

## Formosa Pharmaceuticals, Inc.

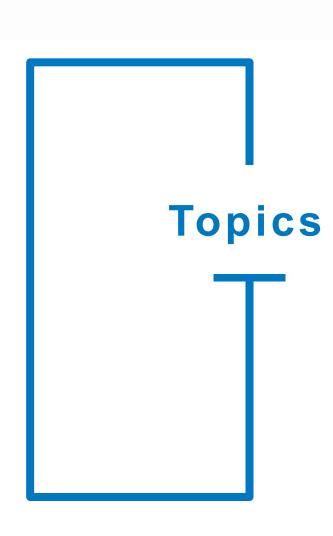
## Investor's Meeting

June 30, 2025

### **Disclaimer**

- The forward-looking information, including the operating outlook and financial statements, mentioned in this presentation and related information released at the same time, is based on the current internal and external economic development of the Company.
- The Company's actual future results of operations, financial condition and business results may differ from those provided in the projections. The reasons for this may arise from various factors, including but not limited to market demand, price fluctuations, competitive situation, changes in various policies and laws and financial and economic conditions, and other risks beyond the control of the Company.
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## **Meeting Outline**



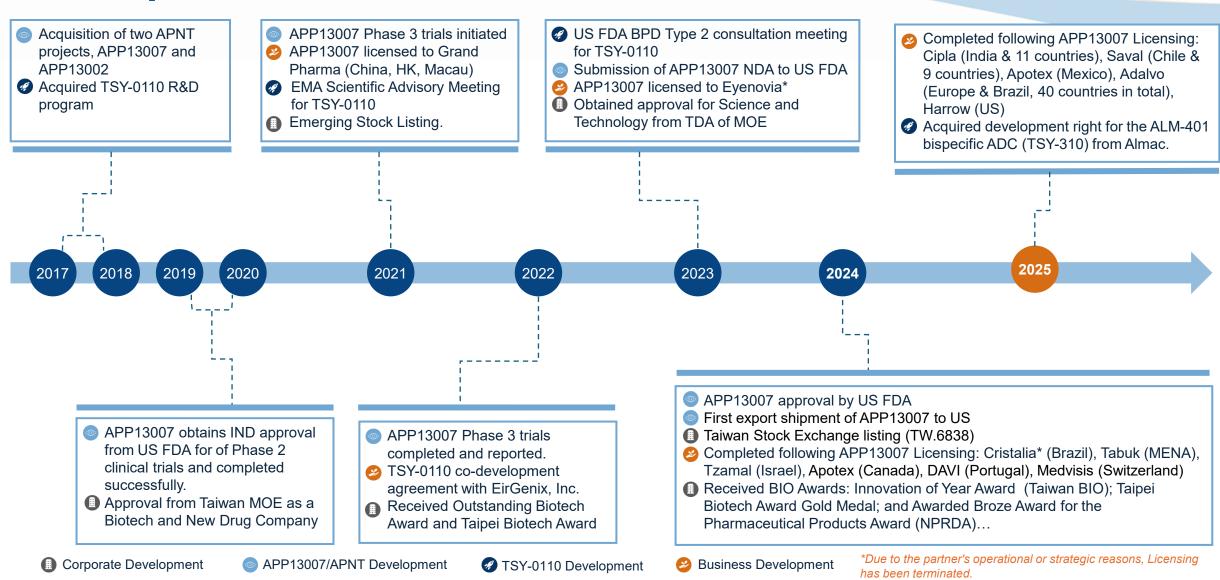
- **1** Formosa Pharma Company Profile
- **2** APNT® Nanoparticle Formulation Projects
  - 2-1 BYQLOVI (APP13007) Clobetasol Ophthalmic Suspension
  - **2-2** Other APNT® Nanoparticle Formulation Projects
- **3** ADC Projects
  - **3-1** TSY-110 Kadcyla Biosimilar
  - 3-2 Enhertu Biosimilar for HER2 related cancers
  - 3-3 TSY-310 Bispecific ADC for solid tumors
- **4** Financial Information
- **5** Q&A



# **1 Formosa Pharma**Company Profile



## **Corporate Milestones**



#### Formosa Pharma Board of Directors and **Shareholder Structure**



Dr. Chen-Yu Cheng, Ph.D. Board Chairman







**Shareholder Structure** 

Paid-in capital NT\$1.51bn

**Board Directors:** 



Dr. Hong-Jen Chang, MD, MPH, MS











Professor Sophia Su, Ph.D.









Dr. Jo Shen, Ph.D. ScinoPharm



Dr. Weng-Foung Huang, Ph.D.





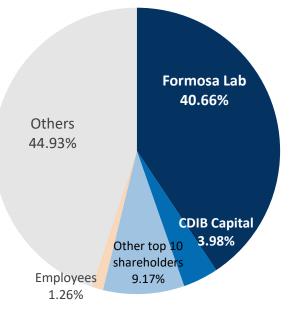


Professor Jaw-Jou Kang, Ph.D.











## R&D Strategy & Management Team



See the power in the small.



總經理 許力克博士 台灣神隆 Nitto Denko Corp Takeda Pharmaceuticals Exelixis, Inc. (San Francisco) 加州大學洛杉磯分校有機化學博士 本業經驗23年



奈米技術處

陳佑汲 博士 處長 萬能科技大學妝品系教授 國家衛生研究院 (NHRI) 靜岡大學營養與環境科學博士

本業經驗17年

#### 專案管理處



佳生科技顧問股份有限公司 密西根大學毒理學碩士 國立台灣大學動物系學士

本業經驗: 19年

#### 製浩開發處



游國明 博士 處長 Director of Biologics Development,

倫敦帝國學院生化碩士 香港理工大學應用生化學科技博士 本業經驗: 26年

R&D

**Project** 

CMC and Mfg

Regulatory

Affairs and

Assurance

Quality

Nanotechnology 2. Direct technical advantages and R&D strategy.

