



Advanced Immunology for your Health.

ADIMMUNE CORPORATION

TWSE 4142

Nov, 2016

Disclaimer



- The presentation and the relevant information mentioned in this material, including operating performance, financial performance and the business outlook, have been compiled from both internal and external resources.
- These forward looking statements involve known and unknown risks, uncertainties and other factors, including price variation, competition, global economy, exchange rate movement and market demand, which may cause actual results to differ materially from those implied by such forward-looking statements.
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Executive Summary

Experienced and Solid Mgmt Team

Top in Asia

Strategy for Future Growth



Executive Summary

Experienced and Solid Mgmt Team

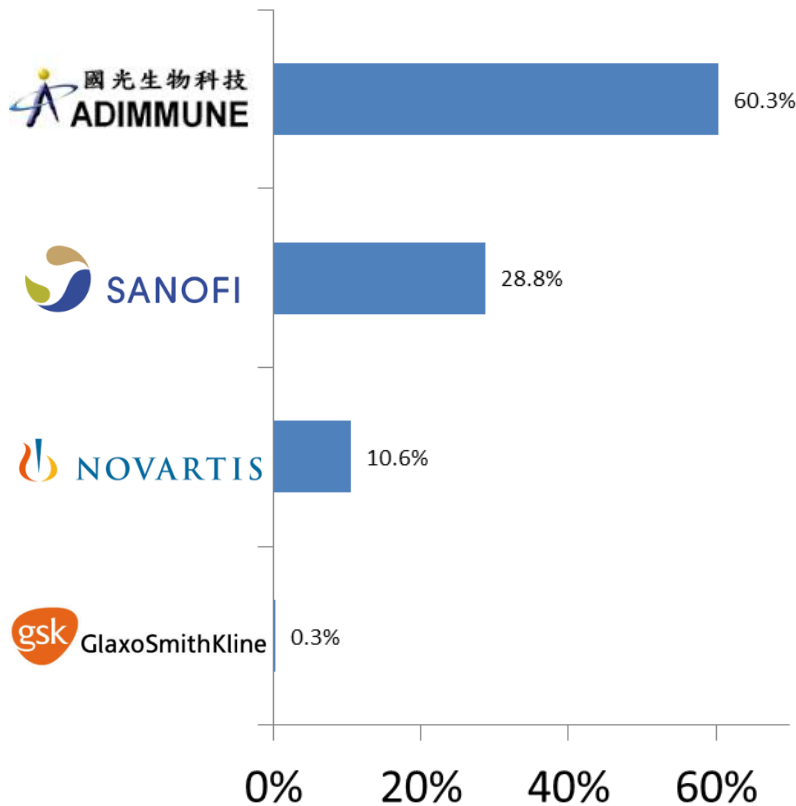
Top in Asia

Strategy for Future Growth

The Most Qualified Vaccine Provider in Asia



2016 Taiwan Flu Vaccine Market Share



Founded in 1965

Ticker: 4142 TT

278 Full Time Employees

Dedicated research, development and manufacturing of human vaccine and aseptic PFS Filling

Revenue of NT\$290mn/156 mn in 2015/1H2016

Market cap of US\$171 mn (as of 2016/10/24)

- Headquarters: Taichung, Taiwan

- cGMP Vaccine Facility:

Certificate: EU, China, Korea and Taiwan cGMP obtained.
Capacity: 25mn doses/yr (flu)

- cGMP PFS Filling Facility:

Certificate: USA, EU and Taiwan cGMP obtained. Capacity:
25mn doses/yr

Value Creation – Adimmune Style



- *We are a vertically-integrated, innovative bio-pharma company excel in high-quality human vaccine R&D and manufacturing, aseptic prefilled syringe filling, multinational vaccine registration, branding and strategic producing partnership, with a steady revenue stream.*
- *We have deep collaboration relationship with national academic institutes (e.g. Academia Sinica, NHRI, DCB, ITRI) and ready to move on to other bio-pharma products.*
- *We are the only vaccine provider in Asia that has obtained USA, EU, China, Korea and Taiwan cGMP. And we will obtain Japan cGMP in 2017.*
- *Our superior quality is led by > 50 years of experience in cGMP vaccine manufacturing and collaborating with Japan and European MNCs.*
- *Our solid capabilities in high-quality commercial scale human vaccine manufacturing and PFS filling enables us to expand our business to China, Europe, Japan and the US.*





