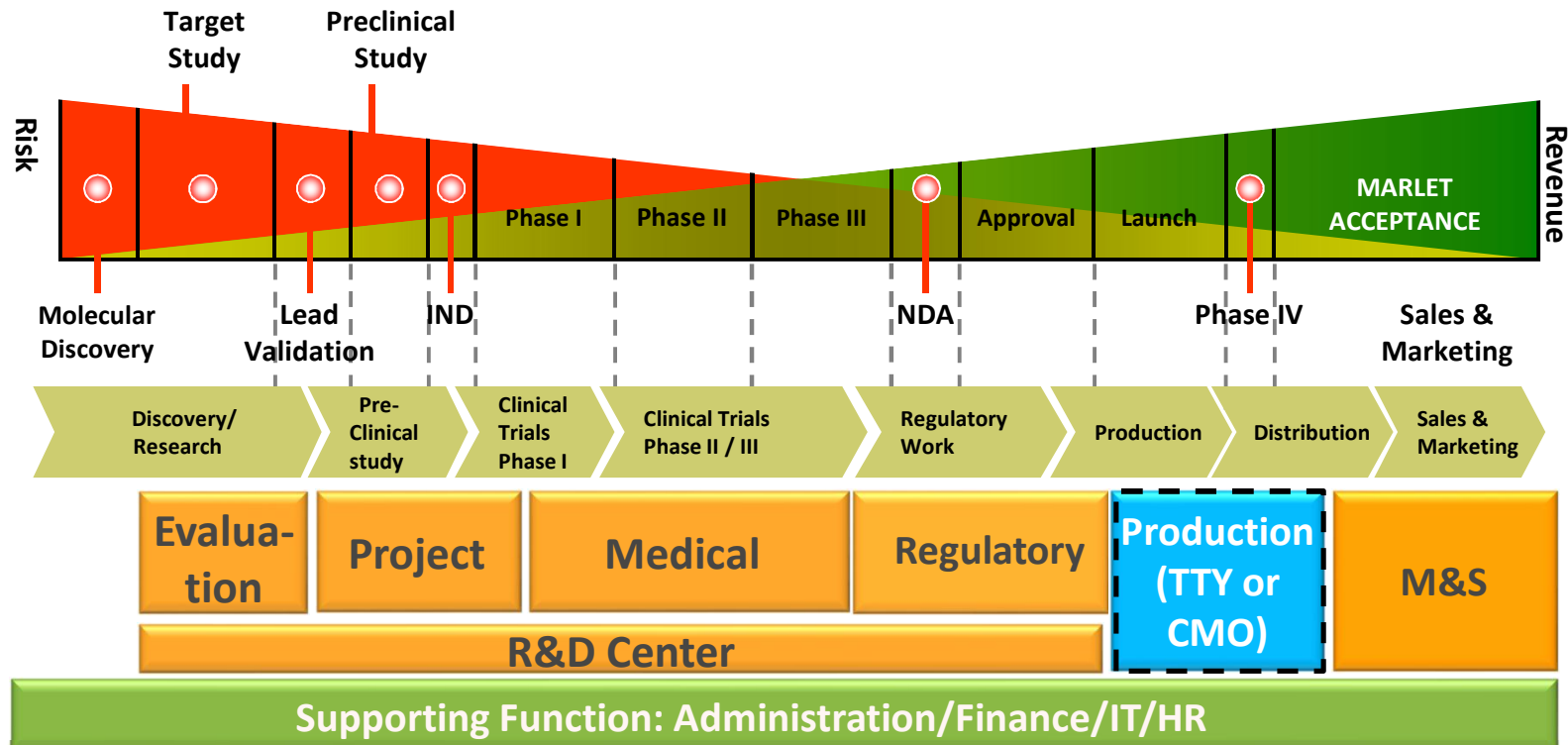
Becoming

To become a **best partner** for global
pharmaceutical companies in drug developing & **Asia** marketing expert.

