

# *InnoLAMP™: A Scalable Microsphere Platform for Next-Generation Long-Acting Injectables*

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# Therapeutic Drug Use & Non-Adherence



**Over 50% of the world's population takes more than one medication per day.**

*"Global Medicines Use in 2020" by IMS Institute for Healthcare Informatics.*

✓ CivicScience data show 70% of U.S. adults taking at least one prescription medication per day.



# Medication Nonadherence Comes at a High Cost for both Patients & Health Systems

## World Health Organization

**“More health benefits worldwide would result from improving adherence to existing treatments than developing any new medical treatment”**



United States

**50%** of the 3.2 billion annual prescriptions dispensed in the US are not taken as prescribed.

- Approximately **125,000 deaths per year** in the US are linked to **medication nonadherence**.



## Europe

**50%** of patients don't take their medications properly.

- approximately 200,000 premature deaths in EU

**30~50% of prescribed medications are not taken as recommended in UK.**

- Research shows that £500 million a year is being lost due to patients not taking their medicines properly.

**At least 33% of Germans repeatedly fail to follow their doctor's recommendations regarding pharmacological treatments and only 25% of Germans describe themselves as fully adherent.**

**20% of patients don't even by prescribed medications in France.**

- approximately **8,000 deaths per year** & **1.1 million hospital days** are linked to **medication nonadherence**.
- total cost estimated to be **€19 billion** each year.

# Long-Acting Injectables (LAIs) = Improved Medication Adherence & Patient Convenience Compared to Existing Commercial Drugs



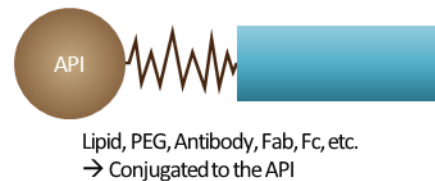


# Microsphere Technology = Long-Acting Technology, without Chemical Modification of API, Enabling Precise Drug Release Control and Fast Commercialization

## Long-Acting Technology Comparison

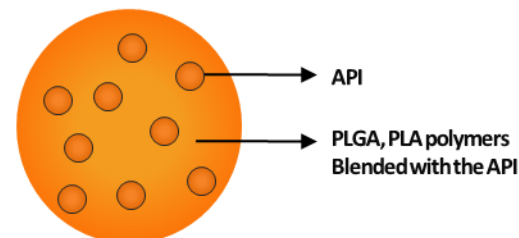
### Chemical Modification

- ✓ New Drug
- ✓ Safety and Efficacy Proof Required
- ✓ Timeline and Cost Burden
- ✓ Limitations in Drug Release Rate and Duration Controls

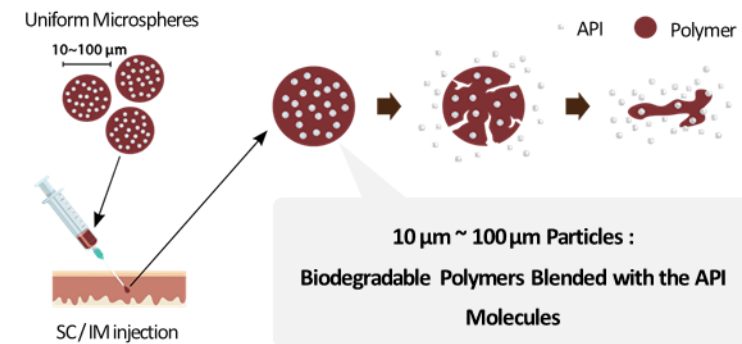


### No Chemical Modification

- ✓ Incrementally **Modified Drug**
- ✓ Safety/Efficacy Mostly **Exempted**
- ✓ Time and Cost **Shortened**
- ✓ **Easy Control** of Drug Release Rate and Duration



## Microsphere Drug Release Mechanism



- ✓ Administered via Subcutaneous (SC) or Intramuscular (IM) Injections
- ✓ Drug Release Driven by Hydrolysis of Polymers



# About G2GBIO

## Good to Globe **by Innovative Bio-therapeutics**



### Location

- HQ/R&D/GMP:  
Osong, S. Korea
- Clinical/BD:  
Seoul, S. Korea



### Employees

- 52 (Dec 2025)



### Patents

- Total 170
- 105 filed, 65 granted



**Established:** Mar 22, 2017

**KOSDAQ listed (#456160):** Aug 2025

### Key SR Injectable Experiences of Leadership Team

#### Commercialization

- Luphere Depot® (QM Leuprolide, Ultrasonic Spray Drying)
- Lorelin Depot® (QM Leuprolide, In Water Drying (Emulsion))

#### Clinical Experience

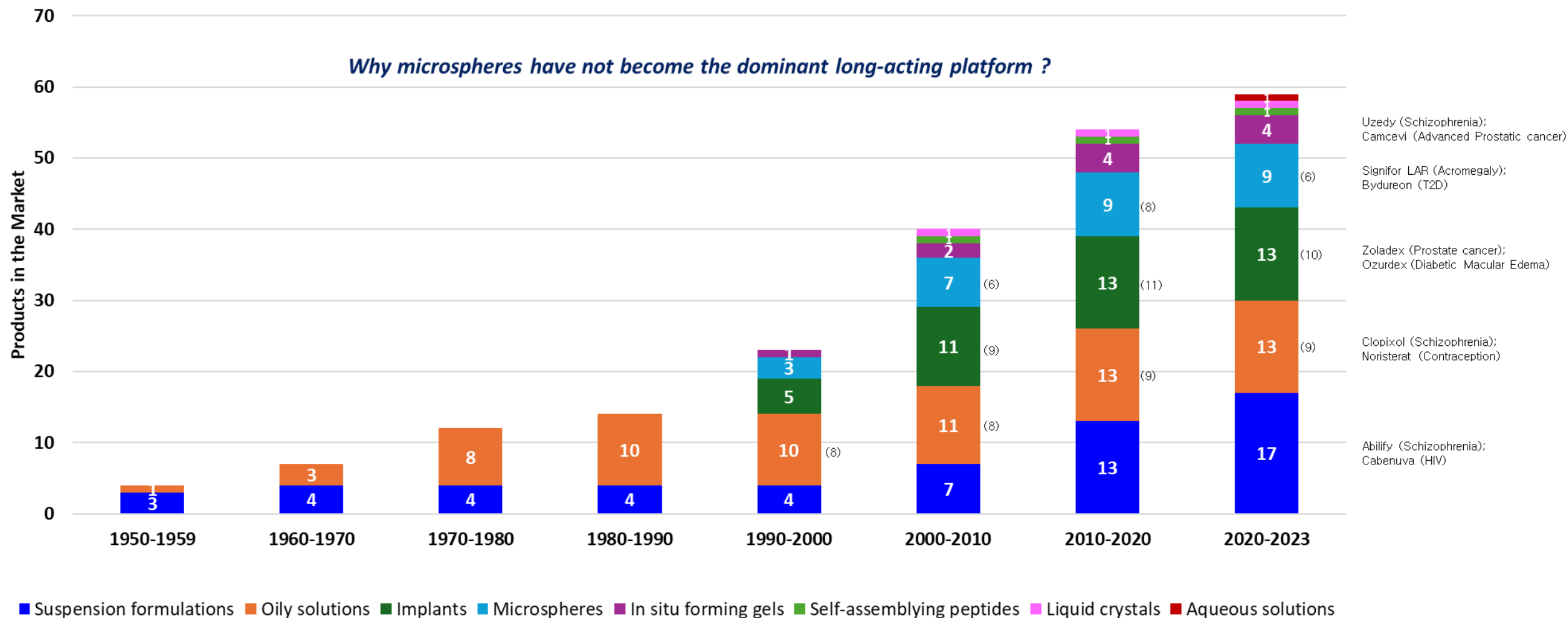
- SR-Exenatide (Q2W: P2)
- SR-Octreotide (QM: BE)
- SR-Leuprolide (QM: P4, Q3M: P3)
- SR-Goserelin (QM: P3)
- SR-Donepezil (QM: P1)
- SR-Ropivacaine (QW: P1)

