Recent trends in Business Development and Gan & Lee's Strategic move from Biosimilar to Novel Biologics

- Partnership opportunities

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At PharmaSynergy, London-UK
Date. 05-06, February 2026

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- ❑ Key Highlights of Gan&Lee's Novel Biologics – A Strategic Shift from Biosimilar to Novel Biologics and International Expansion Plans.
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Current Trends in Global Biopharma Business Development

Current Trends in Global Biopharma Business Development

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Increased Strategic Collaborations and Partnerships

Licensing and Co-Development:

Biopharma companies are increasingly entering into partnerships for R&D, licensing, and co-development, especially with smaller biotech firms.

M&A and Consolidation collaboration

Mega-Mergers:

Large-scale M&A is a key strategy for building robust pipelines and acquiring cutting-edge technologies. In 2015-2025, we saw a surge in deals focusing on oncology, immunology, and rare diseases.

Growing Biosimilar Market

Biosimilar Development:

As **patents on major biologics expire, companies are investing in biosimilars.** This trend is especially prominent in Europe and emerging markets. **Business development in this space often involves partnerships for regional distribution.**

Geographic Expansion and Market Access

Emerging Markets:

Biopharma companies are **expanding into emerging markets** (e.g., China, India, Latin America, ME etc.,) to tap into growing demand. **Strategic partnerships with local firms are essential to navigate regulatory challenges and gaining market access.**

Shift Towards Value-Based Healthcare

Outcomes-Based Contracts:

Biopharma companies are increasingly entering **value-based contracts where reimbursement is linked to the clinical outcomes achieved by their therapies**.

Regulatory Innovation and Real-World Evidence

Accelerated Approvals:
Regulators like the FDA and EMA are supporting faster drug approvals through mechanisms like **Breakthrough Therapy Designation and Conditional Marketing Authorization.** This creates opportunities for earlier market entry, especially for innovative therapies.

Real-World Evidence (RWE): Companies are leveraging **RWE to support regulatory filings and market access strategies, particularly in the post-market phase.** Strategic partnerships with companies specializing in RWE are increasing.

Current Trends in Global Biopharma Business Development Continue…

Rising Interest in Rare Diseases

Orphan Drugs:

Orphan Drugs: Developing treatments **for rare diseases remains a high priority, driven by regulatory incentives, shorter development timelines,** and premium pricing models. Orphan drug designations are highly sought after, and partnerships in this space are flourishing.

Advanced Therapy Focused

Cell and Gene Therapies:

There is **significant momentum behind the development of gene therapies, cell therapies, and other advanced biologics**. Companies are investing in manufacturing and distribution capabilities for these complex therapies.

mRNA and Vaccine Platforms:

Following the success of mRNA vaccines for COVID-19, biopharma is extending these platforms to other infectious diseases and therapeutic areas, including oncology.

Personalized Medicine and Precision Oncology

Targeted Therapies:

Personalized medicine, particularly in oncology, is **gaining attraction with treatments tailored to patients** ' genetic profiles. Business development efforts are focused on in-licensing or acquiring precision medicine assets.

AI and Digital Health Integration

AI in Drug Discovery:

Artificial intelligence (AI) is being used to streamline drug discovery, optimize clinical trials, and personalize therapies. Biopharma companies are partnering with AI startups to accelerate R&D.

Digital Biomarkers and Remote Monitoring:

The rise of digital health and connected devices has expanded the use of digital biomarkers and remote patient monitoring in clinical trials and post-approval patient management.

Biopharmaceutical IPOS

Late-Stage and Data-Driven Focus:

Investors are showing a preference for biopharma companies with mid-to-late-
stage clinical assets, especially those with compelling clinical data in therapeutic areas like o ncology and rare diseases.
This trend reflects investor caution, as these com panies offer more visibility into clinical progress an d revenue potential.

Positive Market Performance and Upsized IPO s: Successful IPOs indicate renewed investor conf idence, particularly for companies with strong prod uct pipelines and clear paths to market..

Licensing and Strategic Partnerships in Biopharmaceutical Industries

Licensing and Strategic Partnerships in Biopharmaceutical Industries

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Licensing-In

A company licenses a product or technology from another entity to enhance its own pipeline or capabilities.

Licensing-Out

A company that licenses Product or Technology. This also allows another to use its IP in exchange for business and financial terms.