3. Provide guidance for intellectual property rights.

1. Coordinate internal and external R&D resources.

4. Outsourced manufacturing and supervision.

1. Project management, support and coordination of cooperation between various units

2. Project quality assurance operations, quality of R&D and CMO/CRO documents.

3. Clinical trial planning and schedule management.

1. Process dev, scale-up, and improvement.

2. Transfer of technology to the entrusted manufacturer and production management.

3. Assessment/control of drug production costs.

1. Inspection and registration strategies and schedules, consult with domestic and foreign regulatory units, and obtain drug certificates.

2. Direct GMP and good distribution practices.

3. Overall quality management and implementation of continuous quality improvement.

4. Evaluate and manage suppliers, coordinate and solve qualityrelated problems.

5. Review quality system and arrange audit activities.

#### 法規品保慮



何怡婷 博士 資深經理 祥翊製藥股份有限公司法規副處長 國立交大化學系博士

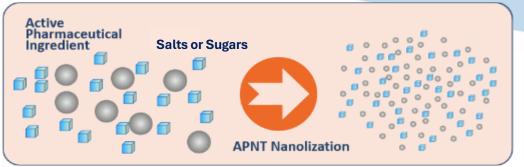
本業經驗: 13年



# 2 APNT® Nanoparticle Formulation Projects



## **APNT® Nanoparticle Formulation Technology**

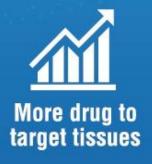














#### **Key Features**

Amenable to aseptic filtration

Tunable particle size

No polymorphic change in API

Mild operational temperature

No solvents and harsh additives

Low risk of contamination

Use of GRAS excipients



## **APNT® / APP13007 Global Patent Landscape**

Patent Family	PCT Application	# of Patents	Granted Countries
5 Patent Families		<u>140</u>	12 Countries + EU* Territories
Method for producing pulverized organic compound particle	2008	22	CA, CN, EU (14), IL, JP, KR, TW, US
Method for producing a composite organic compound powder for medical use	2009	23	CA, CN, EU (14), JP, IL, KR, MX, RU, TW, US
Organic compound nano-powder, method for producing the same and suspension	2013	30	AU, BR, CA, CN, EU(16), ID, IN, IL, JP, KR, MX, RU, TW, US
Aqueous suspension preparation comprising nanoparticles of macrolide antibacterial agent	2014	28	AU, CA, CN, EU(14), ID, IN, IL, JP, KR, RU, TW, US
Aqueous suspension agent containing glucocorticosteroid nanoparticles	2016	37	AU, BR, CA, CN, EU (20), ID, IN, IL, JP, KR, MX, RU, TW, US
Method of treating operative complications of cataract surgery	2023	Under examination	EU, US, and 25 additional countries



## 2-1 BYQLOVI (APP13007)

Clobetasol Propionate Ophthalmic Suspension



## Clobetasol Propionate Ophthalmic Suspension (APP13007)



APNT Nanoparticle Formulation Technology

Clobetasol propionate

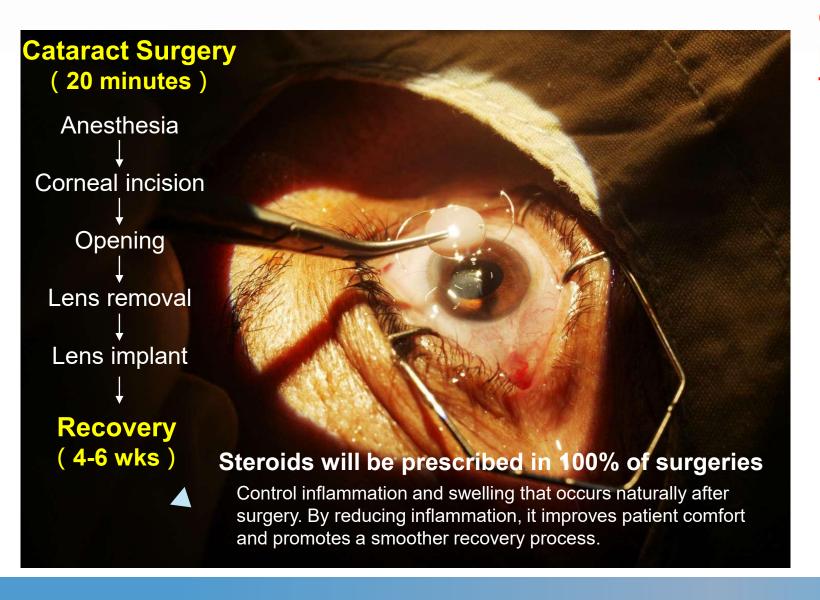
Topical Ophthalmic Nanosuspension for Inflammation and Pain after Ocular Surgery

Sing Twice daily dosing for 14 days

Rapid and Sustained resolution of inflammation and pain

Safety profile comparable to that of placebo; Well-tolerated and comfortable

### Ophthalmic surgery and postoperative anti-inflammatory therapy



Challenges of existing ophthalmic postoperative anti-inflammatory therapies:

#### 1. Difficult dosing regimen

- 3-4 times a day, resuting in poor compliance
- Tapering, complicated regimen
- Standard course is ~4 weeks