Flexible Business Collaboration to Access Asia Market

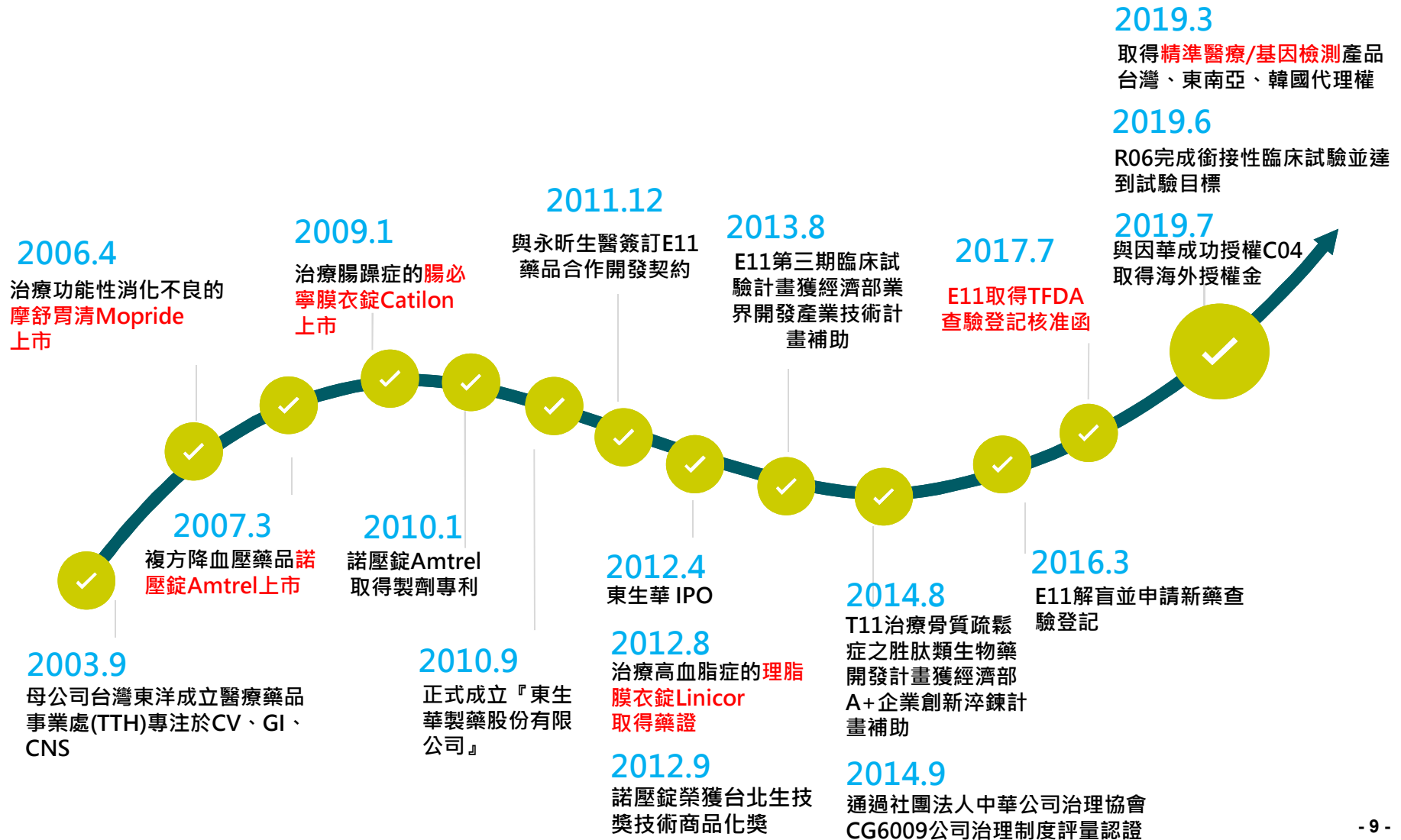


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tsh biopharm



- We have very innovative professional teams covering the entire industry value chain
- We possess the capabilities to optimize the R&D of new drugs
- We are able to evaluate and strike a balance between the financial outlay associated with new drug development and optimization of product revenue

重要大事紀

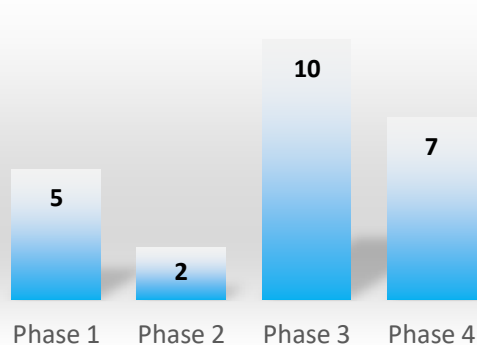


TSH Clinical Experience

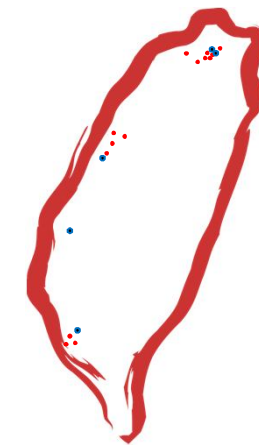
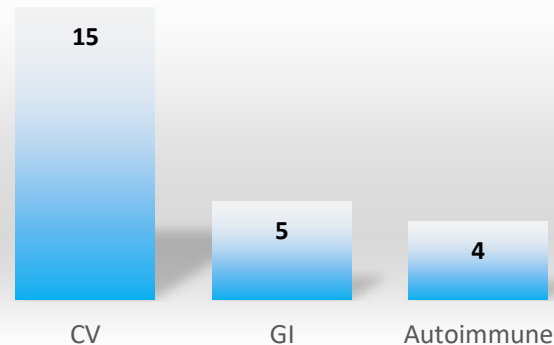


- TSH is dedicated to the advancement of medical research, with emphasis on the field of cardiovascular, gastrointestinal, and autoimmune diseases.
- High quality clinical trial experiences from Phase I to Phase IV.
- From 2010 to 2018, **24** regulatory authority and IRB approval clinical trials has been completed, or ongoing.
- 5 published SCI journals papers.