Key Aspects of Licensing Deals

- **Upfront Payments:** Initial payments made by the licensee upon signing the deal.
- **Milestone Payments:** Payments tied to regulatory or commercial achievements, such as clinical trial results or sales benchmarks.
- **Royalties:** Ongoing payments based on product sales, typically a percentage of the revenue.
- **Exclusivity:** Some licenses are exclusive, giving the licensee the sole rights in certain territories or therapeutic areas.

Licensing and Strategic Partnerships in Biopharmaceutical Industries

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R&D Collaborations

Companies work together to discover or develop new drugs or therapies.

Platform or Technology Partnerships

One partner provides a technology or platform, while the other brings product expertise or market access.

Co-Development and Co-Commercialization

Partners share both the development and commercialization responsibilities, including costs and revenues.

Manufacturing Partnerships

To meet capacity needs, companies often partner with Contract Manufacturing Organizations (CMOs) or other pharma companies for large-scale production.

Key Elements in Strategic Partnerships

• **Shared Resources:** Partners pool their resources, including R&D, clinical trial infrastructure, regulatory expertise, and commercial teams. • **Risk Sharing:** Strategic partnerships allow companies to spread financial and operational risks, which is especially important for high-risk projects like gene therapies or complex biologics. • **Market Access and Expertise:** Companies can leverage each other's regional market knowledge, regulatory expertise, and distribution networks to expand globally.

Recent Strategic Partnership Trends

• **Cross-Border Collaborations:** Partnerships between Western biopharma companies and Chinese firms are on the rise, as China grows in importance as both a market and a center for innovation.• **Tech-Biopharma Collaborations**: Biopharma companies are increasingly partnering with tech companies to leverage AI, big data, and machine learning for drug discovery and patient care.• **Focus on Advanced Modalities:** Partnerships around cutting-edge areas like gene editing (e.g., CRISPR), cell therapies, and mRNA technology are gaining momentum

Lifecycle of Biopharmaceutical Partnership and Challenges

Lifecycle of Biopharmaceutical Partnership and Challenges

The partnership lifecycle in Biopharma is a dynamic and complex process, with each stage requiring careful management to ensure success.

Partnership Planning and Initiation

- Identifying Potential Partners
- Defining Strategic Objectives
- Due Diligence
- Negotiation
- Deal Structuring

Deal Execution and Implementation

- Formalizing Agreements
- Team Integration
- Establishing Governance

R&D and/or RA Phase

- Joint Research Programs
- Resource Sharing
- Technology Transfer
- Regulatory Filings
- Establishing Governance

Commercial Phase

- Product Launch
- Revenue Sharing
- Market Expansion

Partnership Management

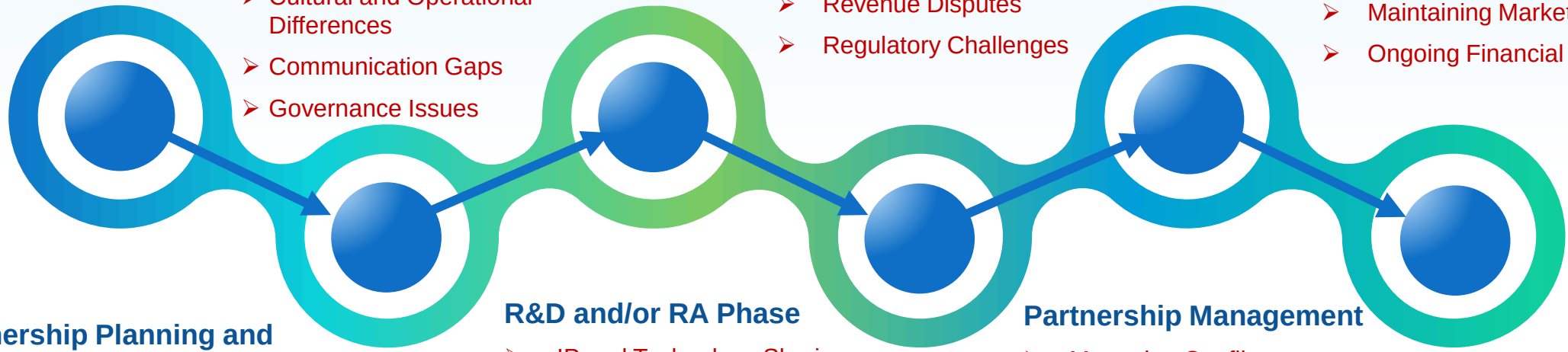
- Continuous monitoring
- Supply Management
- Disputes resolution
- Expansion and Modification

Conclusion & Exit

- Termination or Renewal
- Asset Transfer
- Post-Partnership Support

Lifecycle of Biopharmaceutical Partnership and Challenges….