#### 2. Delayed or ineffective response

- Leads to longer-term use
- Lower satisfaction rate

#### 3. Risk of Intraocular Pressure

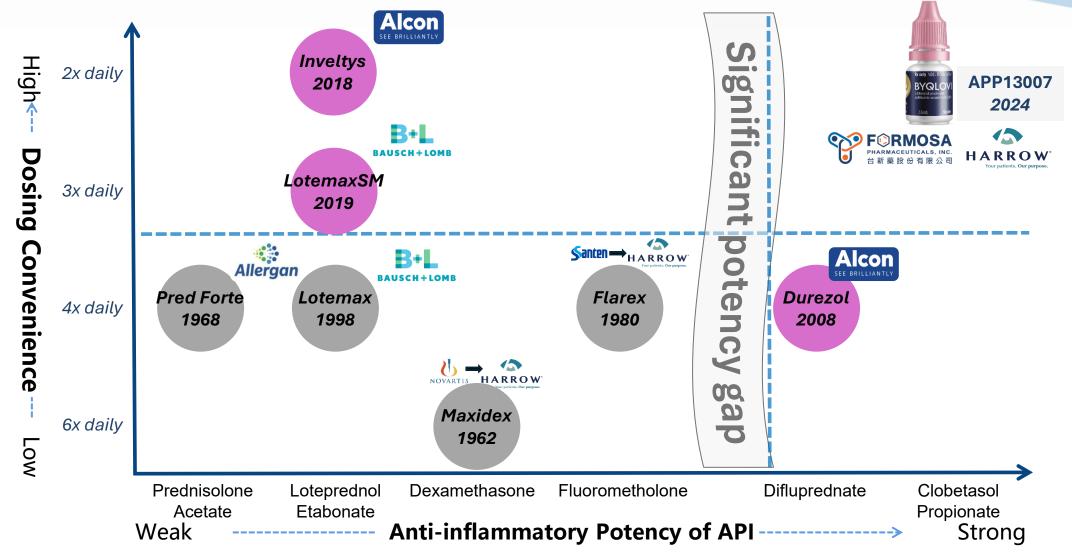
 Steroid use commonly results in eye pressure leading to blindness

#### 4. Discomfort upon administration

Blurred vision, pain, foreign body sensation



## **Evolution of Ophthalmic Steroids and APP13007** positioning



## **APP13007 Comparison to Standards of Care** (Posology and Comfort / Compliance)

Superpotent

Medium

Weak

**APP13007** (Clobetasol Propionate **Ophthalmic Suspension** 0.05%)

#### Standard of Care #1

Lotemax (Bausch) (loteprednol etabonate ophthalmic suspension 0.5%) · 1998 approved

#### **Standard of Care #2**

Pred Forte (Allergan) (prednisolone acetate ophthalmic suspension 1%) 1968 approved



**Eye Pain or** # Drops **Foreign Body** per treatment course Sensation Homogeneous 28 drops No precipitate; 2 times per day for No shaking required 14 days Not homogeneous 56 drops Precipitation after 4 times per day for 14 standing days 168 drops Not homogeneous 4 times a day for 14 days, then 2 times a day for 14 days

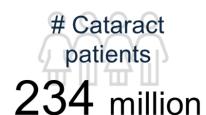




## **APP13007 Comparison to Available Therapies**

	Product	Durezol	Inveltys	LotemaxSM	AF	PP13007 (BYQLO)	/I)
US Approval Year		2007	2018	2019		2024	
Key Active Ingredient (API)		difluprednate	loteprednol	loteprednol	clobetasol propionate		е
Strength of API		Potent	Medium to weak	Medium to weak	Most Potent		•
Dosage Form		ophthalmic emulsion	ophthalmic suspension	ophthalmic gel	ophthalmic nanosuspension		sion
Concentration		0.05%	1%	0.38%		0.05%	<b>*</b>
Manufacturers/Distributors		Alcon	Alasia Kala/Alasia	Bausch+Lomb	Formosa Pharma		
		Alcon	Kala/Alcon		CPN-301	CPN-302	CPN-303 🔨
Clearance of pain	No pain (0%) on POD4		56%		77%	85%	
	No pain (0%) on POD8	58%	66%	74%	82%	87%	
	No pain (0%) on POD15	63%	69%	80%	91%	87%	<u> </u>
	No inflammation on POD8	22%	29%	29%	33%	30%	
	No inflammation on POD15	41%	50%	48%	59%	58%	<u> </u>
Sustained efficacy	No recurrence of pain (POD4 – POD15)		43%		68%	75%	91%
	No recurrence of flare (POD8 – POD15)				75%	79%	91%
	No recurrence of inflamm. (POD8 – POD15)		24%		27%	27%	32%
Dosing	Posology (dosing regimen)	QID x 14, then BID x 7	1-2 drops BID x 14	1 drop TID x 14		1 drop BID x 14	
	Maximum # drops	70	56	42		28	

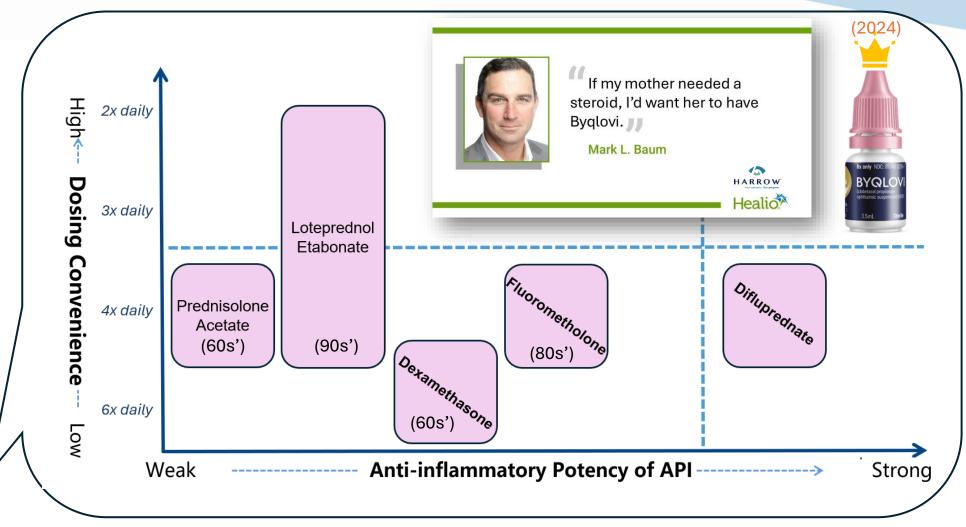
## **Ophthalmic Steroids Market Overview**



# Cataract surgeries 25 million

Ophthalmic Steroid Market Size (US\$)

1.38 billion



16major pharmaceutical (United States, China, EU5 (UK, Germany, France, Italy, and Spain), and other countries (Canada, Japan, Korea, India, Russia, Brazil, Mexico, Australia, etc.)