#### Construction of GMP facility

- SR-hGH (cGMP/EUGMP)
- SR-Exenatide microsphere (EUGMP)



# Landscape of LAI Formulations by Commercialized LAI Products Grouped by Formulation Platform

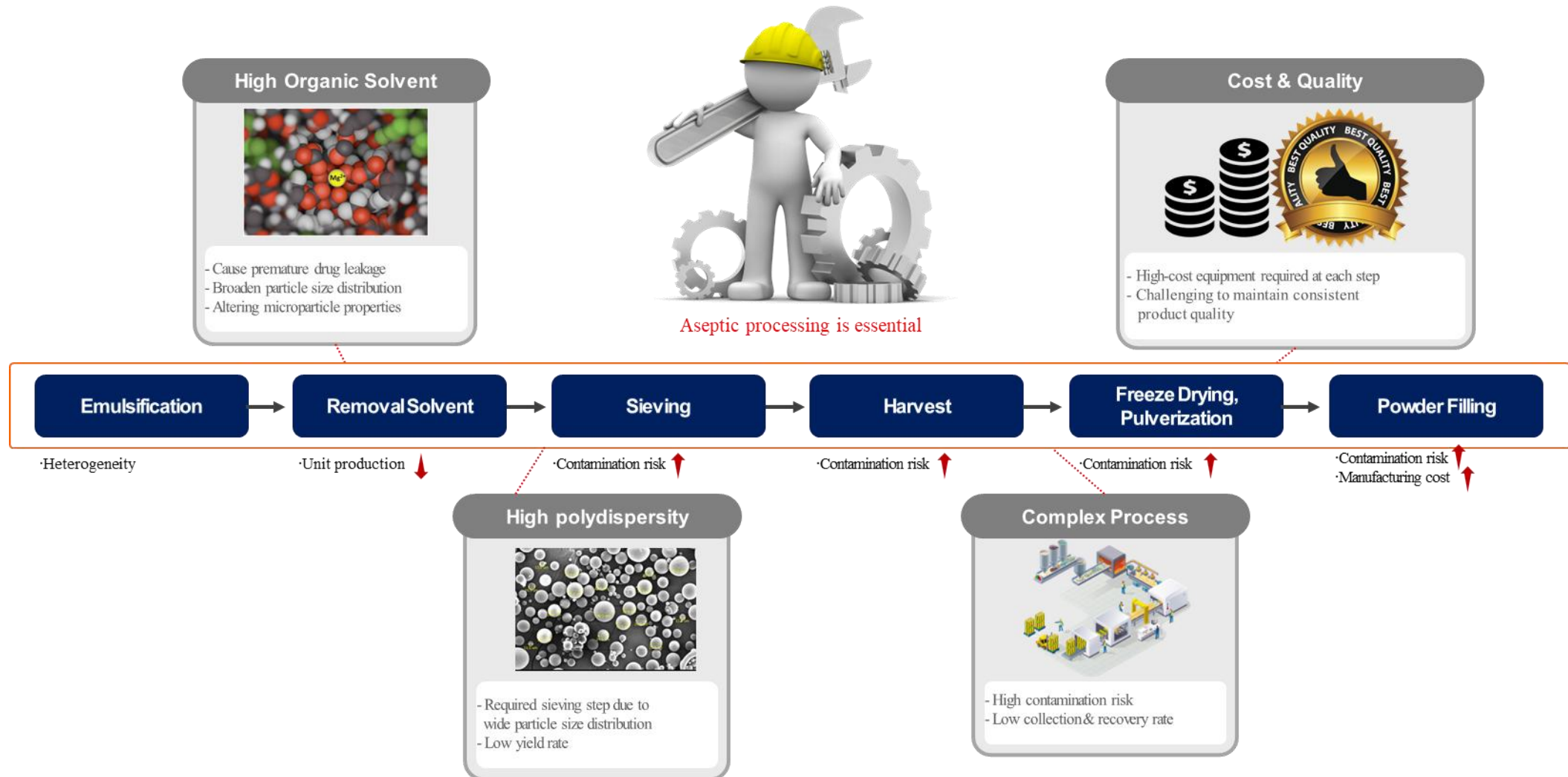


\*Number in the brackets: # of marketed products, excluding products that have been retracted from the market.



# Technical Challenges for the Same and Similar Microsphere Technologies

## 1. Difficulty developing mass production processes.



# Key Features of InnoLAMP : ① Easy Mass Production

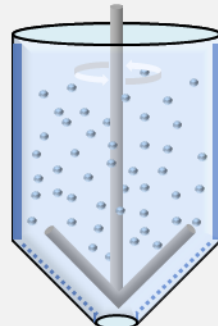
❖ *Enables easy and reproducible mass production with low cost.*

High Barriers in Multi-step, Large-scale Manufacturing

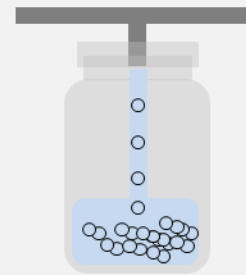
InnoLAMP: Simplified Process & Easy to Scale Up



- Monodisperse



- Unit production ↑  
(x5~20)