By Phase



By Disease



Collaborate with
Medical centers

Registration and Reimbursement

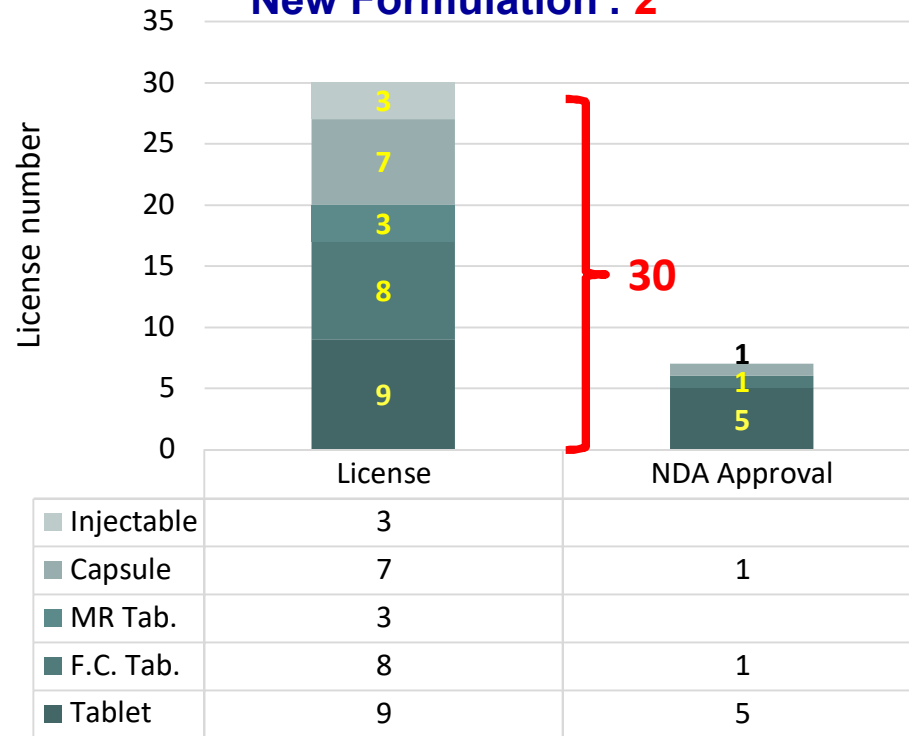
Marketing Authorizations in

Taiwan: **30**

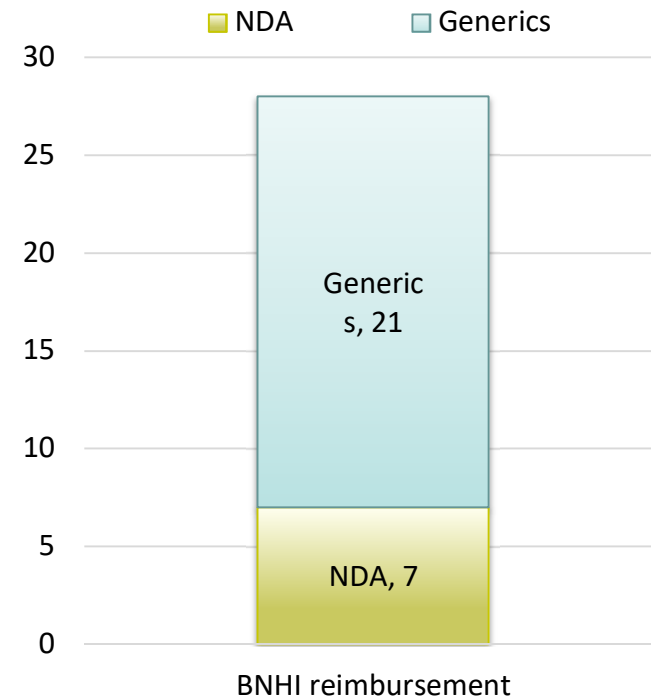
New Chemical Entity: **3**

New Combination : **2**

New Formulation : **2**



BNHI reimbursement application: **28**



TSH Core Products Information



Total World MKT Size* USD/M= 220M,
AP MKT Size USD/M^ = 170M

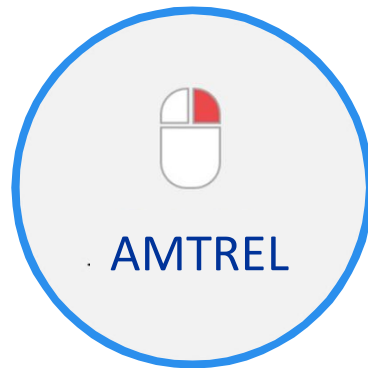


MOPRIDE

TNCE

Heartburn, nausea
or vomiting

JP MKT Size USD
= 35M,
AP MKT Size USD
= 135M



AMTREL

TNCE + Specialty

Hypertension

World MKT Size* USD
= 110M,
AP MKT Size USD^
= 17M

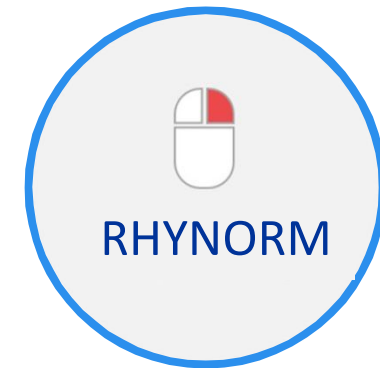


LINICOR

TNCE

Hyperlipidemia

World MKT Size* USD
= 25M,
AP MKT Size USD^
= 2.8M



RHYNORM

Special Generic

Arrhythmia

World MKT Size* USD
= 50M,
AP MKT Size USD^
= 16M

* Clarivate Analytics

^IMS data: 2018Q4 (AP excluding JP)