## **APP13007 Global Licensing Footprint**



### **APP13007's License Partners Overview**

Partner	# of Markets	Region	Signing Date	APP13007 Status	Description	Notes
Harrow	1	USA	2025 Q2	Launched (USA)	One of the leading branded ophthalmic companies in the U.S., with strong presence in post-surgical eyecare.	Replacing Eyenovia
Apotex	2	Canada, Mexico	2024 Q3 / 2025 Q2	Under registration (CA)	Canada's largest pharma company; strong market share in Mexico and active in branded ophthalmic expansion.	
Adalvo	40	Europe, Brazil	2025 Q2	Preparing for registration	One of Europe's top B2B pharma firms; promotes nearly 1,100 products with rapid growth in EU and Brazil.	Replacing Cristalia in Brazil
Grand Pharma	1	Mainland China, HK & Macau	2021 Q2	Preparing for registration	Leading ophthalmic company in China with strong innovation; completed Phase III trial of APP13007.	
Tabuk	15	MENA	2023 Q2	Under registration (SA)	The largest private pharma in Saudi Arabia; full sales coverage in MENA and distributor of many branded drugs.	
Cipla	11	India, South Asia, Africa	2025 Q1	Preparing for registration	Global pharma with over 30 years of experience, partner of MSD in India; strong sales in South Africa and beyond.	
Saval	9	Chile, Latin America	2025 Q2	Preparing for registration	Headquartered in Chile, commercial operations in 14 Latin American countries; one of Chile's top ophthalmic companies.	
Tzamal	1	Israel	2024 Q2	Under registration (IL)	One of Israel's largest branded pharma distributors; also handles surgical ophthalmology devices.	
DAVI	1	Portugal	2024 Q4	Preparing for registration	Portuguese partner with rich experience in eyecare; cooperates with major U.S. and European ophthalmic brands.	
Medvisis	2	Switzerland	2024 Q4	Under registration (CH)	Swiss specialty pharma company; supplies hospitals with rare disease and ophthalmology medications.	
Formosa	1	Taiwan	2025 Q3	Under registration (TW)	NDA submitted in Taiwan; in discussions with potential commercial partners in ophthalmology.	

## **Harrow – US Licensing Partner**



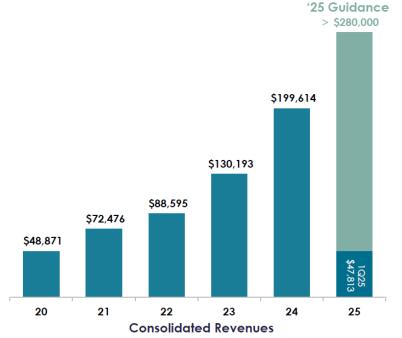


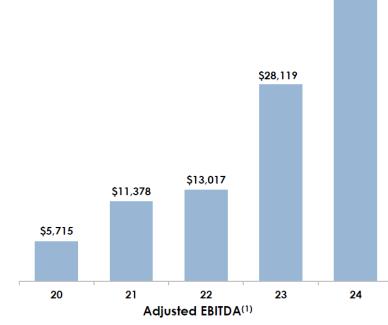
Mark Baum
Harrow CEO and Co-Founder

Harrow focuses on the commercialization of ophthalmic products. its product portfolio includes both prescription and non-prescription drugs for a wide range of eye conditions, such as dry eye, allergies, infections, and other inflammatory ocular diseases.

Harrow markets its products under the Harrow brand and operates ImprimisRx, a leading ophthalmic compounding pharmacy. Its products are used by physicians, hospitals, and ASCs across various healthcare settings.

#### Key Financial Metrics (in thousands)







\$40,327

## **Harrow – US Licensing Partner**



#### Go-to-market plans for BYQLOVI

- Market to existing customers and users of Harrow branded steroid products including: FLAREX, MAXIDEX, TOBRADEX ST, MAXITROL
- Build program to leverage Imprimis customer base and ordering platform to message the unique clinical attributes of BYQLOVI to ImprimisRx customers who on an annual basis are purchasing over 1mm units of ImprimisRx compounded products containing steroids.

#### Leverage existing commercial infrastructure

- Product will be supported by more than 100+ commercial persons (reps, managers, etc.)
- Leverage learnings and experiences from recent product launches and re-launches (e.g., IHEEZO, VEVYE, TRIESENCE)
- Significant built-in Market Access, key account infrastructure, and experience for BYQLOVI to bolt onto to enhance commercial success
- Differentiate BYQLOVI with payers to maximize access, leverage Harrow Branded Direct to maximize access



## **Apotex – Canada/Mexico Licensing Partner**



#### **About Apotex**

Apotex is the largest pharmaceutical company in Canada, employing over 8,000 people. Its business spans across generics, biosimilars, and more, with a portfolio of over 300 prescription drugs.

Apotex has been operating in the Mexican market for over 25 years and is the No. 1 generic drug company in Mexico, offering more than 350 products. The company has extensive experience in regulatory registration and market access.

**Canada + Mexico Market** Overview:Ophthalmic steroid market size: approximately CAD 80 millionAround 800,000 to 900,000 ophthalmic surgeries performed annually.

## In 2024, a variety of ophthalmic brand drugs and new drugs are in-licensed from Jarrow

Ophthalmic preoperative anesthesia, allergic conjunctivitis, Symptomatic relief of dry eye syndrome, spring keratoconjunctivitis in children











Inflammation and Pain after Ocular Surgery



Strategic Alliances with Two Major North American Pharma Companies to Strengthen Market Position:









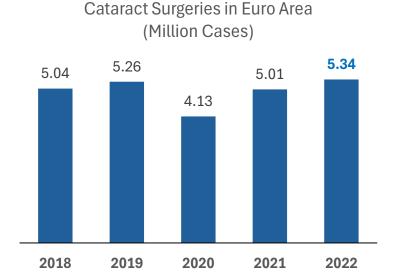
1.APOTEX | 2.GlobalData

## Adalvo – Europe Licensing Partner





- Top 3 B2B Company in Europe with to market capabilities in 130+ countries
- A sister company and European partner of Lotus Pharmaceuticals (Taiwan).
- Backed by a strong regulatory affairs team, with over 1,090 drug marketing authorizations completed.
- Exceptional business development capabilities to identify the most suitable distribution partners in each market and strong market access expertise.
- A comprehensive product portfolio, including GLP-1 drugs and biosimilars within the group.