Challenges….



Partnership Planning and Initiation.

- Misaligned Objectives
- Valuation Discrepancies
- Complexity of Deal Terms

Deal Execution and Implementation.

- Cultural and Operational Differences
- Communication Gaps
- Governance Issues

R&D and/or RA Phase

- IP and Technology Sharing
- Resource Imbalances
- Differing Approaches to Development

Commercial Phase.

- Differing Market Strategies
- Revenue Disputes
- Regulatory Challenges

Partnership Management

- Managing Conflicts.
- Shifting Objectives
- Leadership Changes

Conclusion & Exit

- Disentangling Responsibilities
- Maintaining Market Presence
- Ongoing Financial Obligations

Partnerships can drive significant value, challenges related to alignment, communication, governance and IP are common. Proactively addressing these challenges through clear contracts, strong governance structures, and open communication can greatly enhance the likelihood of a successful collaboration.

Key highlights of the G&L's Novel Biologics – A Strategic Shift from Biosimilar to Novel Biologics and International Expansion Plans

Company Overview

Overview of Gan & Lee Pharmaceuticals – 25+ years…still growing

Founded in 1998, Gan & Lee is a leading pharmaceutical company in China, that specialized in the development, production, and commercialization of insulin products. Headquartered in Beijing, Gan & Lee successfully developed the first Chinese insulin analog and now strives to broaden its global coverage in the field of diabetes diagnosis and treatment. G&L's third-generation insulin products secured the highest contracted volume in the 2024 Insulin Successive Volume-Based Procurement (VBP), accounting for 30% of the total.

Employees 6000+

Registration approved in 55 countries

Ranked second in terms of insulin analogues market share in China

Listed in A-share market in 2020

With around 5.8 billion USD market capitalization*

Head Office:
No.8 Nanfeng West 1st Street,
Huoxian Tongzhou District,Beijing,101109,China.
Established in 1998

Affiliates and Subsidiaries:
HongKong, US, EU, Brazil

Expression System:
E. Coli Expression System based Bioprocessed Biopharmaceutical Products

GMP Certificate :
Eudra, ANVISA, COFEPRIS, PIC/s,DCGI, USFDA(U/P) and Many more

Market Share:
China : >25%
Overseas : 10%- 30%
International Revenue growth : 45.5% - Q3.2025

Product's International Presence :
19 countries - Launched
22 Countries –Registered.
12-countries – Clinical Trials

Products : Insulins analogs Glargine,Aspart ranges and Lispro ranges,
Novel Biologics, Small Molecules
Medical devices for Drug Deliveries.
Therapeutic Area: Diabetes,Obesity, Autoimmune, Anticancer,CVD

Production Sites: Beijing,Shandong.
- Insulin DS capacity 7,500Kg —Beijing & Shandong
- Small Molecules – Shandong