- Speed ↑
- Cost ↓
- Contamination risk ↓

Emulsification

Solvent Removal

Suspension Filling & Drying

## Monodisperse particle

Needle size ↓, patient compliance ↑  
High production yield

## High unit production

Easy & reproducible mass production with low cost

## Simple process with improved filling step

High sterility assurance & Low construction cost

Emulsification

Solvent Removal

Sieving

Recovery

Drying & Pulverization

Powder Filling

- Polydisperse

- Unit production ↓

- Contamination risk ↑

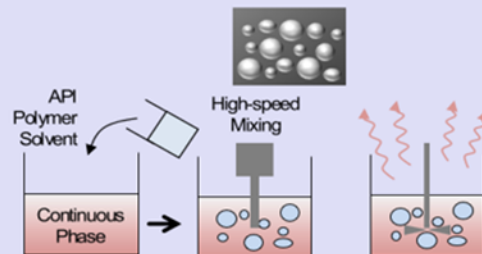
- Contamination risk ↑

- Contamination risk ↑
- Recovery ↓

- Speed ↓

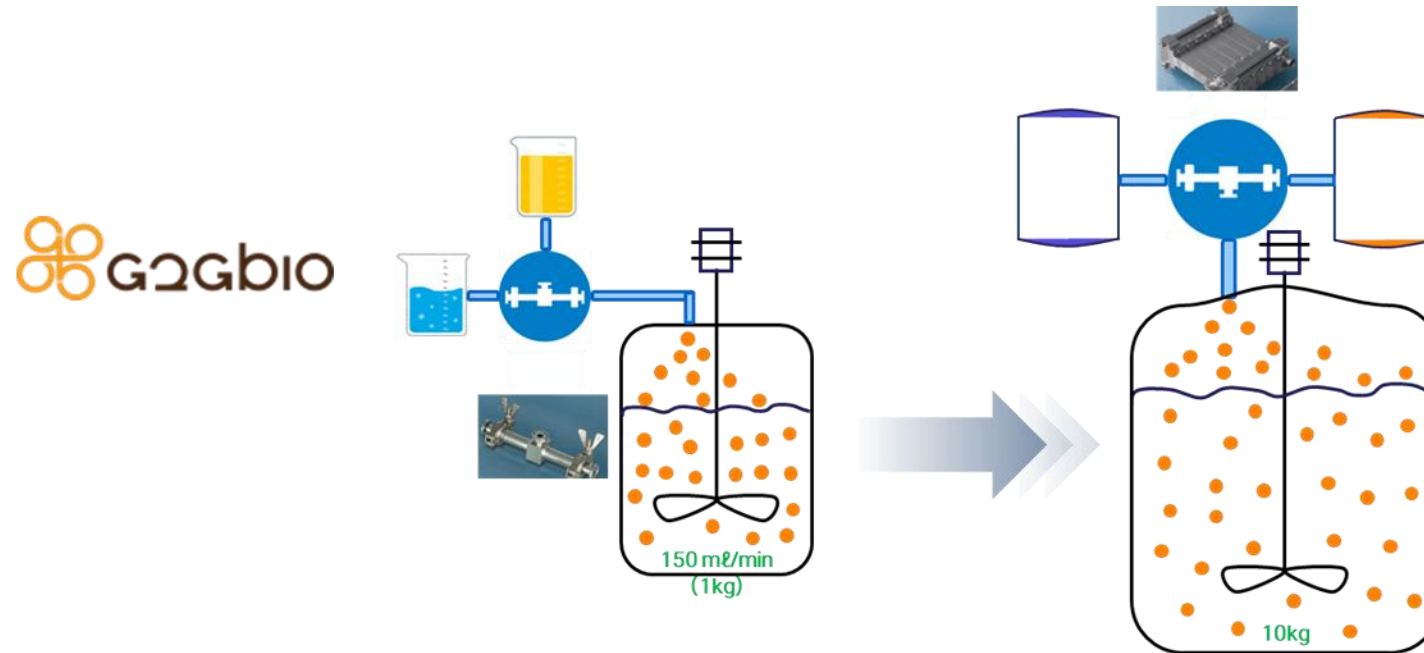
- Cost ↑

- Contamination risk ↑

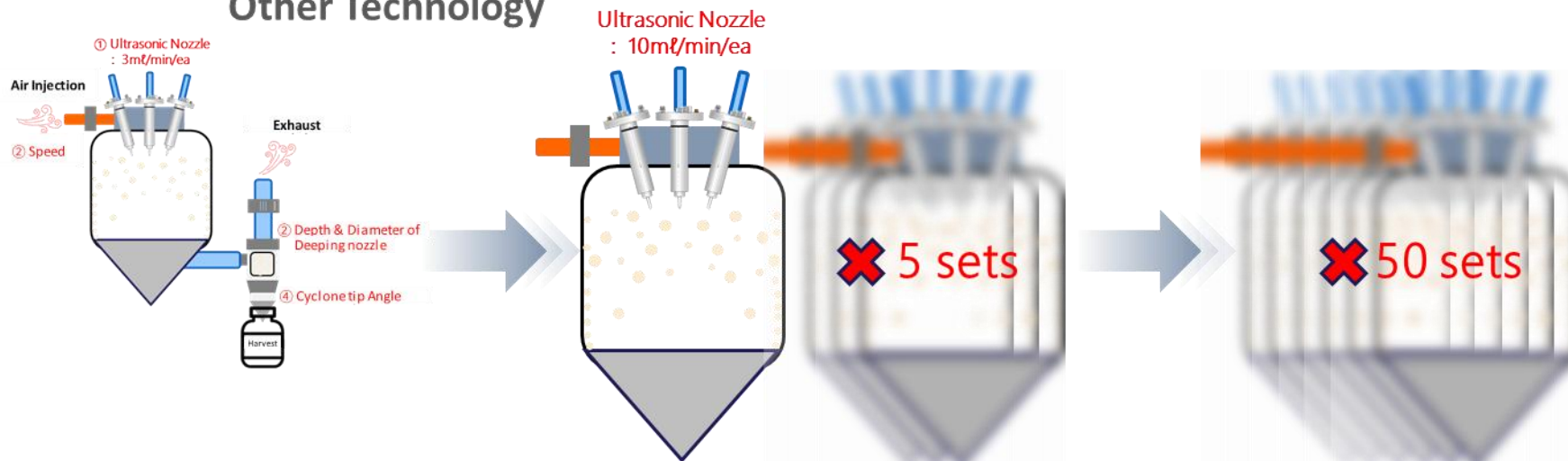


Conventional Technology

# Key Features of InnoLAMP : ① Easy Mass Production



## Other Technology



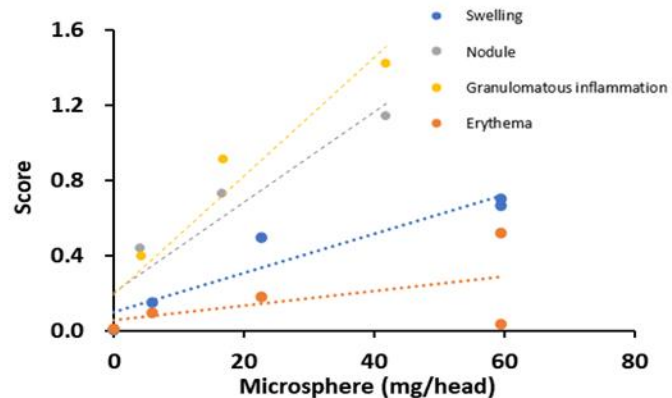
## Technical Challenges for the Same and Similar Microsphere Technologies

## **2. Limited Injection Dosage & Volume: High API loading is Key**

## Limitations on Drug Loading in Microspheres

- ✔ **High dosage in a single injection is required** for 1 month or 3 months
- ✔ **Challenges in achieving high drug-loading** in microspheres
- ✔ Even when high-drug loading is achieved, **initial burst remains a major issue**

### Increased Microsphere Dosage : Increased AES



(Ref. Local tolerance of Bydureon in monkey)

The diagram illustrates the relationship between injection volume and the amount of microspheres for two different routes of administration. A large blue arrow at the top points to the right, indicating increasing volume.