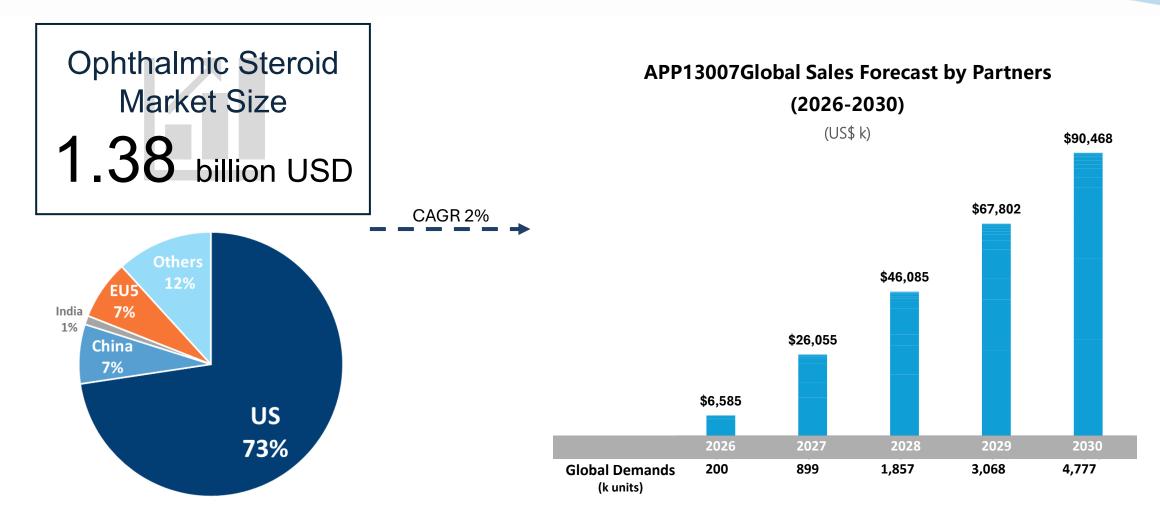


- In 2024, the European ophthalmology market generated approximately USD 16 billion in revenue.
- In 2022, a total of 5.34 million cataract surgeries were performed across 35 European countries.
- The European ophthalmology market is significant and is projected to reach USD 38 billion by 2032, with a compound annual growth rate (CAGR) of 7% from 2025 to 2032.



## **BYQLOVI (APP13007) Global Market Size Estimate**

(not including dry eye and other indications)





# 2-2 Other APNT® Nanoparticle Formulation Projects

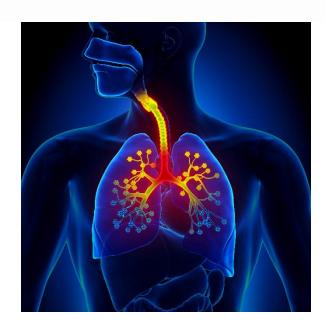


## Other APNT® Nanoparticle Formulation Projects





- APP13002 Ophthalmic Antibiotic
- Two APNT-based formulations under co-development



#### Inhalational:

- 505(b)(2) Inhaled Antibiotic Solution
- Published in OnDrugDelivery Magazine(In collaboration with HCMed) )



#### **Topical Injectable:**

- Potential Applications in Dermatology and Orthopedics
- Formulation Development in Progress (In collaboration with AimMax)



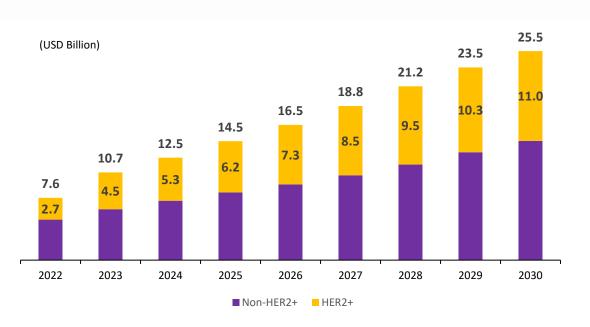


# 3 ADC Projects

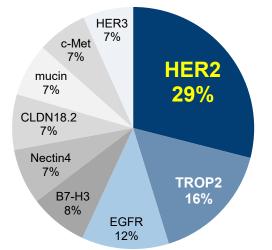


### ADC Market Size / Trastuzumab-based ADC Market Size

**Global ADC Sales Forecast (2022-2030)** 







#### **ADC Drug Development Has Surged in Recent Years:**

- A total of 15 ADCs are approved and on the market.
- In 2024, global sales of all ADCs reached USD 12 bn.
- The market is projected to grow at a CAGR of 9–16%, potentially reaching USD 25.5 bn by 2030.
- With increasing target diversification, emerging targets are expected to address current treatment challenges.

#### **HER2+ ADCs Achieved Commercial Success and Market Expansion:**

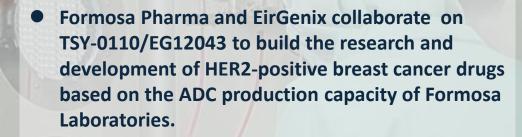
- HER2+ is one of the most prominent therapeutic targets for ADC development. Kadcyla (FIC) and Enhertu (BIC) are successful on the market. Enhertu has demonstrated efficacy across various breast cancer subtypes & other tumor types.
- By 2030, these two HER2+ ADCs are projected to reach approximately USD 1.1 billion in combined sales.



## 台康生技 EG12014 抗體供應







- EirGenix's Herceptin biosimilar EG12014 used has obtained approval in EU and Taiwan, and its quality and efficacy have been recognized.
- Based on the development foundation of TSY-0110, other Trastuzumab-based ADC business opportunities are possible.