TSH Core Competency



NRDO + Market Orientation

Project M.+ Integration+ Risk Management



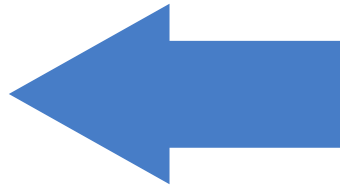
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Global Trend....

Past & Future

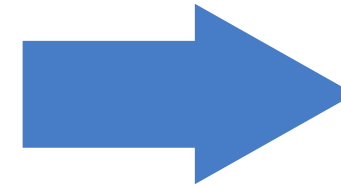
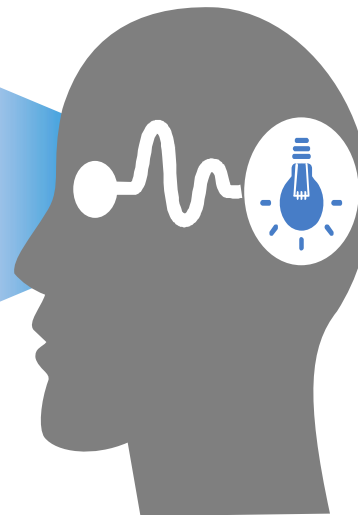


過去....RD by ourselves

- ✓ RD自己主導研發
- ✓ RD自建/外包+從頭(合成或是製程)開始做到上市)

過去.....

- ✓ 藥品歸藥品
- ✓ 檢測歸檢測



現在....BD & Strategic alliance

- ✓ 以外購/ BD(business development)方式加速上市速度與跨界合作
- ✓ 競爭速度加速N倍!!
- ✓ 在特定區域通路稱王

現在.....

