台灣疫苗產業
發展的機會與挑戰

國光生物科技股份有限公司

詹啟賢 董事長

生技產業

R&D研發 ▶ Clinical Trial 臨床試驗 ▶ Production 商業量產

G.C.P / G.M.P

機會

- 醫學教育及其他相關學術機構
- 全民健保 / 醫療網
- 法規制度 / 世界接軌
- 智慧財產 IP Right
- 技術人才–高教育 / 工作倫理 / QA / 海外經驗
- 語言能力

國光經驗

國際之光．免疫先鋒

國光生物科技股份有限公司

國際之光．免疫先鋒

國光生物科技股份有限公司

- 亞洲唯一

歐盟EMA認證&美國FDA認證

流感疫苗製造公司(每2年re-certify)

- 合作廠商： SANOFI PASTEUR

Crucell

Johnson & Johnson

Techdow

Sumitomo Corporation

Enriching lives and the world

北里第一三共ワクチン株式会社

多國GMP查廠認證

- **2010/8/22~27**
- EMA audit for Flu vaccine

- **2014/9/2~5**
- **TFDA** inspection for PIC/S GMP compliance

- **2012/11/27~27**
- **Pharmathen** audit for Enoxaparin Sodium Injection filling process

- **2015/4/14~15**
- **TFDA** inspection for AdimJE-V® filling process

- **2013/4/23~25**
- **EMA** Routine inspection

- **2015/7/20~23**
- **EMA** inspection for Enoxaparin Sodium Injection filling process

- **2013/10/2~4**
- **TFDA** inspection for H7N9 vaccine

- **2017/5/1~5**
- **Brazil ANVISA** inspection for Flublok ® QIV filling process

- **2014/6/30~7/3**
- **KFDA** inspection for Flu vaccine

- **2018/7/19~7/30**
- **US FDA** Routine inspection for Flublok ® QIV filling process

國光生技榮獲歐盟GMP認證

Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/GMP/E/3-2018***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:

The manufacturer: ***Adimmune Corporation***

Site address: ***No.3, Sec.1, Tanxing Rd., Tanzi Dist., Taichung City, 42743, Taiwan***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-11-23*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

國光生技美國FDA GMP認證

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administrati
Silver Spring MD 20993

November 3, 2016

Adimmune Corporation
Attention: Dr. Chungchen Liu
President
3, Tanxing Rd., Sec. 1,
Tanzi Dist. Taichung City
Tanzi District 42743
TAIWAN

Dear Dr. Liu:

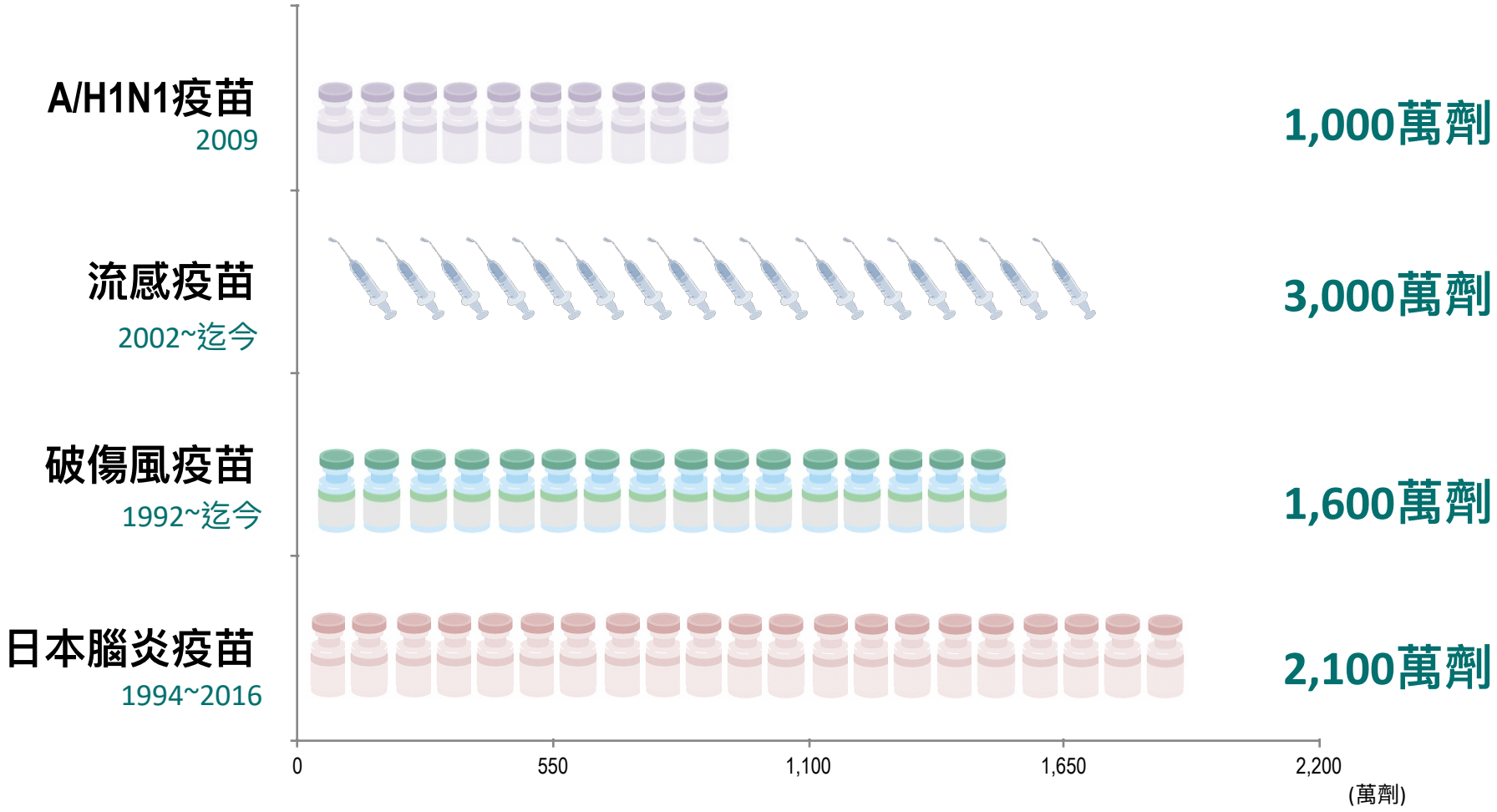
We are enclosing a copy of the Establishment Inspection Report (EIR) as a result of the inspection conducted at your premises located at 3, Tanxing Rd., Sec. 1, Tanzi Dist. Taichung City, Tanzi District 42743, Taiwan on March 24 through April 01, 2016 by the U.S. Food and Drug Administration (FDA). This pre-approval inspection was performed regarding your manufacturing activity as a contractor of Protein Sciences Corporation (PSC) for their purified recombinant influenza hemagglutinin (Influenza Vaccine), Flublock® Quadrivalent. When the Agency concludes that an inspection is "closed," under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory processes and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy we are providing to you contains the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting additional information available under FOIA.

Sincerely yours,

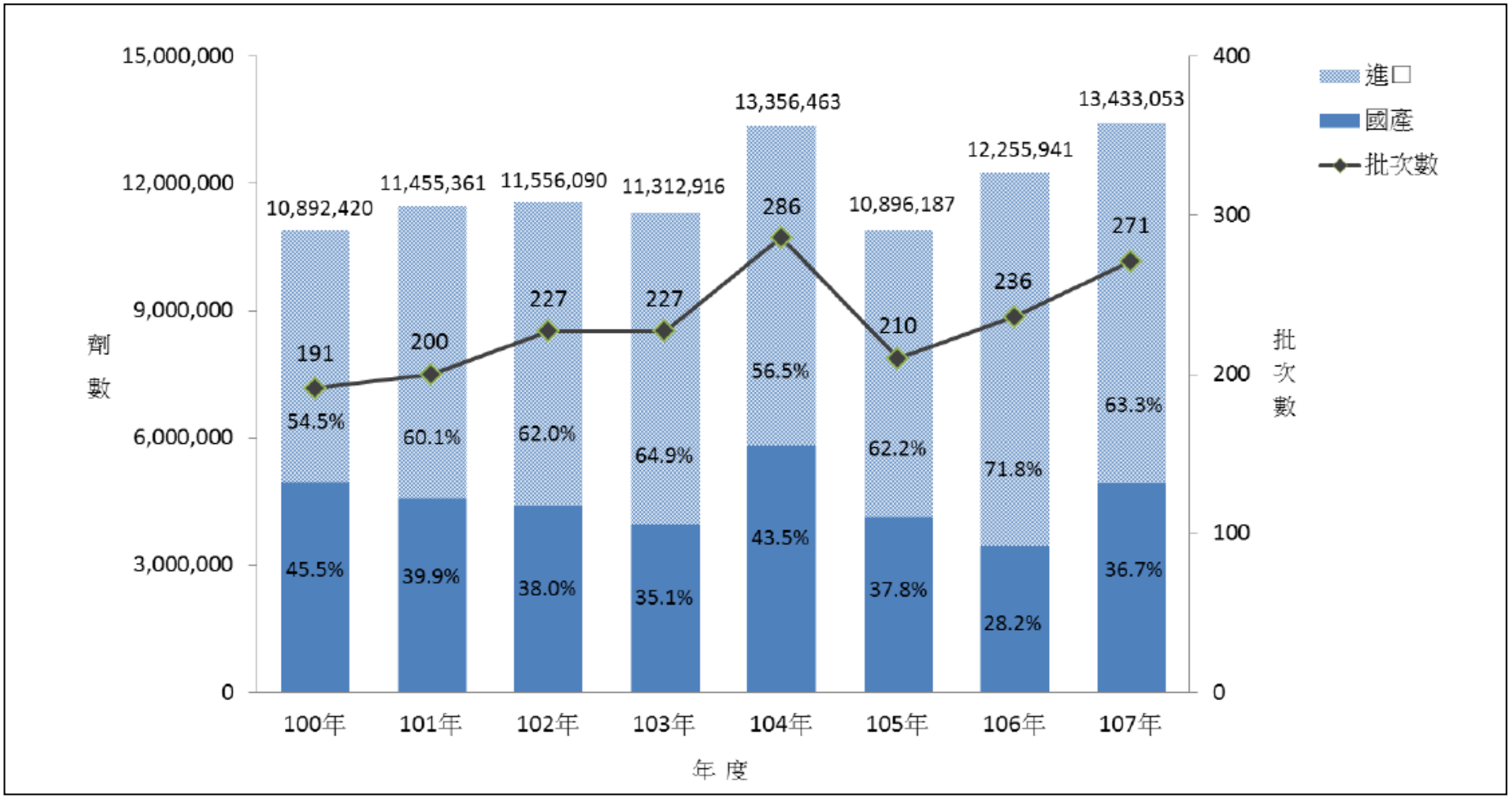
Carrie M. Mampilly
Director, Division of Inspections & Surveillance
Office of Compliance & Biologics Quality