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### **Trastuzumab-based ADC Biosimilars**

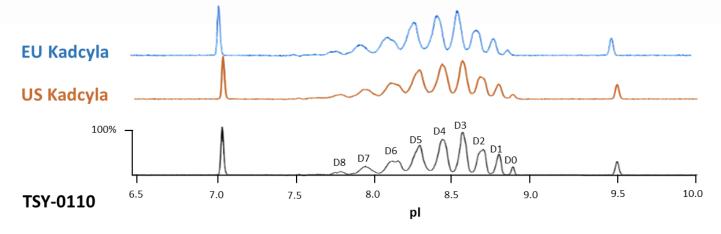
#### **Development Targets: Trastuzumab-based ADCs**

#### First-in-class Best-in-class HER2+ drugs Kadcyla **Enhertu** Drug name (賀癌寧) (優赫得) Main Trastuzumab Trastuzumab ingredient emtansine deruxtecan Daiichi Sankyo Roche Company AstraZeneca First year of 2013 2019 approval **Available** (India) 0 biosimilars

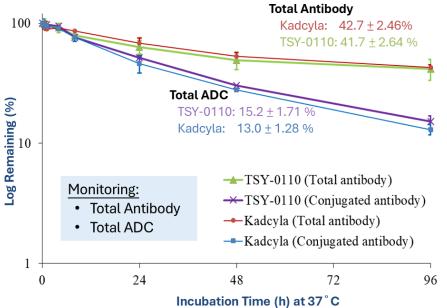
#### Comparison of ADC Biosimilars and Traditional Biosimilars

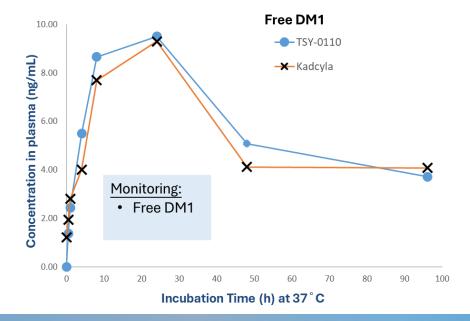
Item	Traditional Biosimilars	ADC Biosimilars
Market Competition	High	Low
Structural Complexity	Moderate	High
Characteriza-tion	Antibody structure, function, glycosylation	Antibody + DAR + payload + linker structure and stability
Process Sensitivity	Moderate	Extremely high
Regulatory Maturity	Mature (clear EMA/FDA guidelines)	Still evolving (no unified standards yet)
Clinical Requirement	Phase III might be waivable in the future	Frequently requires clinical confirmation
Patent Challenges	Primarily antibody-related	Multilayered and difficult to circumvent

# **Biosimilarity Assessment of ADC Biosimilars: Example: TSY-110**



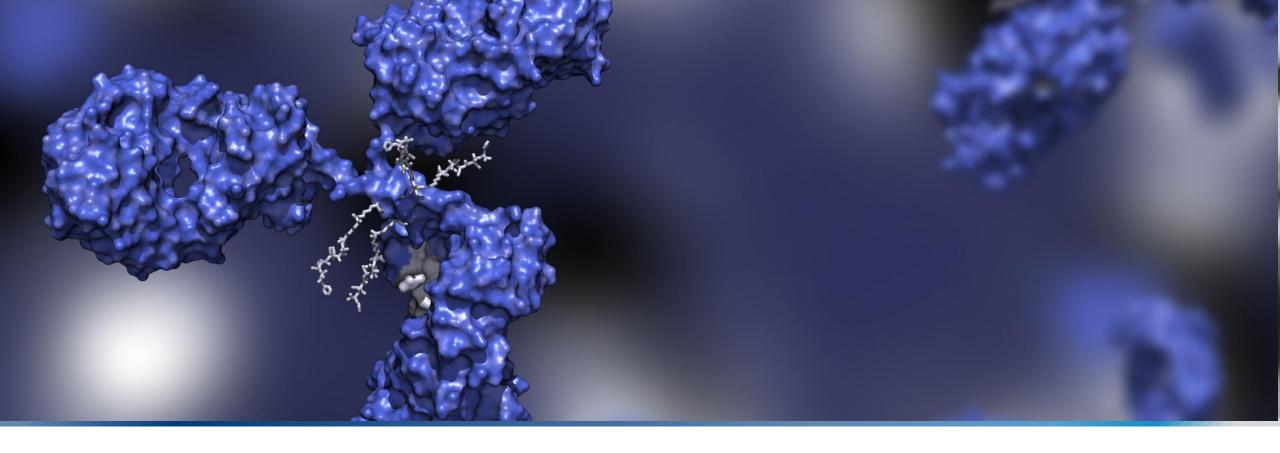
Distribution of Drug-Antibody Ratio (DAR) of TSY-110 compared to Kadcyla demonstrates high similarity.





Plasma stability is regarded as a critical preclinical assessment for biosimilarity.

→ The trends of TSY-110 and Kadcyla® in plasma are similar



## 3-1 TSY-110 - Kadcyla Biosimilar



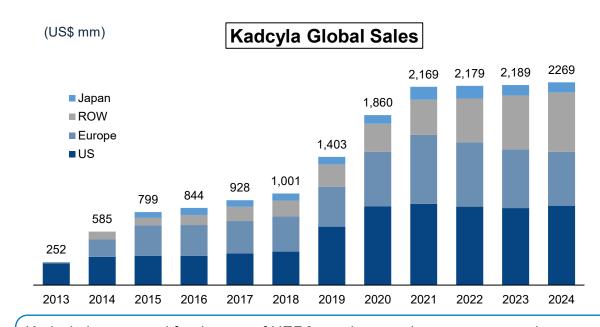
## TSY-110 / Kadcyla Biosimilar



- Kadcyla is another blockbuster drug for HER2positive breast cancer after Herceptin, based on Herceptin antibody, for the treatment of HER2+ early breast cancer and metastatic breast cancer.
- TSY-0110 aims to be the first Kadcyla biosimilar to be marketed in Europe and the United States.



TSY-0110 was developed to be an ADC drug with biosimilarity, efficacy and safety consistent with Kadcyla.



Kadcyla is approved for the use of HER2+ early-stage breast cancer and metastatic breast cancer alone:

- The 7-year follow-up results of Roche's Phase 3 early breast cancer clinical trial showed that its overall survival (OS), recurrence-free survival (iDFS) was better than Herceptin's, and the incidence of serious side effects was also lower, indicating benefit of receiving Kadcyla. (2023)
- Kadcyla + Tecentriq (PD-L1) is in phase III clinical trials for the treatment of early-stage breast cancer.