	Microsphere (100mg/mL)	Microsphere (200mg/mL)	
5			Intramuscular (900mg)
4			
3			
2			
1			
			Subcutaneous (300mg)
	Most Preferable (100mg)		

The diagram shows a grid with 5 rows and 2 columns. The rows are labeled 1 to 5 on the left. The columns are labeled 'Microsphere (100mg/mL)' and 'Microsphere (200mg/mL)' at the top. A red dashed line is drawn between rows 1 and 2, labeled 'Subcutaneous (300mg)' on the right. Another red dashed line is drawn between rows 4 and 5, labeled 'Intramuscular (900mg)' on the right. The cell at row 1, column 1 is highlighted in orange and labeled 'Most Preferable (100mg)'. A large blue arrow points from left to right at the top of the diagram.

**Next Question:**  
**High initial burst?**

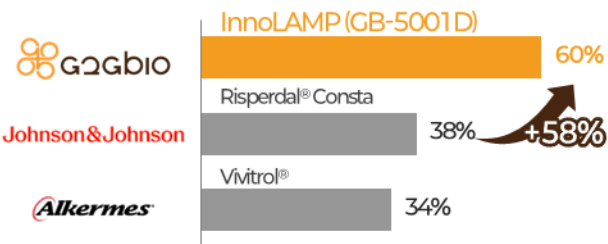


# Key Features of InnoLAMP : ② High Drug Content (Overview)

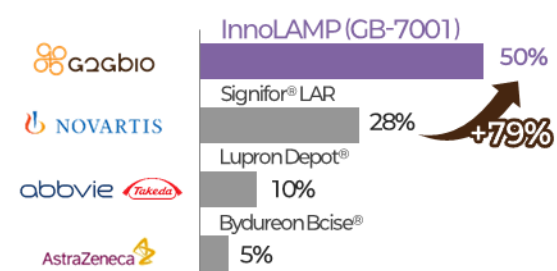
❖ *Ultra-High Drug-Loading in Microspheres:  
Effective Control of Initial Drug Release and Maximized Medication Convenience*

## InnoLAMP for Ultra-High Drug-Loading LAI Product Development

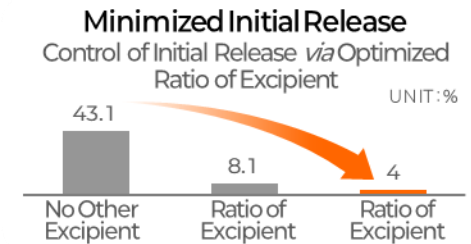
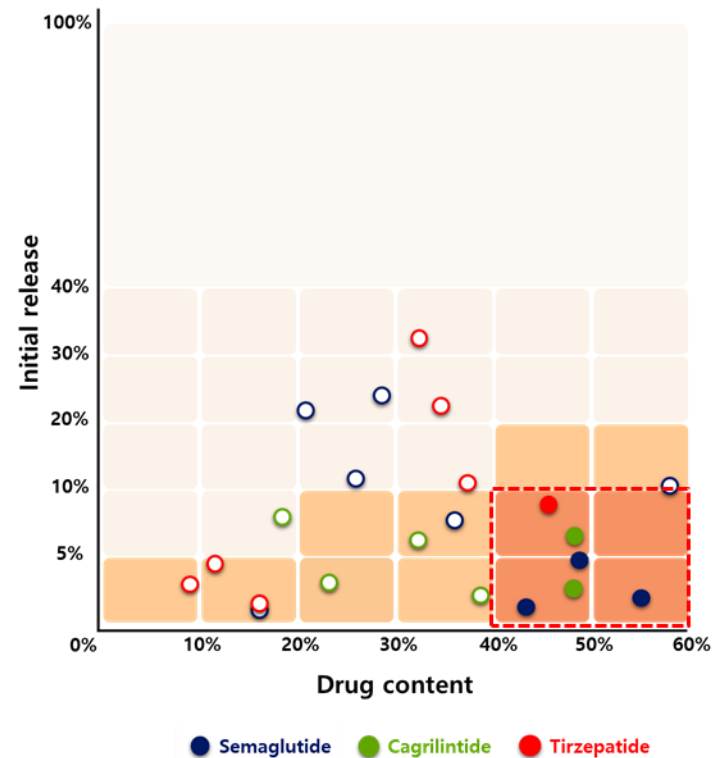
### Small molecules



### Peptides



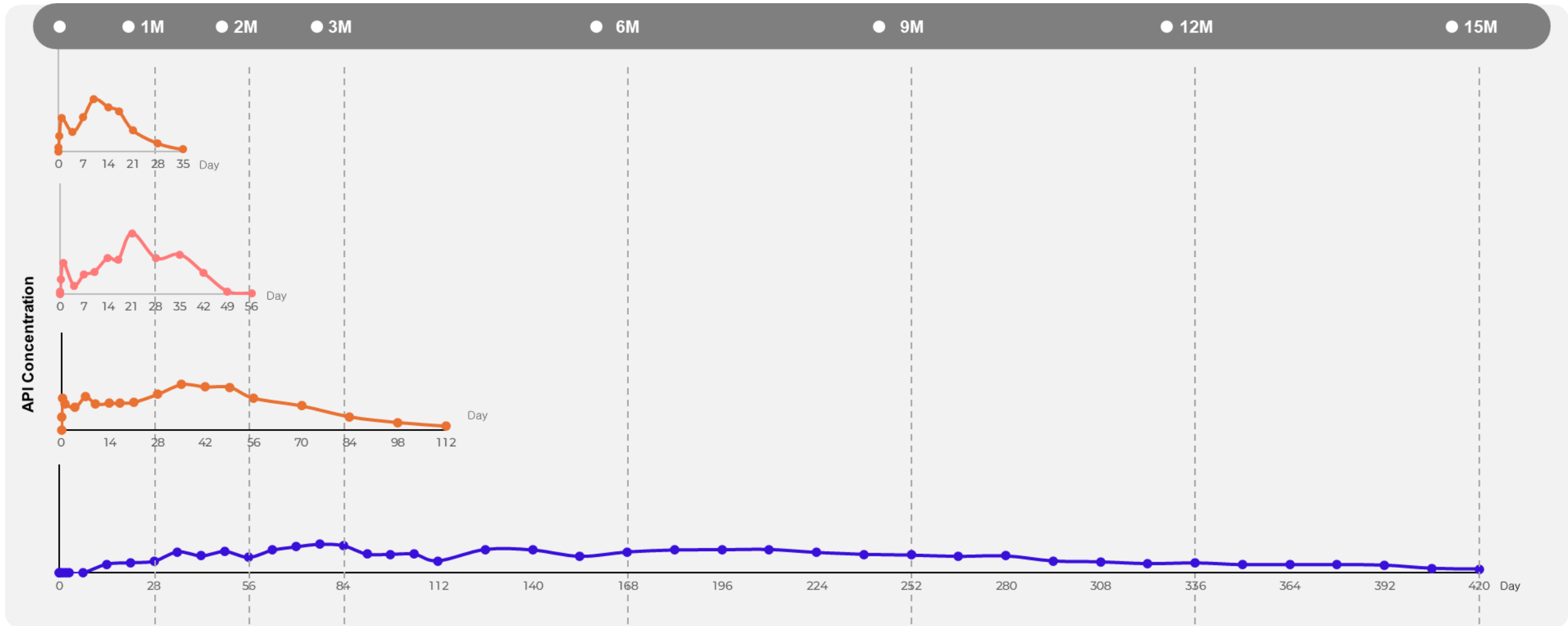
Reduced microsphere dosage *via* higher drug-loading  
→ Decreased injection site reactions (e.g., pain);  
improved medication adherence and convenience