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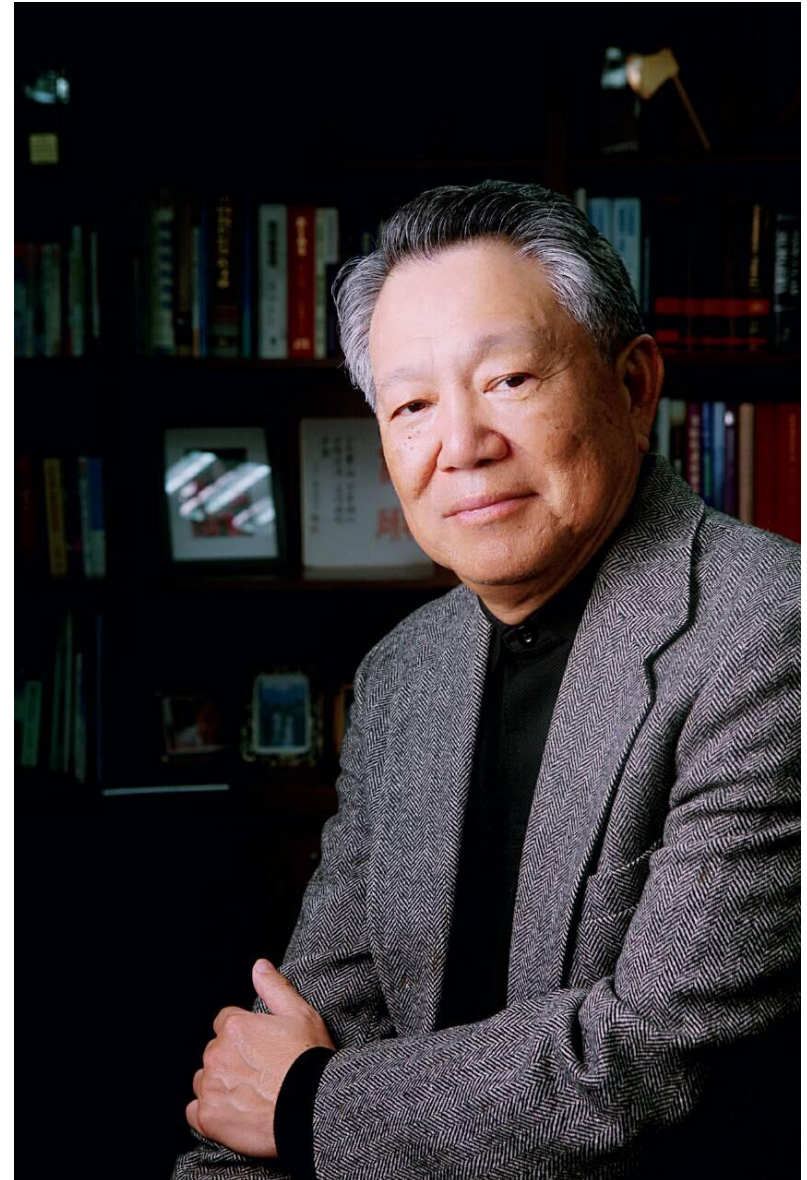
Excellent Leadership



Chi-Hsien Chan, M.D.

Chairman & CEO

- From 1997, Dr. Chan held several important positions in Taiwan government, including the Minister of Health and Welfare, Chairman of National Health Research Institutes, National Policy Advisor to the President and Senior Advisor to the President.
- He was the president at Chi Mei Medical Center for 15 years beginning in 1989.
- Dr. Chan trained as a medical doctor (Yale and Thomas Jefferson, USA), and following clinical practice at Pomona Valley Hospital Medical Center, California, and became the Director of the Department of Surgery at Pomona Valley Hospital Medical Center.
- Owing to his solid experience in both the private and public sectors, and extensive knowledge of the healthcare industry, Dr. Chan was nominated and elected to be the Chairman of Adimmune, since 2008.



Experienced and Solid Management Team



Chung-Cheng Liu, Ph.D.

General Manager

Over 30-yrs experience

VP General Director of Industrial
Technology Research Institute (ITRI)

Ph.D., Biochemistry, Princeton University



Chin-Chuan Chang, Ph.D.

COO, VP of R&D

Over 25-yrs experience

Scientist, Development Center for Biotech.
Ph.D. Chemical Engineering and Material
Science, UC Davis



Chin-Yi Chiu, Ph.D.

VP of Quality Assurance

Over 25-yrs experience

Sector Manager, Bureau of Food & Drug
Analysis, TFDA

Ph.D. Cell & Mol. Biology, Univ. of Massachusetts



Simon Kao

VP of Business Division

Over 25-yrs experience

Taiwan General Manager & Greater China
Regional Manager, Medtronic
EMBA, National Chengchi University