- ✓ 精準化醫療興起, 檢測變成治療或是預防醫學的一部分
- ✓ AI/大數據更加的普及與方便取得, AI與醫療的結合事業已經來臨

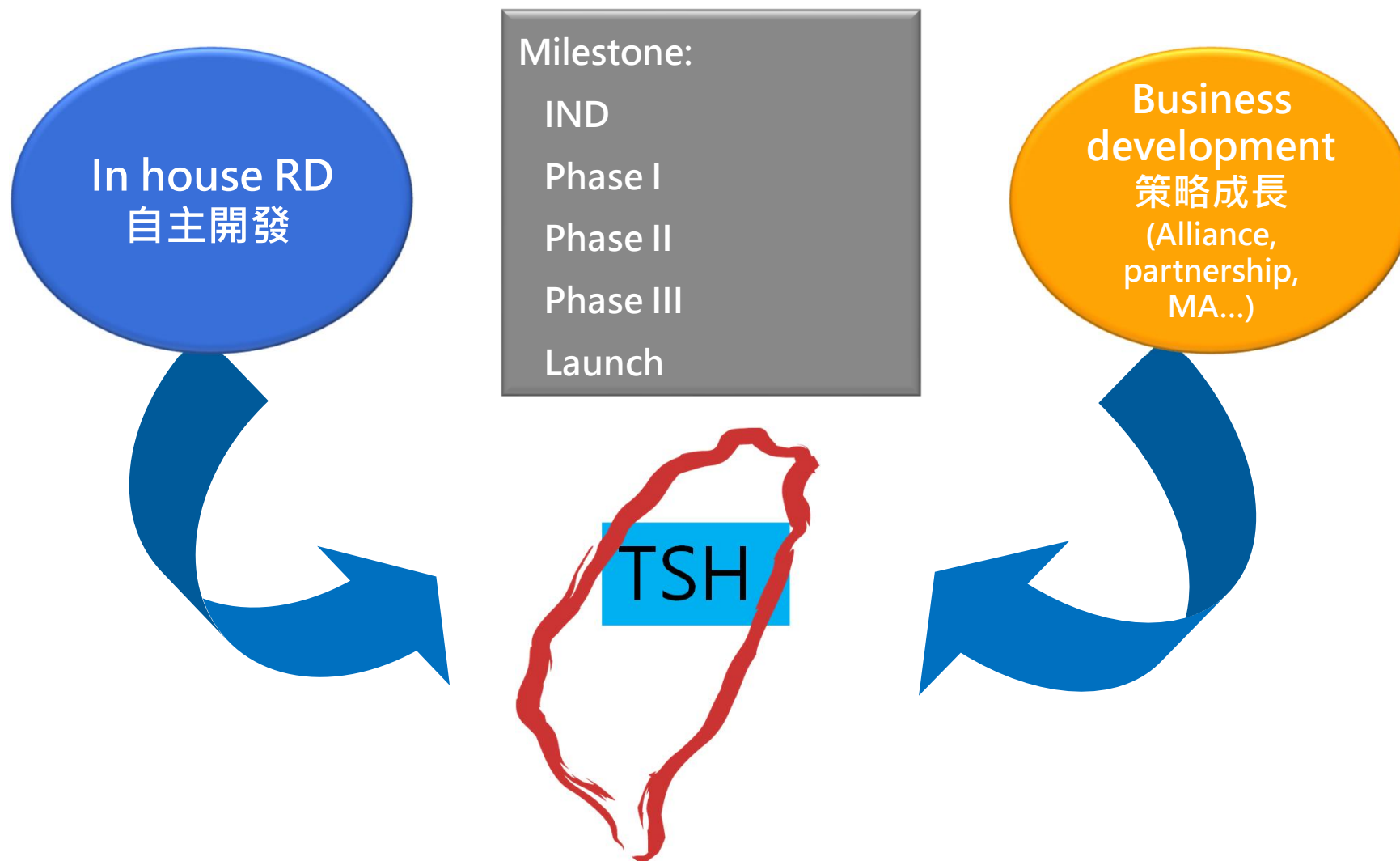


Double “雙引擎” 策略

致力於提升慢性病患者之生活品質

Double“ 雙引擎” 策略~

產品來源 “雙引擎”



Double“ 雙引擎” 策略~

業績成長 “雙引擎”



Milestone:

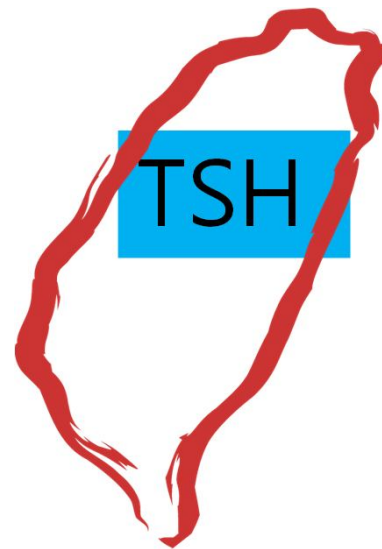
IND

Phase I

Phase II

Phase III

Launch



Home Market:

TW /CN

Asia Market :

PH,KR,VN,HK,SG,MY,TL

Pharmerging Market:

BR,IN,ID,RU,SA

Global Market:

EU,USA,JPN

What is we focus...

Technology



Specialty



Sustained
Release

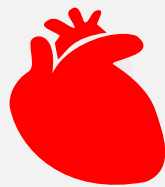


Combination
Technology



Bio-Drug

Disease Management



Cardiovas
cular



Gastroint
estinal



Auto-
immune



Critical Pt
Care

Established Partnership Record



INNOPHARMAX



Wyeth



Sumitomo Dainippon
Pharma



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Future RD Focus

TSH Development Focus

New Chemical
Entity
新成分新藥

- Co-development for NCE

Specialty or
Bio-Drugs
特殊劑型或
生物藥

- Specialty or Bio-drug
- New indication

Innovative
Therapeutics
創新療法

- Liquid biopsy: 液態切片, 次世代定序NGS · 基因檢測, CTC循環腫瘤細胞
- Immunotherapy
- Cell therapy

Pipeline-1: Drugs

| Indication | Project | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 |
|------------|---------|------|------|------|------|------|------|------|
| CV | R06 | | * | | | | | |
| CV | Pre-R19 | | * | | | | | |
| Immune | T11 | | | | * | | | |
| GI | L19 | | | | | * | | |

* Launched

Pipeline-1: MKT Size



| Product | Class | Right | World MKT Size USD/M* | SEA MKT Size USD/M^ | Advantage |
|---------|--------------|--------|-------------------------------|------------------------|--|
| R06 | T-NEC | TW/SEA | 758M | 45M | Co-development & local study USA/EMA quality |
| Pre-R19 | NEW Combo | TW/SEA | Australia: 17M Korea: 122M | 100M | License-in Specialty |
| T11 | Biosimilar | Global | 1700M | 60M | Self-development USA/EMA quality |
| L19 | T-NCE | Global | 299M | 23M | Specialty USA/EMA quality |
| Total | - | - | 2896 M | 228 M | - |

* Clarivate Analytics

^Prediction: SEA's is around 6% and Australia is 1% of global market.