<< Target Prototypes

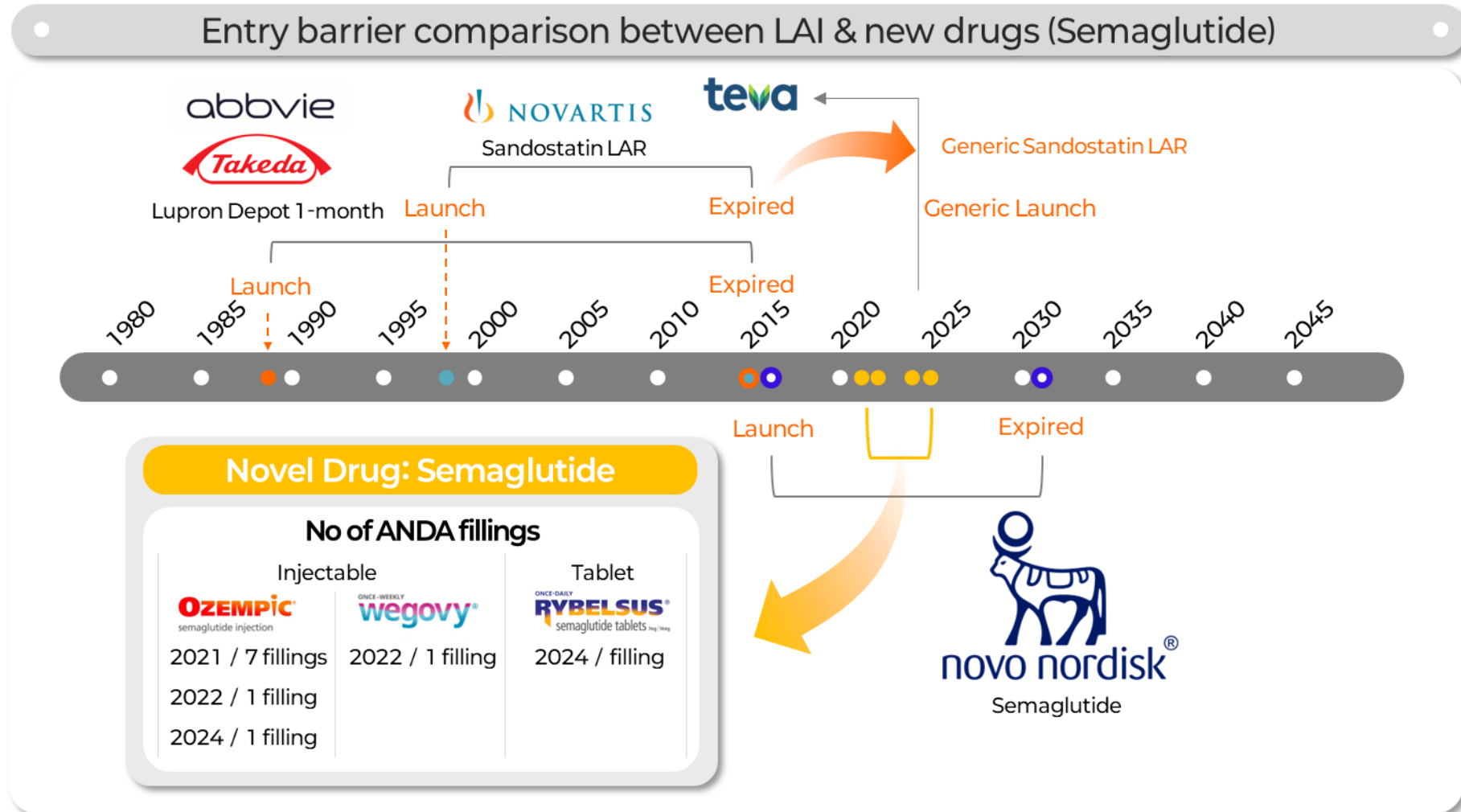


# Controlling Drug Release Duration by G2GBIO's InnoLAMP™ Technology



# Long-acting Injectables: Higher Profitability than Conventional Drugs

- ❖ LAIs *maintain market exclusivity for a prolonged period even after patent expiry due to high entry barriers.*



# Pipeline & Global Partnership

❖ *Advancing a robust pipeline of next-generation long-acting injectable therapeutics across multiple indications*

				Discovery		Clinical Studies		Approval
				Formulation	Efficacy/Tox	IND	Phase 1/2/3	Launch
G2GBIO Human Drug	Central Nervous System	Alzheimer's Disease	GB-5001A				P1 completed > MAD	Study (ongoing)
			GB-5112				IND Enabling (Korea)	
		Schizophrenia (1M/3M)	GB-5021/5023	Scale up			*Government-supported project (MTI, Korea)	
	Pain Management	Post operative pain	GB-6002				P1 completed (Korea)	
	Metabolic/Endocrine	T2D/Obesity (1M/3M)	GB-7001/7003	Scale up and			IND Enabling (Korea)	
	Immunology/Transplantation	Organ rejection	GB-5011	Formulation Screening			*Government-supported project (MSS, Korea)	
G2GBIO Animal Drug	Reproductive/Endocrinology	Chemical Castration (6M)	GB-2001				IND Enabling (Korea)	
	Pain Management	Post operative pain	GB-2006				P2 completed (Korea)	