* denotes market value as of 2026.02.02

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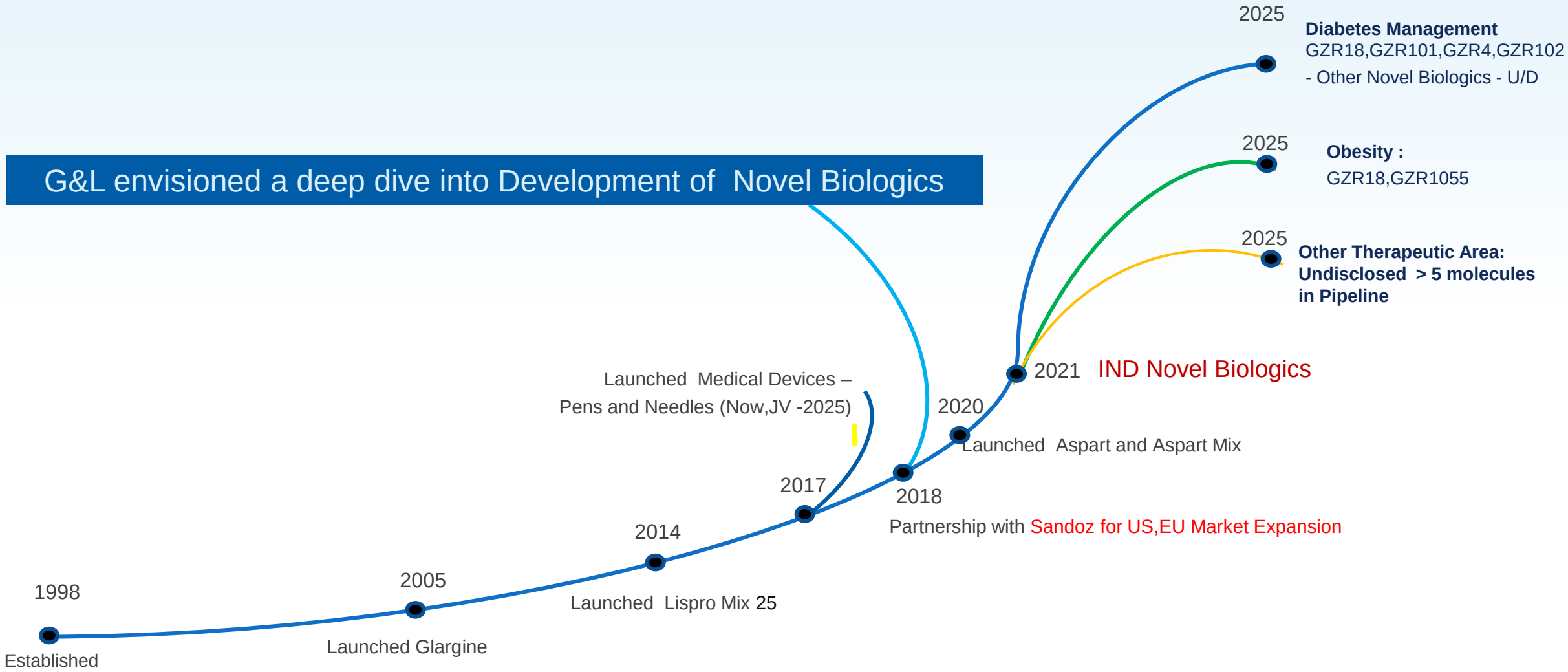
Glimpse of Strategic Shift and Product Pipeline

G&L's Strategic Shift from Biosimilar to Novel Biologics Development

G&L envisioned a deep dive into Development of Novel Biologics



Biosimilar to Novel Biologics:
Strategic Shift drivers, Opportunities and Challenges

G&L's Strategic Shift from Biosimilar to Novel Biologics Development

Gan & Lee

The movement from biosimilar development to novel biologics development represents a **strategic shift for many biopharma companies.** It reflects the **desire to create differentiated, high-value therapies that offer new therapeutic benefits and address unmet clinical needs, rather than competing solely on price and manufacturing efficiency** in the biosimilar market. This transition poses both opportunities and challenges for companies.

SHIFT DRIVERS

Higher Value in Novel Biologics
- Revenue Potential
- Innovation-Driven Growth

Market Saturation and Competition in Biosimilars
- Biosimilar Market Maturity
- Erosion of Differentiation

Investment in R&D and Innovation Capabilities
- R&D Infrastructure.
- Advanced Technologies

Patent and Exclusivity Advantages
- Extended Market Protection
- Protection from Generics

Focus on Unmet Medical Needs and New Disease Areas
- New Therapeutic Targets
- Personalized Medicines

Strategic Shift and Partnerships
- Partnership with Innovators
- Collaborations with Academics

Need for Diffrentiation and Brand Building
- Establishing a Strong Brand
- Medical and Patient community engagement

Risk Vs Dynamics
- Increased Risk
- Balanced Risk in Portfolio

Long Term Vision and Market Leadership
- Sustainable growth
- Innovation Ecosystem

The movement from biosimilars to novel biologics marks a strategic evolution for many biopharma companies seeking **to drive innovation, create sustainable growth, and capture higher value in the market.**

ANY BIG DRIVE was ONCE A SMALL IDEA.....!!

G&L's Strategic Shift from Biosimilar to Novel Biologics Development

Gan & Lee

The movement from biosimilar development to novel biologics development …..**This transition poses both opportunities and challenges for companies.**

OPPRTUNITIES…

Higher Profit Margins and Market Differentiation:
Novel biologics allow companies to establish strong brand identity and exclusivi through patents and proprietary technologies.
Novel biologics offer the potential for premium pricing, as they address unique therapeutic needs that are often unmet by existing treatments.

Expanded Global Market Reach:
By shifting to innovative drugs, companies can target markets in the U.S., Euro , and Japan, where there is a greater acceptance of premium therapies.