## TSY-110 / Kadcyla Biosimilar

#### **Development Achievements**

- Achieve batch-to-batch consistency
- Potency and stability were confirmed to be similar to those of the comparator Kadcyla
- Completed the European Medicines Agency (EMA)
   Pharmaceutical Consultation Meeting
- Completed the US FDA BPD Type 2 Pharmaceutical
   Consultation Meeting

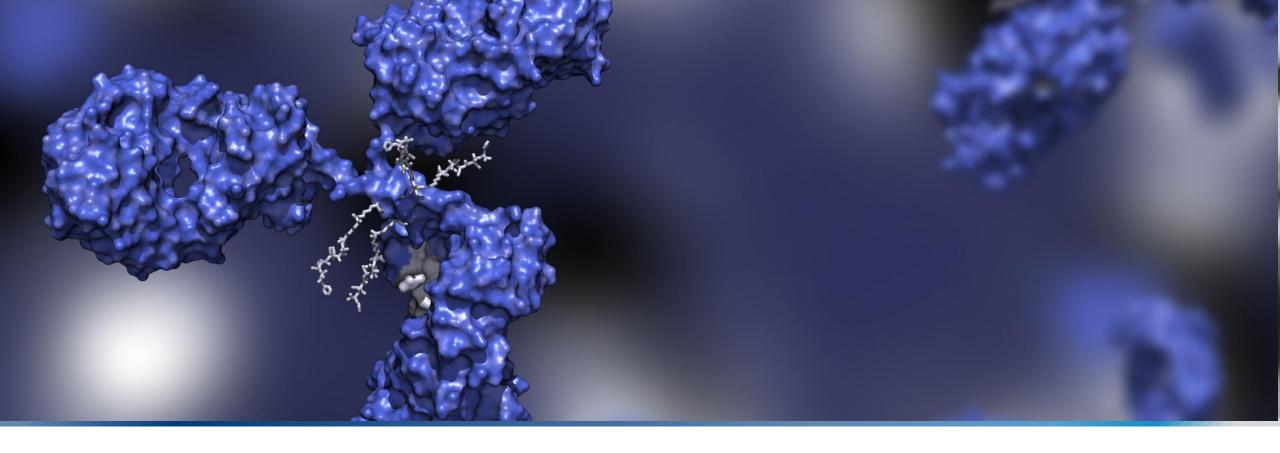
#### Strategy & Goals

- After the completion of the outsourcing license,
   the clinical trial will be led by commercial partners.
- The goal is to obtain certification in the European and American markets in 2031.

#### **Progress in Co-Development Discussions**

- Held preliminary business discussions with more than 15 multinational or regional biosimilar companies during BIO Boston.
- Currently, for a potential global licensing deal in Term Sheet discussions with a global pharmaceutical company generating over
   USD 1 billion in annual revenue.



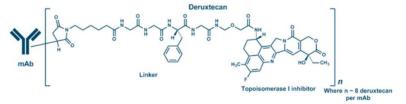


# 3-2 Enhertu Biosimilar for HER2 related cancers



## **Enhertu Biosimilar Oppotunity**





trastuzumab deruxtecan

 Enhertu is the second HER2-target ADC to be marketed globally after Kadcyla, and it is also the ADC with the highest sales volume. It has a broader range of indications and revenue growth potential.



#### **Approved Indications:**

Gastroesophageal junction gland cancer, bladder cancer, uterine neck cancer, large intestine cancer, uterine endometrial cancer, epithelial ovarian cancer, gastric cancer HER2+breast cancer HER2 Low breast cancer Metastatic biliary tract cancer, non-small cell lung cancer, salivary gland cancer, solid tumors.

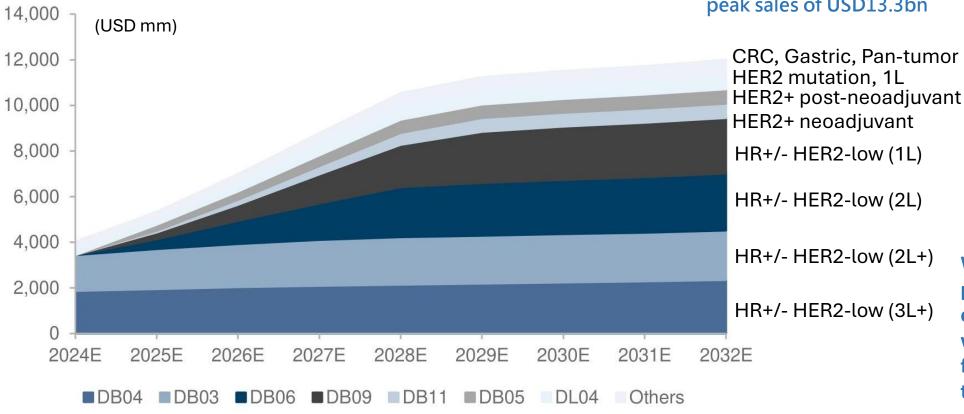
#### **New Indications under investigation:**

Ductal cancer, cystic carcinoma, esophageal cancer, HER2- breast cancer, tri-negative breast cancer (TNBC), cerebral meningeal cancer, transitional pancreatic cancer, osteosarcoma, breast cancer brain transfer, recurrent pleomorphic palaticoplasmic mother cell tumor (GBM), urothelial cell carcinoma.