Partner's  
API



Feb. 2023



Mar. 2023



Feb. 2025



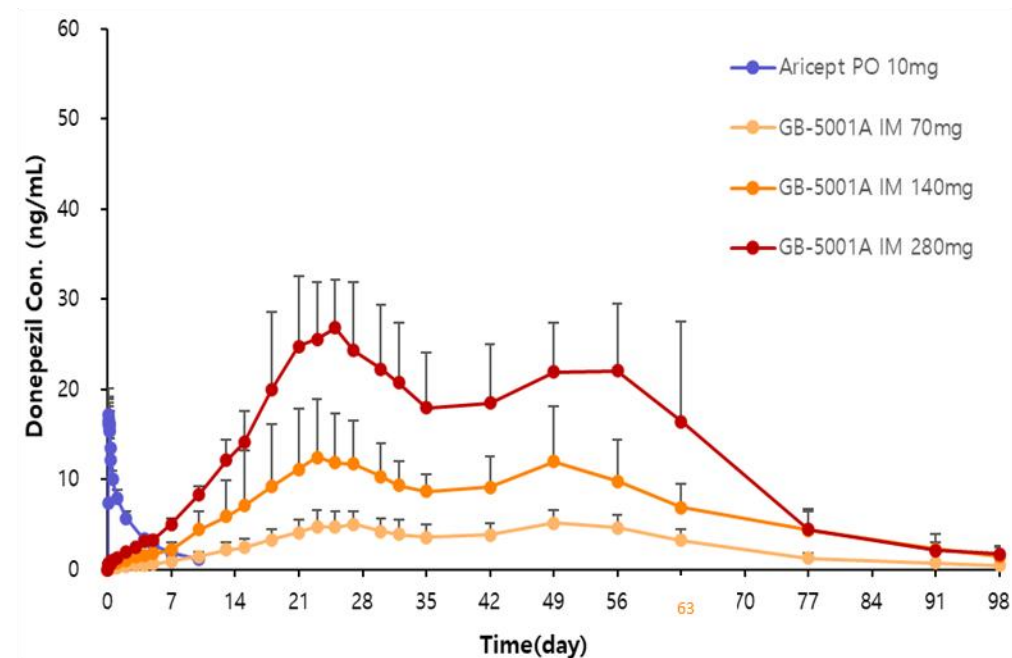
Oct. 2025

# Manufacturing Facilities

- ❖ **1st GMP (~1.2kg/batch) : Successfully manufactured GB-5001A (monthly & bimonthly donepezil) at our 1st GMP facility, with no safety issues observed and human PK data demonstrating an ideal profile for both monthly and bimonthly injectable formulations**



## GB-5001A : monthly & bimonthly Donepezil

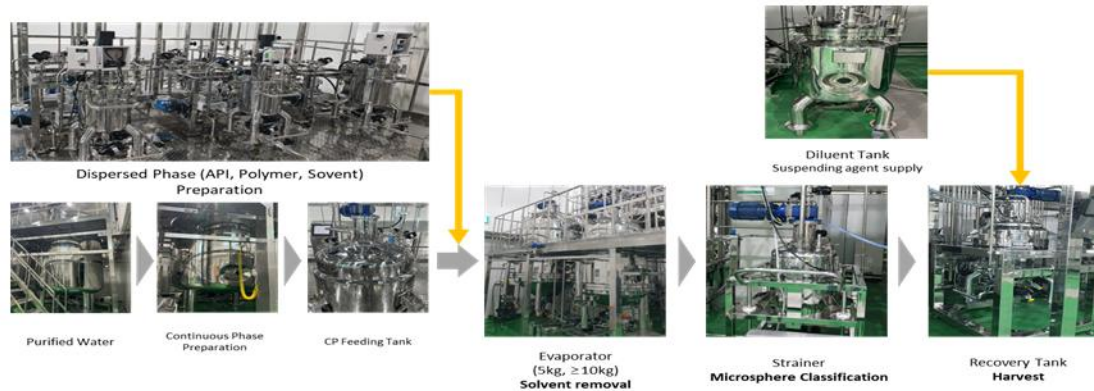


- ✓ No safety issue observed
- ✓ Obtained human PK data satisfying ideal profile for **monthly & bimonthly donepezil injectables**



# Large-Scale Manufacturing Facility

- ❖ **2nd GMP** : The world's largest high-capacity GMP plant is set to be completed in 2027, featuring a production capacity of 30~60 kg per batch.



Optimized Mass Production

Maximum Capacity (Plan)