Peter Pan

General Counsel

Over 30-yrs experience

General Counsel, Vanguard International
Semiconductor Corporation

LL.M. University of Pennsylvania



Vic Chang, CIA

CFO, Director of Strategic Planning

20-yrs experience

Internal Auditing Manager, Special Assistant
to Chairman

MBA, University of Houston



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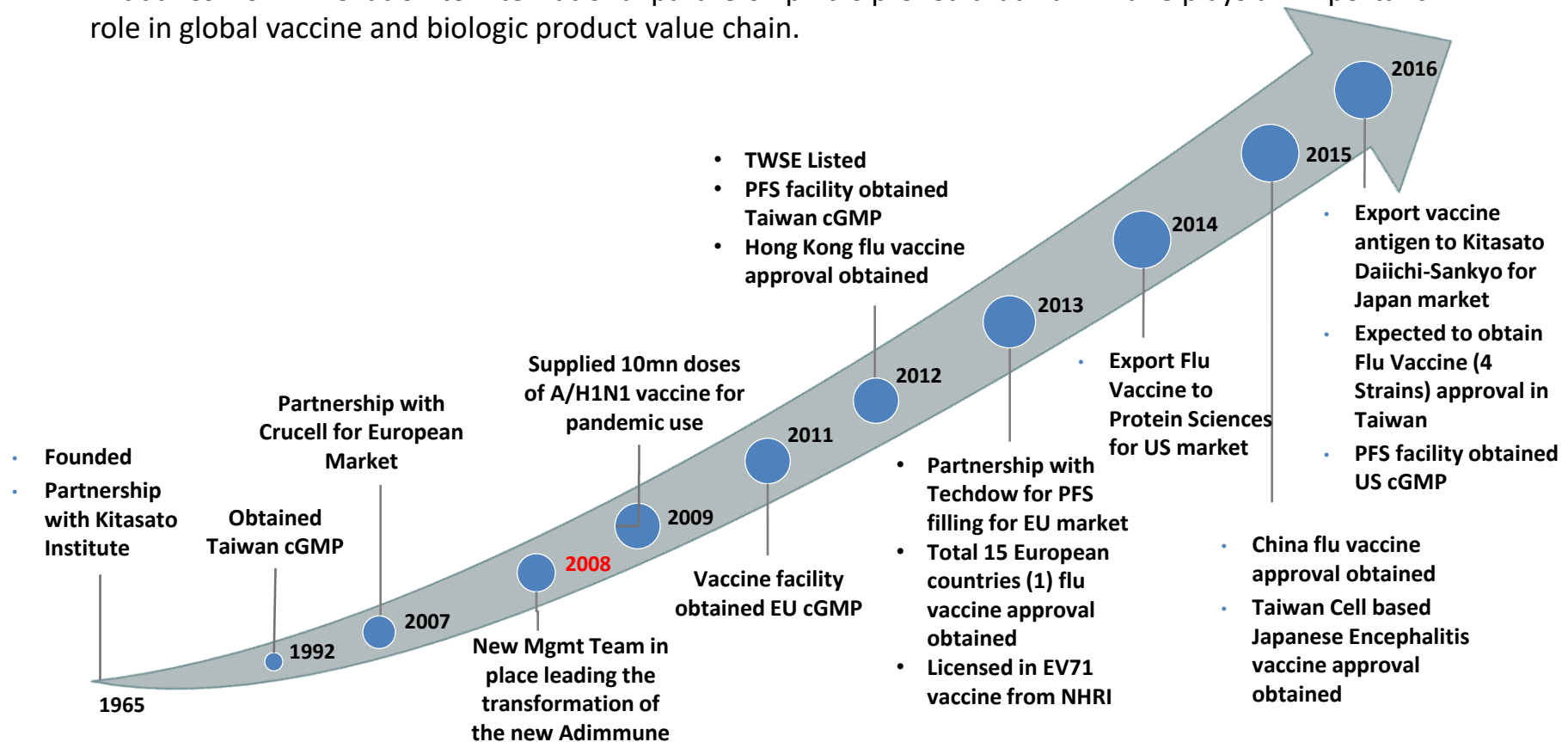
Top in Asia

Strategy for Future Growth

Current Leadership Engineers Transformation



- Adimmune has over time developed from a vaccine agent to the state of the art cGMP facility with proprietary know-how and intellectual property.
- Led by Chairman Chan, Adimmune has transformed into a profit and shareholder value focused company and listed on TWSE since 2012. Dr. Chan introduced new management team and started a series of initiatives from innovation to international partnership. It is proved that Adimmune plays an important role in global vaccine and biologic product value chain.



Note: (1) 15 European countries are including Germany, UK, Italy, Switzerland, Austria, Ireland, Spain, Portugal, Nederland, Belgium, Luxembourg, Sweden, Norway, Denmark, Finland

Key Strength



Key Strength



- **Solid R&D Capability**
 - *R&D Track Record: Influenza Vaccine, Pandemic A/H1N1 Vaccine, Japanese Encephalitis Vaccine and Tetanus Vaccine*
 - *Pipeline: pandemic H7N9/H5N1 Vaccine, Cell-cultured Japanese Encephalitis Vaccine, Enterovirus 71 vaccine, Recombinant Protein Production Platform and therapeutic/diagnostic monoclonal antibody*
 - *Collaboration for future pipeline: National academic institutes such as Academia Sinica, NHRI, DCB and ITRI*
- **Strong Technology Background**
 - *Flu vaccine international partner in the past: Kitasato Institute, Japan. Crucell (a J&J company)*
 - *Obtained Certification: USA, Europe, China, Korea and Taiwan cGMP certificate*
 - *Expecting Certification: Japan will start inspection process in 2017 (vaccine)*
- **Internationalized Talent Pool**
 - *Management team captained leading academia institution and renowned MNCs with successful track record*
 - *Highly professional production line staff with extensive experience from R&D to commercial scale manufacturing*

Key Strength



- **Scale-up & Commercial manufacturing**

Since founded in 1965, Adimmune has supplied:

- *Flu vaccine: 20mn doses*
- *A/H1N1: 10mn doses*
- *Japanese Encephalitis: 21mn doses*
- *Tetanus: 16mn doses*
- *Capacity: vaccine 25mn/yr, PFS 25mn/yr*
- *Current capacity is sufficient for the growth strategy, no significant Capex needed in next 5 years*

- **Strategic Producing Partnership**

- *Upstream Partnership: Export 4 strains Flu Vaccine bulk to Kitasato Daiichi-Sankyo for Japan market*
- *Downstream Partnership: Collaborate with Techdow for Enoxaparin to export to Europe. Export PFS flu vaccine to Protein Sciences for US market*
- *Owing to the nature of bio-pharma industry, once a strategic producing partnership is established, relationships necessarily remain long term*

Top Flu Vaccine provider in Asia



- Adimmune is the most qualified and internationally recognized flu vaccine provider/ PFS filling facility in Asia, with ample capacity