Pipeline-2: Diagnostic Under Evaluation

| Type of Products | Indication | 2019 | 2020 | 2021 | 2022 | |
|------------------|--|------|------|------|------|---|
| Diagnostic | Cancer Diagnosis treatment | → | | | * | |
| Diagnostic | Cancer screening and diagnosis | → | | | | * |
| Diagnostic | CV, DM screening, diagnosis, and prognosis | → | | | * | |

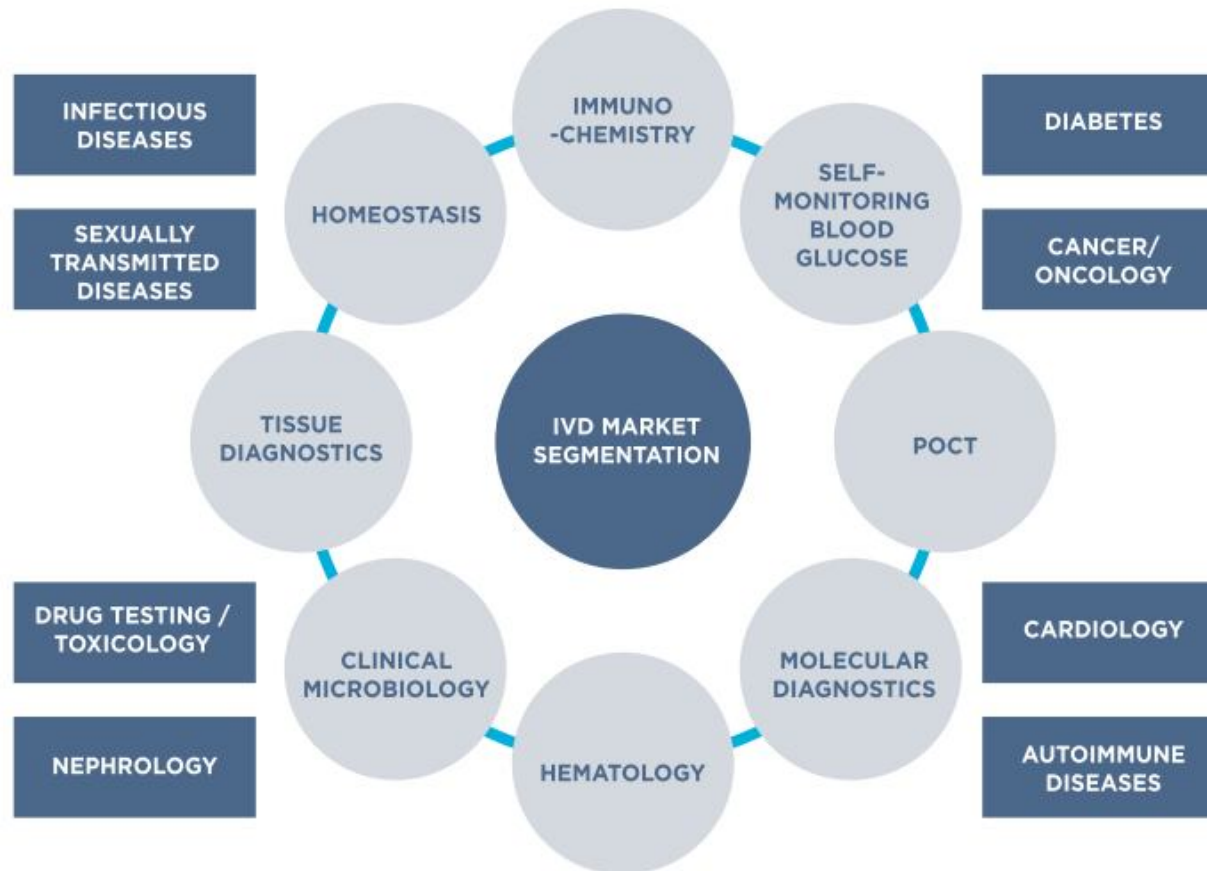


* Launched

Pipeline-2: GLOBAL IVD MARKET OVERVIEW



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Pipeline-2: GLOBAL IVD MARKET OVERVIEW



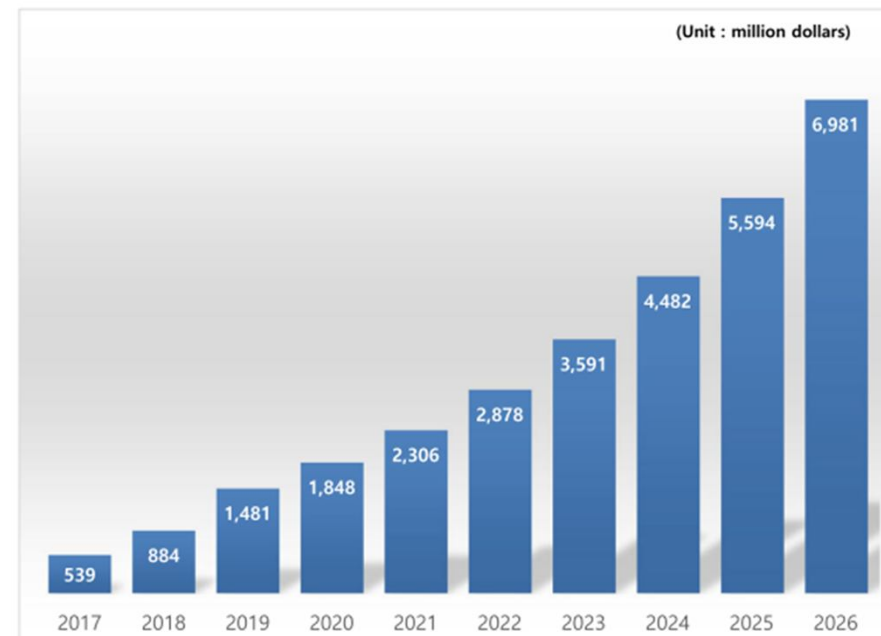
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Forecasts for the global market for blood cancer molecular diagnostics kits