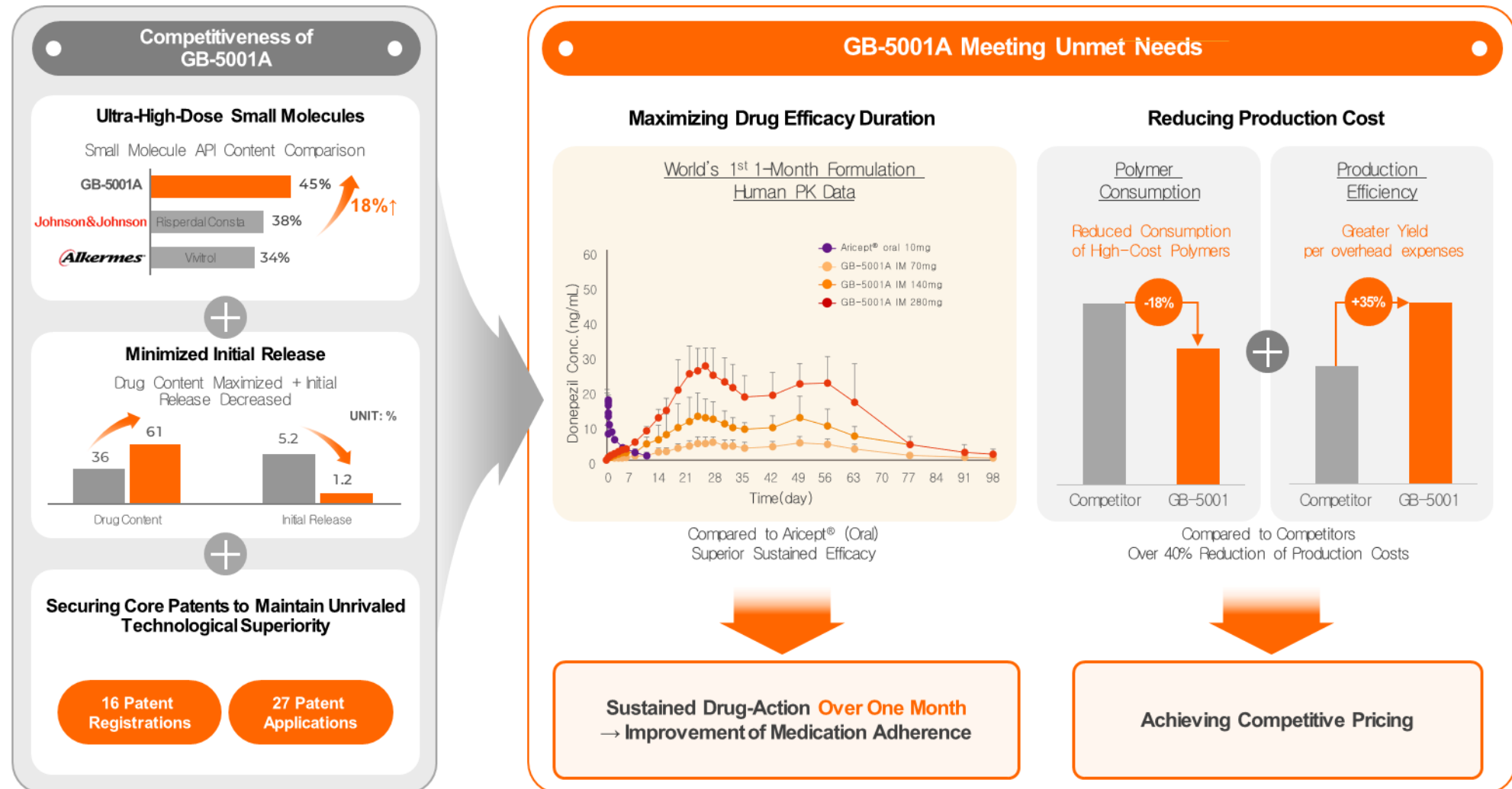
Total **30~60** kg/Batch





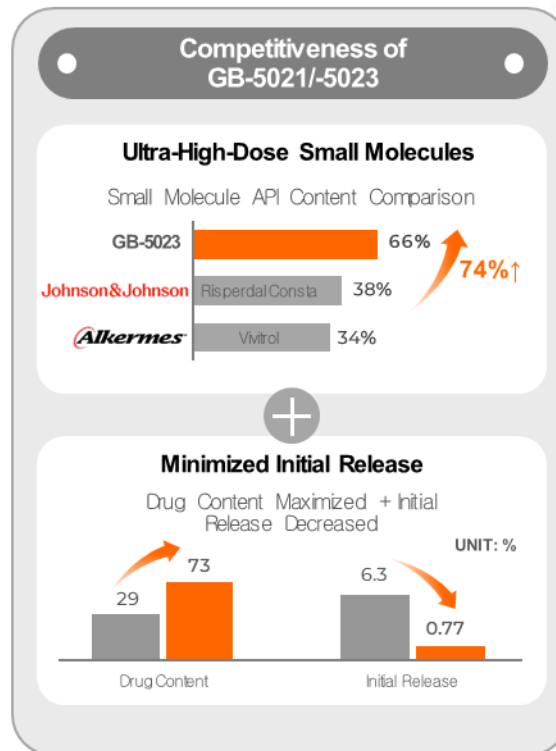
# GB-5001A

◆ A Phase 1 Clinical Study Completed for [the World's First Once-Monthly Formulation](#) GB-5001 :  
Securing Superior Sustained Efficacy and Commercial Competitiveness



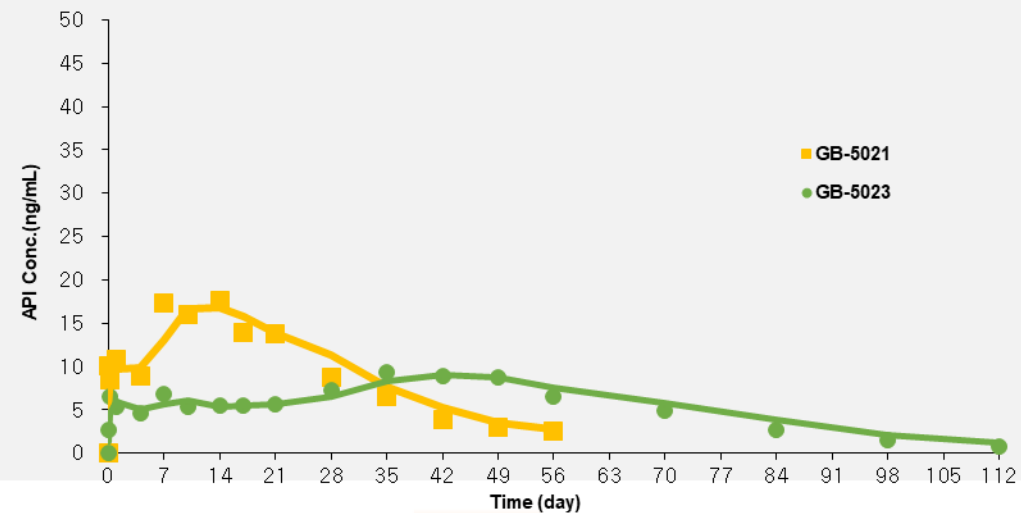
# GB-5021 & GB-5023

- ◆ Sustained therapeutic effects for 1 and 3 months are achieved with a single administration for schizophrenia.