Company	Country	Flu Vaccine					
		cGMP Obtained					Capacity (mn)
		EU	USA	Japan	China	Korea	
Adimmune	Taiwan	✓	✓	✓ ₍₁₎	✓	✓	25
BioFarma	Indonesia						4
IVAC Vabiotech	Viet Nam						1
GPO	Thailand						5
Panacea Biotec SII	India						10
Green Cross	Korea					✓	
Biken	Japan			✓			10
Chemo-Sero-Therapeutic Research Institute	Japan			✓			10
Denka Seiken	Japan			✓			10
Kitasato Daiichi Sankyo	Japan			✓			12
Hualan	China				✓		25
Sinopharm (Tiantan)	China				✓		4
Sinovac	China				✓		10
Tianyuan	China				✓		15

(1) Japan will start inspection in 2017



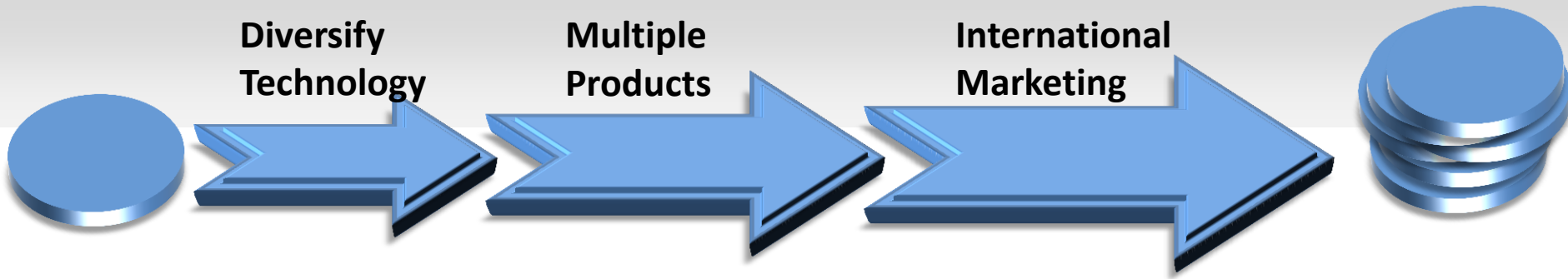
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Strategy for Future Growth

Growth Strategy



- Existing technology to maintain high-quality, high throughput manufacturing
- New technology for new products
- New technology to reduce risk of contamination
- New technology to reduce time-to-market for emergency outbreak

- New product to respond to the needs of next generation vaccine
- New product to fulfill unmet medical needs
- New product to enrich product mix and create new revenue source
- New product to tackle new markets

- Achieve market access through cGMP certification from different countries/region
- Solid track record to become long term strategic producing partner with US, Japan and Europe MNCs
- Adimmune branded product for Europe and China
- Improve utilization rate
- Become the gateway into China and major healthcare countries

Diversify Technology

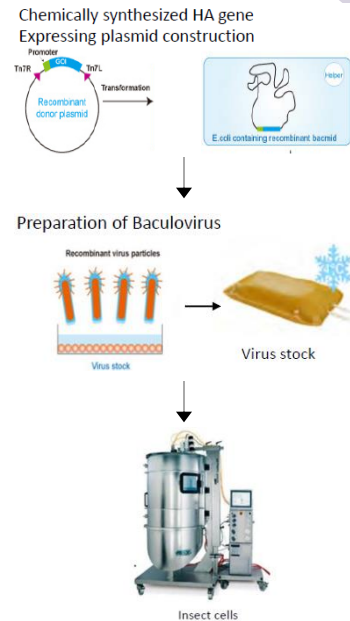
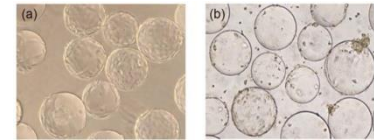


Egg Based Process

- Flagship technology of Adimmune
- Mature and stable
- Flu vaccine mass production

Serum Free Cell Culture

- Risk free from Mad cow disease
- Easy to scale up with Bioreactor
- Flu, Japanese Encephalitis, and Enterovirus vaccine, Monoclonal antibody