防疫尖兵

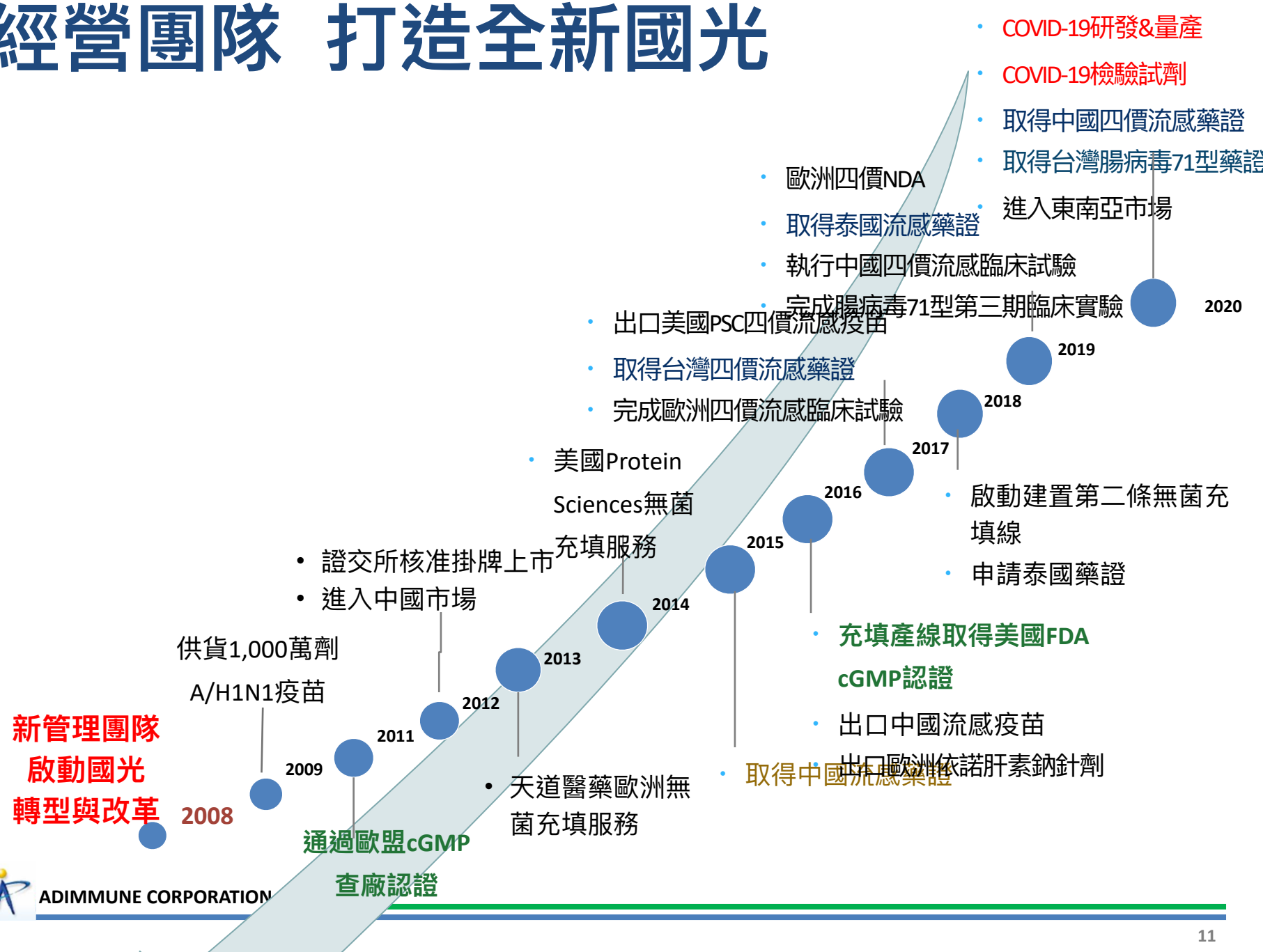

A/H1N1疫苗
2009
1,000萬劑
流感疫苗
2002~迄今
3,000萬劑
破傷風疫苗
1992~迄今
1,600萬劑
日本腦炎疫苗
1994~2016
2,100萬劑
0
550
1,100
1,650
2,200
(萬劑)