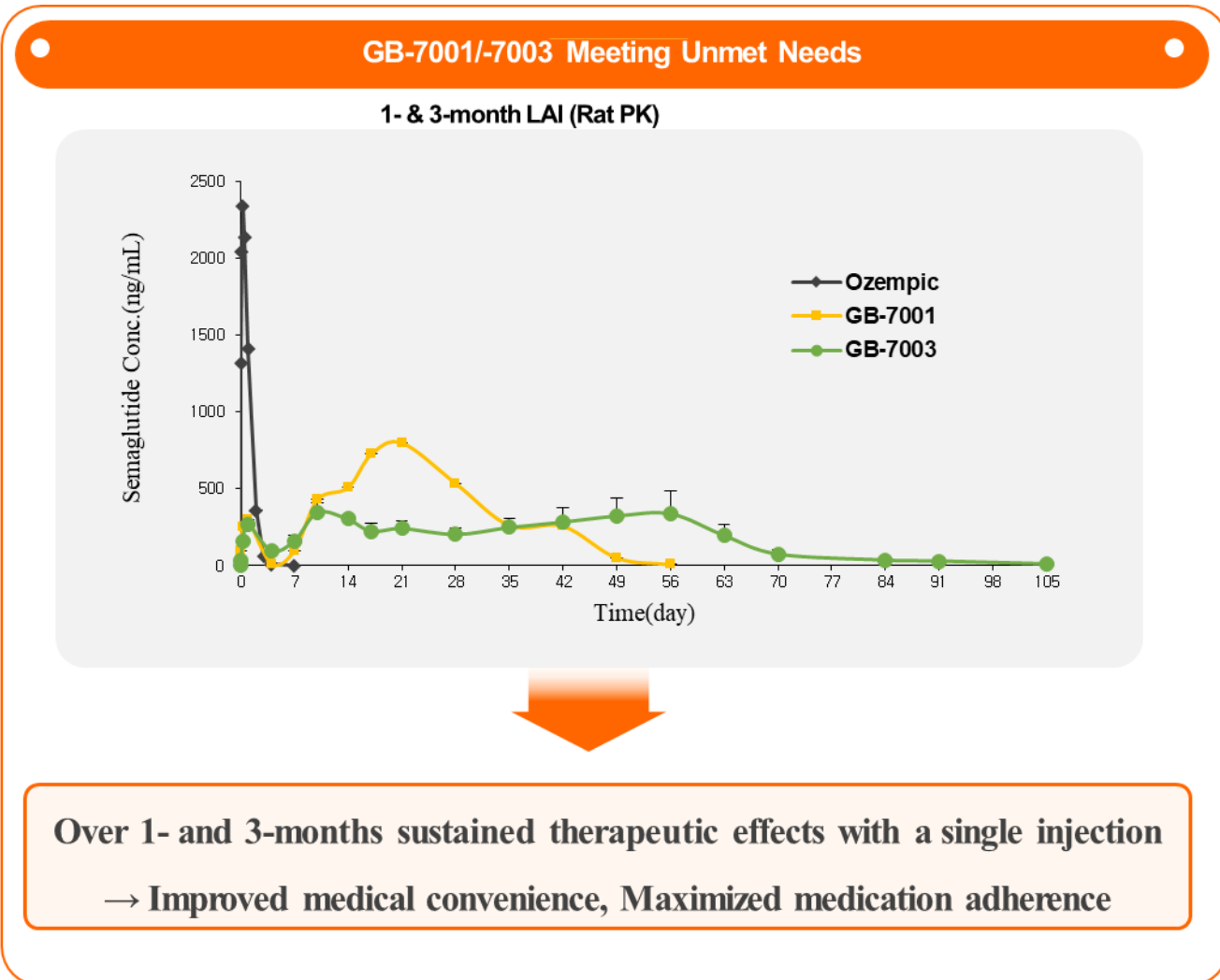
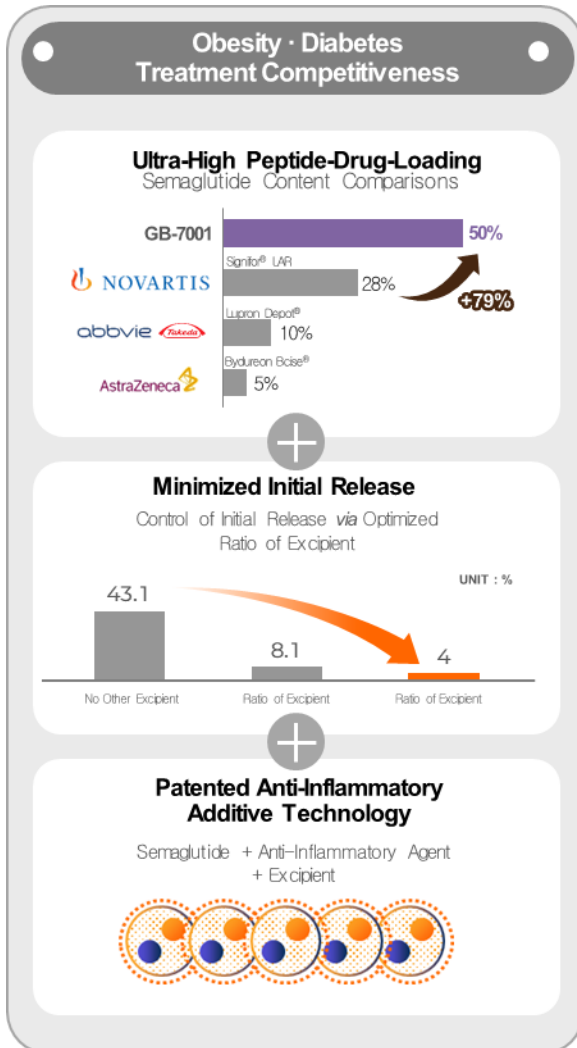
## GB-5021/-5023 Meeting Unmet Needs

### 1- & 3-month LAI (Rat PK)



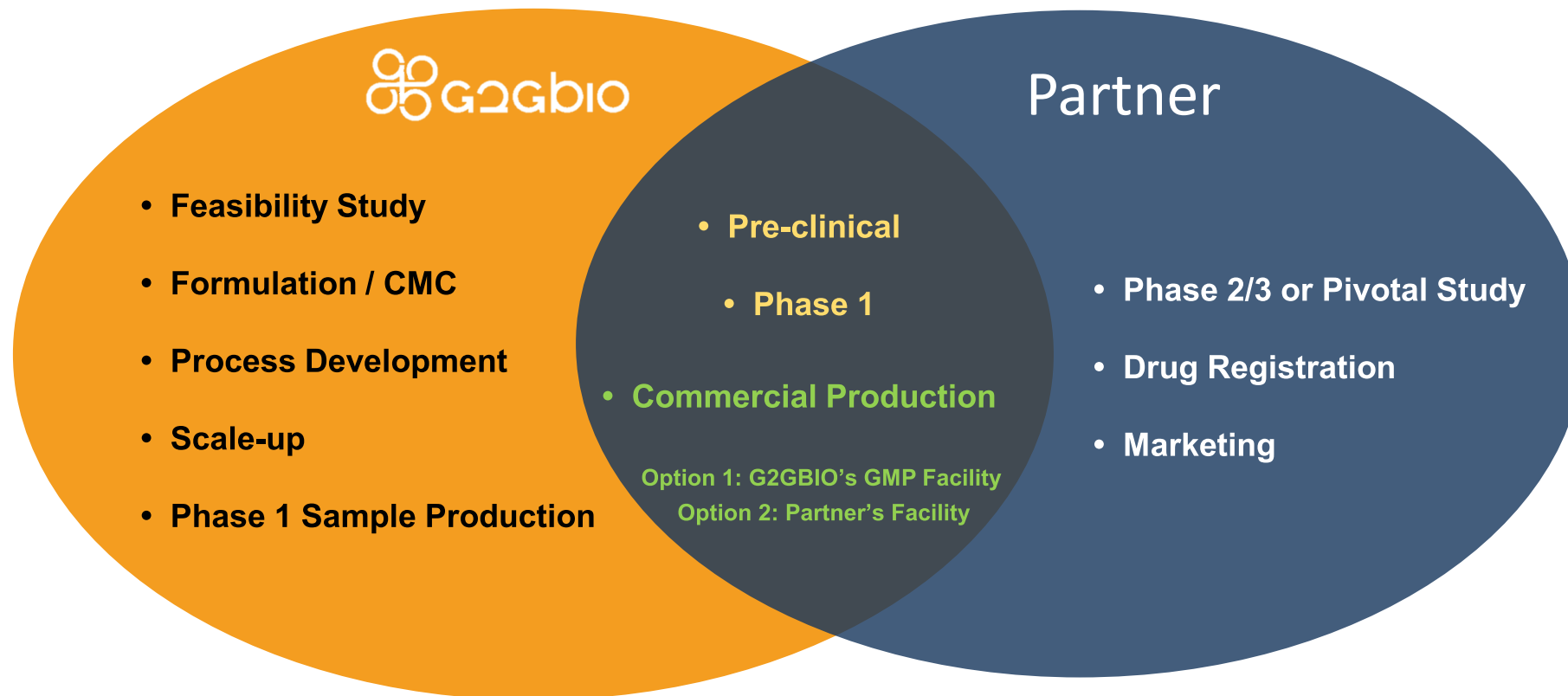
**Over 1- and 3-months sustained therapeutic effects with a single injection**  
→ Improved medical convenience, Maximized medication adherence

# GB-7001/7003: Sustained Therapeutic Effects for 1 and 3 Months with a Single Administration of Semaglutide



# Business Model

1. G2GBIO's existing SR Assets: License Agreement
2. New Project: CDMO, Co-development





# Thank you

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Chungcheongbuk-do 28161, South Korea

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