Recombinant Protein

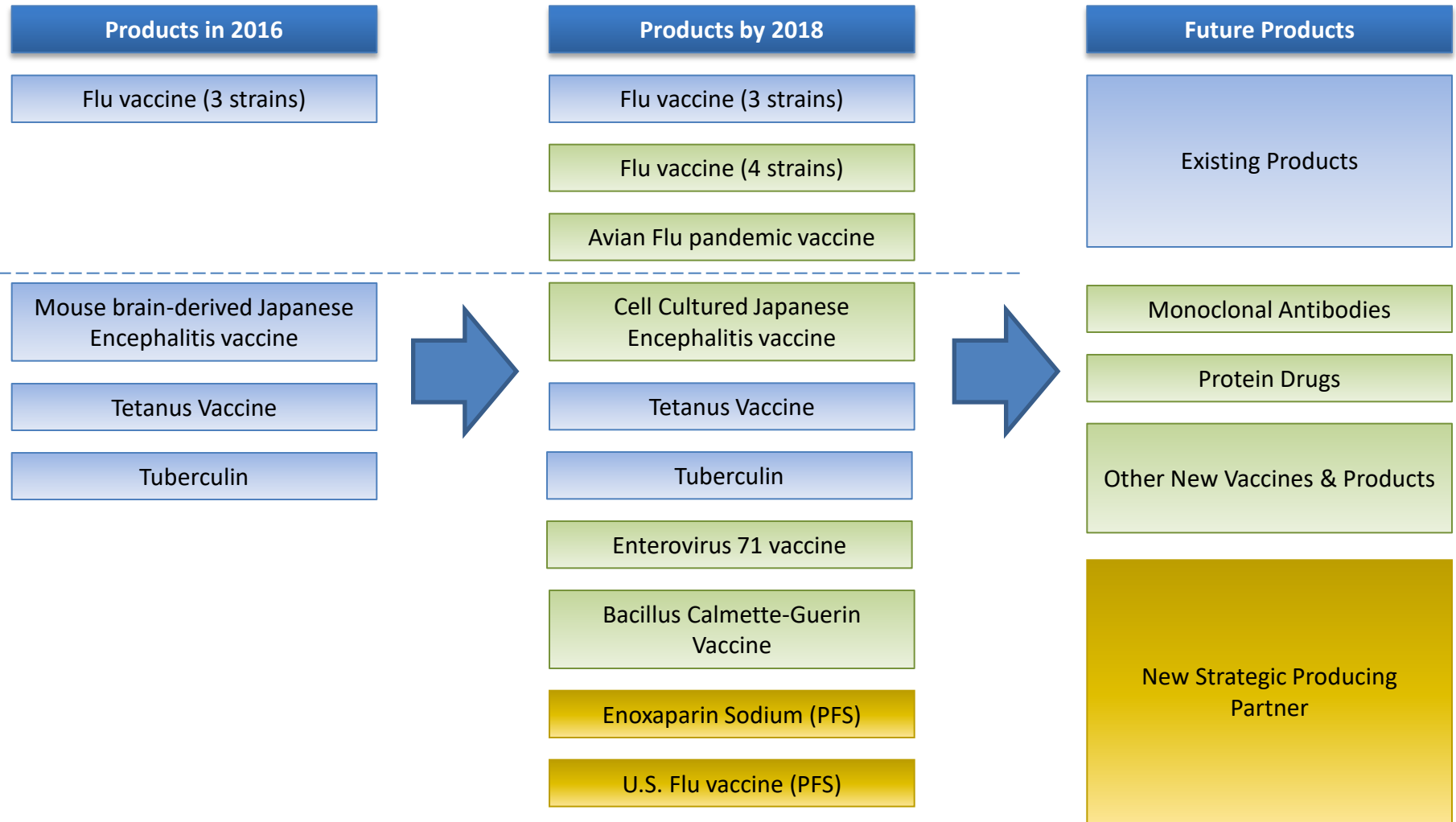
- Months faster than Egg-based and cell-culture process to tackle outbreak
- Consistent high quality and competitive manufacturing costs
- Flu vaccine