Total IVD Market Revenue Forecast, Global, 2012–2019



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Risk Management is Key

Project management
+
Integration
+
Risk management



產品組合-藥品



| | | | | | |
|-----|---|-----------------------|------------------------|--------------------------|--------------------------------------|
| 產品 |  Amtrel® 諾壓錠 | LINICOR 理脂錠 | ISORMOL 愛速脈錠 | Licodin 利血達膜衣錠 | RHYNORM® PROPAFENONE 律諾 |
| 適應症 | 高血壓 | 高血脂症 | 預防狹心症之發作 | 血流栓塞之治療 | 治療心室性心律不整 |

GI
肝膽胃腸



| | | |
|-----|---------------------------|-------------------------|
| 產品 | MOPRIDE 摩舒胃清膜衣錠 | Ribarin 瑞肝寧膠囊 |
| 適應症 | 心窩灼熱、噁心、嘔吐 | C型肝炎 |

其他



| | | | | | |
|-----|----------------------------------|-------------------------|---------------------------|-------------------------------------|-----------------------|
| 產品 | Regrow® 愛舒可羅 持續性膜衣錠 | Lonine 勞寧止痛膠囊 | LACOXASR 樂夠效緩釋錠 | Aleviatin® 阿雷彼阿慶錠 /注射液 | BELVIQ® 沛麗婷 |
| 適應症 | 止咳 | 類風濕性關節炎、 骨關節炎、止痛 | 類風濕性關節炎、 骨關節炎 | 癲癇症 | 體重管理 |

產品組合-精準醫療檢測產品



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| 檢測項目 | 檢測項目英文名 | 檢測技術平台 | 檢測對象與標的 |
|-------------------------|---|------------------|--|
| 腸護安 | CRC Protect | CTC | 健康人，評估早期大腸癌風險 |
| 癌追蹤 | PanCa Monitor | CTC | 18種實體癌患者，追蹤治療或復發轉移(建議抽血前7天無接受治療) |
| 攝護安 | Prostate Cancer Test | CTC | PSA異常或灰色帶4-10ng/ml免除切片疑慮者 |
| 循環腫瘤細胞之細胞程式死亡-PDL-1檢測 | PD-L1 CTC test | CTC | 癌症患者，評估適合免疫治療 |
| 安識因遺傳性癌症風險基因檢測(血液 / 唾液) | CellMax Genetic Cancer Risk Test (Assure) | NGS技術 / SMSEQ 平台 | 提早健康管理者或對遺傳癌症疑慮者或已罹癌者，分析98種遺傳基因，含25種癌症風險評估 |
| 肺癌檢測套組(血液/組織) | CellMax LBx NCCN Lung | NGS+CTC | 肺癌病患，分析10個基因+MSI+PD-L1，決定標靶藥或免疫治療 |
| 癌可明(血液) | CellMax LBx | NGS技術 / SMSEQ 平台 | 實體癌症病患(腦瘤除外)，分析73個基因+MSI找對標靶或免疫藥，增加用藥選擇，搶治療先機(正在做化療或放射性治療的病人，建議等到療程結束再送出檢體。) |
| 癌可明(組織) | CellMax TBx | NGS技術 / SMSEQ 平台 | 癌症病患，分析73個基因，找對標靶或免疫藥增加用藥選擇，搶治療先機 |

Out-License Program to 2022



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AMTREL & RHYNORM

China, Thailand, Indonesia
Vietnam, Myanmar, Malaysia
Philippines, Singapore



T11

EU, Japan, Korea, USA
China, Australia, South
Africa, Argentina, UCC



MOPRIDE

SEA, Mexico
Center America



Aleviatin

HK
Center America

研發里程碑R06

- 類型：T-NCE
- 目前進度：2019/6 完成臨床試驗
- 預計取證時間：2020年Q2
- 地區：台灣
- 合作廠商：歐洲與美國上市
- 適應症：穩定型心絞痛
- 適用對象：B-blocker/CCB/nitrate 不耐受或治療效果不足者
- 特色：
 - 不影響血壓與心跳
 - 適用族群寬廣，無須擔心共病禁忌或限制
 - 提升用藥安全，改善頭痛問題、增加醫囑性