## **Enhertu Biosimilar Oppotunity**

#### Enhertu total sales risk adjusted by different indication



Danske Bank (UK): Enhertu has the potential to achieve peak sales of USD13.3bn

- HER2-low (2L+)

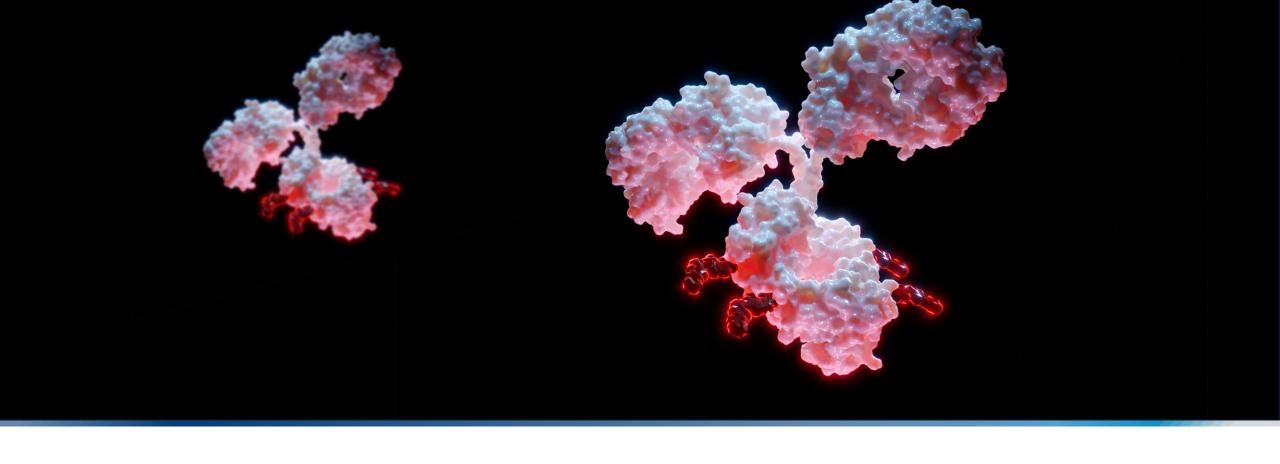
- HER2-low (2L+)

- HER2-low (3L+)

- HER2-low (

through its strategic ADC

alliances.



# 3-3 TSY-310 - Bispecific ADC for solid tumor



## TSY-310 (ALM-401) Overview

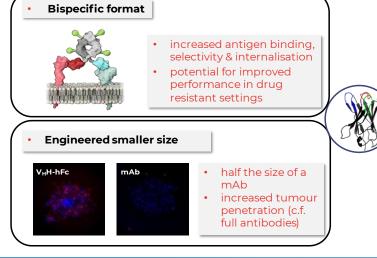
ALM-401 is a bispecific ADC developed by Almac Discovery and in-licensed by Formosa Pharma in 2025 intended for the treatment of solid tumors, including NSCLC.

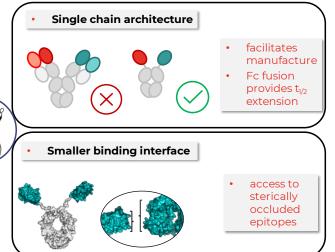
It's core is a novel bispecific antibody engineered to be smaller in size by utilizing a single-chain architecture. This critical attribute potentially enhances epitope engagement and tumor penetration and is designed to improve ease of manufacturing.

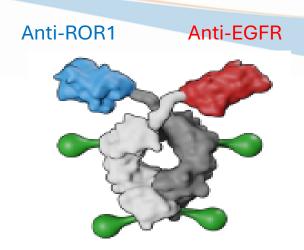
The ADC has demonstrated durable and sustained tumor inducing a pronounced bystander effect to further boost overall therapeutic effect.

#### **ADC Platform**

Next Generation Engineered Molecular-Targeted Therapies







ROR1 (Receptor tyrosine kinase-like Orphan Receptor 1) is an embryonic developmental receptor abnormally expressed in various cancers such as lung cancer, breast cancer, and hematologic malignancies. It is recognized as a highly promising target for anticancer therapy.

**EGFR** promotes tumor growth and metastasis and is a well-established therapeutic target in several cancers.

By simultaneously targeting ROR1 with a bispecific ADC, ALM-401 is designed to selectively eliminate tumor cells while minimizing damage to healthy tissues, thereby enhancing both treatment safety and efficacy.

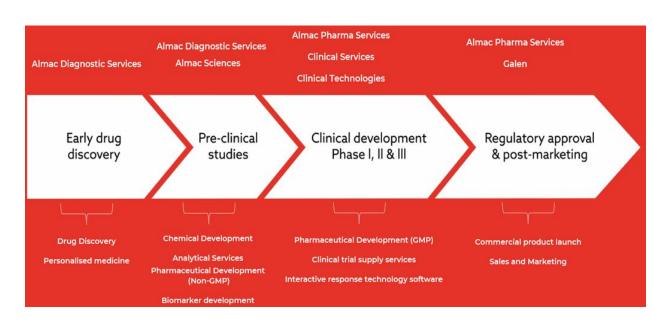


## **ALM-401 Developer - ALMAC Discovery**



Almac Group provides services to the pharmaceutical and biotechnology industries, including, Drug Development, Clinical Trial Supply, Commercial Manufacturing and Analytical Services. Group turnover surpasses £1 billion.

Almac Discovery is a drug discovery company creating and develop First-in-Class and Best-in-Class NMEs through to the pre-clinical candidate-ready stage.



#### **Almac Global Footprint**





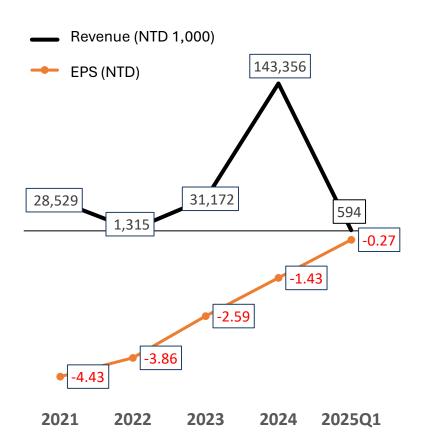


## 04 Financial Information



## Trends in Revenue, EPS, and Asset Changes

#### **Trends in Revenue and EPS**



#### **Trends in Liquidity**



As APP13007 has successfully obtained FDA approval in the United States, and secured multiple out-licensing agreements, EPS has improved significantly, and working capital has steadily increased. This will support the advancement of the Company's new drug development projects.



## Thank you for your interest