Advance Aseptic PFS Filling Technology

- Avoid cross contamination
- Protein product need full aseptic environment

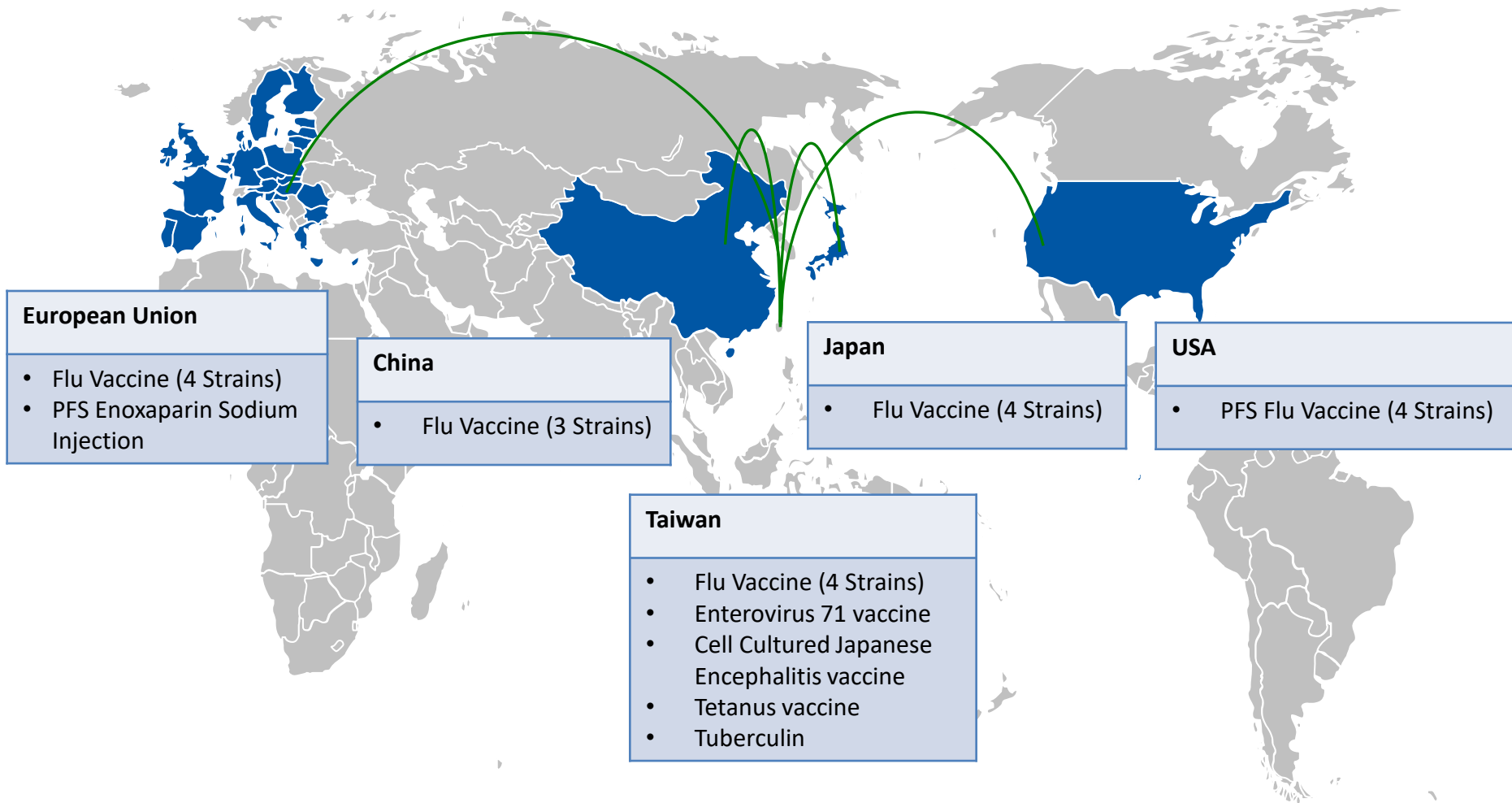


Multiple Products



- Through its diligence in R&D, more products will enter domestic and global markets in the following 3 years.
- By 2018, new products: 4 strains Flu vaccine, Cell cultured Japanese Encephalitis vaccine, Enterovirus 71 vaccine will hit the market. As well as PFS filling product Enoxaparin Sodium Injection and Flu vaccine for Protein Science.

Global Market Expansion



Europe Phase III Clinical trial—Quadrivalent Flu vaccine





Multi-Center Clinical Trial Non-inferiority-trial

2016

2017

2018

CLINIPACE
WORLDWIDE



1,050人
• Ghent
• Antwerpen

10/15
試驗執行

收案期

12/30
試驗收案

觀察期

06/30 08/30 09/01
觀察完成 結案報告 藥證申請

Decentralized

審查期

09/01
藥證核發



1,050人
• Taipei

11/07
試驗執行



AdimFlu-S (QIS)[®]

Quadrivalent Influenza vaccine

U.S.

FDA approves Protein Sciences quadrivalent flu vaccine



Influenza Vaccine **FLUBLOK® QUADRIVALENT**

2016/2017 Formula

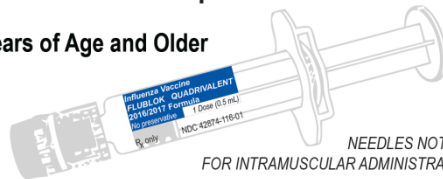
NDC 42874-116-10

Rx only

10 Disposable Prefilled Luer-Lok® Syringes
each containing one 0.5 mL dose

No Thimerosal or other preservatives

For 18 Years of Age and Older



NEEDLES NOT INCLUDED
FOR INTRAMUSCULAR ADMINISTRATION ONLY



Protein Sciences
CORPORATION

Final bulk : US Pearl River
US Meriden
Japan Gifu (Unigen Corp.)
Aseptic Filling: Adimmune Corp.

CMO for Quadrivalent Flu vaccine Aseptic filling



2014

Q4 臨床試驗專業充填服務簽約
Q4 臨床試驗批充填作業

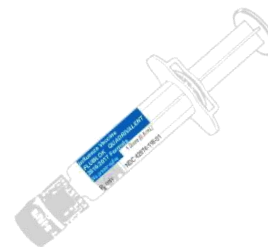
1月 臨床試驗批出貨



2015

Q4 試產確效批充填作業
Q4 試產確效充填專業服務簽約

1月 試產確效批出貨



FLUBLOK®QUADRIVALENT

2016

03/24~4/02
美國 FDA 來台查廠

10/07
藥證核發

審查期



Permit license



FDA U.S. FOOD & DRUG
ADMINISTRATION

Our STN: BL 125285/194

SUPPLEMENT APPROVAL PMR FULFILLED LETTER

October 7, 2016

Protein Sciences Corporation
Attention: Penny L. Post, Ph.D.
1000 Research Parkway
Meriden, CT 06450-7159

Dear Dr. Post:

We have approved your request to supplement your Biologics License Application for Influenza Vaccine, Flublok®, to include a quadrivalent formulation (Flublok® Quadrivalent), for use in persons 18 years of age and older and to include data from the confirmatory clinical study to verify and describe the clinical benefit of Flublok (trivalent formulation) in persons 50 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT02290509 and NCT02285998.

FULFILLMENT OF POSTMARKETING REQUIREMENT FOR ACCELERATED APPROVAL

We approved Flublok (trivalent formulation) for use in persons 50 years of age and older on October 29, 2014, under the accelerated approval regulations with a post marketing requirement (PMR) (21 CFR 601.41) (STN: BL 125285/78). This submission contains the final report for the following PMR, listed in the October 29, 2014, supplement approval letter:

PMR #1: To conduct a confirmatory clinical efficacy and safety study (PSC12) in

The final formulated Flublok Quadrivalent drug product will be filled, labeled, and packaged into single dose syringes at **Adimmune, Taichung City, Taiwan.** The dating

We have completed the review of your submission and find that this requirement has been fulfilled.