臺灣疫苗自製比率至少達三成以上

Domestic	36.70%	4.9 M doses
Foreign	63.30%	8.5 M doses

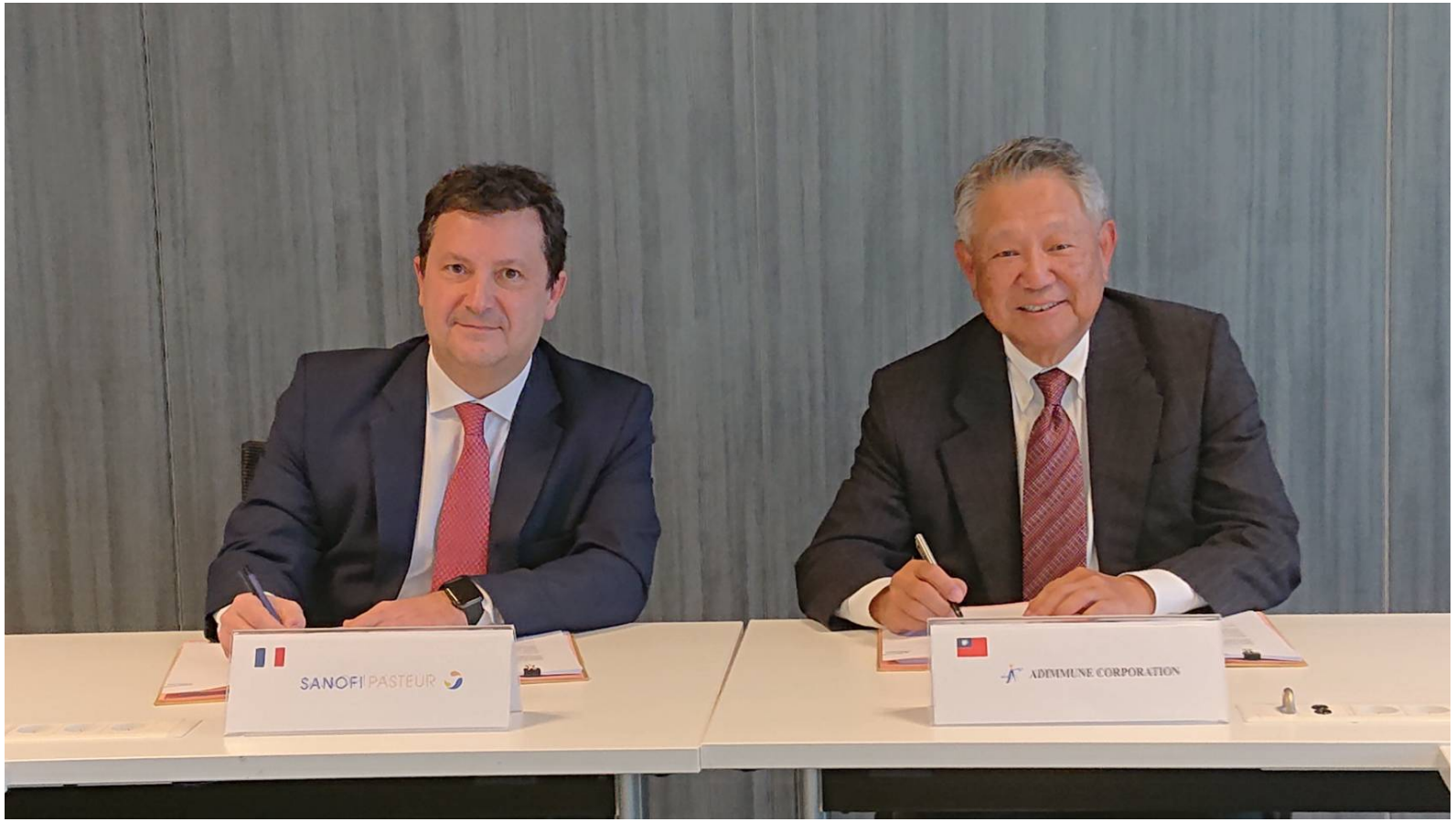


經營團隊 打造全新國光

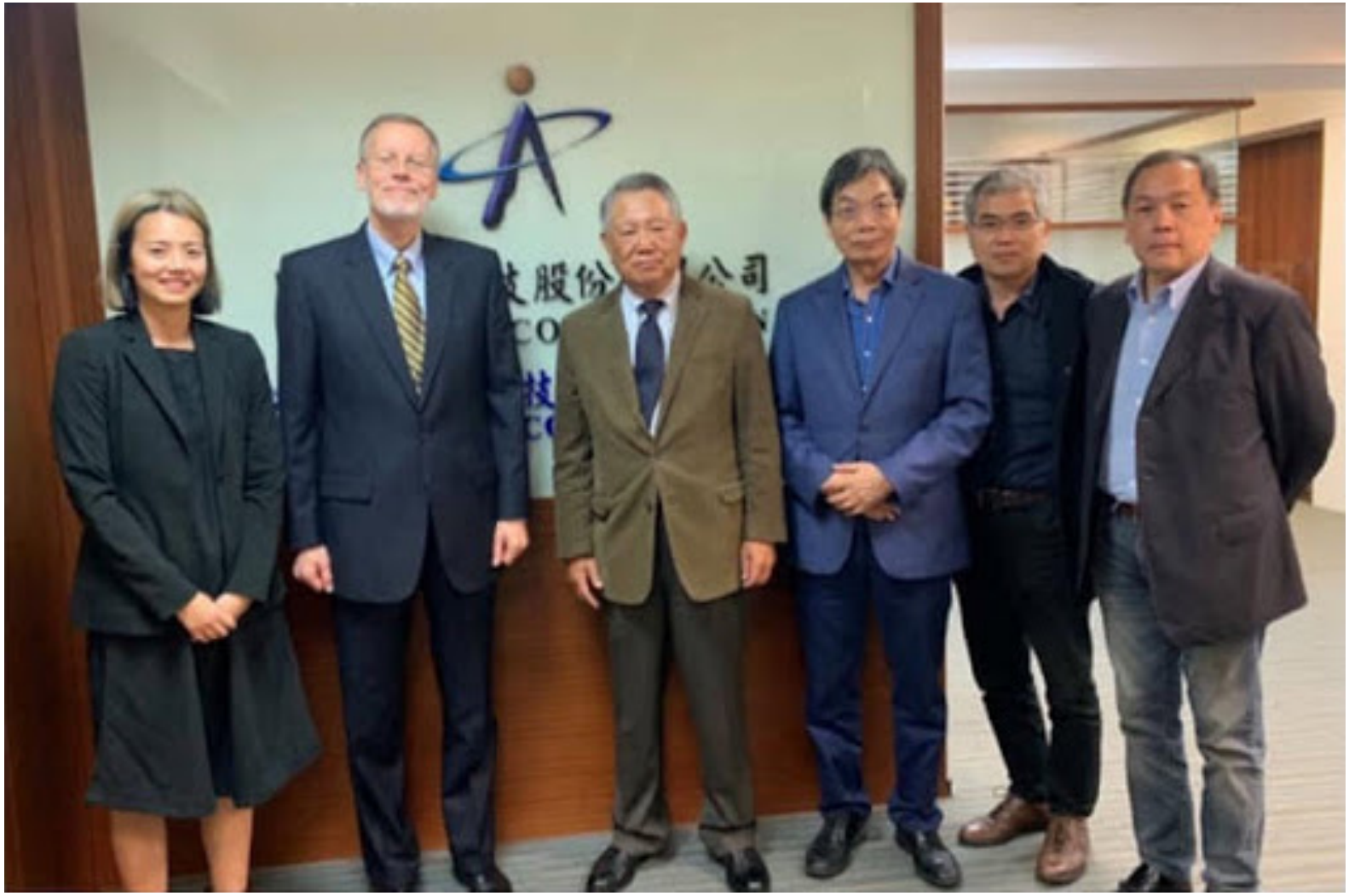

新管理團隊
啟動國光
轉型與改革
2008
供貨1,000萬劑
A/H1N1疫苗
2009
通過歐盟cGMP
查廠認證
2011
證交所核准掛牌上市
進入中國市場
2012
天道醫藥歐洲無
菌充填服務
2013
美國Protein
Sciences無菌
充填服務
2014
取得中國流感藥證
2015
充填產線取得美國FDA
cGMP認證
出口中國流感疫苗
出口歐洲依諾肝素鈉針劑
2016
啟動建置第二條無菌充
填線
申請泰國藥證
2017
出口美國PSC四價流感疫苗
取得台灣四價流感藥證
完成歐洲四價流感臨床試驗
2018
歐洲四價NDA
取得泰國流感藥證
執行中國四價流感臨床試驗
完成腸病毒71型第三期臨床實驗
2019
COVID-19研發&量產
COVID-19檢驗試劑
取得中國四價流感藥證
取得台灣腸病毒71型藥證
進入東南亞市場
2020