研發里程碑 C04: 成功授權

- 開發標的：
Carvedilol 緩釋錠劑
- 適應症：
鬱血性心臟衰竭、高血壓
- 開發成果



七大專案發功 新藥授權報捷 里程金破200億

04:09 2019/07/14 | 工商時報 | 杜蕙蓉



2019年以來有藥品授權的生技公司



| 公司 | 藥物/技術平台 | 授權公司 | 金額 |
|---------------|--------------------------------|------------|--|
| 基亞&日本 Oncolys | 溶瘤病毒新藥 OBP-301 (Telomelysin) | 羅氏旗下日本中外製藥 | ● 500億日圓(約138.46億新台幣) ● 上市後銷售分潤 |
| 台康 | 乳癌生物相似藥 EG12014 | Sandoz AG | ● 6,500萬美元里程碑 ● 上市後銷售分潤 |
| 東生華 因華 | 治高血壓併發心臟衰竭新劑型新藥 C08001 | 山東新時代藥業 | ● 4,500萬人民幣(約1.82億台幣) ● 上市後銷售分潤 |
| 逸達 | 治前列腺癌新劑型新藥FP-001 | 英國 Accord | ● 最高8,600萬美元里程碑 ● 上市後銷售分潤 |
| 台微體 | 癌症及抗感染微脂體藥物 | 香港三生製藥 | ● 最高2,500萬美元里程碑 ● 上市後銷售分潤 |
| | NanoXR | 博迪生 | ● 最高4,900萬美元里程碑 ● 上市後銷售額分潤 |
| 景凱 | 治非酒精性脂肪肝炎(NASH)JKB-122、JKB-133 | 恒翼醫藥(上海) | ● 簽約金200萬美元、最高2,400萬美元里程碑 ● 上市後銷售分潤 |

資料來源：採訪整理

製表：杜蕙蓉

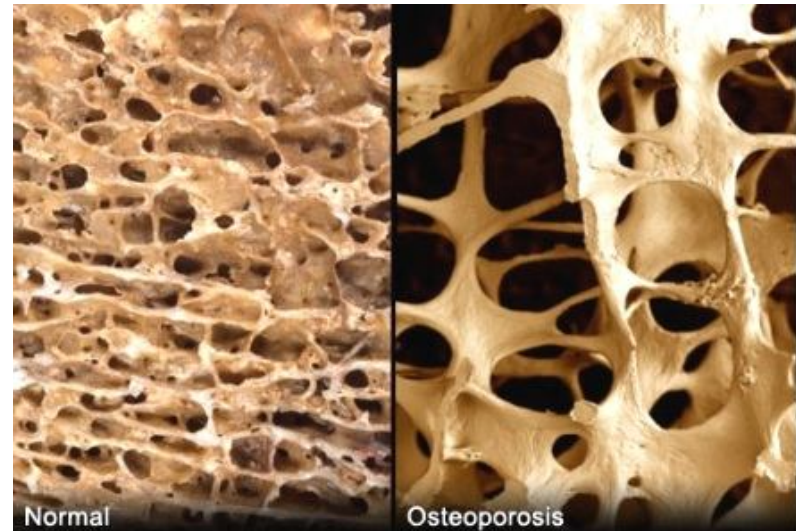
2019年以來有藥品授權的生技公司

研發里程碑 T11: 完成DS 開發



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- 類型：
Bio-similar 生物相似性藥品
- 目前進度：
完成DS開發，將進行第一期臨床試驗
- 預計取證時間：2022年EU
- 地區：全球
- 適應症/適用對象：
停經後婦女骨質疏鬆症、男性原發性或次發於性腺功能低下症之骨質疏鬆症、女性及男性因糖化皮質類固醇治療引起之骨質疏鬆症患者



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歷年績效表現及股利發放情形



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| 年度 | 營收 | 稅後淨利 | 研發費用 | 研發佔 營收比 | 現金股利 | 盈餘配股 | 公積配股 | 股利 | EPS |
|------------------|------------|---------|---------|------------|------|------|------|-----|------|
| | (單位：新台幣千元) | | | | | | | | |
| 2019Q1 | 136,909 | 25,202 | 15,292 | 11.2% | | | | | 0.66 |
| 2018 | 515,646 | 57,784 | 96,768 | 18.8% | 1.6 | | | 1.6 | 1.50 |
| 2017 | 486,277 | 64,971 | 74,429 | 15.3% | 2.1 | | | 2.1 | 1.69 |
| 2016 | 492,465 | 141,203 | 115,878 | 23.5% | 3.1 | | | 3.1 | 3.68 |
| 2015 | 513,651 | 82,890 | 106,203 | 20.6% | 2.1 | | | 2.1 | 2.16 |
| 2014 | 561,714 | 74,440 | 85,942 | 15.2% | 2.0 | | | 2.0 | 1.94 |
| 2013 | 597,102 | 110,210 | 87,100 | 14.5% | 2.8 | | | 2.8 | 2.87 |
| 2012 | 597,429 | 141,558 | 69,632 | 11.6% | 2.8 | | 1 | 3.8 | 4.22 |
| 2011 | 659,950 | 168,636 | 48,596 | 7.3% | 3.2 | 1 | | 4.2 | 5.48 |
| 2010 (9月~12月) | 217,014 | 43,144 | 17,839 | | 0.3 | 1.2 | | 1.5 | 2.19 |



Thank You for Your Attention