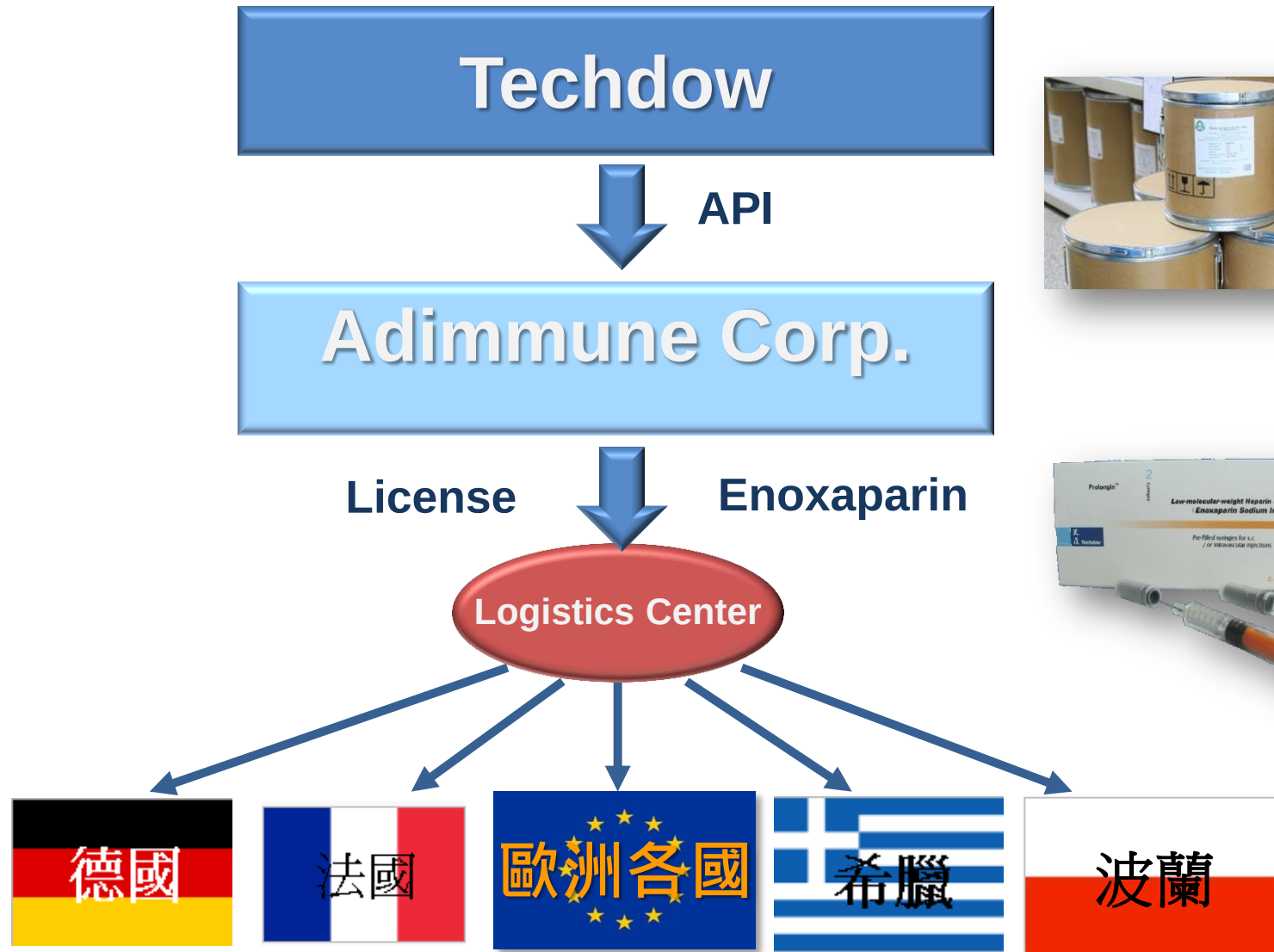
MANUFACTURING

The final formulated Flublok Quadrivalent drug product will be filled, labeled, and packaged into single dose syringes at (b) (4). The dating period for Flublok Quadrivalent shall be 6 months from the date of manufacture of final container vaccine, but not to exceed June 30th of the influenza season for which it was

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

China

CMO for Aseptic filling



Enoxaparin, the new favorite Antithrombotic drug



	低分子量肝素Enoxaparin	肝素Heparin
來源	自肝素分離或是 肝素降解	自腸粘膜或 牛肺臟中提取
抗凝血機轉	主要抑制凝血因子factor Xa 次要抑制凝血因子factor IIa	增加抗凝血酶antithrombin III的 作用
應用	①急性靜脈血栓 ②急性冠脈綜合症(心絞痛、心肌梗塞) ③手術後血栓形成	①抗凝血和抗血栓 ②治療瀰漫性血管內凝血 ③透析、手術中抗凝血處理
優點	①抗血栓的作用強 ②生物利用度高 ③出血危險少 ④減少使用之肝素副作用(如易出血、血小板減少和骨質疏鬆等)	
市場	● 低分子肝素是全球抗血栓藥物銷售排名前五位的藥品之一 ● 主要供應商為Sanofi (73%市佔)、其他為Pfizer、GSK、LEO ● 3.6億劑/年 in Europe	