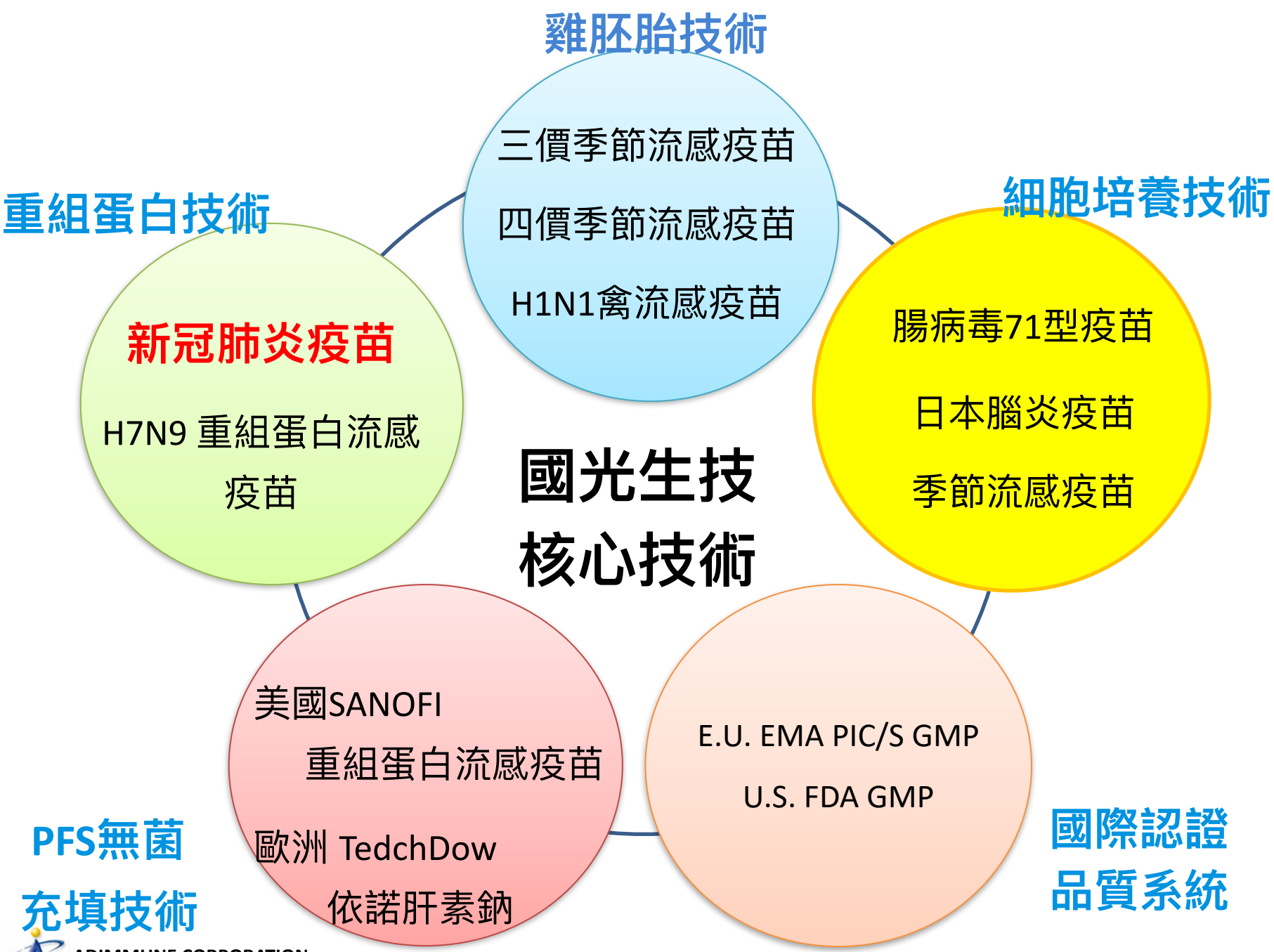
國光團隊赴法國與賽諾菲簽約

國光團隊赴法國與賽諾菲簽約



AIT美國在臺協會拜訪國光生技

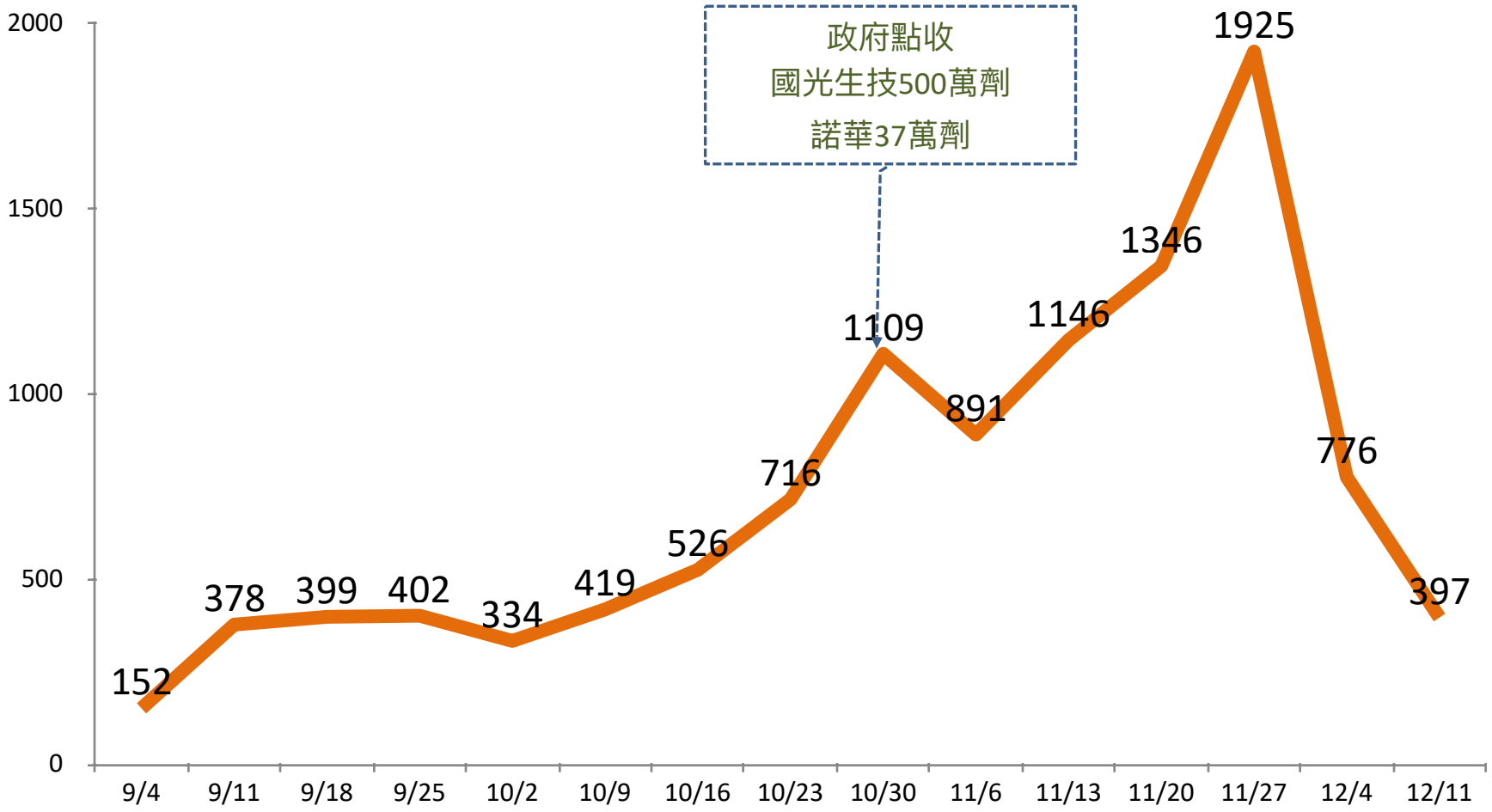



雞胚胎技術
三價季節流感疫苗
四價季節流感疫苗
H1N1禽流感疫苗
重組蛋白技術
新冠肺炎疫苗
H7N9 重組蛋白流感疫苗
細胞培養技術
腸病毒71型疫苗
日本腦炎疫苗
季節流感疫苗
國光生技
核心技術
美國SANOFI
重組蛋白流感疫苗
歐洲 TedchDow
依諾肝素鈉
E.U. EMA PIC/S GMP
U.S. FDA GMP
PFS無菌
充填技術
國際認證
品質系統