Advancements in Biologic Technology: Novel biologics often use cutting edge techniques, including cell and gene therapy, monoclonal antibodies ,and mRNA technology, allowing companies to pioneer next-generation therapies.

Intellectual Property (IP) Challenges and Market Exclusivity:
Novel biologics offer the opportunity for IP protection and enhances exclusive market opportunity.

CHALLENGES…

High R&D Costs and Long Development Timelines:
Developing novel biologics is significantly more expensive than biosimilars due to complex manufacturing processes and extended clinical trials.

Stringent Regulatory Requirements:
Novel biologics must meet rigorous regulatory standards for safety and efficacy, which are often more demanding than those for biosimilars.

Manufacturing and Scalability Issues:
The shift to novel biologics involves sophisticated manufacturing capabilities, including the need for precise environments and quality control measures.

Intellectual Property (IP) Challenges:
While novel biologics offer the opportunity for IP protection, this also requires companies to invest heavily in building and defending their patent portfolios.

Market Access and Pricing Pressure:
Novel biologics often face high market access barriers due to cost, as many healthcare systems and insurance providers place limits on reimbursement for high-priced therapies.

ANY BIG DRIVE was ONCE A SMALL IDEA…..!!

Pipelines to meet unmet patient needs

Novel drugs

Program/Mechanism	Indication (s)	Pre-Clinical / IND / Ph I / Ph II / Ph III / NDA/BLA
GZR18 Injection (Bofanglutide) Bi-weekly GLP-1 RA	T2DM	CN US EU
	Obesity / Overweight	CN US EU
GZR4 Injection Weekly Basal Insulin	T2DM	CN US EU
GZR101 Injection Co-Formulation Insulin	T1DM / T2DM	CN US/EU
GZR102 Injection Weekly Fixed-Ratio Combination of Basal Insulin and GLP-1 RA	T2DM	CN US/EU
Biosimilar		
GLR1044 Dupilumab	Atopic Dermatitis	CN
GLR1023 Secukinumab	Psoriasis	CN

Overview on Novel Biologics and its Significance

G&L's Development Strategy and Partnership model

Clinical Development	Conventional Model (biosimilar)	Current Model (Novel Drugs and other pipeline Biosimilar)
IND	Yes	Yes
Phase I	Yes in China (Country of Origin)	Yes in China, US and EU
Phase II	-	Yes in China, US and EU (parallel or one after another Phase)
Phase III	Yes in China (country of Origin)	Yes in China, US and EU (parallel or one after another Phase)
Clinical Studies in US and EU	Through partnership after approval in China	In parallel which ongoing studies by G&L and/or through partnership with Regional players. Strategic MRCT in some cases.
Clinical Studies Row	Through partnership after approval in China	In parallel which ongoing studies by G&L. In parallel which ongoing studies by G&L and/or through partnership with Regional players. Strategic MRCT in some cases.
Advantage : Parallel development, early market entry, benefit of patent period to have more market access.		

Licensing-Out

Key Aspects of Licensing Deals

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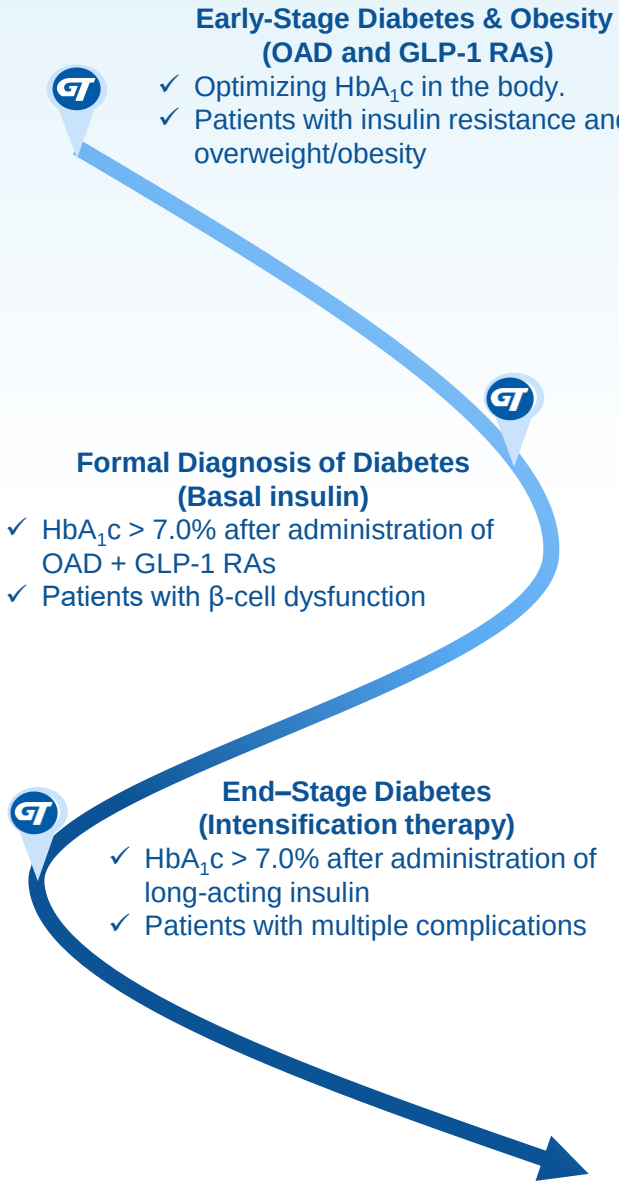
- **And/or Royalties:** payments based on product sales, typically a percentage of the revenue.
- **Exclusivity:** Some licenses are exclusive, giving the licensee the sole rights in certain territories or therapeutic areas.