CMO for Enoxaparin Aseptic filling

2013

Q4 試驗批生產
Q4 安定性試驗

2014

Q4 歐盟 NDA 啟動

2015

Q1 歐盟 NDA 送件

7月 歐盟 EMA 來台查廠

11月 國光獲歐盟 EMA GMP 查廠認證

審查期

2016

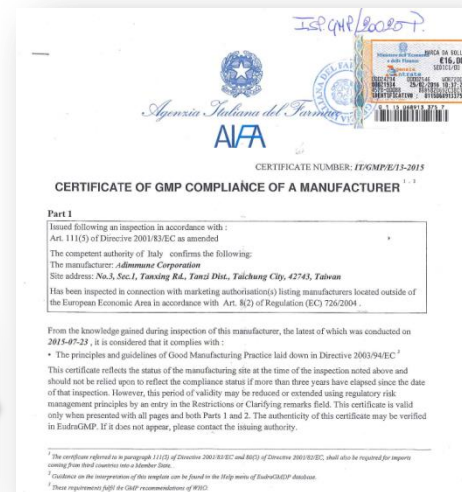
3月 藥商 S.P 獲波蘭藥證

7月 藥商 P.T 獲歐盟藥證

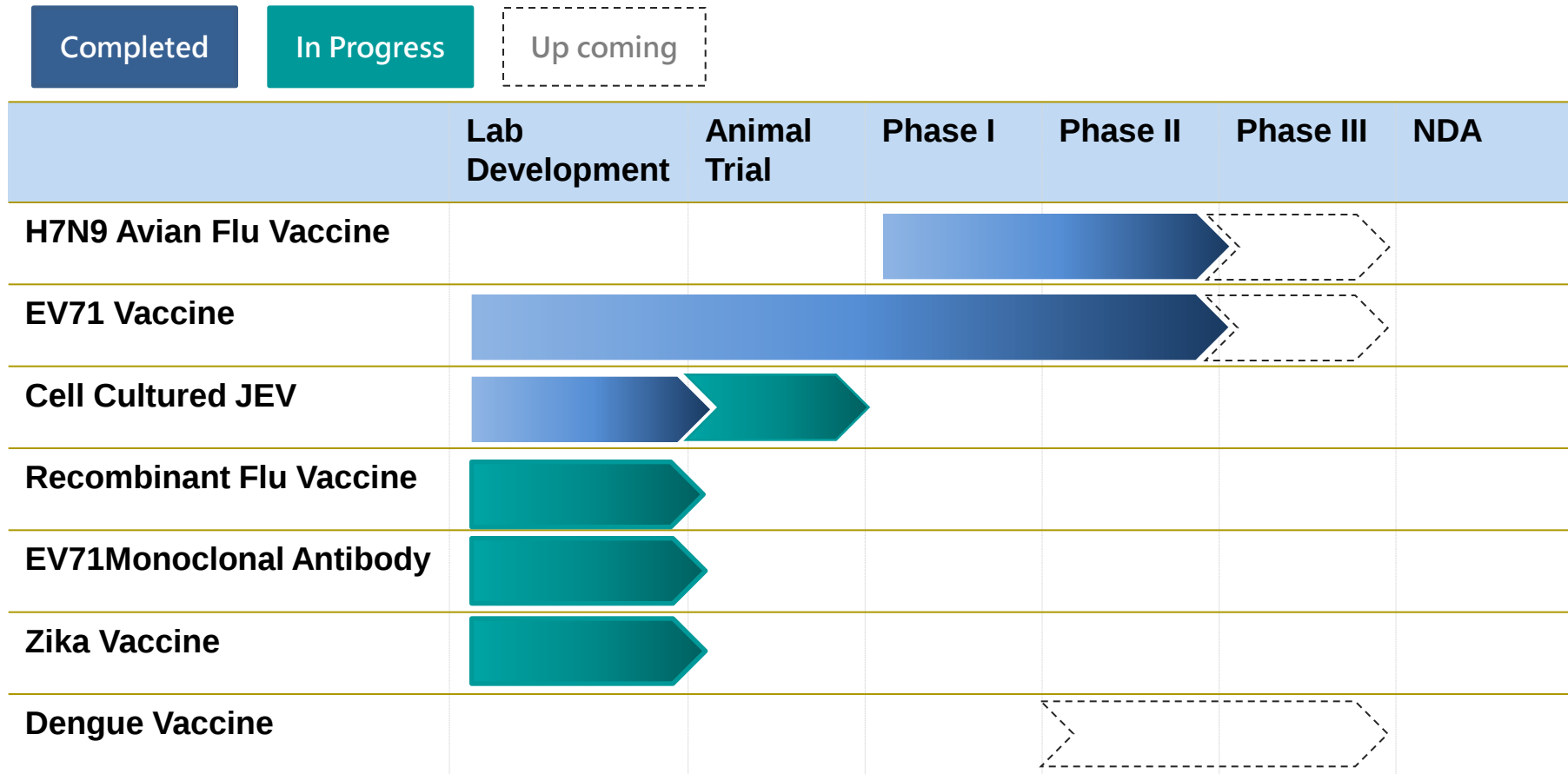
2017

1~12月 依合約陸續出貨

效期安定性資料建立



Product Pipeline



Our Commitment to Shareholders



- *To maintain our position as the leading vaccine and PSF filling solution provider in Asia.*
- *To become the gateway to China and Global Market.*
- *To deliver a consistent high quality with proprietary technology, and to fully utilize our capacity.*
- *We also pledge that our primary focus will be the maximization of returns to our shareholders via the potential of our promising growth strategy.*
- *We believe in high standards of corporate governance and investing in our employees and the communities where we do business.*



Thank you!

Παύλος Λογιάς