國光生技全方位廠區

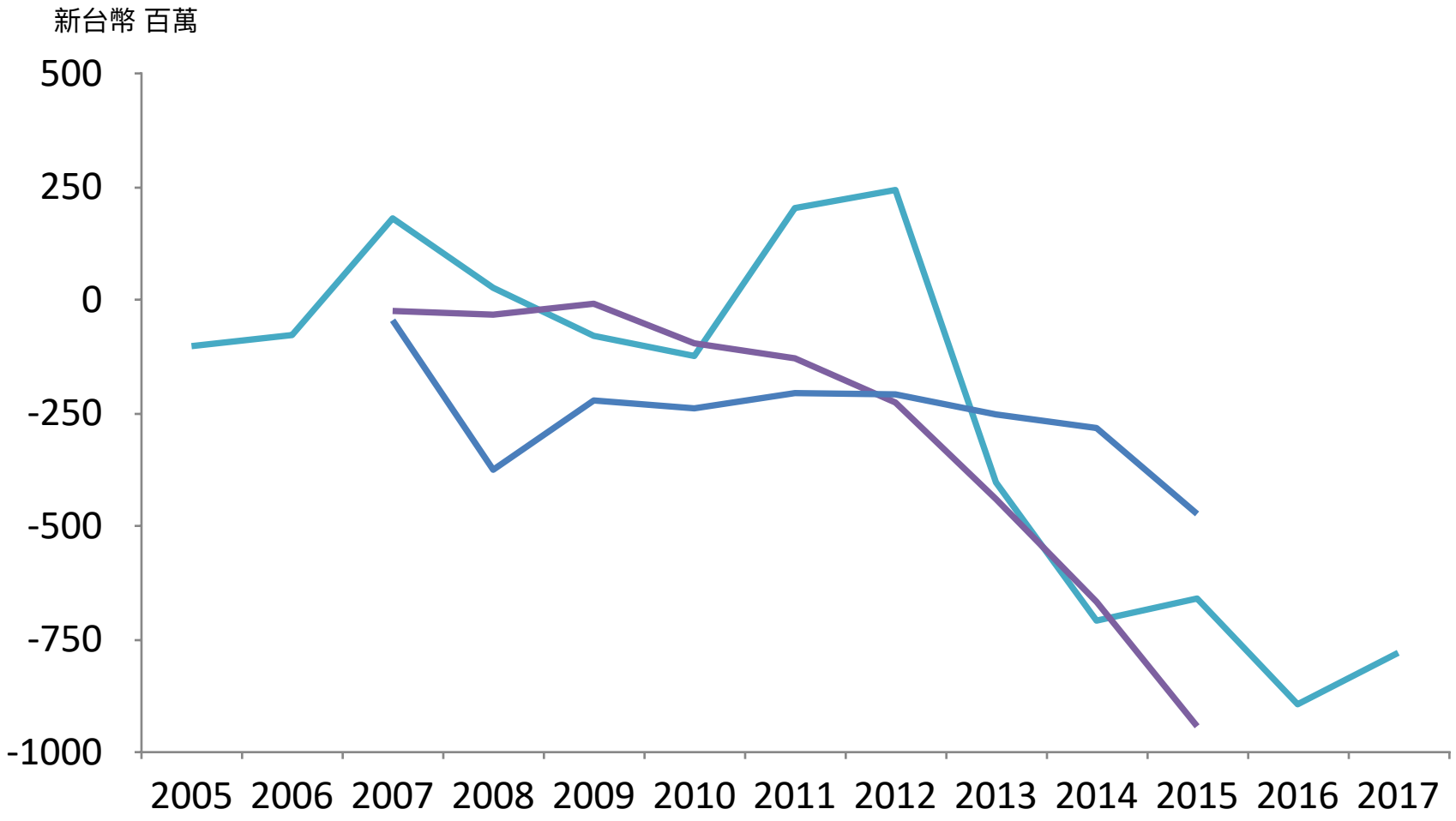
- **細胞培養廠 1,000L 生物反應器**
  - ✓ 年產 500-800 萬劑
  - ✓ 2021下半年投產
- **PFS 充填二線**
  - ✓ 年產1億劑
  - ✓ 2021/ 2月投產
- **破傷風疫苗原液廠**
  - ✓ 2023/ 7月商業量產
- **行政後勤棟 (專業倉儲)**
  - ✓ 2022/ 5月啟用

2009 H1N1大流行停課情形



生技公司需長時間投入才會有獲利

台灣大多數生技公司成立至今都還是虧損，甚至尚無營收



挑戰

市場小

- 資源有限
- 政府政策不明—

  分散或集中

  保護國內市場政策或尋求國外協助

社會觀念分歧

- Domestic/Import
- 產業vs.金融市場操作
- 研發、臨床、生產一貫作業

關鍵領域人才不足

- 法規、QA、生產
- 國際市場–商業談判、商業模式
- 合約能力

國際競爭激烈

- 國際大廠資源雄厚
- 通路、市場保護策略

Thanks