G&L's Novel Biologics for Diabetes and obesity Management



Early-Stage Diabetes & Obesity (OAD and GLP-1 RAs)

- ✓ Optimizing HbA_1c in the body.
- ✓ Patients with insulin resistance and overweight/obesity

Formal Diagnosis of Diabetes (Basal insulin)

- ✓ HbA_1c > 7.0% after administration of OAD + GLP-1 RAs
- ✓ Patients with β-cell dysfunction

End–Stage Diabetes (Intensification therapy)

- ✓ HbA_1c > 7.0% after administration of long-acting insulin
- ✓ Patients with multiple complications

GZR18 (GLP-1 RA)

- ✓ Potential ***Best-in-Class*** biweekly GLP-1RA, with ***remarkable efficacy*** in treatment of T2DM and obesity.
- ✓ The first ***Head-to-Head*** phase III clinical trial with Semaglutide in China.
- ✓ Ongoing studies in US at different stage
- ✓ The ***good safety and tolerance profile*** of GZR18 is attributed to modified peptide activity and a meticulously designed up-titration approach.

GZR4 (Ultralong-Acting Insulin)

- ✓ Potential ***Best-in-Class*** weekly basal insulin analogue, with excellent efficacy and manageable risk of hypoglycemia in clinics.
- ✓ ***Top 3 clinical advancements*** in weekly insulin clinical development globally.
- ✓ ***Unique pharmacokinetics profile*** ensure stable blood glucose control within 7 days.
- ✓ Planning MRCT in US.

GZR101 (GZR33 + Rapid-Acting Insulin)

- ✓ IDegAsp Level novel insulin analogue, combining **long-acting insulin and rapid acting insulin,** align with the physiological proportion of human insulin secretion.
- ✓ **"Decrease peaks-to-trough effect",** GZR33 has stable pharmacokinetics and pharmacodynamics profiles, providing a safer, more effective and less-injection treatment for diabetes.

GZR102 (GZR4 + GZR18)

- ✓ The combination of GZR4 and GZR18 is anticipated to demonstrate non-inferiority compared to basal-insulin therapy, while offering multiple benefits.
- ✓ Low or minimal drug-drug interaction between GZR4 and GZR102 in the fixed ratio combination.

Summary

These Current trends of Business Development highlight the biopharma industry's dynamic nature, with increasing collaboration, technology integration, and focus on advanced therapeutic modalities. Business development teams are navigating a complex environment of scientific, regulatory, and commercial challenges, all while seeking new growth opportunities globally.

The SHIFT from biosimilar to novel biologics marks a strategic evolution for many biopharma companies seeking to drive innovation, create sustainable growth, and capture higher value in the market. While the transition requires significant investment, a focus on R&D, and a willingness to take on more risk, it offers the opportunity for companies to become leaders in high-value therapeutic areas, addressing unmet medical needs and building a strong market presence.

As **We ,G&L transit** from **Biosimilar to Novel Biologics,** our commitment to society remains our driving force. We are steadfast in our mission to deliver breakthrough treatments and to make meaningful impact on the health and quality of life for generations to come.